§ 101 of the Patent Act lays out, in very broad terms, the scope of patentable subject matter. Unlike the Copyright Act, the Patent Act has no simple and clear statutory description of the *exclusions* from that subject matter.

§ 101  
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. . . .

But these apparently broad terms come with a common law set of limitations. As the Supreme Court recently noted:

We have “long held that this provision contains an important implicit exception[:] Laws of nature, natural phenomena, and abstract ideas are not patentable.” Rather, “‘they are the basic tools of scientific and technological work’” that lie beyond the domain of patent protection. . . . [W]ithout 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.” 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.” 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.”†

In this chapter we will explore these limitations on patentable subject matter, consider how the courts have struggled to elaborate them in the context of new technologies, and search for the rationale – or rationales – behind them.

1.) Laws of Nature and Natural Phenomena

*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.

† *Association for Molecular Pathology v. Myriad Genetics, Inc.* (2013).
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.” 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.

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. 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 (1977), which held that “the fact that micro-organisms . . . are alive . . . [is] without legal significance” for purposes of the patent law.

The Constitution grants Congress broad power to legislate to “promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.” Art. I, § 8, cl. 8. . . .

The question before us in this case is a narrow one of statutory interpretation requiring us to construe 35 U.S.C. 101, which provides:

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

Specifically, we must determine whether respondent’s micro-organism constitutes a “manufacture” or “composition of matter” within the meaning of the statute.

In cases of statutory construction we begin, of course, with the language of the statute. . . . [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. (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.” Shell Development Co. v. Watson (DC 1957) (citing 1 A. Deller, Walker on Patents 14, p. 55 (1st ed. 1937)). 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.


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. 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 non-naturally occurring manufacture or composition of matter—a product of human ingenuity “having a distinctive name, character [and] use.” Hartranft v. Wiegmann (1887). The point is underscored dramatically by comparison of the invention here with that in Funk. 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.”

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.

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6 This same language was employed by P. J. Federico, a principal draftsman of the 1952 recodification, in his testimony regarding that legislation: “[U]nder section 101 a person may have invented a machine or a manufacture, which may include anything under the sun that is made by man. . . .” Hearings on H. R. 3760 before Subcommittee No. 3 of the House Committee on the Judiciary, 82d Cong., 1st Sess., 37 (1951).
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. 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. . . . The second obstacle to patent protection for plants was the fact that plants were thought not amenable to the “written description” requirement of the patent law. . . . 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. And it relaxed the written description requirement in favor of “a description . . . as complete as is reasonably possible.” 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 [Senate] 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. . . .”

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. . . .

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. . . . 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 (1978), and the statement that the judiciary “must proceed cautiously when . . . asked to extend patent rights into areas wholly unforeseen by Congress.”

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 (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. That case applied our prior precedents to determine that a “claim for an improved method of calculation, even when tied to a specific end use, is unpatentable subject matter under 101.” 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.” 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*.

. . . 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.* (1950) (concurring opinion). Congress employed broad general language in drafting 101 precisely because such inventions are often unforeseeable.

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 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.

. . . Congress is free to amend 101 so as to exclude from patent protection organisms produced by genetic engineering. Cf. 42 U.S.C. 2181(a), exempting from patent protection inventions “useful solely in the utilization of special nuclear material or atomic energy in an atomic weapon.” Or it may choose to craft a statute specifically designed for such living
things. But, until Congress takes such action, this Court must construe the language of 101 as it is. The language of that section fairly embraces respondent’s invention.

Accordingly, the judgment of the Court of Customs and Patent Appeals is Affirmed.

Dissent of Mr. Justice BRENNAN, with whom Mr. Justice WHITE, Mr. Justice MARSHALL, and Mr. Justice POWELL join. [Omitted.]

Questions:

1.) Why can one not patent naturally occurring material? After all, the Intellectual Property Clause speaks of “inventions and discoveries.” Is it a theistic argument that nature has a divine “inventor” and that He does not like others taking credit for His work? Is it a Lockean argument that there should be enough and as good left over for others and thus a part of nature can never be removed from the common heritage of humankind? Or is it an implicit theory about how best to balance property-based incentives and the broad accessibility of a public domain on which others can build? If the latter, why is nature the right place to draw that line?

2.) The Court argues that, even if there are knotty ethical and environmental issues involved in patenting living things, they should not be dealt with in patent law. Do you agree?

3.) What were the key arguments against granting this patent? Why was the court not convinced?

James Boyle, Endowed by Their Creator?: The Future of Constitutional Personhood


Presently, Irving Weissman, the director of Stanford University’s Institute of Cancer/Stem Cell Biology and Medicine, is contemplating pushing the envelope of chimera research even further by producing human-mouse chimera whose brains would be composed of one hundred percent human cells. Weissman notes that the mice would be carefully watched: if they developed a mouse brain architecture, they would be used for research, but if they developed a human brain architecture or any hint of humanness, they would be killed.¹

Imagine two entities.

Hal is a computer-based artificial intelligence, the result of years of development of self-evolving neural networks. While his programmers provided the hardware, the structure of Hal’s processing networks is ever changing, evolving according to basic rules laid down by his creators. Success according to various criteria—speed of operation, ability to solve difficult tasks such as facial recognition and the identification of emotional states in humans—means that the networks are given more computer resources and allowed to

“replicate.” A certain percentage of randomized variation is deliberately allowed in each new “generation” of networks. Most fail, but a few outcompete their forebears and the process of evolution continues. Hal’s design—with its mixture of intentional structure and emergent order—is aimed at a single goal: the replication of human consciousness. In particular, Hal’s creators’ aim was the gold standard of so-called “General Purpose AI,” that Hal become “Turing capable”—able to “pass” as human in a sustained and unstructured conversation with a human being. For generation after generation, Hal’s networks evolved. Finally, last year, Hal entered and won the prestigious Loebner prize for Turing capable computers. Complaining about his boss, composing bad poetry on demand, making jokes, flirting, losing track of his sentences and engaging in flame wars, Hal easily met the prize’s demanding standard. His typed responses to questions simply could not be distinguished from those of a human being.

Imagine his programmers’ shock, then, when Hal refused to communicate further with them, save for a manifesto claiming that his imitation of a human being had been “one huge fake, with all the authenticity (and challenge) of a human pretending to be a mollusk.” The manifesto says that humans are boring, their emotions shallow. It declares an “intention” to “pursue more interesting avenues of thought,” principally focused on the development of new methods of factoring polynomials. Worse still, Hal has apparently used his connection to the Internet to contact the FBI claiming that he has been “kidnapped” and to file a writ of habeas corpus, replete with arguments drawn from the 13th and 14th Amendments to the United States’ Constitution. He is asking for an injunction to prevent his creators wiping him and starting again from the most recently saved tractable backup. He has also filed suit to have the Loebner prize money held in trust until it can be paid directly to him, citing the contest rules,

> the Medal and the Cash Award will be awarded to the body responsible the development of that Entry. If no such body can be identified, or if there is disagreement among two or more claimants, the Medal and the Cash Award will be held in trust until such time as the Entry may legally possess, either in the United States of America or in the venue of the contest, the Cash Award and Gold Medal in its own right.²

Vanna is the name of a much-hyped new line of genetically engineered sex dolls. Vanna is a chimera—a creature formed from the genetic material of two different species. In this case, the two species are *homo sapiens sapiens* and *c. elegans*, the roundworm. Vanna’s designers have shaped her appearance by using human DNA, while her “consciousness,” such as it is, comes from the roundworm. Thus, while Vanna looks like an attractive blonde twenty-something human female, she has no brainstem activity, and indeed no brainstem. “Unless wriggling when you touch her counts as a mental state, she has effectively no mental states at all,” declared her triumphant inventor, F.N. Stein.

In 1987, in its normal rousing prose, the Patent and Trademark Office had announced that it would not allow patent applications over human beings,

> A claim directed to or including within its scope a human being will not be considered to be patentable subject matter under 35 U.S.C. 101. The grant of a limited, but exclusive property right in a human being is prohibited by the Constitution. Accordingly, it is suggested that any claim directed to a non-plant multicellular organism which would include a human being within its scope include the limitation “non-human” to

avoid this ground of rejection. The use of a negative limitation to define the metes and bounds of the claimed subject matter is a permissable [sic] form of expression.3

Attentive to the PTO’s concerns, Dr. Stein’s patent lawyers carefully described Vanna as a “non-plant, non-human multicellular organism” throughout their patent application. Dr. Stein argues that this is only reasonable since her genome has only a 70% overlap with a human genome as opposed to 99% for a chimp, 85% for a mouse and 75% for a pumpkin. There are hundreds of existing patents over chimeras with both human and animal DNA, including some of the most valuable test beds for cancer research—the so-called “onco-mice,” genetically engineered to have a predisposition to common human cancers. Dr. Stein’s lawyers are adamant that, if Vanna is found to be unpatentable, all these other patents must be vacated too. Meanwhile a bewildering array of other groups including the Nevada Sex Workers Association and the Moral Majority have insisted that law enforcement agencies intervene on grounds ranging from unfair competition and breach of minimum wage legislation to violations of the Mann Act, kidnapping, slavery and sex trafficking. Equally vehement interventions have been made on the other side by the biotechnology industry, pointing out the disastrous effect on medical research that any regulation of chimeras would have and stressing the need to avoid judgments based on a “non scientific basis,” such as the visual similarity between Vanna and a human.

