

Patentable subject matter under the US Patent Act, 1952: cases

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What is patentable subject matter under the U.S. Patent Act, 1952 is governed by Section 101. Case law related to this Section has an interesting history. It led to the patenting of living matter, software inventions, and business methods, all of which were believed to be unpatentable before the courts decided otherwise. Even after decades of litigation involving Section 101, its interpretation is not yet settled.

Keywords: Innovation, intellectual property, patentable subject matter, US Patent Act.

There is no surer way to misread any document than to read it literally.... As nearly as we can, we must put ourselves in the place of those who uttered the words, and try to define how they would have dealt with the unforeseen situation; and, although their words are by far the most decisive evidence of what they would have done, they are by no means final.

Billings Learned Hand, in *Giuseppe v. Walling*, 1944

THE word 'patent' is the short form of 'letters patent', a government letter granting a privilege. Such letters are open to the public. A patent does not give the receiver the right to practice his invention. It only excludes others from practising his invention without his permission!

An invention is the creation of a new technical idea and of the physical means to accomplish or embody it. Thus, there must be a concept and a way of putting the concept into some practical form. An unimplemented idea is not patentable.

The US Government grants three types of patents: utility, design and plant patents. Each type gives the owner the right to prevent others from infringing his patent over a stipulated period from a precisely defined scope of technology, industrial design or plant variety. In return for such rights, an inventor discloses complete details of the invention and its use to the public before the grant of a patent so that others, *inter alia*, may further develop the technology and even seek patents on improved versions of the invention. Once a granted patent expires, others may copy and sell the invention without the patent owner's permission. This article deals with just one question: 'What is patentable subject matter in the context of utility patents?'

The US Constitution empowers Congress, 'To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.' (Article 1, Section 8, Clause 8 of the US Constitution, 17 September 1787). As the terms were used at that time, 'science' referred to knowledge, and the 'useful arts' are what we now call technology. There are two parallel themes here: science–authors–writings, and useful arts–inventors–discoveries. The terms 'invention' and 'discovery' are used synonymously in the US patent laws. Other countries distinguish between the two terms.

Congress passed several patent acts during the first half century following the ratification of the Constitution. The first was the Patent Act of 1790 and the current one is the Patent Act of 1952. The Patent Act is found in Title 35 of the United States Code. §1 of Title 35 (abbreviated to 35 U.S.C. 1) establishes the US Patent and Trademark Office (USPTO) as an agency of the United States, within the Department of Commerce and it is subject to the policy direction of the Secretary of Commerce.

What can be patented is called statutory subject matter. §101 states these to be: process, machine, manufacture, or composition of matter:

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, subject to the conditions and requirements of this title.

The phrase 'invents or discovers' requires that the patentee be the actual creator and not just the first person to come upon something that preexists. Such discoveries are not new processes, machines, manufactures, or composition of matter due to their preexistence. Statutory subject matter must, of necessity, be expressed in broad terms. Because patents are granted for new technology, Congress refrained from enumerating specific categories in the pat-

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ent statutes; it could not possibly forecast future developments in science or technology. The 'utility' requirement of §101 is distinct from the eligible subject matter requirement. We will not discuss the 'utility' requirement.

Despite the broad language of §101, a number of exceptions exist, created by other statutes or by court decisions (case law) interpreting §101. A notable statutory exception due to 42 U.S.C. 2181 is the denial of patents to atomic weapons. Important exceptions due to case law include denial of patents to abstract ideas (such as mathematical formulas), or laws of nature or natural phenomena, since they are neither processes, machines, manufactures, nor compositions of matter. Thus one cannot patent scientific principles (1939) since this would grant unreasonable control to individuals¹, pure mathematical algorithms (1972)², mental processes (1876)³, and data (e.g. coordinates for 3D protein structures). Of course, inventions based on a law of nature are patentable, since all machines obey the laws of physics in their operation (inventions claiming to be perpetual motion machines are regularly rejected by patent offices around the world), compositions of matter follow the laws of chemistry, etc. One might even obtain a patent on a naturally occurring product that is changed into a substantially different form. And one can also get a patent on a new use for a naturally occurring product, although that patent would protect only the use and not the product itself. However, determining whether an applicant is seeking to patent an abstract idea, a law of nature or a natural phenomenon can sometimes be a challenge, as evidenced in the landmark case of *Diamond v. Chakrabarty*⁴.

