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Patent Basics

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This chapter provides a basic introduction to patents, beginning with the constitutional and statutory bases of patent law and the concept of patent rights as exclusionary rights. It also covers the different types of patents, the duration of patent rights, and the boundaries of patentable subject matter.

Constitutional, Statutory, and Administrative Foundation

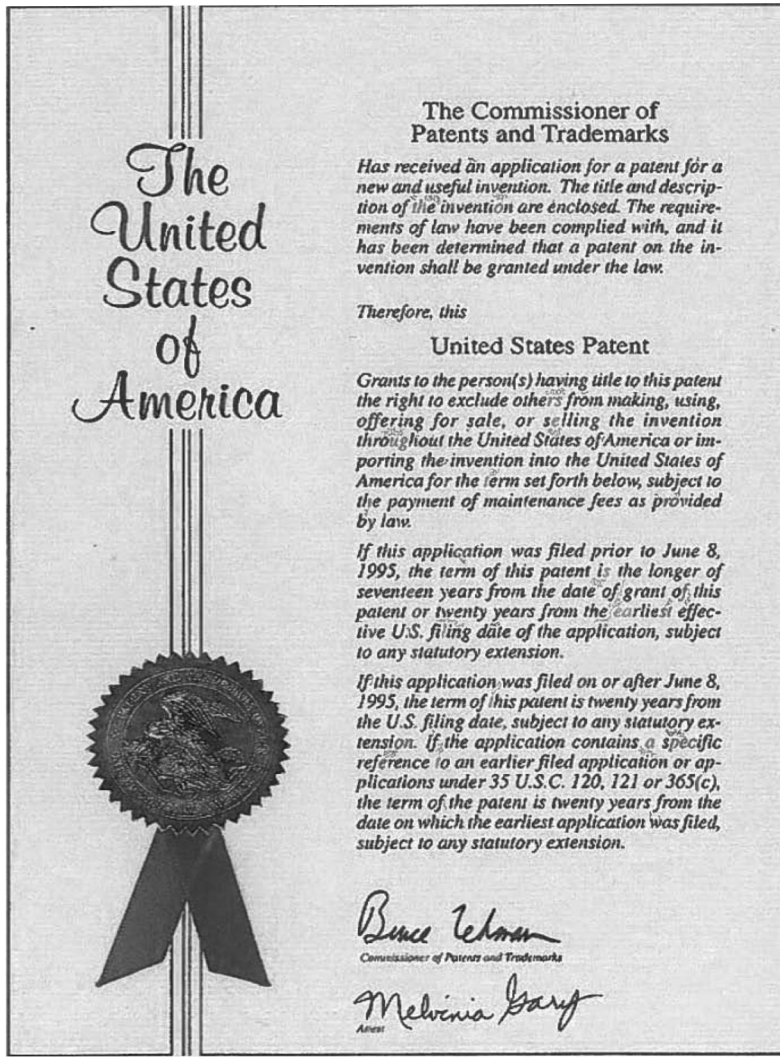
Q 1.1 What is a patent?

A patent is a right, granted by the government, to exclude others from making, using, offering to sell, selling, or importing an invention.[1] A patent grants no affirmative rights to its holder (that is, it does not grant the patentee the right to *do* anything). Instead, a patent permits its owner to exclude others from engaging in certain specified activities, such as making certain products or performing certain processes. In essence, a patent gives the patent holder a functional monopoly over the patented invention.

The patent itself is a printed document that is sent to the patent owner. Shortly after a patent is issued, it is made publicly available by publication on the United States Patent and Trademark Office (PTO) website.[2] As shown in Fig. 1-1, an official, original patent bears the seal of the PTO and a red ribbon.

Each patent includes a cover page containing certain administrative information (such as the patent's title, its number, its issue date, the name of the inventor, and so forth), an abstract providing a brief overview of the invention, a detailed description of the invention, accompanying drawings (if necessary), and the patent claims. The abstract, written description, and claims are considered part of the patent's "specification."[3] The claims are the most important part of the patent, because they identify those aspects of the invention that are legally protected by the patent.[4]

FIGURE 1-1
Patent Grant



The United States of America

The Commissioner of Patents and Trademarks

Has received an application for a patent for a new and useful invention. The title and description of the invention are enclosed. The requirements of law have been complied with, and it has been determined that a patent on the invention shall be granted under the law.

Therefore, this

United States Patent

Grants to the person(s) having title to this patent the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States of America or importing the invention into the United States of America for the term set forth below, subject to the payment of maintenance fees as provided by law.

If this application was filed prior to June 8, 1995, the term of this patent is the longer of seventeen years from the date of grant of this patent or twenty years from the earliest effective U.S. filing date of the application, subject to any statutory extension.

If this application was filed on or after June 8, 1995, the term of this patent is twenty years from the U.S. filing date, subject to any statutory extension. If the application contains a specific reference to an earlier filed application or applications under 35 U.S.C. 120, 121 or 365(c), the term of the patent is twenty years from the date on which the earliest application was filed, subject to any statutory extension.

Bruce Lehman
Commissioner of Patents and Trademarks

Melvinia Garg
Attest

Q 1.2 Where can I find U.S. patent law?

The government's authority to grant patents comes directly from the U.S. Constitution. Under Article I, Section 8, Clause 8, Congress has the power "[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries." Pursuant to this enumerated constitutional power, "Congress has passed a series of patent laws that grant certain exclusive rights over certain inventions and discoveries as a means of encouraging innovation."[5]

The first Congress passed the initial Patent Act in 1790, shortly after the adoption of the Constitution.[6] The currently applicable patent statute—the United States Patent Act of 1952 and its subsequent amendments—was significantly amended on September 16, 2011, by the Leahy-Smith America Invents Act (AIA)[7]. The AIA introduced some major changes to U.S. patent law. The implementation dates for the various changes in the AIA range from September 16, 2011, to September 16, 2020, with the majority of changes having taken effect either one year after the enactment of the AIA, on September 16, 2012, or eighteen months after enactment of the AIA, on March 16, 2013. This text will discuss the procedures in place both before and after the effective dates of various provisions of the AIA, noting the differences between the two time periods when appropriate.

Generally, the U.S. patent laws have been codified in Title 35 of the United States Code, although some provisions can be found in other related statutes. These statutes include Title 7—Agriculture (Chapter 57, containing the laws that make up the Plant Variety Protection Act); Title 15—Commerce and Trade (laws relating to support for technological innovation by the government); Title 19—Customs Duties (laws governing actions in the International Trade Commission and unfair competition laws involving patents); Title 21—Food and Drugs (newly developed drugs), Title 26—Internal Revenue Code (federal tax treatment of intellectual property, including patents); Title 28—Judiciary and Judicial Procedure (laws relating to documentary evidence in patent cases and unfair competition remedies); and Title 42—The Public Health and Welfare (laws relating to government interests in patents). Regulations concerning rules of practice before the PTO can be found in Title 37 of the Code of Federal Regulations.

The PTO's Manual of Patent Examining Procedure, commonly known as the MPEP, contains PTO-drafted procedural instructions for use by patent examiners (who work for the PTO) and patent agents (who represent inventors).[8] The MPEP "is commonly relied upon by patent examiners on procedural matters," and "[w]hile the MPEP [does] not have the force of law, it is entitled to judicial notice as an official interpretation of statutes or regulations as long as it is not in conflict therewith."[9]

Congress has granted the federal district courts original, exclusive jurisdiction over patent cases,[10] and has granted the U.S. Court of Appeals for the Federal Circuit exclusive jurisdiction over patent appeals.[11] Patent cases are therefore heard by federal district courts, appealed to the Federal Circuit, and may ultimately be decided by the U.S. Supreme Court. Decisions of the Federal Circuit (and the Supreme Court) on questions of patent law are binding on all district courts.

Q 1.2.1 What is the review process within the PTO?