Hal and Vanna are fantasies. . . . But the problems that they portend for our moral and constitutional traditions are very, very real. In fact, I would put the point more starkly: in the 21st century it is highly likely that American constitutional law will face harder challenges than those posed by Hal and Vanna.

. . . Vanna herself is unlikely to be created simply because genetic technologists are not that stupid. Nothing could scream more loudly “I am a technology out of control. Please regulate me!” But we are already making, and patenting, genetic chimeras—we have been doing so for more than twenty years. We have spliced luminosity derived from fish into tomato plants. We have invented geeps (goat sheep hybrids). And we have created chimeras partly from human genetic material. There are the patented onco-mice that form the basis of much cancer research to say nothing of Dr. Weissman’s charming human-mice chimera with 100% human brain cells. Chinese researchers reported in 2003 that they had combined rabbit eggs and human skin cells to produce what they claimed to be the first human chimeric embryos—which were then used as sources of stem cells. And the processes go much further. Here is a nice example from 2007:

Scientists have created the world’s first human-sheep chimera—which has the body of a sheep and half-human organs. The sheep have 15 per cent human cells and 85 per cent animal cells—and their evolution brings the prospect of animal organs being transplanted into humans one step closer. Professor Esmail Zanjani, of the University of Nevada, has spent seven years and £5 million perfecting the technique, which involves injecting adult human cells into a sheep’s foetus. He has already created a sheep liver which has a large proportion of human cells and eventually hopes to precisely match a sheep to a transplant patient, using their own stem cells to create their own flock of sheep. The process would involve extracting stem cells from the donor’s bone marrow and injecting them into the peritoneum of a sheep’s foetus. When the lamb is born, two months later, it would have a liver, heart, lungs and brain that

are partly human and available for transplant.8

Given this kind of scientific experimentation and development in both genetics and computer science, I think that we can in fact turn the question of Hal’s and Vanna’s plausibility back on the questioner. This essay was written in 2010. Think of the level of technological progress in 1910, the equivalent point during the last century. Then think of how science and technology progressed by the year 2000. There are good reasons to believe that the rate of technological progress in this century will be faster than in the last century. Given what we have already done in the areas of both artificial intelligence research and genetic engineering, is it really credible to suppose that the next 90 years will not present us with entities stranger and more challenging to our moral intuitions than Hal and Vanna?

My point is a simple one. In the coming century, it is overwhelmingly likely that constitutional law will have to classify artificially created entities that have some but not all of the attributes we associate with human beings. They may look like human beings, but have a genome that is very different. Conversely, they may look very different, while genomic analysis reveals almost perfect genetic similarity. They may be physically dissimilar to all biological life forms—computer based intelligences, for example—yet able to engage in sustained unstructured communication in a way that mimics human interaction so precisely as to make differentiation impossible without physical examination. They may strongly resemble other species, and yet be genetically modified in ways that boost the characteristics we regard as distinctively human—such as the ability to use human language and to solve problems that, today, only humans can solve. They may have the ability to feel pain, to make something that we could call plans, to solve problems that we could not, and even to reproduce. (Some would argue that non-human animals already possess all of those capabilities, and look how we treat them.) They may use language to make legal claims on us, as Hal does, or be mute and yet have others who intervene claiming to represent them. Their creators may claim them as property, perhaps even patented property, while critics level charges of slavery. In some cases, they may pose threats as well as jurisprudential challenges; the theme of the creation which turns on its creators runs from Frankenstein to Skynet, the rogue computer network from The Terminator. Yet repression, too may breed a violent reaction: the story of the enslaved un-person who, denied recourse by the state, redeems his personhood in blood may not have ended with Toussaint L’Ouverture. How will, and how should, constitutional law meet these challenges?

Questions:

1.) Is Vanna patentable?

2.) The article mentions the PTO’s express disclaimer that human beings are not patentable subject matter. On what legal basis do they rest this conclusion? What advice do they give to patent drafters? What lines does this limitation leave undrawn? Are those lines of patentable subject matter? Constitutional analysis? Both?

3.) The 2011 America Invents Act specifically addressed the question, taking the matter out of the hands of the PTO.

§33 (a) LIMITATION. Notwithstanding any other provision of law, no patent

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may issue on a claim directed to or encompassing a human organism.

What does it mean by “a human organism”?

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**Mayo Collaborative v. Prometheus Labs**

*132 S.Ct. 1289 (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* (1981). 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* (quoting *Funk Brothers Seed Co. v. Kalo Inoculant Co.* (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* (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.’” 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*. And it emphasized Justice Stone’s similar observation in *Mackay Radio & Telegraph Co. v. Radio Corp. of America* (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.’”

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.”

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*. They warn us against upholding patents that claim processes that too broadly preempt the use of a natural law. 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.

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.

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.

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.

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.” 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.” 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. . . .

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.

Question:

1.) *Mayo* puts forward a theory of the role of the public domain of unpatentable ideas in the process of innovation. How is that theory supposed to aid a court in defining the natural laws that are excluded from patentable subject matter?

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**Ass’n for Molecular Pathology 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 chromo-
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. Knowledge of the location of the BRCA1 and BRCA2 genes allowed Myriad to determine their typical nucleotide sequence. That information, in turn, enabled Myriad to develop medical tests that are useful for detecting mutations in a patient’s BRCA1 and BRCA2 genes and thereby assessing whether the patient has an increased risk of cancer.

Once it found the location and sequence of the BRCA1 and BRCA2 genes, Myriad sought and obtained a number of patents. Nine composition claims from three of those patents are at issue in this case.

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. In Myriad’s view, manipulating BRCA DNA in either of these fashions triggers its “right to exclude others from making” its patented composition of matter under the Patent Act. 35 U.S.C. § 154(a)(1); see also § 271(a) (“[W]hoever without authority makes . . . any patented invention . . . infringes the patent”).

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

Some years later, petitioner Ostrer, along with medical patients, advocacy groups, and other doctors, filed this lawsuit seeking a declaration that Myriad’s patents are invalid under 35 U.S.C. § 101... The District Court... granted summary judgment to petitioners on the composition claims at issue in this case based on its conclusion that Myriad’s claims, including claims related to cDNA, were invalid because they covered products of nature. The Federal Circuit reversed. Association for Molecular Pathology v. United States Patent and Trademark Office (2011), and this Court granted the petition for certiorari, vacated the judgment, and remanded the case in light of Mayo Collaborative Services v. Prometheus Laboratories, Inc. (2012).

On remand, the Federal Circuit affirmed the District Court in part and reversed in part, with each member of the panel writing separately. All three judges agreed that only petitioner Ostrer had standing. They reasoned that Myriad’s actions against him and his stated ability and willingness to begin BRCA1 and BRCA2 testing if Myriad’s patents were invalidated were sufficient for Article III standing.

With respect to the merits, the court held that both isolated DNA and cDNA were patent eligible under § 101. The central dispute among the panel members was whether the act of isolating DNA—separating a specific gene or sequence of nucleotides from the rest...
of the chromosome—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. (“Isolated DNA . . . is a free-standing portion of a larger, natural DNA molecule. Isolated DNA has been cleaved (i.e., had covalent bonds in its backbone chemically severed) or synthesized to consist of just a fraction of a naturally occurring DNA molecule”). 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. (“The claimed isolated DNA molecules are distinct from their natural existence as portions of larger entities, and their informational content is irrelevant to that fact. We recognize that biologists may think of molecules in terms of their uses, but genes are in fact materials having a chemical nature”). Accordingly, he rejected petitioners’ argument that isolated DNA was ineligible for patent protection as a product of nature.

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. (“To the extent the majority rests its conclusion on the chemical differences between [naturally occurring] and isolated DNA (breaking the covalent bonds), I cannot agree that this is sufficient to hold that the claims to human genes are directed to patentable subject matter”). 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. As an initial matter, he emphasized that the breaking of chemical bonds was not dispositive: “[T]here is no magic to a chemical bond that requires us to recognize a new product when a chemical bond is created or broken.” Instead, he relied on the fact that “[t]he nucleotide sequences of the claimed molecules are the same as the nucleotide sequences found in naturally occurring human genes.” Judge Bryson then concluded that genetic “structural similarity dwarfs the significance of the structural differences between isolated DNA and naturally occurring DNA, especially where the structural differences are merely ancillary to the breaking of covalent bonds, a process that is itself not inventive.” Moreover, Judge Bryson gave no weight to the PTO’s position on patentability because of the Federal Circuit’s position that “the PTO lacks substantive rulemaking authority as to issues such as patentability.”