Diamond v. Chakrabarty

In 1972, Ananda M. Chakrabarty created a new bacterium not found in nature. It had the unique ability to break down crude oil. Seeing great potential in treating oil spills, he filed a patent application. *Inter alia*, he claimed the live, genetically engineered bacterium per se, rather than in combination with the culture medium. The USPTO denied his claims to the live bacteria, arguing his creation was a product of nature and hence not patentable. The matter eventually reached the US Supreme Court.

In *Diamond v. Chakrabarty*⁴, the court delved into legislative history of the Patent Act and concluded that Congress intended 'manufacture' to mean 'anything under the sun that is made by man' (quoting S. Rep. No. 1979, 82d Cong., 2d Sess., 5 (1952); H.R. Rep. No. 1923, 82d Cong., 2d Sess., 6 (1952)) to be eligible for patenting. Accordingly, it interpreted the statute to cover a 'non-naturally occurring manufacture or composition of matter – a product of human ingenuity' and in June 1980, in a 5–4 majority, ruled in favour of Chakrabarty. It held that Chakrabarty's bacteria met the statutory definition of

patentable subject matter. The mere fact that Chakrabarty's invention happened to be alive was deemed immaterial. Chief Justice Warren Burger delivering the majority opinion, declared that, 'the relevant distinction was not between living and inanimate things, but between products of nature, whether living or not, and human-made inventions'. Chakrabarty's bugs were new compositions of matter, the product of his ingenuity, not of nature's. They were thus innovative manufacturers, and hence, patentable. The USPTO granted the patent (US 4,259,444) in March 1981.

Transgenic animals

The Chakrabarty case opened the gate for patents on transgenic animals. In 1988, the USPTO issued the first transgenic animal patent on the now famous Harvard mouse, a mouse genetically engineered to be more susceptible to tumour growth. Since then it has become an incredibly powerful cancer research tool. By now several hundred transgenic or bioengineered animal patents have been granted. These include mice (in the hundreds), rats, rabbits, sheep, pigs, cows (in the tens), etc. Does this mean that transgenic humans will be allowed? According to the USPTO⁵:

If the broadest reasonable interpretation of the claimed invention as a whole encompasses a human being, then a rejection under 35 U.S.C. 101 must be made indicating that the claimed invention is directed to nonstatutory subject matter.

The USPTO has, however, granted patents on inventions that have some human genetic component (instances include insertion of human genes into *Escherichia coli* for manufacturing insulin for treatment of diabetes, and pigs produced that express the gene for human growth hormone). Whether the USPTO's decision, if contested, would be upheld by the Supreme Court is unknown.

Biological material

In 1979, the Court of Customs and Patent Appeals in *In re Bergy*, 596 F.2d 952, 201 U.S.P.Q. 352 (C.C.P.A. 1979), held that an invention drawn to a 'biologically pure culture' of a certain microorganism *Streptomyces vellosus* constitutes a man-made product which qualifies as patentable statutory subject matter.

The patenting of compositions or compounds isolated from nature follows well-established principles, and is not a new practice. For example, Louis Pasteur received a patent (US 141,072) in 1873, claiming '[y]east, free from organic germs of diseases, as an article of manufacture'. Four years later, William Cutler received a patent (US 197,612) for a 'vaccine virus' made from crushed pus-

tules mixed with fluid lymph and employed in vaccinating persons against smallpox. Another example is an early patent for adrenaline. In a case contesting the patent's validity, the court held that compounds isolated from nature in pure form are patentable⁶.

Patents have been allowed on human genes of known function – for example, the gene for insulin – in a form that did not occur naturally, but had been derived from DNA by scientific manipulation. Genes in their native state in the DNA appear with additional nucleotide sequences that do not code for protein. Isolation and purification of a gene by retaining only the exons makes them eligible to be patented as chemical compounds. With regard to chemicals, a patent grants exclusionary rights over a patented composition but does not grant ownership of the composition.

Unenforceable medical-procedure patents

The medical profession, bound by the Hippocratic Oath, abhors patents. So when in 1993 ophthalmologist Samuel Pallin sued another doctor for infringing his (Pallin's) patent (US 5,080,111 Method of making self-sealing episcleral incision), an uproar ensued. Although the case ended in a consent order declaring the four patent claims of the Pallin patent in controversy to be invalid, and Pallin agreed not to enforce the remaining patent claims (see Samuel L. Pallin, M. D. v. Jack, A. Singer, M. D. and The Hitchcock Clinic, 36 U.S.P.Q. 2d 1050 (D. Vt. 1995)), the event led to the law related to enforcement of medical-procedure patents being changed⁷ in 1996. This law now denies patent owners the right to enforce patents covering medical or surgical procedures that do not involve patented drugs or devices. In addition, it made unenforceable, patents on medical and surgical procedures performed on a human body, organ or cadaver, or even on an animal used in medical research or instruction directly relating to the treatment of humans.