Patent applications are reviewed by the PTO in a process commonly referred to as "patent prosecution." During the prosecution of an application, patent examiners within the PTO review the application and make decisions about the patentability of its inventions. Those decisions may be appealed to the PTO's internal review board, called the Patent Trial and Appeal Board (PTAB).[12] The PTAB publishes its decisions, which are useful in interpreting U.S. patent laws and regulations.

Q 1.2.2 How are PTO decisions appealed?

A patent applicant dissatisfied with the decision of the PTAB regarding a patent application may appeal to the Federal Circuit[13] or may file a civil action in the U.S. District Court for the Eastern District of Virginia.[14] Similarly, a party to a special case called an interference[15] who is dissatisfied with the decision of the PTAB may appeal to the Federal Circuit or may file a civil action in the U.S. District Court for the Eastern District of Virginia.[16] On March 16, 2013, interference proceedings were replaced by derivation proceedings for patent applications that contain or that ever contained one or more claims

with an effective filing date on or after March 16, 2013. Derivation proceedings may be appealed in the same manner as interference proceedings—to the Federal Circuit or by filing a civil action.[17] By contrast, a patent owner in a reexamination or a party to other PTO proceedings—known as inter partes reviews and post-grant reviews—who is dissatisfied with the decision of the PTAB "may appeal the Board's decision *only* to the United States Court of Appeals for the Federal Circuit."[18]

Q 1.2.3 What is the standard of review for PTO decisions?

As a government agency, the PTO falls within the rubric of the Administrative Procedure Act (APA),[19] and the scope of judicial review of PTO actions is typically governed by section 706 of the APA.[20] As set forth in that section, a court reviewing an agency decision "shall decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of an agency action."[21] With respect to factual determinations, "[t]he reviewing court shall . . . hold unlawful and set aside agency action, findings, and conclusions found to be . . . unsupported by substantial evidence."[22] Reviewing a factual decision for "substantial evidence," in turn, "requir[es] a court to ask whether a reasonable mind might accept a particular evidentiary record as adequate to support a conclusion."[23] In contrast, legal decisions of the PTAB are reviewed without deference, that is, de novo.[24]

However, as a result of a recent Supreme Court case, if a patent applicant brings a civil action pursuant to 35 U.S.C. § 145 to challenge the PTO's rejection of a patent application and presents new factual evidence, the reviewing court must review the new evidence as well as the PTO's factual findings de novo.[25]

Purpose of Patents

Q 1.3 What is the purpose of granting patents?

Patents are intended to reward and encourage innovation while at the same time ensuring that useful knowledge and developments are made available to the public. These goals are achieved through what is commonly referred to as the "patent bargain"—the patentee agrees to disclose his or her invention publicly (through the patenting process)

in exchange for the right to exclude others from making, using, selling, offering to sell, or importing the invention for a limited time.[26] U.S. patent law does not impose any obligation on a patent owner to use the patent, to manufacture any article covered by it, or to license it.

Q 1.4 What are the advantages of obtaining a patent?

Because the patent holder has the right to exclude others from making, using, selling, offering to sell, or importing the patented invention, the patent holder has, in effect, a government-granted monopoly over the invention for the duration of the patent term. This permits the patentee to benefit financially (1) by exploiting the patent himself, for example, by using the patented invention in a commercial product, and/or (2) by granting licenses to others to exploit the invention in exchange for royalties or other consideration.

Types of Patents

Q 1.5 What are the types of patents?

There are three basic kinds of patents: (1) utility patents, (2) design patents, and (3) plant patents. Utility patents are the most common type of patent and provide patent protection for the kinds of useful items and processes that most people think of when they think of patents (for example, the light bulb, the phonograph, or pharmaceutical compounds). In contrast, design patents and plant patents are specialty patents defined by specific provisions of Title 35 that set forth the corresponding patentability requirements.

Q 1.5.1 What is a utility patent?

Utility patents offer protection for "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof."[27] These four statutory categories (process, machine, manufacture, and composition of matter) comprise the entirety of patentable subject matter for utility patents. Each category is discussed in greater detail below, in QQ 1.9.1 to 1.9.4. Unless otherwise stated in this book, reference to a "patent" generally refers to a utility patent.

Q 1.5.2 What is a design patent?

A design patent protects "any new, original, and ornamental design for an article of manufacture."[28] In essence, it protects the nonfunctional aspects of an item. Design patents can be awarded for designs of jewelry, fabrics, furniture, vehicles, or other equipment. It is possible to obtain both utility and design patents for the same invention. Design patents are governed specifically by the provisions of 35 U.S.C. §§ 171–173.

Q 1.5.3 What is a plant patent?

A plant patent protects the invention or discovery of "any distinct and new variety of plant" that the inventor has "asexually reproduce[d]."[29] Asexual reproduction is reproduction that does not involve fertilization of seeds; it can include reproduction methods such as grafting, layering, or division. Plant patents are not available for tubers (that is, modified plant structures that swell to store nutrients to support re-growth, such as potatoes) or for any plants discovered in an uncultivated (that is, wild) state. Plant patents are governed specifically by the provisions of 35 U.S.C. §§ 161–164.

Duration of Patent Rights

Q 1.6 How long does a patent last?

Generally, once issued, a patent term begins on the date of issue and lasts for twenty years from the date on which the patent application was filed, except for design patents, which last for fourteen or fifteen years from the date of issuance.[30]

Q 1.7 Can the term of a patent be extended or adjusted?

Yes.[31] Before 1994, the effective term of a patent was seventeen years and commenced on the date the patent was issued. However, after statutory revisions, the patent term was extended to twenty years, commencing on the date the application for the patent was filed (instead of the issue date).[32] Under the new scheme, it was possible for the effective term of the patent to be reduced if delays in the PTO

prolonged the time between filing and issuance. To ensure that patent holders received a minimum seventeen-year patent term, in 1999 Congress enacted several provisions that promote the timely resolution of patent prosecutions within the PTO and allow extensions of the twenty-year period when delays caused by the PTO prevent the timely issuance of a patent.[33] Legislation also provides for extensions to a patent's term if issuance is held up by regulatory delays.[34] These extensions are most common in the field of pharmaceuticals.

Collectively, these statutory provisions give the patentee three patent term "guarantees"—also called patent term adjustments (PTAs). First, the patent applicant will receive a prompt initial response from the PTO. Second, the patent application will remain pending for no more than three years. Third, the patent term will be adjusted for delays due to certain extraordinary PTO procedures, such as interferences/derivation proceedings,[35] secrecy orders, and appeals.[36]

For example, if the PTO fails to provide an applicant with a first substantive response within fourteen months of the date of application, the term of the patent is extended by one day for each day of delay after the fourteen-month deadline.[37] Likewise, if a patent has not issued within three years of the date of an original application (that is, the first of a possible chain of applications relating to the same invention), the patent term can be extended one day for each day after the end of the three-year period (thereby guaranteeing a minimum of seventeen years of patent protection).[38]

An applicant, however, cannot unnecessarily delay prosecution of a patent. Each extension provision contains explicit carve-outs for delays caused by the applicant, and a separate, stand-alone provision calls for a reduction in the available term adjustments if the applicant fails to make reasonable efforts to conclude prosecution of the application. For example, if an applicant requests continued examination of a patent, the time taken by the PTO to conduct that continued examination will not provide grounds for a term extension.[39] It is, therefore, important to consult the patent provisions to determine if extensions are available under section 154, and if so, for what length of time.[40]

Q 1.7.1 What is a Hatch-Waxman extension?

A statutory extension—often called the Hatch-Waxman extension—was added as part of the Drug Price Competition and Patent Term Restoration Act of 1984.[41] This extension is codified in 35 U.S.C. § 156, and applies primarily to pharmaceutical compounds, medical devices, and food additives that are subject to testing and review by the Food and Drug Administration. The Hatch-Waxman extension runs from the normally determined expiration date of the patent (adjusted by section 154 as appropriate) and lasts for a term equal to the time of the regulatory review period (subject to certain exceptions).[42] To obtain this extension, the patentee (or the patentee's agent) must submit an application to the PTO setting forth administrative information concerning the invention and the circumstances of the regulatory review.[43] Additional specific and detailed requirements for the extension are set forth in the statute.