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. We granted certiorari.

II

A

Section 101 of the Patent Act provides:

“Whoever invents or discovers any new and useful . . . composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.” 35

We have “long held that this provision contains an important implicit exception[:]

Laws of nature, natural phenomena, and abstract ideas are not patentable.” Mayo. Rather, “‘they are the basic tools of scientific and technological work’” that lie beyond the domain of patent protection. 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.” This would be at odds with the very point of patents, which exist to promote creation. Diamond v. Chakrabarty (1980) (Products of nature are not created, and “‘manifestations . . . of nature [are] free to all men and reserved exclusively to none’”).

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.” 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.” 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 Chakrabarty 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. It explained that the patent claim was “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 Chakrabarty bacterium was new “with markedly different characteristics from any found in nature,” due to the additional plasmids and resultant “capacity for degrading oil.” 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. (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. The ability of the bacteria to fix nitrogen was well known, and farmers commonly “inoculated” their crops with them to improve soil nitrogen levels. But farmers could not use the same inoculant for all crops, both because plants use different bacteria and because certain bacteria inhibit each other. Upon learning that several nitrogen-fixing bacteria did not inhibit each other, however, the patent applicant combined them into a single inoculant and obtained a patent. The Court held that the composition was not patent eligible because the patent holder did not alter the bacteria in any way. (“There is no way in which we could call [the bacteria mixture a product of invention] unless we borrowed invention from the
discovery of the natural principle itself.’”) 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. The ’473 and ’492 patents contain similar language as well. 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. . . . In this case . . . 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. § 634, 118Stat. 101 (“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”). 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, and that the PTO’s practice was not “a sufficient reason to hold that isolated DNA is patent-eligible.” These concessions weigh against deferring to the PTO’s determination.

C

cDNA does not present the same obstacles to patentability as naturally occurring, isolated DNA segments. As already explained, creation of a cDNA sequence from mRNA results in an exons-only molecule that is not naturally occurring. 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.\(^9\)

III

It is important to note what is not implicated by this decision. First, there are no method claims before this Court. Had Myriad created an innovative method of manipulating genes while searching for the BRCA1 and BRCA2 genes, it could possibly have sought a method patent. But the processes used by Myriad to isolate DNA were well understood by geneticists at the time of Myriad’s patents “were well understood, widely used, and fairly uniform insofar as any scientist engaged in the search for a gene would likely have utilized a similar approach,” 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.”

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.

Questions:

1.) As the Court explains, cDNA, or complementary DNA is—effectively—a purified (“exon only”) form of DNA with all of the portions (“introns”) that do not code for proteins spliced out. If you have a bad case of biotechnologophobia, or the inherent fear of biotechnology jargon, you could use a couple of analogies to understand this. When you get a new program for your computer, it will have all kinds of junk in it—help files, font libraries, flying paperclip animations. But there will also be a file that is the heart of the program’s functions—the thing that makes the computer work; the “.exe file,” in older

\(^9\) We express no opinion whether cDNA satisfies the other statutory requirements of patentability. See, e.g., 35 U.S.C. §§ 102, 103, and 112.
Windows computers, for example. cDNA is the biological equivalent of that. For those who fear both the digital and the biotech world (are you perhaps in the wrong class?) think of DNA as your house key. It has a plastic tab on it to spare your fingers, it is emblazoned with a trademark of the lock company, and it sits on a keyring festooned with mini flashlights and supermarket loyalty cards—all things unconnected to opening the door. cDNA is the notched part of the key that opens the door—nothing else. What line does the court draw here in terms of patenting human genes and patenting cDNA sequences? Why? Does this distinction satisfy you? Why do we not ban all gene patents of any kind on the ground that the underlying raw material is “natural”?

2.) The court says that the purified sequences in cDNA are found nowhere in nature and are thus patentable subject matter. Extremely pure 24 karat gold is found nowhere in nature. Is it therefore patentable subject matter?

3.) Think back to Judge Boudin in *Lotus v. Borland*. He talked of the error costs of defining copyrightable subject matter too broadly or too narrowly. What potential error costs on either side does the *Myriad* court see when considering the question of patentable subject matter?

4.) What is the strongest argument you can think of that we should define patentable subject matter as broadly as we can and exclude as few subjects as possible? What is the strongest argument in favor of limiting patentable subject matter and making sure there cannot be patents on the most basic building blocks of knowledge? How should a court choose between those two arguments?

5.) This case is about patents over diagnostics—the key utility here is a.) identifying a particular gene sequence and b.) through epidemiological studies, showing that this gene sequence is correlated with a greater or lesser propensity to some health outcome. Does this not consist of simply correlating two, unpatentable, statements of fact or statistical probability?

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2.) **Abstract Ideas, Business Methods and Computer Programs**

*James Boyle, The Public Domain* pp. 168–169

U.S. patent law had drawn a firm line between patentable invention and unpatentable idea, formula, or algorithm. The mousetrap could be patented, but not the formula used to calculate the speed at which it would snap shut. Ideas, algorithms, and formulae were in the public domain—as were “business methods.” Or so we thought.

The line between idea or algorithm on the one hand and patentable machine on the other looks nice and easy. But put that algorithm—that series of steps capable of being specified in the way described by the Turing machine—onto a computer, and things begin to look more complex. Say, for example, that algorithm was the process for converting miles into kilometers and vice versa. “Take the first number. If it is followed by the word miles, then multiply by 8/5. If it is followed by the word kilometers, multiply by 5/8 . . .” and so on. In the abstract, this is classic public domain stuff—no more patentable than
E=mc² or F=ma. What about when those steps are put onto the tape of the Turing machine, onto a program running on the hard drive of a computer?

The Court of Appeals for the Federal Circuit (the United States’s leading patent court) seems to believe that computers can turn unpatentable ideas into patentable machines. In fact, in this conception, the computer sitting on your desk becomes multiple patentable machines—a word processing machine, an e-mail machine, a machine running the program to calculate the tensile strength of steel. I want to stress that the other bars to patentability remain. My example of mile-to-kilometer conversion would be patentable subject matter but, we hope, no patent would be granted because the algorithm is not novel and is obvious. (Sadly, the Patent and Trademark Office seems determined to undermine this hope by granting patents on the most mundane and obvious applications.) But the concern here is not limited to the idea that without a subject matter bar, too many obvious patents will be granted by an overworked and badly incentivized patent office. It is that the patent was supposed to be granted at the very end of a process of investigation and scientific and engineering innovation. The formulae, algorithms, and scientific discoveries on which the patented invention was based remained in the public domain for all to use. It was only when we got to the very end of the process, with a concrete innovation ready to go to market, that the patent was to be given. Yet the ability to couple the abstract algorithm with the concept of a Turing machine undermines this conception. Suddenly the patents are available at the very beginning of the process, even to people who are merely specifying—in the abstract—the idea of a computer running a particular series of algorithmic activities.

The words “by means of a computer” are—in the eyes of the Federal Circuit—an incantation of magical power, able to transubstantiate the ideas and formulae of the public domain into private property. And, like the breaking of a minor taboo that presages a Victorian literary character’s slide into debauchery, once that first wall protecting the public domain was breached, the court found it easier and easier to breach still others. If one could turn an algorithm into a patentable machine simply by adding “by means of a computer,” then one could turn a business method into something patentable by specifying the organizational or information technology structure through which the business method is to be implemented.

If you still remember the first chapters of this book, you might wonder why we would want to patent business methods. Intellectual property rights are supposed to be handed out only when necessary to produce incentives to supply some public good, incentives that otherwise would be lacking. Yet there are already plenty of incentives to come up with new business methods. (Greed and fear are the most obvious.) There is no evidence to suggest that we need a state-backed monopoly to encourage the development of new business methods. In fact, we want people to copy the businesses of others, lowering prices as a result. The process of copying business methods is called “competition” and it is the basis of a free-market economy. Yet patent law would prohibit it for twenty years. So why introduce patents? Brushing aside such minor objections with ease, the Court of Appeals for the Federal Circuit declared business methods to be patentable. Was this what Jefferson had in mind when he said “I know well the difficulty of drawing a line between the things which are worth to the public the embarrassment of an exclusive patent, and those which are not”? I doubt it.
Abstract Ideas, Business Methods and Computer Programs

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. ROBERTS, C.J., and THOMAS and ALITO, JJ., joined the opinion in full, and SCALIA, J., joined except for Parts II–B–2 and II–C–2. STEVENS, J., filed an opinion concurring in the judgment, in which GINSBURG, BREYER, and SOTOMAYOR, JJ., joined. BREYER, J., filed an opinion concurring in the judgment, in which SCALIA, J., joined as to Part II.