Software patents

Prior to 1980, legal protection for software inventions was thought to be quite weak. In 1980, Congress brought software under copyright protection, but whether software could be patented remained unclear. In particular, the decisions in *Gottschalk v. Benson* (1972)² and *Parker v. Flook* (1978)⁸ were assumed to be hostile towards software patents.

In *Gottschalk v. Benson*, the inventor claimed a method for converting binary-coded decimal numerals into pure binary numerals for use with a general-purpose digital computer. The Supreme Court held that the invention was no more than an abstract mathematical formula. The invention did not qualify as a process because it did not result in the transformation or reduction of anything 'to a

different state or thing'. It held that a mathematical algorithm itself is not patentable, but added that it may be that the patent law should be extended to cover computer programs.

In *Parker v. Flook*, the Supreme Court once again rejected patent protection for software, this time claimed as a 'method for updating alarm limits' in a chemical process. The court determined that while a process may be patentable even though it contained a law of nature or mathematical algorithm, 'the process itself, not merely the mathematical algorithm, must be new and useful'. Here the inventor had discovered only the mathematical algorithm, not the process. The algorithm was deemed within the prior art. Consequently, the application contained no patentable invention. It refused to overrule or expand *Gottschalk* without a clear signal from Congress. It said, 'Difficult questions of policy concerning the kinds of programs that may be appropriate for patent protection and the form and duration of such protection can be answered by Congress on the basis of current empirical data not equally available to this tribunal'.

Hopes for software patents became brighter following the Supreme Court's observation in 1980 in the *Chakrabarty* case that patentable subject matter 'include[d] anything under the sun that is made by man', thereby implicitly acknowledging the inclusion of computer software within the patent regime. And in 1981, in *Diamond v. Diehr*⁹, the US Supreme Court finally opened the way for patents on software systems when it ordered the USPTO to grant a patent on an invention that utilized computer software. The invention in question was related to a method for curing rubber. It utilized a computer to calculate and control heating times for the rubber. Apart from the computer program, the invention also included steps related to heating rubber, and removing rubber from the heat. The Supreme Court held the invention was patentable because it was a process for moulding rubber and not merely a mathematical algorithm, even though the only novel feature for this invention was the timing process controlled by the computer.

But when is an invention merely an unpatentable mathematical algorithm and when is it a patentable invention that has embedded in it a mathematical algorithm? In the early 1990s, the Courts clarified that if the invention in actuality was only a mathematical algorithm, such as a computer program designed to convert binary-coded decimal numbers into binary numbers, then the invention was not patentable². However, if a computer was used in an invention to transform numbers that represented concrete, real-world values (such as a program that interprets electrocardiograph signals to predict arrhythmia¹⁰ or a program that analyses seismic measurements¹¹), then the invention is a process relating to those real-world concepts and is patentable. So, software was always patentable, if claimed properly.

Software can be considered a process or a component of a machine (when programmed into a computer). Even

then, software per se was not patentable – rather what had to be patented was a machine, or process. Thus companies began patenting software using careful sophistry: ‘making sure to say that a program was an apparatus or a system and that it was embodied on a computer-readable medium’¹².

Software v. hardware

In *In re Alappat*¹³, which involved a patent application where the issue was whether a rasterizer for graphical images was statutory subject matter, the US Court of Appeals for the Federal Circuit used the opportunity to restate and clarify its past decisions on whether software-related inventions are patentable. It made the significant statement:

‘We have held that such programming 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.’

It further added,

‘Digital electronic devices implement mathematical manipulations of electronic signals, as chemical structures and reactions implement principles of molecular behavior. An apparatus that is configured to perform specific electronic procedures in accordance with instructions that require numerical measurements and mathematical calculations is no less statutory than any other combination of steps and components. A combination of mechanical or chemical components, structured to operate in accordance with the principles of mechanics or chemistry, does not become nonstatutory because those interactions and reactions follow basic scientific principles. Mathematics is not a monster to be struck down or out of the patent system, but simply another resource whereby technological advance is achieved.’

Thus the ‘mathematical algorithm’ exception to statutory subject matter first discussed by the Supreme Court in *Gottschalk v. Benson*² is limited to abstract mathematical concepts, not mathematics applied to a practical problem. Machines, even though they carry out mathematical operations, are patentable. This is not surprising, since cash registers which do mathematical operations are patentable.