Q 1.8 Can the term of a patent be reduced?

The term of a patent may also be reduced under certain circumstances. For example, when a patentee claims that the content of a patent application relates to an earlier-filed application—known as "claiming priority" to an earlier U.S. patent application—the term of the patent (twenty years from the filing date) must be calculated from the filing date of the *earlier* application instead of the application under consideration. This subject is discussed further in Q 3.9.

A patent's term may also be reduced if the patent applicant files what is known as a "terminal disclaimer." A terminal disclaimer is a response to a "double-patenting" rejection from a patent examiner. A "double-patenting" rejection is issued by an examiner if he or she believes that the same invention was claimed in an earlier patent or patent application by the same inventor. Double patenting and terminal disclaimers are discussed further in QQ 5.12.1 and 5.12.2.

Patentable Subject Matter

Q 1.9 What kinds of inventions are considered patentable?

Section 101 of the Patent Act identifies those inventions that may qualify for protection under a utility patent: "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof."[44] Thus, excluding design and plant patents, four types of inventions are protectable by patent: (1) process; (2) machine; (3) manufacture; and (4) composition of matter. The purpose of these statutory classes is to comply with the constitutional mandate restricting patent protection to the field of "useful arts" or applied technologies, thereby excluding abstract, theoretical, or purely academic discoveries.[45] Each category is discussed below.

Q 1.9.1 What is a process?

A patentable process is a method, operation, or series of steps taken to achieve a certain useful result. The process may consist of a series of steps that lead to something new and useful (in which case the article produced may be separately patentable), or the process may be a new way of achieving something that is already known. The Patent Act 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."[46] Patentable processes can include, among other things, chemical processes (leading to certain chemical compounds), mechanical processes, or electrical processes.

A "method patent" is one common kind of process patent. Method patents are patents protecting a series of steps to be performed to achieve a certain result. As the Federal Circuit has explained, "[a] method, by its very nature, is nothing more than the steps of which it is comprised. The invention recited in a method claim is the performance of the recited steps."[47] For example, a patent claim may provide for a method of "removal of post reactive ion etch by-product from a semiconductor having organic low K material."[48]

Q 1.9.2 What is a machine?

A machine is a mechanical apparatus. It is perhaps the most obvious category of patentable subject matter, because it encompasses familiar mechanical devices like printing presses and engines.

Q 1.9.3 What is a manufacture?

A manufacture is a man-made apparatus. Unlike a machine, a manufacture typically lacks moving parts. Whereas a printing press is a machine, a screwdriver or a pencil is a manufacture. For example, a patent claim may disclose "[a] vertical channel field effect transistor disposed on a surface of a substrate."[49]

Q 1.9.4 What is a composition of matter?

A composition of matter consists of a mixture of ingredients. A common example is a chemical compound created in a lab that possesses useful properties or effects, perhaps as a pharmaceutical drug or a detergent. To be patentable, compositions of matter must be created and not merely "found" in nature. Although naturally occurring substances may serve as the ingredients for a composition of matter, the mere discovery of a previously unknown and unmodified natural substance is not patentable.

Q 1.10 What are the limits of the kinds of inventions that can be patented?

The four statutory categories of patentable subject matter listed in section 101 are a useful starting point for determining whether or not a particular process or thing is patentable, but, as the Supreme Court has recognized (see *Diamond v. Chakrabarty* Case Study below), there are limits to the application of the bright line categories—some objects may not fit neatly into any category, and other objects may seem to fit several categories at the same time.

Q 1.10.1 Can products of nature be patented?

No, a "product of nature" is a naturally occurring substance or organism, such as "a new mineral discovered in the earth or a new plant found in the wild."[50] A product of nature is considered to be

"the handiwork of nature" rather than a "product of human ingenuity" and falls within the "law of nature" exception to patentability.[51] (See Q 1.10.2.) An invention based on a product of nature, however, including an invention based on a living organism, is patentable when the invention has "markedly different characteristics" from anything found in nature. In the 1980 case of *Diamond v. Chakrabarty*[52] (see Case Study below), the Supreme Court approved the grant of patents for living organisms, allowing a patent to be granted for a new micro-organism. There are limits to the patentability of living organisms, however. The America Invents Act specifically prohibited the issuance of any patent claim directed to or encompassing a human organism.[53]

CASE STUDY: *Diamond v. Chakrabarty*

In 1980, the Supreme Court decided the seminal case of *Diamond v. Chakrabarty*, in which an applicant sought patent protection for a living micro-organism: a genetically engineered bacterium capable of breaking down crude oil. Without deciding whether such an organism was a "manufacture" or "composition of matter"—and over objections concerning the patentability of living things—the Supreme Court held that the "micro-organism plainly qualifie[d] as patentable subject matter."[54] As the Court explained, the inventor's "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."[55] The Court noted that the patentee 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."[56]

Diamond not only confirmed the patentability of items that do not neatly fit into one of the statutory categories, and approved the grant of patents for living things, but also reaffirmed the Supreme

Court's view that the categories of patentable subject matter identified in section 101 must be construed broadly in order to fulfill the Constitution's mandate to promote "the Progress of Science and useful Arts."[57]

In *Association for Molecular Pathology v. Myriad Genetics, Inc.*[58] (see Case Study below), the Supreme Court recently considered the question of whether human genes are patentable. The Court unanimously held that isolated human genes cannot be patented because they share the same genetic information as naturally occurring DNA molecules, meaning that nothing new has been created.[59] The Court did, however, find that synthetic DNA, which has been created in a laboratory and does not share all of the same genetic material as natural DNA, can be patented because it is distinct from natural DNA and is therefore not a "product of nature."[60]

CASE STUDY: *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*

Myriad Genetics, Inc. discovered the precise location and sequence of the BRCA1 and BRCA2 genes, within which certain mutations are sometimes found that correlate with an increased risk of breast and ovarian cancer. Based upon this information, Myriad developed medical tests to detect if such mutations are present and allow a doctor to assess whether a patient has an increased risk of cancer. Myriad sought and obtained patents related to its discovery.[61]

Plaintiffs brought a declaratory judgment action challenging claims from seven Myriad patents relating to "isolated gene sequences and

diagnostic methods of identifying mutations in these sequences."[62] Of interest here were two groups of composition of matter claims: (1) claims related to isolated DNA, which has been extracted from cells but shares all of the same genetic information as naturally occurring DNA; and (2) claims related to complementary DNA (cDNA), which has been synthetically created in a laboratory and "which contains the same protein-coding information found in a segment of natural DNA [called "exons"] but omits portions within the DNA segment that do not code for proteins [called "introns"]."[63] The district court held that all of the challenged composition claims were invalid because they were directed to unpatentable "products of nature."[64]

In a split decision, the Federal Circuit reversed on the issue of subject matter eligibility, with the majority holding that the composition claims were directed to patent-eligible subject matter.[65] All three members of the panel agreed that the cDNA claims were patent-eligible, but the court split on the issue of the isolated DNA claims. Judge Lourie opined that the isolated DNA claims were patentable, relying on the fact that when DNA is isolated, the covalent bonds at each end of the segment must be severed, which technically creates a new, non–naturally occurring molecule with a new chemical composition.[66] Judge Moore agreed that the isolated DNA claims were patentable, but in addition to chemical differences, she also relied on the USPTO's longstanding policy of granting patents on isolated DNA and the reliance interests of patent holders.[67] Judge Bryson, dissenting in part, opined that the isolated DNA claims were unpatentable, noting that the nucleotide sequences in the claimed molecules were the same as in naturally occurring human genes, and arguing that merely isolating a gene "is akin to snapping a leaf from a tree."[68]