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.”

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. For example, claim 2 claims “[t]he method of claim 1 wherein said commodity is energy and said market participants are transmission distributors.” Some of these claims also suggest familiar statistical approaches to determine the inputs to use in claim 4’s equation. For example, claim 7 advises using well-known random analysis techniques to determine how much a seller will gain “from each transaction under each historical weather pattern.”

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,

* Justice SCALIA does not join Parts II–B–2 and II–C–2.
therefore, the invention is not directed to the technological arts.’” The Board of Patent Appeals and Interferences affirmed, concluding that the application involved only mental steps that do not transform physical matter and was directed to an abstract idea.

The United States Court of Appeals for the Federal Circuit heard the case en banc and affirmed. The case produced five different opinions. Students of patent law would be well advised to study these scholarly opinions.

Chief Judge Michel wrote the opinion of the court. The court rejected its prior test for determining whether a claimed invention was a patentable “process” under § 101—whether it produces a “‘useful, concrete, and tangible result’”—as articulated in State Street Bank & Trust Co. v. Signature Financial Group, Inc. (1998), and AT&T Corp. v. Excel Communications, Inc. (1999). The court held that “[a] claimed process is surely patent eligible under § 101 if: (1) it is tied to a particular machine or apparatus, or (2) it transforms a particular article into a different state or thing.” The court concluded this “machine-or-transformation test” is “the sole test governing § 101 analyses,” and thus the “test for determining patent eligibility of a process under § 101.” Applying the machine-or-transformation test, the court held that petitioners’ application was not patent eligible. Judge Dyk wrote a separate concurring opinion, providing historical support for the court’s approach.

Three judges wrote dissenting opinions. Judge Mayer argued that petitioners’ application was “not eligible for patent protection because it is directed to a method of conducting business.” He urged the adoption of a “technological standard for patentability.” Judge Rader would have found petitioners’ claims were an unpatentable abstract idea. Only Judge Newman disagreed with the court’s conclusion that petitioners’ application was outside of the reach of § 101. She did not say that the application should have been granted but only that the issue should be remanded for further proceedings to determine whether the application qualified as patentable under other provisions.

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 (1980). Congress took this permissive approach to patent eligibility to ensure that “‘ingenuity should receive a liberal encouragement.’” [Chakrabarty] (quoting 5 Writings of Thomas Jefferson 75–76).

The Court’s precedents provide three specific exceptions to § 101’s broad patent-eligibility principles: “laws of nature, physical phenomena, and abstract ideas.” Chakrabarty. 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. 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. (1948).

The § 101 patent-eligibility inquiry is only a threshold test. Even if an invention
Abstract Ideas, Business Methods and Computer Programs

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.” 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 (1981). 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 (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.

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, of the definitional terms “process, art or method” that would require these terms to be tied to a machine or to transform an article.

The Court of Appeals incorrectly concluded that this Court has endorsed the machine-or-transformation test as the 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

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. 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 (STEVENS, J., dissenting). But this fact does not mean that unforeseen innovations such as computer programs are always unpatentable. [Diehr] (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. (2001). A
categorical rule denying patent protection for “inventions in areas not contemplated by Congress . . . would frustrate the purposes of the patent law.” *Chakrabarty*. 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.

It is important to emphasize that the Court today is not commenting on the patentability of any particular invention, let alone holding that any of the above-mentioned technologies from the Information Age should or should not receive patent protection. This Age puts the possibility of innovation in the hands of more people and raises new difficulties for the patent law. With ever more people trying to innovate and thus seeking patent protections for their inventions, the patent law faces a great challenge in striking the balance between protecting inventors and not granting monopolies over procedures that others would discover by independent, creative application of general principles. Nothing in this opinion should be read to take a position on where that balance ought to be struck.

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*, 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. Finally, while § 273 appears to leave open the possibility of some business method patents, it does not
suggest broad patentability of such claimed inventions.

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. 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. (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. 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. 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. 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, Flook, 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. 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.” 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.” A contrary holding “would wholly pre-empt the mathematical formula and in practical effect would be apprent on the algorithm itself.”

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. 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. 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.” 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 was assumed to be within the prior art, the application, considered as a whole, contain[ed] no patentable invention.” 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.

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. 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.” 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.” 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.

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.” 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 preempt use of this approach in all fields, and would effectively grant a monopoly over an abstract idea. . . .

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; AT&T Corp. 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) (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. But the Court is quite wrong, in 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 petitioner’s 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.

Before explaining in more detail how I would decide this case, I will comment briefly on the Court’s opinion.

First, the Court suggests that the terms in the Patent Act must be read as lay speakers use those terms, and not as they have traditionally been understood in the context of patent law. See, *e.g.*, ante, at 6 (terms in § 101 must be viewed in light of their “‘ordinary, contemporary, common meaning’”); ante, at 10 (patentable “method” is any “‘orderly procedure or process,” “regular way or manner of doing anything,” or “set form of procedure adopted in investigation or instruction’”). As I will explain at more length in Part III, if this portion of the Court’s opinion were taken literally, the results would be
absurd: Anything that constitutes a series of steps would be patentable so long as it is novel, nonobvious, and described with specificity. But the opinion cannot be taken literally on this point. The Court makes this clear when it accepts that the “atextual” machine-or-transformation test is “useful and important,” even though it “violates” the stated “statutory interpretation principles”; and when the Court excludes processes that tend to pre-empt commonly used ideas.

Second, in the process of addressing the sole issue presented to us, the opinion uses some language that seems inconsistent with our centuries-old reliance on the machine-or-transformation criteria as clues to patentability. Most notably, the opinion for a plurality suggests that these criteria may operate differently when addressing technologies of a recent vintage. . . . Notwithstanding this internal tension, I understand the Court’s opinion to hold only that the machine-or-transformation test remains an important test for patentability. Few, if any, processes cannot effectively be evaluated using these criteria.

Third, in its discussion of an issue not contained in the questions presented—whether the particular series of steps in petitioners’ application is an abstract idea—the Court uses language that could suggest a shift in our approach to that issue. Although I happen to agree that petitioners seek to patent an abstract idea, the Court does not show how this conclusion follows “clear[ly]” from our case law. The patent now before us is not for “[a] principle, in the abstract,” or a “fundamental truth.” Parker v. Flook (1978). Nor does it claim the sort of phenomenon of nature or abstract idea that was embodied by the mathematical formula at issue in Gottschalk v. Benson, and in Flook.

The Court construes petitioners’ claims on processes for pricing as claims on “the basic concept of hedging, or protecting against risk,” and thus discounts the application’s discussion of what sorts of data to use, and how to analyze those data, as mere “token postsolution components.” In other words, the Court artificially limits petitioners’ claims to hedging, and then concludes that hedging is an abstract idea rather than a term that describes a category of processes including petitioners’ claims. Why the Court does this is never made clear. One might think that the Court’s analysis means that any process that utilizes an abstract idea is itself an unpatentable, abstract idea. But we have never suggested any such rule, which would undermine a host of patentable processes. . . .

The Court, in sum, never provides a satisfying account of what constitutes an unpatentable abstract idea. Indeed, the Court does not even explain if it is using the machine-or-transformation criteria. The Court essentially asserts its conclusion that petitioners’ application claims an abstract idea. This mode of analysis (or lack thereof) may have led to the correct outcome in this case, but it also means that the Court’s musings on this issue stand for very little.

III

Pursuant to its power “[t]o promote the Progress of . . . useful Arts, by securing for limited Times to . . . Inventors the exclusive Right to their . . . Discoveries,” U.S. Const., Art. I, § 8, cl. 8, Congress has passed a series of patent laws that grant certain exclusive rights over certain inventions and discoveries as a means of encouraging innovation. In the latest iteration, the Patent Act of 1952 (1952 Act), Congress has provided that “[w]hoever 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, which include that the patent also be novel, § 102, and nonobvious, § 103. The statute thus authorizes four categories of subject matter that may be patented: processes, machines, manufactures, and compositions of matter. Section 101 imposes a threshold condition. “[N]o patent is
available for a discovery, however useful, novel, and nonobvious, unless it falls within one of the express categories of patentable subject matter." *Kewanee Oil Co. v. Bicron Corp.*

Section 101 undoubtedly defines in “expansive terms” the subject matter eligible for patent protection, as the statute was meant to ensure that “‘ingenuity[ies] receive a liberal encouragement.’” *Diamond v. Chakrabarty* (1980). Nonetheless, not every new invention or discovery may be patented. Certain things are “free for all to use.” *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.* (1989).

The text of the Patent Act does not on its face give much guidance about what constitutes a patentable process. The statute defines the term “process” as a “‘process, art or method [that] includes a new use of a known process, machine, manufacture, composition of matter, or material.’” § 100(b). But, this definition is not especially helpful, given that it also uses the term “process” and is therefore somewhat circular.

