

## Chapter 7 Statutory Subject Matter and Utility

### 35 U.S.C. § 100. Definitions

When used in this title unless the context otherwise indicates—

- (a) The term “invention” means invention or discovery.
- (b) The term “process” means process, art, or method, and includes a new use of a known process, machine, manufacture, composition of matter, or material. . . .

### 35 U.S.C. § 101. Inventions Patentable

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

The two requirements of eligible subject matter and utility both spring from § 101. The first, eligible subject matter describes the broad reach or domain of the U.S. patent system. The second, utility, is a low threshold requirement demanding that the claimed invention be pragmatically useful.

### § 7.01 Statutory Subject Matter

The legal evaluation of eligible subject matter is an inclusion/exclusion assessment. When is a product or process claim included as eligible subject matter? Why might it be excluded? Who should decide this, and how should innovation policy influence the decision?

Patent lawyers sometimes use a variety of synonymous phrases for the statutory subject matter requirement: patent eligibility; patentable subject matter; or eligible subject matter. Regardless of the label, the legal inquiry is to ask whether the claimed invention, as interpreted and understood against its disclosure and prosecution history, fits within the judicially given meaning of the § 101 statutory language.

A helpful construct is to think of § 101 as contemplating two basic types of claims: claims for a set or class of processes; or claims for a set or class of “products”—where the word “product” is a label for the other three statutory phrases: “machine, manufacture, or composition of matter.” The construct is artificial; “product” is not a § 101 statutory term and claims can recite both process steps and product characteristics. Although artificial, the product/process dichotomy helps organize one’s understanding of the case law around eligible subject matter. Conspicuously absent from the list of eligible items is *ideas*. Contrary to popular notions, an idea is not patent-eligible. The idea needs to be put into application to have exclusionary effect as an eligible patent claim.

That case law typically proceeds with two inquiries for an eligible subject matter issue: determine whether the claimed invention seems to fit within the statutory meaning for process or product claims; but also determine whether one of three venerable judicially-created exceptions sweep the claimed invention outside the reach of eligible subject matter.

The Supreme Court in *Chakrabarty* emphasized that “Congress plainly contemplated that the patent laws would be given wide scope.” See § 4.01. On the other hand, the Court also emphasized three exceptions to eligible subject matter: “laws of nature, physical phenomena, and

abstract ideas.” The precise meaning of these terms is by no means clear. For example, should a computer software program be considered merely an unpatentable algorithm? Are there categories of invention that should be excluded from patentability because they are too valuable to be owned by a private entity, such as green technology or biomedical innovations? Ultimately the Court in *Chakrabarty* found that the inventor’s micro-organism was not a natural phenomenon fitting in one of the exceptions, but rather a nonnaturally occurring item that fit within the meaning of § 101’s statutory phrases, with a particular emphasis on the phrase “manufacture.” See *Chakrabarty*, 447 U.S. 303, 308–10 (1980).

*Chakrabarty* is the leading case for “product” claims that might veer near the edge of § 101 eligibility. However, at the time of publication of this book, the Supreme Court has granted certiorari to review the Federal Circuit’s opinion in *Association for Molecular Pathology v. U.S. Patent and Trademark Office*, 689 F.3d 1303 (Fed. Cir. 2012) (finding certain types of isolated DNA sequences eligible). The notes after the next case expand on *Association for Molecular Pathology*. The question presented upon which certiorari was granted is: “are human genes patentable?”

Next, consider the following case with “product” claims where the tension is among notions of abstractness, tangibility and transitoriness for a construct that is human-made. The case name includes the inventor’s last name, Nuijten, pronounced “knight en.”

~~[A] “Product” Claims~~

~~IN RE NUIJTEN~~

~~500 F.3d 1346 (Fed. Cir. 2007)~~

~~GAJARSA, J.~~

~~Petrus A.C.M. Nuijten appeals the decision of the Board of Patent Appeals and Interferences (“Board”) of the United States Patent and Trademark Office (“PTO”), which rejected claims 14, 22, 23, and 24 in his patent application Serial No. 09/211,928 as unpatentable subject matter outside the scope of 35 U.S.C. § 101. The claims seek to patent any “signal” that has been encoded in a particular manner. . . .~~