The Supreme Court granted certiorari on the single question of whether human genes are patentable.[69] The Court unanimously held that the claims to isolated DNA are not patent-eligible, but that the claims to cDNA are patent-eligible. Justice Thomas,

writing for the Court,[70] opined that Myriad's claims to isolated DNA "fell squarely within the law of nature exception."[71] Even though Myriad had engaged in "extensive effort" to locate the BRCA1 and BRCA1 genes, "extensive effort alone is insufficient to satisfy the demands of § 101."[72] He also noted:

> 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.[73]

The Court rejected Myriad's argument that the minor chemical differences between naturally occurring and isolated DNA were sufficient to hold isolated DNA patentable. Myriad's claims focused not on the chemical composition of the BRCA1 and BRCA2 genes, but on the genetic information encoded in those genes, and this information is the same in naturally occurring and isolated DNA.[74]

The Court, however, held that the cDNA claims *were* patent-eligible because "the creation of a cDNA sequence from mRNA results in an exons-only molecule that is not naturally occurring."[75] Synthetic cDNA does not include introns, which are present in naturally occurring DNA.[76] Thus, while "cDNA retains the naturally occurring exons of DNA, . . . 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."[77]

In August 2015, in a panel opinion, the Federal Circuit concluded that a patent claiming a method for testing the fetal DNA of an unborn child by amplifying the paternally inherited DNA in a plasma sample taken from a pregnant female was not patent-eligible under section 101, even though it was novel and groundbreaking.[78] The Federal Circuit denied the patent holder's petition for en banc review, but several judges indicated in concurrences that the panel was bound by the decisions in *Mayo* and *Alice*.[79]

In 2016, in *Rapid Litigation Management v. CellzDirect, Inc.*,[80] the Federal Circuit determined that a patent directed to a method of producing a biological product passed step one of the *Mayo/Alice* test. The Federal Circuit observed that step one of the *Mayo/Alice* test is whether the claims are directed to "a patent-ineligible concept" and concluded that the claims at issue were not, because even though the patented method identified a newly discovered law of nature, "that is not where [the inventors] stopped, nor is it what they patented."[81] Instead, the inventors "employed their natural discovery to create a new and improved way" of producing a biological product.[82] In the alternative, the Federal Circuit evaluated whether the patent also satisfied step two of the *Mayo/Alice* test, and concluded that it did.[83] In particular, the court concluded that even if the method were held to be directed to a "patent-ineligible concept," the claimed steps were not "routine or conventional" because the prior art taught away from employing those steps in the claimed fashion.[84]

In 2018, the Federal Circuit held that the method-of-treatment claims at issue in *Vanda Pharmacueticals v. West-Ward Pharmaceuticals* are patent eligible, the first case to do so since the Supreme Court's *Mayo* decision.[84.1] The method-of-treatment claims at issue in *Vanda* are directed to a method of treating schizophrenia patients with iloperidone wherein the dosage range is based on the patient's genotype.[84.2] The court held that the claims in question were "directed to a specific method of treatment for specific patients using a specific compound at specific doses to achieve a specific outcome." Therefore, the court found that *Rapid Litigation* supports the conclusion that these claims are patent-eligible, since they are not directed to the body's natural ability to undergo a process, but rather to a new and useful method.

Q 1.10.2 Can natural processes or ideas be patented?

No. The four categories of patentable material (process, machine, manufacture, and composition of matter) are construed broadly, but they are not limitless. Although it is not the exclusive test of patentable subject matter under recent Supreme Court precedent, courts typically employ the so-called "machine or transformation" test to determine if subject matter is a patentable "process" under 35 U.S.C. § 101.[85] The "machine or transformation" test requires that an item be created, transformed, or manipulated by man to be considered

patentable.[86] As the Supreme Court has stated, "[h]e who discovers a hitherto unknown phenomenon of nature has no claim to a monopoly of it which the law recognizes. If there is to be invention from such a discovery, it must come from the application of the law of nature to a new and useful end."[87] Accordingly, laws of nature or physical phenomena are not patentable.[88] For example, neither Einstein's formula $E = mc^2$ nor Newton's laws of gravity would be patentable because they represent "manifestations of . . . nature, free to all men and reserved exclusively to none."[89] Similarly, ideas alone or abstract principles that are not reduced to useful practice or devices are not patentable.

Recently, in *Alice Corp. Pty. Ltd. v. CLS Bank International*[90] (see Case Study below), the Supreme Court unanimously held that claims directed to a scheme for mitigating settlement risk in business transactions were directed to an abstract idea and "merely requiring generic computer implementation fails to transform that abstract idea into a patent-eligible invention."[91] The Court also provided a framework for analyzing whether a patent claims patent-eligible subject matter.

CASE STUDY: *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*

Alice Corporation is the assignee of the patents in suit, which were directed to a computerized scheme for mitigating settlement risk.[92] CLS Bank operates a global network which facilitates currency transactions.[93] CLS filed a declaratory judgment action against Alice asserting that the claims at issue were invalid, unenforceable, or not infringed.[94] After the *Bilski v. Kappos* decision[95] was issued, the parties filed cross-motions for summary judgment regarding whether the claims were directed to patent-eligible subject matter.[96] The district court granted summary judgment in favor of CLS, holding all asserted claims invalid under section 101 because they were "directed to an abstract idea."[97] The Federal Circuit reversed, finding that

> [u]nless the single most reasonable understanding is that a claim is directed to nothing more than a fundamental truth or disembodied concept, with no limitations in the claim attaching that idea to a specific application, it is inappropriate to hold that the claim is directed to an unpatentable "abstract idea" under 35 U.S.C. § 101.[98]

The Federal Circuit, rehearing the case en banc, issued a fractured decision in which it upheld the district court's determination of patent-ineligible subject matter.[99] In all, the en banc decision included seven separate opinions, none of which garnered a majority, and it set out three different approaches to evaluating whether a claim is patent-eligible under section 101 or is directed to a patent-ineligible "abstract idea."

The Supreme Court granted certiorari on the single question of whether the claims directed to a computerized system and method of mitigating settlement risk were patent-eligible or instead directed to a patent-ineligible abstract idea.[100] The Court unanimously held that the claims were not patent-eligible."[101]

The Court began its analysis by reciting the basis for patentable subject matter in section 101 and its holding in *Myriad* that created the exception for laws of nature, natural phenomena, and abstract ideas.[102] The Court stated that "in applying the § 101 exception, we must distinguish between patents that claim '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."[103]

The Court explained that the proper framework for analysis to distinguish patents that claim patent-eligible versus patent-ineligible subject matter was set out in its *Mayo* opinion.[104] First, there must be a determination of whether the claims are directed to the "patent-ineligible concepts"—that is, laws of nature, natural phenomena, and abstract ideas.[105] Second, if the answer is yes,

then the question is whether there is 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."[106] In answering this question, the elements of the claim must be considered both individually and "'as an ordered combination' to determine whether the additional elements 'transform the nature of the claim' into a patent-eligible application."[107]

Proceeding with the *Mayo* analysis, the Court first determined that the patent claims were drawn to an abstract idea.[108] The Court noted that in its *Gottschalk v. Benson* opinion,[109] it found ineligible patent claims to "an algorithm for converting binary-coded decimal numerals into pure binary form."[110] In *Parker v. Flook*,[111] the Court found ineligible "a mathematical formula for computing 'alarm limits' in a catalytic conversion process."[112] And in *Bilski v. Kappos*,[113] the Court found ineligible "a method for hedging against the financial risk of price fluctuations."[114] It then noted that, like *Bilski*, the claims to "intermediated settlement" in this case were drawn to an abstract idea.[115]

The Court then turned to the second prong of the *Mayo* analysis to determine that the claims "fail to transform [the] abstract idea into a patent-eligible invention."[116] The Court noted that *Mayo* is instructive in this regard since it found that the claimed methods of determining metabolite levels were nothing more than instructions to doctors to apply known methods when treating patients.[117] The Court reasoned that adding a computer into the claims does not alter the result.[118] Furthermore, the Court explained that "the prohibition against patenting abstract ideas cannot be circumvented by attempting to limit the use of [the idea] to a particular technological environment."[119] The Court contrasted the outcomes of *Benson* and *Flook* with *Diamond v. Diehr*,[120] because, in *Diehr*, the subject computer-implemented process for curing rubber solved a problem the industry was unable to solve and therefore the added steps "transformed a patent-ineligible

abstract idea into a patent-eligible invention.[121] The Court observed that, regarding the methods of mitigating settlement risk, "each step does no more than require a generic computer to perform generic computer functions," and considering the steps in combination, the claimed method did not add anything that was not already present when the steps were considered individually.[122]

Q 1.10.3 Can business methods be patented?