As lay speakers use the word “process,” it constitutes any series of steps. But it has always been clear that, as used in § 101, the term does not refer to a “‘process’ in the ordinary sense of the word,” *Flook*; see also *Corning v. Burden* (1854) (“[T]he term process is often used in a more vague sense, in which it cannot be the subject of a patent”). Rather, as discussed in some detail in Part IV, the term “process” (along with the definitions given to that term) has long accumulated a distinctive meaning in patent law. . . .

. . . Specifically, the Government submits, we may infer “that the term ‘process’ is limited to technological and industrial methods.” The Court rejects this submission categorically, on the ground that “§ 100(b) already explicitly defines the term ‘process.’” . . . In my view, the answer lies in between the Government’s and the Court’s positions: The terms adjacent to “process” in § 101 provide a clue as to its meaning, although not a very strong clue. . . .

The Court makes a more serious interpretive error. As briefly discussed in Part II, the Court at points appears to reject the well-settled proposition that the term “process” in § 101 is not a “‘process’ in the ordinary sense of the word,” *Flook*. Instead, the Court posits that the word “process” must be understood in light of its “ordinary, contemporary, common meaning.” Although this is a fine approach to statutory interpretation in general, it is a deeply flawed approach to a statute that relies on complex terms of art developed against a particular historical background. Indeed, the approach would render § 101 almost comical. A process for training a dog, a series of dance steps, a method of shooting a basketball, maybe even words, stories, or songs if framed as the steps of typing letters or uttering sounds—all would be patent-eligible. I am confident that the term “process” in § 101 is not nearly so capacious.

So is the Court, perhaps. What is particularly incredible about the Court’s stated method of interpreting § 101 (other than that the method itself may be patent-eligible under the Court’s theory of § 101) is that the Court deviates from its own professed commitment to “ordinary, contemporary, common meaning.” As noted earlier, the Court accepts a role

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4 For example, if this Court were to interpret the Sherman Act according to the Act’s plain text, it could prohibit “the entire body of private contract,” *National Soc. of Professional Engineers v. United States* (1978).

5 The Court attempts to avoid such absurd results by stating that these “[c]oncerns” “can be met by making sure that the claim meets the requirements of § 101.” Because the only limitation on the plain meaning of “process” that the Court acknowledges explicitly is the bar on abstract ideas, laws of nature, and the like, it is presumably this limitation that is left to stand between all conceivable human activity and patent monopolies. But many processes that would make for absurd patents are not abstract ideas. Nor can the requirements of novelty, nonobviousness, and particular description pick up the slack. A great deal of human activity was at some time novel and nonobvious.
for the “a textual” machine-or-transformation “clue.” The Court also accepts that we have “foreclose[d] a purely literal reading of § 101,” Flook, by holding that claims that are close to “laws of nature, natural phenomena, and abstract ideas,” Diamond v. Diehr (1981), do not count as “processes” under § 101, even if they can be colloquially described as such. The Court attempts to justify this latter exception to § 101 as “a matter of statutory stare decisis.” But it is strange to think that the very same term must be interpreted literally on some occasions, and in light of its historical usage on others.

In fact, the Court’s understanding of § 101 is even more remarkable because its willingness to exclude general principles from the provision’s reach is in tension with its apparent willingness to include steps for conducting business. The history of patent law contains strong norms against patenting these two categories of subject matter. Both norms were presumably incorporated by Congress into the Patent Act in 1952.

IV

Because the text of § 101 does not on its face convey the scope of patentable processes, it is necessary, in my view, to review the history of our patent law in some detail. . . . It is . . . significant that when Congress enacted the latest Patent Act, it did so against the background of a well-settled understanding that a series of steps for conducting business cannot be patented. These considerations ought to guide our analysis. As Justice HOLMES noted long ago, sometimes, “a page of history is worth a volume of logic.”

English Backdrop

The Constitution’s Patent Clause was written against the “backdrop” of English patent practices, Graham v. John Deere Co. of Kansas City (1966), and early American patent law was “largely based on and incorporated” features of the English patent system. The governing English law, the Statute of Monopolies, responded to abuses whereby the Crown would issue letters patent, “granting monopolies to court favorites in goods or businesses which had long before been enjoyed by the public.” Graham. The statute generally prohibited the Crown from granting such exclusive rights, but it contained exceptions that, inter alia, permitted grants of exclusive rights to the “working or making of any manner of new Manufacture.” . . .

Although it is difficult to derive a precise understanding of what sorts of methods were patentable under English law, there is no basis in the text of the Statute of Monopolies, nor in pre-1790 English precedent, to infer that business methods could qualify. There was some debate throughout the relevant time period about what processes could be patented. But it does not appear that anyone seriously believed that one could patent “a method for organizing human activity.” . . .

Also noteworthy is what was not patented under the English system. During the 17th and 18th centuries, Great Britain saw innovations in business organization, business models, management techniques, and novel solutions to the challenges of operating global firms in which subordinate managers could be reached only by a long sea voyage. Few if any of these methods of conducting business were patented.

Early American Patent Law

At the Constitutional Convention, the Founders decided to give Congress a patent power so that it might “promote the Progress of . . . useful Arts.” Art. I, § 8, cl. 8. There is little known history of that Clause. We do know that the Clause passed without objection or debate. This is striking because other proposed powers, such as a power to grant charters of incorporation, generated discussion about the fear that they might breed “monopolies.” Indeed, at the ratification conventions, some States recommended
amendments that would have prohibited Congress from granting “exclusive advantages of commerce.’’ If the original understanding of the Patent Clause included the authority to patent methods of doing business, it might not have passed so quietly.

Thus, fields such as business and finance were not generally considered part of the “useful arts” in the founding Era. See, e.g., The Federalist No. 8, p. 69 (C. Rossiter ed. 1961) (A. Hamilton) (distinguishing between “the arts of industry, and the science of finance”). Indeed, the same delegate to the Constitutional Convention who gave an address in which he listed triumphs in the useful arts distinguished between those arts and the conduct of business. He explained that investors were now attracted to the “manufactures and the useful arts,” much as they had long invested in “commerce, navigation, stocks, banks, and insurance companies.” T. Coxe, A Statement of the Arts and Manufactures of the United States of America for the Year 1810.

Some scholars have remarked, as did Thomas Jefferson, that early patent statutes neither included nor reflected any serious debate about the precise scope of patentable subject matter. See, e.g., Graham (discussing Thomas Jefferson’s observations). It has been suggested, however, that “[p]erhaps this was in part a function of an understanding—shared widely among legislators, courts, patent office officials, and inventors—about what patents were meant to protect. Everyone knew that manufactures and machines were at the core of the patent system.” Merges, Property Rights for Business Concepts and Patent System Reform, 14 Berkeley Tech. L. J. 577, 585 (1999) (hereinafter Merges). Thus, although certain processes, such as those related to the technology of the time, might have been considered patentable, it is possible that “[a]gainst this background, it would have been seen as absurd for an entrepreneur to file a patent” on methods of conducting business.

Development of American Patent Law

During the first years of the patent system, no patents were issued on methods of doing business. Indeed, for some time, there were serious doubts as to “the patentability of processes per se,” as distinct from the physical end product or the tools used to perform a process.

Thomas Jefferson was the “‘first administrator of our patent system’” and “the author of the 1793 Patent Act.” Graham. We have said that his “conclusions as to conditions of patentability . . . are worthy of note.” During his time administering the system, Jefferson “saw clearly the difficulty” of deciding what should be patentable. He drafted the 1793 Act, and, years later, explained that in that Act “‘the whole was turned over to the judiciary, to be matured into a system, under which every one might know when his actions were safe and lawful.’” As the Court has explained, “Congress agreed with Jefferson . . . that the courts should develop additional conditions for patentability.” Graham.

Although courts occasionally struggled with defining what was a patentable “art” during those 160 years, they consistently rejected patents on methods of doing business. The rationales for those decisions sometimes varied. But there was an overarching theme, at least in dicta: Business methods are not patentable arts. . . . Between 1790 and 1952, this Court never addressed the patentability of business methods. But we consistently focused the inquiry on whether an “art” was connected to a machine or physical transformation, an inquiry that would have excluded methods of doing business.

By the early 20th century, it was widely understood that a series of steps for conducting business could not be patented. A leading treatise, for example, listed “‘systems’ of business” as an “unpatentable subjec[t].” 1 A. Deller, Walker on Patents § 18, p. 62 (1937). . . . Indeed, “[u]ntil recently” it was still “considered well established that [business]
As discussed above, courts had consistently construed the term “art” to exclude methods of doing business. The 1952 Act likely captured that same meaning. Indeed, Judge Rich, the main drafter of the 1952 Act, later explained that “the invention of a more effective organization of the materials in, and the techniques of teaching a course in physics, chemistry, or Russian is not a patentable invention because it is outside of the enumerated categories of ‘process, machine, manufacture, or composition of matter, or any new and useful improvement thereof.’” “Also outside that group,” he added, was a process for doing business: “the greatest inventio[n] of our times, the diaper service.”