~~I. BACKGROUND~~

~~A. Nuijten’s Invention and Patent Application~~

~~Nuijten’s patent application discloses a technique for reducing distortion induced by the introduction of “watermarks” into signals. In the context of signal processing, watermarking is a technique by which an original signal (such as a digital audio file) is manipulated so as to embed within it additional data. The additional data is preferably imperceptible to someone who views or listens to the signal—for instance, a listener who plays back a watermarked digital audio file would, if the watermark is sufficiently unobtrusive, not be able to distinguish between the watermarked and unwatermarked versions. However, an analysis of the file by software capable of detecting the watermark will reveal the mark’s contents. This ability to encode additional data into a signal is useful to publishers of sound and video recordings, who can use watermarks to embed in the media they distribute information intended to protect that media against unauthorized copying. For these publishers and others, watermarking represents a tradeoff: the desired additional data is encoded directly into the signal, but like any change to a signal, the watermark introduces some level of distortion. Thus, a key goal of watermarking techniques is to~~

signal is embodied in the principle that it is perceptible—e.g., changes in electrical potential can be measured. All signals within the scope of the claim do not themselves comprise some tangible article or commodity. This is particularly true when the signal is encoded on an electromagnetic carrier and transmitted through a vacuum—a medium that, by definition, is devoid of matter. Thus, we hold that Nuijten’s signals, standing alone, are not “manufacture[s]” under the meaning of that term in § 101.

#### 4. ~~Composition of Matter~~

~~As to the final statutory category, Nuijten does not challenge in his opening brief the Board’s conclusion that “[t]he signal is not composed of matter and is clearly not a ‘composition of matter.’” We note, however, that the Supreme Court has defined “composition of matter” to mean “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.” *Chakrabarty*. A signal comprising a fluctuation in electric potential or in electromagnetic fields is not a “chemical union,” nor a gas, fluid, powder, or solid. Nuijten’s signals are not “composition[s] of matter.”~~

### III. CONCLUSION

~~A transitory, propagating signal like Nuijten’s is not a “process, machine, manufacture, or composition of matter.” Those four categories define the explicit scope and reach of subject matter patentable under 35 U.S.C. § 101; thus, such a signal cannot be patentable subject matter.~~

### NOTES AND QUESTIONS

1. ~~Judge Linn dissented from the panel’s opinion that the claim was not directed to eligible subject matter:~~

~~“Nuijten’s signal involves the same degree and type of human ingenuity whether or not it happens to be encoded in the magnetic fields of a hard disk drive, the optical pits of a compact disc, a stream of photons propagating across a vacuum, or any other specific form that technology might put it in.”~~

~~Arguing that his approach follows *Chakrabarty*, Judge Linn would start the statutory construction by asking whether the signal was human-made and a product of human ingenuity. If so, then the issue would remain as to whether it is an abstract idea since it clearly is not a law of nature or natural phenomena. The majority also roots its analysis in *Chakrabarty*, emphasizing the case’s focus on the transformation of “articles” into “new forms, qualities, properties, or combinations.” The majority notes that many claims in the application were allowed because they go to “articles” along the way to its holding that the signals themselves are too transitory to fit within that word. This is so even with the claim construction discussion acknowledging that some physical carrier is needed for a transitory signal.~~

2. *Isolation/Purification*. A corollary to the exclusion from eligible subject matter of “laws of nature” and “physical phenomena” is the idea that discovered substances can be transformed to escape those exclusions and qualify as product claims that are eligible subject matter, as in *Chakrabarty*. For many types of material, a purification or isolation transformation will result in eligible subject matter as a “composition of matter.” These principles, along with other influences, have channeled much genetic research into the patent system.

Patents are not available for the handiwork of nature. Thus a newly discovered mineral or plant found in the wild is not patentable subject matter under 35 U.S.C. § 101. Those who make such discoveries or findings have certainly made an important contribution to society, but public policy demands that such advances remain freely available for all to use and build upon.

In contrast, so-called “purified” forms of natural products may be patentable . . . . [U]nderstand that genes, *as they exist in the human body* would, indeed, be considered products of nature outside 35 U.S.C. § 101. The discovery of a gene, however, can be the basis of a patent on a gene as “isolated from its natural state and processed through purifying steps that separate the gene from other molecules naturally associated with it.”

JANICE M. MUELLER, PATENT LAW 274–76 (3d ed. 2009) (emphasis in original).