A business method patent covers a particular manner of conducting business. For example, a business method claim could cover "[a] method of managing transactions with multiple broker affiliates, each broker affiliate having an affiliate computer and an affiliate database connected thereto."[123]

The Supreme Court held in *Bilski v. Kappos* (see Case Study below) that business methods may be patentable.[124] The availability of such patents, however, like all patents, is subject to the ordinary limiting principles of patent law—for example, the principle that mere abstract ideas are not patentable.[125] Therefore, to be patentable, a business method must meet all of the other statutory requirements of the Patent Act.[126]

Concerns have been raised in recent years that many poor business method patents were issued by the PTO from the late 1990s through the early 2000s, at a time when the PTO "lacked a sufficient number of examiners with expertise in the relevant art area" and "there was a dearth of available prior art to assist examiners as they reviewed business method applications."[127] Critics contend that these patents have contributed to the proliferation of lawsuits by nonpracticing entities (often called "NPEs" or "patent trolls").[128]

To address these concerns, the AIA established an eight-year temporary post-grant program for the review of business method patents called the "Transition Program for Covered Business Method Patents."[129] Under this program, a party who has been sued for infringement or charged with infringement under a business method patent

may petition the PTO for a review of the patent's validity.[130] After filing under this program, the petitioner is precluded from later asserting invalidity before a federal court or the ITC "on a ground that was considered and resulted in a written decision by the agency in the course of a transitional proceeding."[131] The program took effect on September 16, 2012, and expires on September 16, 2020.[132] All business method patents, regardless of filing date, are subject to this program during its applicability. For further information regarding the patent eligibility of methods patents generally, see the discussion of *Alice* in Q 1.10.2.

CASE STUDY: *Bilski v. Kappos*

In June 2010, the Supreme Court examined the patentability of business methods in *Bilski v. Kappos*.[133] Plaintiffs sought to patent an invention "that explains how buyers and sellers of commodities in the energy market can protect, or hedge, against the risk of price changes."[134] There were two main claims at issue: claim 1 set forth a series of steps describing how to hedge risk and claim 4 put the steps of claim 1 into a mathematical formula. The patent examiner rejected the application as an "abstract idea" that "is not implemented on a specific apparatus."[135] The patent examiner's rejection was upheld by the former Board of Patent Appeals and Interferences (BPAI) and subsequently by the Federal Circuit, sitting en banc but issuing five separate opinions including three dissents.[136] The Federal Circuit's majority opinion held that the so-called "machine-or-transformation" test was the sole test for determining whether a process is patentable under section 101.[137]

The Supreme Court took up the various issues raised by the Federal Circuit's review and reached the following conclusions:

(1) The machine-or-transformation test is not the exclusive test for a patentable "process," because, among other

things, technology progresses in unexpected ways and "new technologies may call for new inquiries." Adopting the machine-or-transformation test as the exclusive test for patentable processes might improperly exclude from patentability emerging technologies (such as software, advanced diagnostic medical techniques, and data compression) that may not fit squarely into that test.[138]

(2) Business methods are not categorically outside the scope of patentable subject matter under section 101; in other words, business methods may be patentable. Because the category of business methods is potentially broad, however, the Court emphasized that the usual limiting principles in the Patent Act must be applied when determining whether a business method warrants patent protection. In particular, the Supreme Court identified two such principles that must be taken into consideration: (1) the rule that mere "abstract ideas" are not patentable; and (2) the other statutory requirements of the Patent Act, such as section 102 (describing the novelty requirement), section 103 (describing the nonobviousness requirement), and section 112 (setting the requirements for the specification).[139]

(3) The invention claimed by plaintiffs (described above) was not a patentable process under section 101, because it was an "abstract idea."[140]

Q 1.10.4 Can software be patented?

The first Supreme Court opinion relating to the patentability of software was *Gottschalk v. Benson*, decided in 1972.[141] The Court held that the software in question was not patentable because it related solely to a method of programming a general purpose computer to convert numbers from binary-coded decimal form to binary form and, as such, was directed to an unpatentable abstract idea.[142]

The Court noted that "[u]ncertainty now exists as to whether the statute permits a valid patent to be granted on programs"[143] and that "considered action by Congress is needed."[144]

The next Supreme Court decision to involve the patentability of software was *Parker v. Flook*, decided in 1978.[145] The Court held that Flook's application for a method of updating alarm limits in which a time-weighted average is taken of a variable to determine a smoothing function is not patentable as it is merely a mathematical formula. The Court noted that, in *Gottschalk v. Benson*, the discovery of a new and novel mathematical formula was held to be unpatentable and, in this case, the question of whether the disclosure of an *application* of a mathematical formula is patentable is merely exalting form over substance.[146] The Court also noted, however, that "it is equally clear that a process is not unpatentable simply because it contains a law of nature or a mathematical algorithm."[147]

The third in this trilogy of early Supreme Court cases on the eligibility of software patent protection is the *Diamond v. Diehr* opinion, decided in 1981.[148] This time, the Court found that the software claims did comprise patentable subject matter;[149] in this case, the claims were directed to a process for curing synthetic rubber using an iterative software algorithm to obtain uniformly accurate cures that had not been able to be achieved by the industry because the varying temperature inside the molding press could not be measured precisely using manual methods.[150] The Court reasoned that

> respondents' claims involve the transformation of an article, in this case raw, uncured synthetic rubber, into a different state or thing [and that conclusion] cannot be disputed. The respondents' claims describe in detail a step-by-step method for accomplishing such, beginning with the loading of a mold with raw, uncured rubber and ending with the eventual opening of the press at the conclusion of the cure. Industrial processes such as this are the types which have historically been eligible to receive the protection of our patent laws.[151]

Subsequent decisions, however, have made clear that the availability and extent of patent protection for software is not well settled in the law. In 1994, the Federal Circuit had held that "a computer operating pursuant to software *may* represent patentable subject matter,

provided, of course, that the claimed subject matter meets all of the other requirements of Title 35."[152] Supporting patentability, in 1999, the Federal Circuit ruled that disclosure of an algorithm that is processed on a microprocessor or computer provides sufficient corresponding structure for software patents to meet patentability requirements.[153]

The Federal Circuit's *Bilski* decision in 2008 again called into question the general patentability of software given its holding that the so-called "machine-or-transformation" test (requiring that a "process" be tied to a particular machine or apparatus, or transform an article into a different state or thing to be eligible for patenting) is the sole test for determining the patentability of a process.[154] However, in its *Bilski* decision, the Supreme Court rejected the exclusivity of the machine-or-transformation test in part to avoid "uncertainty as to the patentability of software."[155] Thus, the Court reaffirmed that software may be patentable.[156]

While many thought the Supreme Court's *Alice* decision in 2014 (see Case Study above) would finally resolve the issue, it instead also cast significant doubt on the continued patentability of software-related claims.[157] This uncertainty was evident in many district court decisions that followed *Alice*.[158] In addition, in a show of confidence by the industry, recent trends indicate that a high percentage of recent patent issuances for some of the largest technology companies are directed to software.[159]