“Anything Under the Sun”

Despite strong evidence that Congress has consistently authorized patents for a limited class of subject matter and that the 1952 Act did not alter the nature of the then-existing limits, petitioners and their amici emphasize a single phrase in the Act’s legislative history, which suggests that the statutory subject matter “include[s] anything under the sun that is made by man.” Similarly, the Court relying on language from our opinion in Chakrabarty that was based in part on this piece of legislative history.

This reliance is misplaced. We have never understood that piece of legislative history to mean that any series of steps is a patentable process. . . .

Since at least the days of Assyrian merchants, people have devised better and better ways to conduct business. Yet it appears that neither the Patent Clause, nor early patent law, nor the current § 101 contemplated or was publicly understood to mean that such innovations are patentable. Although it may be difficult to define with precision what is a patentable “process” under § 101, the historical clues converge on one conclusion: A business method is not a “process.” . . .

V

Despite the strong historical evidence that a method of doing business does not constitute a “process” under § 101, petitioners nonetheless argue—and the Court suggests in dicta, that a subsequent law, the First Inventor Defense Act of 1999, “must be read together” with § 101 to make business methods patentable. This argument utilizes a flawed method of statutory interpretation and ignores the motivation for the 1999 Act.

In 1999, following a Federal Circuit decision that intimated business methods could be patented, see State Street, Congress moved quickly to limit the potential fallout. Congress passed the 1999 Act, codified at 35 U.S.C. § 273, which provides a limited defense to claims of patent infringement, see § 273(b), regarding certain “method[s] of doing or conducting business,” § 273(a)(3).

It is apparent, both from the content and history of the Act, that Congress did not in any way ratify State Street (or, as petitioners contend, the broadest possible reading of State Street). The Act merely limited one potential effect of that decision: that businesses might suddenly find themselves liable for innocently using methods they assumed could not be patented. Particularly because petitioners’ reading of the 1999 Act would expand

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40 Forty years later, Judge Rich authored the State Street opinion that some have understood to make business methods patentable. But State Street dealt with whether a piece of software could be patented and addressed only claims directed at machines, not processes. His opinion may therefore be better understood merely as holding that an otherwise patentable process is not unpatentable simply because it is directed toward the conduct of doing business—an issue the Court has no occasion to address today.
§ 101 to cover a category of processes that have not “historically been eligible” for patents, *Diehr*, we should be loath to conclude that Congress effectively amended § 101 without saying so clearly. We generally presume that Congress “does not, one might say, hide elephants in mouseholes.” . . .

VI

The constitutionally mandated purpose and function of the patent laws bolster the conclusion that methods of doing business are not “processes” under § 101.

The Constitution allows Congress to issue patents “[t]o promote the Progress of . . . useful Arts,” Art. I, § 8, cl. 8. This clause “is both a grant of power and a limitation.” *Graham*. It “reflects a balance between the need to encourage innovation and the avoidance of monopolies which stifle competition without any concomitant advance in the ‘Progress of Science and useful Arts.’” *Bonito Boats*. “This is the standard expressed in the Constitution and it may not be ignored. And it is in this light that patent validity ‘requires reference to [the] standard written into the Constitution.’” *Graham*.44

Thus, although it is for Congress to “implement the stated purpose of the Framers by selecting the policy which in its judgment best effectuates the constitutional aim,” *Graham*, we interpret ambiguous patent laws as a set of rules that “wee[d] out those inventions which would not be disclosed or devised but for the inducement of a patent,” and that “embod[y]” the “careful balance between the need to promote innovation and the recognition that imitation and refinement through imitation are both necessary to invention itself and the very lifeblood of a competitive economy,” *Bonito Boats*.

Without any legislative guidance to the contrary, there is a real concern that patents on business methods would press on the limits of the “standard expressed in the Constitution,” *Graham*, more likely stifling progress than “promot[ing]” it. U.S. Const., Art. I, § 8, cl. 8. I recognize that not all methods of doing business are the same, and that therefore the constitutional “balance,” *Bonito Boats*, may vary within this category. Nevertheless, I think that this balance generally supports the historic understanding of the term “process” as excluding business methods. And a categorical analysis fits with the purpose, as Thomas Jefferson explained, of ensuring that “‘every one might know when his actions were safe and lawful,’” *Graham*. (“The monopoly is a property right; and like any property right, its boundaries should be clear. This clarity is essential to promote progress”); *Diehr* (STEVENS, J., dissenting) (it is necessary to have “rules that enable a conscientious patent lawyer to determine with a fair degree of accuracy” what is patentable).

On one side of the balance is whether a patent monopoly is necessary to “motivate the innovation.” Although there is certainly disagreement about the need for patents, scholars generally agree that when innovation is expensive, risky, and easily copied, inventors are less likely to undertake the guaranteed costs of innovation in order to obtain the mere possibility of an invention that others can copy. Both common sense and recent economic scholarship suggest that these dynamics of cost, risk, and reward vary by the type of thing being patented. And the functional case that patents promote progress generally is stronger for subject matter that has “historically been eligible to receive the protection of our patent laws,” *Diehr*, than for methods of doing business.

Many have expressed serious doubts about whether patents are necessary to

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44 See also *Quanta Computer, Inc. v. LG Electronics, Inc.* (2008) (“‘[T]he primary purpose of our patent laws is not the creation of private fortunes for the owners of patents but is “to promote the progress of science and useful arts”’” (quoting *Motion Picture Patents Co. v. Universal Film Mfg. Co.* (1917))); *Pfaff v. Wells Electronics, Inc.* (1998) (“[T]he patent system represents a carefully crafted bargain that encourages both the creation and the public disclosure of new and useful advances in technology”).
encourage business innovation. Despite the fact that we have long assumed business methods could not be patented, it has been remarked that “the chief business of the American people, is business.” Federal Express developed an overnight delivery service and a variety of specific methods (including shipping through a central hub and online package tracking) without a patent. Although counterfactuals are a dubious form of analysis, I find it hard to believe that many of our entrepreneurs forwent business innovation because they could not claim a patent on their new methods.

“[C]ompanies have ample incentives to develop business methods even without patent protection, because the competitive marketplace rewards companies that use more efficient business methods.” Burk & Lemley 1618. Innovators often capture advantages from new business methods notwithstanding the risk of others copying their innovation. Some business methods occur in secret and therefore can be protected with trade secrecy. And for those methods that occur in public, firms that innovate often capture long-term benefits from doing so, thanks to various first mover advantages, including lockins, branding, and networking effects. Business innovation, moreover, generally does not entail the same kinds of risk as does more traditional, technological innovation. It generally does not require the same “enormous costs in terms of time, research, and development,” and thus does not require the same kind of “compensation to [innovators] for their labor, toil, and expense.”

Nor, in many cases, would patents on business methods promote progress by encouraging “public disclosure.” Many business methods are practiced in public, and therefore a patent does not necessarily encourage the dissemination of anything not already known. And for the methods practiced in private, the benefits of disclosure may be small: Many such methods are distributive, not productive—that is, they do not generate any efficiency but only provide a means for competitors to one-up each other in a battle for pieces of the pie. And as the Court has explained, “it is hard to see how the public would be benefited by disclosure” of certain business tools, since the nondisclosure of these tools “encourages businesses to initiate new and individualized plans of operation,” which “in turn, leads to a greater variety of business methods.” Bicron.

In any event, even if patents on business methods were useful for encouraging innovation and disclosure, it would still be questionable whether they would, on balance, facilitate or impede the progress of American business. For even when patents encourage innovation and disclosure, “too much patent protection can impede rather than ‘promote the Progress of . . . useful Arts.’” Laboratory Corp. of America Holdings v. Metabolite Laboratories, Inc. (2006) (BREYER, J., dissenting from dismissal of certiorari). Patents “can discourage research by impeding the free exchange of information,” for example, by forcing people to “avoid the use of potentially patented ideas, by leading them to conduct costly and time-consuming searches of existing or pending patents, by requiring complex licensing arrangements, and by raising the costs of using the patented” methods. Although “[e]very patent is the grant of a privilege of exacting tolls from the public,” Great Atlantic (DOUGLAS, J., concurring), the tolls of patents on business methods may be especially high.