Whether isolation of a gene should be considered sufficient transformation to remove the gene from classification as a product of nature and place it into eligible subject has been hotly debated. In a closely watched case, a Federal District Court judge found in 2010 that patents claiming isolated DNA genetic sequences were without “markedly different characteristics” from the genetic material as found in nature in the human body and thus did not meet the § 101 eligible subject matter requirement. *Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office*, 702 F. Supp. 2d 181 (S.D.N.Y. 2010).

On appeal, the Federal Circuit also applied the “markedly different” standard but differed with the district court for the claimed sequences, finding certain types of isolated DNA sequences eligible because they did not exist in nature. *Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office*, 689 F.3d 1303, 1325 (Fed. Cir. 2012) (en banc).

They are claims to compositions of matter, expressly authorized as suitable patent-eligible subject matter in § 101. As to those claims, the issue of patent-eligibility remains, as it was on the first appeal to this court, whether they claim patent -ineligible products of nature. We hold that they do not. The isolated DNA molecules before us are not found in nature. They are obtained in the laboratory and are man-made, the product of human ingenuity. While they are prepared from products of nature, so is every other composition of matter. All new chemical or biological molecules, whether made by synthesis or decomposition, are made from natural materials. For example, virtually every medicine utilized by today's medical practitioners, and every manufactured plastic product, is either synthesized from natural materials (most often petroleum fractions) or derived from natural plant materials. But, as such, they are different from natural materials, even if they are ultimately derived from them. The same is true of isolated DNA molecules..

*Ass’n for Molecular Pathology*, at 1325.

Dissenting in part, Judge Bryson would treat isolated cDNA differently from isolated DNA:

I concur with the portions of this court's judgment that are directed to . . . the patentability of the cDNA claims . . . . I respectfully dissent from the court's holding that Myriad's BRCA gene claims and its claims to gene fragments are patent-eligible. In my view, those claims are not directed to patentable subject matter, and the court's decision, if sustained, will likely have broad consequences, such as preempting methods for whole-genome sequencing, even though Myriad's contribution to the field is not remotely consonant with such effects.

In its simplest form, the question in this case is whether an individual can obtain patent rights to a human gene. From a common-sense point of view, most observers would answer, "Of course not. Patents are for inventions. A human gene is not an invention." The essence of Myriad's argument in this case is to say that it has not patented a human gene, but something quite different—an isolated human gene, which differs from a native gene because the process of extracting it results in changes in its molecular structure (although not in its genetic code). We are therefore required to decide whether the process of isolating genetic material from a human DNA molecule makes the isolated genetic material a patentable invention. The court concludes that it does; I conclude that it does not.

*Ass'n for Molecular Pathology*, at 1348.

The arguments for the Petitioner-Appellant, The Association for Molecular Pathology, focused on the preclusive effect of the patent claims.

The broad preemptive effect of these patents is further evidence that they claim laws and products of nature. The patents cover all isolated forms of the naturally-occurring genes, whether previously identified or not. The patents grant Myriad the authority to prevent all research and clinical testing of the genes, raising the same concerns about patenting a "building-block" that has troubled the Court. These patents tie up basic uses of the genes, "foreclose[ing] more future innovation than the underlying discovery could reasonably justify." Unlike patents on drugs which can be invented around by developing another drug that treats the same condition, patents on isolated DNA bar access to every person's genetic information

Myriad has vigorously enforced its patents . . . .

The patents also interfere with deepening our knowledge about these genes and breast and ovarian cancer. Currently, Myriad collects a huge amount of data on the nature and significance of variants in the BRCA1/2 genes, but refuses to share that data with the scientific community and has no obligation to collaborate with others. The patents impede new advances in genetic testing that can efficiently sequence the many genes now associated with breast and ovarian cancer, or indeed the entire human genome.

The rationale for granting a patent – the need to create economic incentives to advance science – did not apply in this case. Other researchers were also looking for the BRCA genes and had indicated that they would share their results with the scientific community. The widespread clinical testing of other, unpatented genes and the extraordinary importance of breast and ovarian cancers make it clear that

diagnostic tests resulting from the discoveries of BRCA1/2 would have been made available to the public even without the patent incentive.

Finally, it is of critical importance to patient health that knowledge about these genes increase so as to advance diagnosis and treatment of breast and ovarian cancer, as well as the many other diseases associated with these genes. Because Myriad has authority to prevent research on a part of the human body and to prevent development of new or better clinical tests, the consequences for women's health are enormous. This case does not question the patentability of new instruments, drugs, or methods of diagnosis or treatments. Instead, it concerns perhaps the most basic elements of biology, human genes. As the district court found: "The widespread use of gene sequence information as the foundation for biomedical research means that resolution of these issues will have far-reaching implications, not only for gene-based health care and the health of millions of women facing the specter of breast cancer, but also for the future course of biomedical research."