In 2016, the Federal Circuit issued several section 101 opinions that provided additional guidance on the patent eligibility of software patents, including some of the first cases since 2014 finding claims patent-eligible under the *Mayo/Alice* standard.[160] The Federal Circuit articulated the inquiry of step one of the *Mayo/Alice* test in the case of software patents as "whether the claims are directed to an improvement to computer functionality versus being directed to an abstract idea."[161] In *McRO v. Bandai*, the court developed this idea further, stating that "the abstract idea exception has been applied to prevent patenting of claims that abstractly cover results where it matters not by what process or machinery the result is accomplished," in other words, where the claims preempt the field of invention.[162] Occasionally, the court has also suggested that steps one and two may be collapsed into a single inquiry.[163]

In *Enfish v. Microsoft*, the court concluded that because the software claims at issue were focused "on the specific asserted improvement in computer capabilities," and were not directed at an abstract idea, there was no reason to address step two of the *Mayo/Alice* test.[164] Similarly, in *McRO*, the court held that because the patented claims were directed to only one of many ways to accomplish the same result, in that case to synchronize the lips of animated characters with their speech, the claims were not directed to an "abstract idea."[165]

The patent in *BASCOM* was directed to an improved method for filtering content on the Internet that was less susceptible to hacking than prior art methods.[166] In its analysis, the Federal Circuit indicated that the step one inquiry was not as clear-cut as in *Enfish* and stated that it "presents a close call about how to characterize what the claims are directed to."[167] The court found that while the claim limitations, taken individually, recited generic computer, network, and Internet components, the patent nonetheless satisfied section 101 because it did not preempt all methods of filtering content on the Internet.[168] Instead, the patent was directed to a dynamic, individualized content filter rather than the prior art static filter.[169]

On the other end of the spectrum, in *In re TLI Communications LLC Patent Litigation*, the court first concluded that the claims at issue were abstract because they were generalized steps to be performed on a computer rather than improvements to computer functionality.[170] Then, applying step two of the *Mayo/Alice* test, the court concluded that additional elements of performing these known functions did not support patent eligibility because they were well-understood, routine, conventional activities.[171]

Q 1.10.5 Can tax strategies be patented?

No. Congress has determined that "[t]he ability to interpret the tax law and implement such interpretations should remain in the public domain, available to all taxpayers and their advisors."[172] The AIA mandates that strategies for reducing, avoiding, or deferring tax liability "shall be deemed insufficient to differentiate a claimed invention from the prior art."[173] This means that "any future tax strategy will be considered indistinguishable from all other publicly available information that is relevant to a patent's claim of originality."[174]

Q 1.10.6 Are the requirements for plant patents different from those of utility patents?

Yes, the requirements for plant and utility patents differ. While utility patents require novelty, utility, and nonobviousness, plant patents require novelty, distinctness, and nonobviousness, and there is an additional requirement of asexual reproduction.[175] Distinctness, in turn, has been defined by the Supreme Court as "the aggregate of the plant's distinguishing characteristics."[176]

Q 1.10.7 Are the requirements for design patents different from those of utility patents?

Yes, the requirements for design patents differ from those for utility patents. While utility patents require novelty, utility, and nonobviousness, design patents require novelty, originality, and nonfunctionality—that is, a design patent must be a new, original, and ornamental design for an article of manufacture.[177]

Notes to Chapter 1

1. *See* 35 U.S.C. § 154(a)(1) ("Every patent shall contain . . . a grant to the patentee . . . of the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States. . . .").
2. www.uspto.gov.
3. Patent practitioners sometimes use the term "specification" to refer only to the written description rather than the entire specification.
4. See chapter 2 for additional details.
5. Bilski v. Kappos, 561 U.S. 593, 621 (2010) (Stevens, J., concurring).
6. Act of Apr. 10, 1790, 1 Stat. 109 (1790); Act of Feb. 21, 1793, 1 Stat. 318 (1793).
7. Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) (AIA).
8. The MPEP is organized into chapters, including Ownership and Assignment (chapter 300); Examination of Applications (chapter 700); the Duty of Disclosure (chapter 2000); and Patentability (chapter 2100). These chapters are further broken down into subsections related to specific subjects; for example, under Examination of Applications, the MPEP contains subsections such as Time Periods for Reply (section 704.13) and Examiner's Obligation Following Applicant's Reply (section 704.14(b)). Some versions of the MPEP also include, as appendices, the statutory U.S. patent laws and regulations. The MPEP was last revised in November 2015.
9. *In re* Beasley, 117 F. App'x 739, 743 n.7 (Fed. Cir. 2004) (citations omitted).
10. 28 U.S.C. § 1338.
11. *Id.* § 1295(a)(1).
12. 35 U.S.C. § 6. The PTAB was formerly named the Board of Patent Appeals and Interferences (BPAI). The BPAI was renamed the PTAB on September 16, 2012.
13. *See id.* § 141 ("An applicant who is dissatisfied with the final decision in an appeal to the [PTAB] . . . may appeal the Board's decision to the United States Court of Appeals for the Federal Circuit.").
14. *Id.* § 145 (subject to applicable time restrictions). Prior to the AIA, proceedings against the PTO had to be brought in the District of Columbia.
15. *See* Q 7.8.
16. 35 U.S.C. § 141 (effective until Sept. 16, 2012), § 146 (effective until Mar. 16, 2013); *see also* Vas-Cath, Inc. v. Curators of Univ. of Mo., No. 05-0400-CV-W-GAF, 2007 WL 4287865, at *1 (W.D. Mo. Dec. 6, 2007) ("Following the BPAI's decision [in an interference proceeding], Plaintiff had the opportunity to seek review under 35 U.S.C. § 141 . . . , which provides for a direct appeal to the United States Court of Appeals for the Federal Circuit, or under 35 U.S.C. § 146 . . . , which allows a party dissatisfied with the BPAI's decision to file suit in a United States district court.").

17. 35 U.S.C. §§ 141, 146. An appeal to the Federal Circuit will be dismissed, however, if, within twenty days of the notice of appeal, an adverse party to the derivation proceeding "files notice with the Director that the party elects to have all further proceedings conducted as provided in section 146," that is, as a civil action in district court. The appellant has thirty days from the filing of such notice to file a civil action under section 146 or the PTAB's decision shall govern. 35 U.S.C. § 141. See chapter 7 for a discussion of interference proceedings and derivation proceedings.

18. 35 U.S.C. § 141 (emphasis added); see also QQ 6.3–6.5.6 for a discussion of reexaminations and inter partes reviews.

19. 5 U.S.C. §§ 701–708.

20. *See, e.g.*, Dickinson v. Zurko, 527 U.S. 150, 152 (1999) ("The [APA] sets forth standards governing judicial review of findings of fact made by federal administrative agencies. . . . We conclude that [section 706 of the APA] does apply, and the Federal Circuit must use the framework set forth in that section."); *In re* Chapman, 595 F.3d 1330, 1337 (Fed. Cir. 2010) (explaining that the PTO is governed by the APA "and PTO decisions are reviewed under the APA standard").

21. 5 U.S.C. § 706 ("Scope of Review").

22. *Id.* § 706(2)(E); *Zurko*, 527 U.S. at 164–65; *see also* Mazzari v. Rogan, 323 F.3d 1000, 1005 (Fed. Cir. 2003) ("Therefore, a reviewing court, whether this court or the district court, applies the 'substantial evidence' standard of review to findings of fact made by the board.").

23. *Zurko*, 527 U.S. at 162 (citations omitted) (internal quotation marks omitted).

24. *Chapman*, 595 F.3d at 1337 ("[W]e review [BPAI's] legal conclusions without deference, and review its findings of fact to determine if they are supported by substantial evidence."); *see also* Hitzeman v. Rutter, 243 F.3d 1345, 1353–54 (Fed. Cir. 2001) ("On appeal, this court's review of the Board's decision is confined to the factual record compiled by the Board, and we must affirm the Board's factual determinations if they are supported by substantial evidence. . . . We review questions of law, such as the Board's legal conclusions concerning priority, conception, and reduction to practice, *de novo.*" (citations omitted)).