Business methods patents

In *State Street Bank & Trust Co. v. Signature Financial Group, Inc.*¹⁴, which involved a patent relating to a hub-and-spoke system for monitoring and calculating financial information, enabling several mutual funds (‘spokes’) to pool their funds into a single investment portfolio

(‘hub’), the US Court of Appeals for the Federal Circuit reiterated that mathematical algorithms are not patentable subject matter to the extent that they are merely abstract ideas. It further explained that certain types of mathematical subject matter, standing alone, represent nothing more than abstract ideas until reduced to some type of practical application, i.e. ‘a useful, concrete and tangible result’. So, an application of a law of nature or mathematical formula to a known structure or process may well be deserving of patent protection. However, the Federal Circuit did not stop there. It also did away with the business method exception saying,

‘We take this opportunity to lay this ill-conceived exception to rest.... Since the 1952 Patent Act, business methods have been, and should have been, subject to the same legal requirements for patentability as applied to any other process or method.’

It reasoned that the limitations had been judicially created rather than constitutionally. The court held that instead of focusing on categories of subject matter, it should ascertain the invention’s practical utility, which should then be tested together with the requirements of novelty and nonobviousness. After this decision, business method patents have been granted at a furious pace. Since many business methods are implemented in software or involve electronic commerce on the Internet, patents in these areas often have shared kinship.

Subject matter debate continues

The rapid advances in technology in the past few decades continue to test the bounds of patentable subject matter, especially in the case of process patents. The categories of non-patentable phenomena of nature, mental processes, and abstract intellectual concepts are difficult to define.

Critics of *State Street* had hoped that the US Supreme Court would take the opportunity in *LabCorp v. Metabolite*¹⁵ to revisit §101 and limit the scope of business method patents. However, after hearing oral arguments in March 2006, the Supreme Court surprisingly, in June 2006, opted to dismiss *LabCorp*’s appeal as ‘improvidently granted’. Interestingly, in this case, *Metabolite* argued that its patent was valid because it met the criteria of having a ‘useful, concrete, and tangible result’¹⁴, while *LabCorp* thought it was invalid because one cannot patent ‘laws of nature, natural phenomena, and abstract ideas’.⁹

Judge Breyer and two others believed that the case was incorrectly dismissed¹⁵:

After all, many a patentable invention rests upon its inventor’s knowledge of natural phenomena; many ‘process’ patents seek to make abstract intellectual concepts workably concrete; and all conscious human action involves a mental process.... Nor can one easily use such abstract categories

directly to distinguish instances of likely beneficial, from likely harmful, forms of protection.'

He further added that even though in *State Street*, the Federal Circuit had said that a process is patentable if it produces 'a useful, concrete, and tangible result', the Supreme Court has never made such a statement¹⁵. He pointed out that if the Federal Circuit's statement is taken literally, the statement would cover instances where the Supreme Court has held the contrary. As examples, he cites *Parker v. Flook*⁸, *Gottschalk v. Benson*², etc. where inventions were held unpatentable despite their being 'useful, concrete, and tangible'.

Computer scientists can implement any algorithmic process either through hardware or software. For them, it is a matter of choice. Because hardware implementations can limit the scope of a patent's protection, pressures have mounted to allow software to be directly claimed as a 'process'. However, the prohibitions against patenting abstract ideas and mathematical algorithms may continue to require software to have some kind of physical connection.

Business methods are even more problematical, since some of them may only require human intelligence without involving machines, manufactures or compositions of matter. In *In re Comiskey*¹⁶, the Federal Circuit held that such inventions directed to mental processes are unpatentable under §101. An *en banc* petition is still pending for this case with the Federal Circuit.

Recent events suggest that the Federal Circuit itself is now uncertain about *State Street*. In an unusual step, on 15 February 2008, the Federal Circuit, by its own action, granted a hearing *en banc* in *In re Bilski*¹⁷, even though a panel had heard oral arguments in the case in October 2007. *Inter alia*, it will address the following question:

Whether it is appropriate to reconsider *State Street Bank & Trust Co. v. Signature Financial Group, Inc.*, 149 F.3d 1368 (Fed. Cir. 1998), and *AT&T Corp. v. Excel Communications, Inc.*, 172 F.3d 1352 (Fed. Cir. 1999), in this case and, if so, whether those cases should be overruled in any respect?