Brief of Petitioner-Appellant at 25-28, *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, 689 F.3d 1303 (Fed. Cir. 2012) (en banc).

#### **[B] Process Claims**

Although the lead case for eligible subject matter for product claims remains *Chakrabarty* from 1980, a year later, however, in 1981, the Supreme Court decided a similarly important case for process claims. In *Diamond v. Diehr*, 450 U.S. 175 (1981), the Court determined that claims to "a process for curing synthetic rubber which includes in several of its steps the use of a mathematical formula and a programmed digital computer" were claims that recited eligible subject matter. Just as *Chakrabarty* opened up the patent system to increased use by biotechnology companies, *Diehr* loosened the system for increased patenting of computer-implemented inventions. In 2010, the Supreme Court considered a case concerning whether a patented method of commodity risk hedging, including certain business methods, was sufficiently nonabstract to be eligible subject matter. *Bilski v. Kappos*, 130 S. Ct. 3218 (2010).

Prior to *Bilski*, the most prominent Federal Circuit opinion regarding the patentable nature of business methods and other processes may be *State Street Bank & Trust Co. v. Signature Financial Group, Inc.*, 149 F.3d 1368 (Fed. Cir. 1998). In that decision by a three-judge panel, the Federal Circuit held that the claimed system (a computer programmed to process tax-advantaged mutual fund pools) was, as a strict matter of doctrine, a "machine" and thus eligible subject matter. This outcome depended somewhat on the court eliminating doctrines that allowed a court to conclude that claimed subject matter was ineligible because it was a "mathematical algorithm" or a "business method." These were better subsumed under the venerable "abstract idea" exception.

*State Street* and its aftermath loosened the patent system for increased patenting in an area ripe for explosive growth due to external factors. Computer-implemented inventions and business methods were merging: companies increasingly automated their processes in the 1990s and 2000s using software and information technology. The Internet grew exponentially during the late 1990s and with it came a high level of new venture development. Other Federal Circuit case law had already enabled greater patenting of software in particular forms. These influences combined to generate an upswing in patent applications in the areas of information technology

~~4. Both Justice Kennedy and Justice Stevens present opinions that express concern for the effects of providing patent protection for methods of doing business. Justice Stevens, however, uses notions of impact on innovation and competition to a greater degree in his arguments that business methods should not be patentable. Does the opinion by Justice Kennedy, which is given in full, address these concerns? To what extent do you think Justice Stevens' concerns are correct, or do you think that they are overstated?~~

5. *Processes Based on Laws of Nature or Natural Phenomena.* In *Bilski*, the question was whether the claimed commodity hedging process was too abstract to meet eligible subject matter. Process claims for other types of inventions often depend on natural principles. Just as the claim in *Bilski* was too abstract, a process claim can be too close to a natural principle to be eligible subject matter. In *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289 (2012), the claim at issue was to a process based on how the human body metabolizes certain drugs. Upon ingesting the drug, the body generates metabolites, which are detectable in the blood stream. The claimed method recited a process of (1) administering the drug, (2) detecting the level of metabolites, and based on discovered correlations, (3) increasing or decreasing the amount of the drug additionally administered. The claimed process did not meet eligible subject matter under section 101:

[T]o consider the three steps as an ordered combination adds nothing to the laws of nature that is not already present when the steps are considered separately. . . . Anyone who wants to make use of these laws must first administer a thiopurine drug and measure the resulting metabolite concentrations, and so the combination amounts to nothing significantly more than an instruction to doctors to apply the applicable laws when treating their patients.

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

*Mayo Collaborative Servs.*, at 1298.

## ~~§ 7.02~~                      ~~Utility~~

~~Useful technology in the public domain is a desired result of the patent system, but why is mere utility required instead of better or best utility?~~

~~The utility requirement comes from variants of the word “use” in two locations in the statute. Section 101 authorizes the issuance of patents for “useful” products and processes otherwise meeting patent law’s requirements. The enablement requirement in § 112(a) requires sufficient disclosure about “making and using” so that a POSITA can “make and use” the invention. The~~