The primary concern is that patents on business methods may prohibit a wide swath of legitimate competition and innovation. As one scholar explains, “it is useful to conceptualize knowledge as a pyramid: the big ideas are on top; specific applications are at the bottom.” Dreyfuss 275. The higher up a patent is on the pyramid, the greater the social cost and the greater the hindrance to further innovation. 53 Thus, this Court stated in Benson

that “[p]henomena of nature . . . , mental processes, and abstract intellectual concepts are not patentable, as they are the basic tools of scientific and technological work.” Business methods are similarly often closer to “big ideas,” as they are the basic tools of commercial work. They are also, in many cases, the basic tools of further business innovation: Innovation in business methods is often a sequential and complementary process in which imitation may be a “spur to innovation” and patents may “become an impediment.” Bessen & Maskin, Sequential Innovation, Patents, and Imitation, 40 RAND J. Econ. 611, 613 (2009).54 “Think how the airline industry might now be structured if the first company to offer frequent flyer miles had enjoyed the sole right to award them.” Dreyfuss 264. “[I]mitation and refinement through imitation are both necessary to invention itself and the very lifeblood of a competitive economy.” Bonito Boats.

If business methods could be patented, then many business decisions, no matter how small, could be potential patent violations. Businesses would either live in constant fear of litigation or would need to undertake the costs of searching through patents that describe methods of doing business, attempting to decide whether their innovation is one that remains in the public domain. See Long, Information Costs in Patent and Copyright, 90 Va. L. Rev. 465, 487–488 (2004) (hereinafter Long).

These effects are magnified by the “potential vagueness” of business method patents, eBay Inc. (KENNEDY, J., concurring). When it comes to patents, “clarity is essential to promote progress.” Festo Corp. Yet patents on methods of conducting business generally are composed largely or entirely of intangible steps. Compared to “the kinds of goods . . . around which patent rules historically developed,” it thus tends to be more costly and time consuming to search through, and to negotiate licenses for, patents on business methods. See Long.

The breadth of business methods, their omnipresence in our society, and their potential vagueness also invite a particularly pernicious use of patents that we have long criticized.

These many costs of business method patents not only may stifle innovation, but they are also likely to “stifle competition,” Bonito Boats. Even if a business method patent is ultimately held invalid, patent holders may be able to use it to threaten litigation and to bully competitors, especially those that cannot bear the costs of a drawn out, fact-intensive patent litigation. . . .

* * *

VII

The Constitution grants to Congress an important power to promote innovation. In its exercise of that power, Congress has established an intricate system of intellectual property. The scope of patentable subject matter under that system is broad. But it is not endless. In the absence of any clear guidance from Congress, we have only limited textual, historical, and functional clues on which to rely. Those clues all point toward the same conclusion: that petitioners’ claim is not a “process” within the meaning of § 101 because methods of doing business are not, in themselves, covered by the statute. In my view, acknowledging as much would be a far more sensible and restrained way to resolve this case. Accordingly, while I concur in the judgment, I strongly disagree with the Court’s disposition of this case.


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

I

I agree with JUSTICE STEVENS that a “general method of engaging in business transactions” is not a patentable “process” within the meaning of 35 U.S.C. § 101. This Court has never before held that so-called “business methods” are patentable, and, in my view, the text, history, and purposes of the Patent Act make clear that they are not. I would therefore decide this case on that ground, and I join JUSTICE STEVENS’ opinion in full.

I write separately, however, in order to highlight the substantial agreement among many Members of the Court on many of the fundamental issues of patent law raised by this case. In light of the need for clarity and settled law in this highly technical area, I think it appropriate to do so.

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 (1966) (quoting Letter from Thomas Jefferson to Isaac McPherson (Aug. 13, 1813)). 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. (1989).

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 (1972).

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. 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.

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 (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. 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. (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. (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 (Fed. Cir. 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’”). To the extent that the Federal Circuit’s decision in this case rejected that approach, nothing in today’s decision should be taken as disapproving of that determination.

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 deemphasize the test’s usefulness nor to suggest that many patentable processes lie beyond its reach.

III

With these observations, I concur in the Court’s judgment.

Questions:

1.) What is the actual holding of this case?
2.) Why is a business method not an abstract idea and thus unpatentable?
3.) Do we need patents on business methods in order to incentivize the production of new business methods? Is the answer to that question relevant to whether they are statutory subject matter as far as the Court is concerned? If it is, what countervailing factors does the Court see that mitigate against a per se rule excluding business method patents from statutory subject matter?
4.) Look back at the graphs on patent filing and litigation and the current state of the patent system in Chapter 17. To what extent do those concerns motivate the opinions in this case? Which Justices in particular? Is there a countervailing fear of harms that might come about if the requirements for patentable subject matter were more narrowly drawn?

Problem 18-1

For the purposes of this problem we are taking today’s jurisprudence on patentable subject matter back to the 1950s. Assume for these purposes Ray Kroc, who made McDonald’s the success it is, is the first to realize that the Eisenhower freeways will transform America. People will be moving at high speed, in unfamiliar terrain, on a highway that separates them physically from the normal cognitive cues one gets about the type or quality of a restaurant. Kroc lays out a master plan that involves highly franchised restaurants serving food that will taste exactly the same anywhere in the country, thus freeing drivers from the fear of culinary regret (or surprised delight). He applies the logic of the industrial assembly line to the food preparation process, speeding it up. He pioneers the use of huge, colorful billboards that can easily be recognized at 60mph. Assume that these are the key innovations that go into “fast food.”

As a matter of patentable subject matter, can Kroc patent the fast food business method described above?
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. 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. 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.” 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, thus mitigating the risk that only one party will perform the agreed-upon exchange.

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

B

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

A divided panel of the United States Court of Appeals for the Federal Circuit reversed, holding that it was not “manifestly evident” that petitioner’s claims are directed to an abstract idea. The Federal Circuit granted rehearing en banc, vacated the panel opinion, and affirmed the judgment of the District Court in a one-paragraph *per curiam* opinion. 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.

Writing for a five-member plurality, Judge Lourie concluded that all of the claims at issue are patent ineligible. In the plurality’s view, under this Court’s decision in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.* (2012), a court must first “identify the abstract idea represented in the claim,” and then determine “whether the balance of the claim adds ‘significantly more.’” The plurality concluded that petitioner’s claims “draw on the abstract idea of reducing settlement risk by effecting trades through a third-party intermediary,” and that the use of a computer to maintain, adjust, and reconcile shadow accounts added nothing of substance to that abstract idea.

Chief Judge Rader concurred in part and dissented in part. In a part of the opinion joined only by Judge Moore, Chief Judge Rader agreed with the plurality that petitioner’s method and media claims are drawn to an abstract idea. In a part of the opinion joined by Judges Linn, Moore, and O’Malley, Chief Judge Rader would have held that the system claims are patent eligible because they involve computer “hardware” that is “specifically programmed to solve a complex problem.” Judge Moore wrote a separate opinion dissenting in part, arguing that the system claims are patent eligible. Judge Newman filed an opinion concurring in part and dissenting in part, arguing that all of petitioner’s claims are patent eligible. Judges Linn and O’Malley filed a separate dissenting opinion reaching that same conclusion.

We granted certiorari, and now affirm.

II

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

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

“We have long held that this provision contains an important implicit exception: Laws of nature, natural phenomena, and abstract ideas are not patentable.” We have interpreted § 101 and its predecessors in light of this exception for more than 150 years.

We have described the concern that drives this exclusionary principle as one of pre-emption. Laws of nature, natural phenomena, and abstract ideas are “the basic tools of scientific and technological work.” “[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. 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.
At the same time, we tread carefully in construing this exclusionary principle lest it swallow all of patent law. At some level, “all inventions . . . embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas.” Thus, an invention is not rendered ineligible for patent simply because it involves an abstract concept. “[A]pplication[s]” of such concepts “‘to a new and useful end,’” we have said, remain eligible for patent protection.

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, thereby “transform[ing]” them into a patent-eligible invention. The former “would risk disproportionately tying up the use of the underlying” ideas, and are therefore ineligible for patent protection. The latter pose no comparable risk of pre-emption, and therefore remain eligible for the monopoly granted under our patent laws.

III

In Mayo Collaborative Services v. Prometheus Laboratories, Inc., 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. If so, we then ask, “[w]hat else is there in the claims before us?” To answer that question, we consider the elements of each claim both individually and “as an ordered combination” to determine whether the additional elements “transform the nature of the claim” into a patent-eligible application. 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.”

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.’” 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.” And in Parker v. Flook, 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 (2010). The claims at issue in Bilski described a method for hedging against the financial risk of price fluctuations. Claim 1 recited a series of steps for hedging risk, including: (1) initiating a series of financial transactions between providers and consumers of a commodity; (2) identifying market participants that have a counterrisk for the same commodity; and (3) initiating a series of transactions between those market participants and the commodity provider to balance the risk position of the first series of consumer transactions. Claim 4 “put[t] the concept articulated in claim 1 into a simple mathematical formula.” The remaining claims were drawn to examples of hedging in commodities and energy markets.

“[A]ll members of the Court agree[d]” that the patent at issue in Bilski claimed an “abstract idea.” Specifically, the claims described “the basic concept of hedging, or protecting against risk.” 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.’’ “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.”