The *Bilski* patent application relates to 'A method for managing the consumption risk costs of a commodity sold by a commodity provider at a fixed price'. In the patent application, 'the claims do not recite how the steps are implemented and are broad enough to read on performing the steps without any machine or apparatus (although performing the steps on a machine would, of course, infringe)¹⁸. The fact that just a few days earlier, in *In re Nuijten*, No. 2006-1371, 2008 WL 361044 (Fed. Cir. Feb. 11, 2008), the Federal Circuit had denied a petition for *en banc* rehearing, has surprised some. The panel decision in

In re Nuijten, 500 F.3d 1346, 1358 (Fed. Cir. 2007)¹⁹ had held that electronic signals are not patentable subject matter under §101. Even more surprising is the Supreme Court's decision on 6 October 2008 not to review the *Nuijten* case.

It appears highly probable that whatever be the outcome of the *en banc* hearing in the *Bilski* case, it will end up in the Supreme Court. The future of business methods patents and software patents may well be decided then.

1. *Mackay Radio & Tel. Co. v. Radio Corp. of Am.*, 306 US 94, 1939; <http://supreme.justia.com/us/306/86/case.html>
2. *Gottschalk v. Benson*, 409 US 63, 1972; <http://supreme.justia.com/us/409/63/case.html>
3. *Cochrane v. Deener*, 94 US 780, 1876; <http://supreme.justia.com/us/94/780/case.html>
4. *Diamond v. Chakrabarty*, 447 US 303, 1980; <http://supreme.justia.com/us/447/303/case.html>
5. US Patent and Trademark Office, *Manual of Patent Examining Procedure*, Sec. 2105: 'Patentable Subject Matter – Living Subject Matter', revised February 2003.
6. *Parke-Davis & Co. v. H. K. Mulford Co.*, 189 F. 95, 103 (S.D.N.Y. 1911) (J. Learned Hand).
7. Public Law 104–208, 30 September 1996. See Sec. 616 Limitation on Patent Infringements Relating to a Medical Practitioner's Performance of a Medical Activity; http://www.ows.doleta.gov/dmstree/pl/pl_104-208.pdf
8. *Parker v. Flook*, 437 US 584, 596, 1978; <http://supreme.justia.com/us/437/584/case.html>
9. *Diamond v. Diehr*, 450 US 175, 1981; <http://supreme.justia.com/us/450/175/case.html>
10. *Arrhythmia Research Technology Inc. v. Corazonix Corp.*, 958 F.2d 1053, 1058, 22 USPQ2d 1033 (Fed. Cir. 1992); <http://digital-law-online.info/lpd1.0/cases/22PQ2D1033.htm>
11. *In re Johnson*, 589 F.2d 1070, 200 USPQ 199, 1978; <http://digital-law-online.info/cases/200PQ199.htm>
12. Gleick, J., Patently absurd, *New York Times*, 12 March 2000; <http://www.around.com/patent.html>
13. *In re Alappat*, 33 F.3d 1526, 31 USPQ2d 1545 (Fed. Cir. 1994); <http://digital-law-online.info/lpd1.0/cases/31PQ2D1545.htm>
14. *State St. Bank & Trust Co. v. Signature Fin. Group*, 149 F.3d 1368, 1373 (Fed. Cir. 1998), cert. den., 525 US 1093, 1999, 119 S. Ct. 851, 1999; <http://www.ll.georgetown.edu/federal/judicial/fed/opinions/97opinions/97-1327.pdf>
15. *Laboratory Corporation of America Holdings v. Metabolite Laboratories, Inc.*, 548, US, 2006 (Slip Opinion); <http://www.supremecourt.gov/opinions/05pdf/04-607.pdf>
16. *In re Comiskey*, 499 F.3d 1365 (Fed. Cir. 2007); <http://www.cafc.uscourts.gov/opinions/06-1286.pdf>
17. *In re Bernard L. Bilski and Rand A. Warsaw*, No. 2007-1130, 2008 WL 417680 (Fed. Cir. Feb. 15, 2008); <http://www.cafc.uscourts.gov/opinions/07-1130%20order.pdf>
18. *Ex parte Bernard L. Bilski and Rand A. Warsaw*, No. 2002-2257, App. 08/833,892, 2006 WL 4080055 (BPAI Sept. 26, 2006); <http://www.uspto.gov/web/offices/dcom/bpai/its/fd022257.pdf>
19. *In re Petrus A.C.M. Nuijten*, 500 F.3d 1346, 1358 (Fed. Cir. 2007); <http://www.cafc.uscourts.gov/opinions/06-1371.pdf>

Received 21 April 2008; accepted 13 October 2008