25. Kappos v. Hyatt, 132 S. Ct. 1690, 1696–97 (2012) (also holding that if no new evidence is presented in support of the appeal, the reviewing court must give deference to the PTO's factual findings as promulgated in the APA).

26. *See, e.g.*, Diamond v. Chakrabarty, 447 U.S. 303, 307 (1980) ("The patent laws promote . . . progress by offering inventors exclusive rights for a limited period as an incentive for their inventiveness and research efforts."); *see also* LizardTech, Inc. v. Earth Res. Mapping, Inc., 424 F.3d 1336, 1344 (Fed. Cir. 2005) (explaining that the requirement that an inventor fully describe the patented invention "forms an essential part of the quid pro quo of the patent bargain").

27. 35 U.S.C. § 101.

28. *Id.* § 171.

29. *Id.* § 161.

30. For all design patents granted on applications filed prior to December 18, 2013, the term is fourteen years from issuance. *See* 35 U.S.C. §§ 154(a)(2), 173. For all design patents issuing from applications that were filed on or after December 18, 2013, the term is fifteen years from issuance. *See* PLTIA, Title I—Hague Agreement, 126 Stat. 1531–32, amendment to section 102.

31. *See id.* § 154(b).

32. Uruguay Round Agreements Act, Pub. L. No. 103-465, § 532, 108 Stat. 4809, 4983–88 (1994) (codified at 35 U.S.C. § 154).

33. MPEP § 2730; 35 U.S.C. § 154; 37 C.F.R. § 1.702; *see also* MPEP § 2731 (setting forth the periods of adjustment of patent term due to examination delay within the PTO).

34. MPEP § 2750; 35 U.S.C. § 156. *See also* Q 1.7.1 regarding the "Hatch-Waxman Extension."

35. For a discussion of interferences, see Q 7.8. For a discussion of derivation proceedings, see Q 7.10.

36. 35 U.S.C. § 154(b)(1)(A)–(C).

37. *Id.* § 154(b)(1)(A)(i)(I).

38. *Id.* § 154(b)(1)(B).

39. *Id.* § 154(b)(1)(B)(i).

40. *See, e.g., id.* § 154(b)(2)(C)(i) ("The period of adjustment of the term of a patent . . . shall be reduced by a period equal to the period of time during which the applicant failed to engage in reasonable efforts to conclude prosecution of the application.").

41. The Act is frequently called "Hatch-Waxman Act" or the "Hatch-Waxman Amendments" after its sponsors, Senator Orrin Hatch (UT) and Representative Henry A. Waxman (CA). Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified at 15 U.S.C. §§ 68b–68c, 70b; 21 U.S.C. §§ 301 note, 355, 355 note; 28 U.S.C. § 2201; 35 U.S.C. §§ 156, 271, 282.

42. 35 U.S.C. § 156(c).

43. *Id.* § 156(d)(1).

44. *Id.* § 101.

45. *See* 1 DONALD S. CHISUM, CHISUM ON PATENTS § 1.01 (2010); U.S. CONST. art. I, § 8, cl. 8.

46. 35 U.S.C. § 100.

47. NTP, Inc. v. Research In Motion, Ltd., 418 F.3d 1282, 1322 (Fed. Cir. 2005).

48. U.S. Patent No. 6,758,223, claim 1 (filed June 23, 2000).

49. U.S. Patent No. 6,268,621, claim 1 (filed Aug. 3, 1999).

50. Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980).

51. *Id.*

52. *Diamond*, 447 U.S. 303.

53. AIA § 33.

54. *Diamond*, 447 U.S. at 309.

55. *Id.* at 309–10 (quotation marks and alterations omitted).

56. *Id.* at 310.

57. *Id.* at 315.

58. Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107 (2013) (*Myriad*).

59. *Id.* at 2111; *see also In re* BRCA1-and BRCA2-Based Hereditary Cancer Test Patent Litig., 774 F.3d 755 (Fed. Cir. 2014) (holding that *Myriad* patent claims directed to (1) single-stranded synthetic versions of naturally occurring DNA molecules used as primers in breast cancer tests and (2) methods of detecting mutations in the BRCA1 and BRCA2 genes associated with increased risk of breast cancer are invalid as claiming patent-ineligible subject matter).

60. *Myriad*, 133 S. Ct. at 2119.

61. *Id.* at 2112–13.

62. Ass'n for Molecular Pathology v. USPTO, 689 F.3d 1303, 1310 (Fed. Cir. 2012).

63. *Myriad*, 133 S. Ct. at 2114.

64. The district court also held that several method claims were invalid under section 101, applying the "machine or transformation" test. Ass'n for Molecular Pathology v. USPTO, 702 F. Supp. 2d 181, 232–37 (S.D.N.Y. 2010). The Federal Circuit reversed in part, holding all but one of the method claims to be unpatentable. *Ass'n for Molecular Pathology*, 689 F.3d at 1333–34.

65. The Federal Circuit reversed the district court opinion in 2011. Ass'n for Molecular Pathology v. USPTO, 653 F.3d 1329 (Fed. Cir. 2011). The Supreme Court granted a petition for certiorari, vacated the judgment, and remanded the case for reconsideration in light its opinion in Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289 (2012). *See Myriad,* 132 S. Ct. 1794 (2012). On remand, the Federal Circuit affirmed in part and reversed in part, with each member of the panel writing separately. On the merits, the Federal Circuit reached the same conclusion as it did in 2011. *Ass'n for Molecular Pathology*, 689 F.3d 1303.

66. *Ass'n for Molecular Pathology*, 689 F.3d at 1328–29.

67. Judge Moore indicated that she may have decided differently if she were "deciding this case on a blank canvas." *Id.* at 1343.

68. *Id.* at 1352, 1355.

69. Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 694 (2012).

70. Justice Scalia wrote a short opinion concurring in part and concurring in the judgment, in which he opined that the judgment of the Court went "into fine details of molecular biology" and that he was "unable to affirm those details on [his] own knowledge or even [his] own belief." He agreed with the Court, however, that the claims related to isolated DNA were not patentable, while the cDNA claims were patentable. *Myriad*, 133 S. Ct. at 2120 (Scalia, J., concurring in part).

71. *Id.* at 2117.

72. *Id.* at 2118.

73. *Id.* at 2117.

74. *Id.* at 2118.

75. *Id.* at 2119.

76. *Id.*

77. *Id.* The Court noted, however, that a "very short series of DNA" may have no intervening introns to remove, in which case a short strand of cDNA may be indistinguishable from natural DNA and thus not patent-eligible. *Id.*

78. Ariosa Diagnostics, Inc. v. Sequenom, Inc., 788 F.3d 1371, 1380 (Fed. Cir. 2015) (*Ariosa*), *reh'g en banc denied*, 809 F.3d 1282 (Fed. Cir. 2015) (*Ariosa II*), *cert. denied* (June 27, 2016).

79. *See, e.g.*, *Ariosa II*, 809 F.3d at 1284 (Lourie, J., concurring); *id.* at 1287 (Dyk, J., concurring).

80. Rapid Litig. Mgmt., Ltd. v. CellzDirect, Inc., 827 F.3d 1042, 1044 (Fed. Cir. 2016).

81. *Id.* at 1044, 1048.

82. *Id.* at 1048.

83. *Id.* at 1050.

84. *Id.* at 1050–51.

84.1. Vanda Pharm. Inc. v. West-Ward Pharm. Int'l Ltd, 887 F.3d 1117, 1134 (Fed. Cir. 2018).

84.2. *Id.* at 1121.

85. Bilski v. Kappos, 561 U.S. 593 (2010).

86. *See* Gottschalk v. Benson, 409 U.S. 63, 67–70 (1972).

87. Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 130 (1948).

88. Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980). *See also* Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289 (2012) (finding invalid a patent based on the application of a known method to a newly discovered law of nature, even though the inventor discovered said law of nature).

89. *Diamond*, 447 U.S. at 309 (quoting *Funk Bros. Seed Co.*, 333 U.S. at 130).

90. Alice Corp. Pty. Ltd. v. CLS Bank Int'l, 134 S. Ct. 2347 (2014).

91. *Id.* at 2357.

92. *Alice Corp.*, 134 S. Ct. at 2352.

93. *Id.* at 2353.

94. *Id.*

95. Bilski v. Kappos, 561 U.S. 593 (2010).

96. *Alice Corp.*, 134 S. Ct. at 2353.

97. CLS Bank Int'l v. Alice Corp. Pty. Ltd., 717 F.3d 1269, 1275 (Fed. Cir. 2013) (en banc).

98. CLS Bank Int'l v. Alice Corp. Pty. Ltd., 685 F.3d 1341, 1352 (Fed. Cir. 2012).

99. *CLS Bank Int'l*, 717 F.3d at 1273.

100. *Alice Corp.*, 134 S. Ct. at 2352.

101. *Id.*

102. *Id.* at 2354.

103. *Id.* (quoting Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289, 1303 (2012)) (citations omitted).

104. *Id.* at 2355.

105. *Id.*

106. *Id.* (quoting *Mayo Collaborative Servs.*, 132 S. Ct. at 1294).

107. *Id.* (quoting *Mayo Collaborative Servs.*, 132 S. Ct. at 1297, 1298).
108. *Id.*
109. Gottschalk v. Benson, 409 U.S. 63 (1972).
110. *Alice Corp.*, 134 S. Ct. at 2355.
111. Parker v. Flook, 427 U.S. 584 (1978).
112. *Alice Corp.*, 134 S. Ct. at 2355.
113 Bilski v. Kappos, 561 U.S. 593 (2010).
114. *Alice Corp.*, 134 S. Ct. at 2355.
115. *Id.* at 2356.
116. *Id.* at 2357.
117. *Id.*
118. *Id.* at 2357–58 (discussing *Flook* and *Benson*).
119. *Id.* at 2358 (quoting *Bilski*, 561 U.S. at 610–11) (internal quotation marks omitted).
120. Diamond v. Diehr, 450 U.S. 175 (1981).
121. *Alice Corp.*, 134 S. Ct. at 2358.
122. *Id.* at 2359.
123. U.S. Patent No. 7,792,700, claim 1 (filed June 25, 2003).
124. Bilski v. Kappos, 561 U.S. 593, 606 (2010).
125. *Id.* at 609.
126. *Id.*
127. H.R. REP. NO. 112-98, pt. 1, at 54 (2011); AIA § 18.
128. *Id.* See QQ 10.11–10.11.1 for a discussion of nonpracticing entities.
129. H.R. REP. NO. 112-98, pt. 1, at 54 (2011); AIA § 18.
130. AIA § 18.
131. *Id.*
132. *Id.*
133. Bilski v. Kappos, 561 U.S. 593 (2010).
134. *Id.* at 599.
135. *Id.*
136. *Id.* at 600.
137. *Id.*
138. *Id.* at 604–06.
139. *Id.* at 609.
140. *Id.* at 612–14.
141. Gottschalk v. Benson, 409 U.S. 63 (1972).
142. *Id.* at 71–72.
143. *Id.* at 72.
144. *Id.* at 73.
145. Parker v. Flook, 437 U.S. 584 (1978).
146. *Id.* at 585, 590.
147. *Id.* at 590 (citation omitted).
148. Diamond v. Diehr, 450 U.S. 175 (1981).
149. *Id.* at 184.

150. *Id.* at 178.

151. *Id.* at 184.

152. *In re* Alappat, 33 F.3d 1526, 1545 (Fed. Cir. 1994).

153. WMS Gaming, Inc. v. Int'l Game Tech., 184 F.3d 1339, 1348 (Fed. Cir. 1999) ("A general purpose computer, or microprocessor, programmed to carry out an algorithm creates 'a new machine, because a general purpose computer in effect becomes a special purpose computer once it is programmed to perform particular functions pursuant to instructions from program software.'") (citations omitted). In 2011, an exception was provided for corresponding structure that can be performed solely by a computer microprocessor without "special programming," like the receiving and storing of data. *In re* Katz Interactive Call Processing Patent Litig. v. Am. Airlines, 639 F.3d 1303, 1316 (Fed. Cir. 2011).

154. *See In re* Bilski, 545 F.3d 943, 954–56 (Fed. Cir. 2008).

155. *Bilski*, 561 U.S. at 605.

156. *Id.* The Federal Circuit recently emphasized that for software to be patentable, the "computer limitations" in the claims must "play a '*significant part*' in the performance of the claimed invention." Bancorp Servs., L.L.C. v. Sun Life Assurance Co. of Can. (U.S.), 687 F.3d 1266, 1280–81 (Fed. Cir. 2012) (holding unpatentable a software program that merely incorporated an abstract idea and nothing more) (emphasis added).

157. *See, e.g.*, Bart Eppenauer, *DDR Holdings—Federal Circuit Forges a Sensible Path on Software Patents*, PATENTLY-O (Dec. 14, 2014), http://patentlyo.com/patent/2014/12/holdings-sensible-software.html.

158. *See, e.g.*, Ultramercial v. Hulu, 772 F.3d 709 (Fed. Cir. 2014) (on remand from the Supreme Court to assess whether its earlier decision that a patent directed to a method of offering videos in exchange for watching an ad on the Internet was directed to patentable subject matter still applied in light of the *Alice* opinion; the Federal Circuit reversed itself and invalidated the same patent as directed to nonpatentable subject matter); *see also* Fairfield Indus. v. Wireless Seismic, Inc., No. 4:14-cv-2792, 2014 U.S. Dist. LEXIS 176599, at *11 (S.D. Tex. Dec. 23, 2014).

159. Maulin Shah & Bruce Berman, *Software and Business Methods Over Half of Google, Microsoft US Patents*, IPWATCHDOG (Jan. 21, 2015), www.ipwatchdog.com/2015/01/21/software-and-business-methods-more-than-half-of-google-microsoft-us-patent-grants/id=53936/.

160. The PTO has also issued multiple interim guidances on patent subject matter eligibility to reflect these decisions. The guidelines are intended to assist patent examiners and patent applicants in determining subject matter eligibility of claimed inventions in light of the *Alice* opinion and the two Supreme Court cases on which the *Alice* holding relies. Most recently, the PTO issued the November 2, 2016, memorandum, which discussed the *McRO* and *BASCOM* decisions covered in Q 1.10.4.

161. *In re* TLI Commc'ns LLC Patent Litig., 823 F.3d 607 (Fed. Cir. 2016).

162. McRO, Inc. v. Bandai Namco Games Am. Inc., 837 F.3d 1299, 1314 (Fed. Cir. 2016) (citing O'Reilly v. Morse, 56 U.S. 62, 113 (1853)).

163. BASCOM Glob. Internet Servs., Inc. v. AT&T Mobility LLC, 827 F.3d 1341 (2016).
164. Enfish, LLC v. Microsoft Corp., 822 F.3d 1327, 1336 (Fed. Cir. 2016).
165. *McRO*, 837 F.3d at 1316.
166. *BASCOM*, 827 F.3d at 1348.
167. *Id.* at 1349.
168. *Id.* at 1350.
169. *Id.*
170. *TLI Commc'ns*, 823 F.3d at 615.
171. *Id.*
172. H.R. REP. NO. 112-98, pt. 1, at 51 (2011).
173. AIA § 14.
174. H.R. REP. NO. 112-98, pt. 1, at 51 (2011).
175. Yoder Bros., Inc. v. Cal.-Fla. Plant Corp., 537 F.2d 1347, 1377 (5th Cir. 1976).
176. *Id.* at 1378.
177. 35 U.S.C. § 171.