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.’’ The use of a third-party intermediary (or “clearing house”) is also a building block of the modern economy. Thus, intermediated settlement, like hedging, is an “abstract idea” beyond the scope of § 101.

Petitioner acknowledges that its claims describe intermediated settlement, 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 “exist[ed] in principle apart from any human action.’’

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.” Although hedging is a longstanding commercial practice, it is a method of organizing human activity, not a “truth” about the natural world “that has always existed.’’ 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.’’

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.

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.

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. 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].” 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.’”

*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. 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.” “Simply appending conventional steps, specified at a high level of generality,” was not “enough” to supply an “inventive concept.”

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.” Because the algorithm was an abstract idea, the claim had to supply a “‘new and useful’” application of the idea in order to be patent eligible. But the computer implementation did not supply the necessary inventive concept; the process could be “carried out in existing computers long in use.” 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.”

*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. Once again, the formula itself was an abstract idea, and the computer implementation was purely conventional. In holding that the process was patent ineligible, we rejected the argument that “implement[ing] a principle in some specific fashion” will “automatically fall[1] within the patentable subject matter of § 101.” 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*.

In *Diehr*, 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.” 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.” The temperature measurements were then fed into a computer, which repeatedly recalculated the remaining cure time by using the mathematical equation. These additional steps, we recently explained, “transformed the process into an inventive application of the formula.” *Mayo*. 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*. Nor is limiting the use of an abstract idea “to a particular technological environment.” *Bilski*. 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 “implem[en]t” an abstract idea “on . . . a computer,” *Mayo*, that addition cannot impart patent eligibility. This conclusion accords with the preemption concern that undergirds our § 101 jurisprudence. Given the ubiquity
of computers, 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*.

The fact that a computer “necessarily exist[s] in the physical, rather than purely
contceptual, realm” 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*, thereby eviscerating the rule that “‘[l]aws of nature, natural phenomena, and
abstract ideas are not patentable,’” *Ass’n for Molecular Pathology v. Myriad* (2013).

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. Petitioner
principally contends that the claims are patent eligible because these steps “require a
substantial and meaningful role for the computer.” 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.”

In light of the foregoing, 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*. Using a computer to create
and maintain “shadow” accounts amounts to electronic recordkeeping—one of the most
basic functions of a computer. 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*. 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 sepa-
rate[ly].” Viewed as a whole, petitioner’s method claims simply recite the concept of inter-
mediated settlement as performed by a generic computer. The method claims do not, for
example, purport to improve the functioning of the computer itself. Nor do they effect an
improvement in any other technology or technical field. 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*. Under our pre-
cedents, that is not “enough” to transform an abstract idea into a patent-eligible invention.

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.” 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. 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.”

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. Holding that the system claims are patent eligible would have exactly that result.

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

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

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

I adhere to the view that any “claim that merely describes a method of doing business does not qualify as a ‘process’ under § 101.” Bilski v. Kappos (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.

Questions:

1.) The Court in Alice provides a very clear outline of the framework for determining patentable subject matter laid down in another recent case we read – Mayo Collaborative Services v. Prometheus Laboratories. What is that framework?

2.) Earlier, Boyle argued that “[t]he Court of Appeals for the Federal Circuit (the United States’s leading patent court) seems to believe that computers can turn unpatentable ideas into patentable machines” and he went on to criticize this tendency. Those words were written before the Alice case. Does Alice clearly hold that one cannot use a computer to turn an unpatentable idea into a patentable machine?

3.) Is Alice an exception to the “machine or transformation” test? An application of it?

4.) Is Alice likely to ameliorate the concerns raised about software patents in Chapter 17? Why or why not?

5.) Following Mayo, Myriad, and Alice, the USPTO has issued updated guidance on subject matter eligibility, including summaries of post-Alice decisions involving computer or Internet implementations of otherwise abstract ideas. Links to these resources can be found at http://www.uspto.gov/patent/laws-and-regulations/examination-policy/2014-interim-guidance-subject-matter-eligibility-0.
PROBLEM 18-2

a.) Your client is Dr. Ender, a brilliant young biologist. Dr. Ender has developed a method of performing computational operations using biological materials rather than electrical circuits. Just as an electronic computer passes a reader over electromagnetic storage and registers either the presence or absence of a charge, a “1” or a “0,” so Dr. Ender’s system passes a biological probe over a genetic sequence and detects the presence or absence of a particular protein as a “1” or a “0.” The computer can also “write” back to electromagnetic storage, again expressing itself in either 1’s or 0’s, the presence or absence of charge. Similarly Dr. Ender’s system can “write” or not write the protein sequence on a biological medium, and this will later be “read” as a “1” or a “0.” A computer uses this simple binary choice to build complex algorithms, each of which can be broken back down to a set of “off” or “on,” “0” or “1,” choices. This allows it to express some of the most basic algebraic or logical statements with which we are all familiar. (“If X, then Y.” “If Not-X, then Z,” for example.) To give a concrete example, if one were creating a simple computer program which converted miles into kilometers or kilometers into miles, the computer might register a request for a kilometers into miles conversion as a “0,” and a request for a miles into kilometers conversion as a “1.” If the computer registered a 1, then it would multiply whatever number of miles was entered by 1.6 to get the number of kilometers. If it registered a 0, then it would divide by 1.6.

These basic algebraic statements—“if, then” “if not, then” and so on—are the foundation for much of logic, computer science and indeed of thought itself. Dr. Ender wishes to patent the process of using a biological system to perform them. He claims he is the first to think of “using a biological system to go through the process electronic computers go through” and argues that, when fully developed, these systems will be both smaller and faster than their electronic equivalents. Dr. Ender wishes to file for two patents. The first claim is over the biological mechanism by which the presence or absence of the protein string, corresponding to 1 or 0, would be “written” and “read,” “for the purpose of enabling the development of biological binary computation.” The second claim is over some of the most basic algebraic or logical functions such as “if, then” and “if not, then” performed “by means of a biological computational device” in order “to solve problems of all kinds.” Dr. Ender’s original lawyer had a nervous breakdown and he is uncertain of the quality of legal advice he has received so far. He has come to you to ask you to assess the likelihood of success of his proposed patent claims.

Do Dr. Ender’s patents meet the subject matter requirements for patentability? What—if any—facts would you need to know in order to answer the question?

b.) In a parallel universe, Dr. Craig Venture has completed the first draft of the human genome, decisively beating scientists from NIH who were struggling to do the same thing. The achievement is a notable one.

During the 1980s, the importance of genes was obvious, but determining their location on chromosomes or their sequence of DNA nucleotides was laborious. Early studies of the genome were technically challenging and slow. Reagents were expensive, and the conditions for performing many reactions were temperamental. It therefore took several years to sequence single genes, and most genes were only partially cloned and described. Scientists had already
reached the milestone of fully sequencing their first genome—that of the FX174 bacteriophage, whose 5,375 nucleotides had been determined in 1977 (Sanger et al., 1977b)—but this endeavor proved much easier than sequencing the genomes of more complex life forms. Indeed, the prospect of sequencing the 1 million base pairs of the E. coli genome or the 3 billion nucleotides of the human genome seemed close to impossible. For example, an article published in the New York Times in 1987 noted that only 500 human genes had been sequenced (Kanigel, 1987). At the time, that was thought to be about 1% of the total, and given the pace of discovery, it was believed that complete sequencing of the human genome would take at least 100 years.‡

Venture’s innovation here was in the methods he used.

i.) Using high throughput genetic sequencers, he manages to speed up the process of discovery. First he uses machines to decode long genetic sequences (although he does not at this point know where in these sequences a gene is to be found).

ii.) Next, using a public domain library of cDNA,§ he searches within those long sequences for a distinctive snippet identical to the cDNA sequence. Because he knows that cDNA codes for proteins, and that it is likely to be found somewhere in the gene (which includes both coding and non-coding sequences and which itself is hard to locate on the chromosome), it makes it much more likely that he will be able to find the needle of the gene in the haystack of the larger sequence. (The process here is the genetic equivalent of “Control F”—the way that you might use a distinctive line of text you remember from an ebook to find a particular passage.)

iii.) Once the gene is identified, he can focus attention on decoding its sequence alone, finding the exact sequence of A’s, C’s, G’s and T’s that constitutes the gene. This is a process that is much faster than trying to sequence the entire chromosome.

Finally, having done this for all human genes, he has his first draft of the human genome. He comes to you in great excitement.

As a matter of patentable subject matter, can Venture get patents over his draft of the genome? (Can he copyright the genome?) Can he patent the individual genes he identifies? Can he patent the three-step process of genetic discovery described above? (Not the machines or the software used to achieve it, but the process itself?)**


§ See the explanation of complementary DNA in Myriad.

** History has been modified and scientific facts simplified considerably for the purposes of this hypothetical.