

OVERVIEW OF THE FEDERAL CIRCUIT'S PRE-LABCORP. DECISIONS ON SUBJECT MATTER ELIGIBILITY*

“The grant or denial of patents on microorganisms is not likely to put an end to genetic research or to its attendant risks. The large amount of research that has already occurred when no researcher had sure knowledge that patent protection would be available suggests that legislative or judicial fiat as to patentability will not deter the scientific mind from probing into the unknown any more than Canute could command the tides.

Whether respondent's claims are patentable may determine whether research efforts are accelerated by the hope of reward or slowed by want of incentives, but that is all.

What is more important is that we are without competence to entertain these arguments--either to brush them aside as fantasies generated by fear of the unknown, or to act on them. The choice we are urged to make is a matter of high policy for resolution within the legislative process after the kind of investigation, examination, and study that legislative bodies can provide, and courts cannot.”

Diamond v. Chakrabarty, 447 U.S. 303, 317 (1980).

We live in a time of great public scrutiny and controversy regarding the foundation of our patent system. The important policy question of what should and should not be patentable subject matter has spawned a number of battlegrounds in recent years. The debate pits those supporting patentability, who claim that patents increase innovation and enhance the public good, against opponents who view patents as being sought only for private gain. Patents can encourage research by providing monetary incentives for invention, but too much patent protection can impede rather than promote progress. Flashpoints fueling the debate have included the patenting of mathematical algorithms and programs for computers, business methods, naturally occurring biological material, genetic sequences, stem cells, printed matter, and medical techniques.

Taking sides in the world-wide debate, different jurisdictions have come to different views as to what subject matter can be patented and what cannot. Even within a given jurisdiction, applying the rules of that jurisdiction, the line between patentable and unpatentable subject matter is often fuzzy. *See, e.g., Parker v. Flook*, 437 U.S. 584, 589 (1978) (“line between a patentable ‘process’ and an unpatentable ‘principle’ does not always shimmer with clarity”).

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I. The Framework

In most patent laws, patentable subject matter (or statutory subject matter) is the requirement that an invention, for which patent protection is sought, is of a kind of subject matter that is, by law, allowed patent protection. The subject matter which is regarded as being patentable as a matter of policy, and correspondingly the subject matter which is excluded from patentability as a matter of policy, depends on the national legislation or international treaty. In our country, the Constitution and, through its delegated power, Congress have set forth the policy regarding patentable subject matter. But the courts are left to implement that policy and, in doing so, help to define it.

A. The Constitution

Article I, § 8, clause 8 of the Constitution gives Congress the power “to promote the progress of . . . the useful arts by securing for limited times to . . . inventors the exclusive rights to their . . . discoveries.” The present-day equivalent of the phrase “useful arts” selected by the Founders is “technological arts.” *In re Bergy*, 596 F.2d 952, 958 (CCPA 1979). Exercising its Constitutional authority, Congress enacted Section 101 of the Patent Act.

B. Section 101 of the Patent Act

35 U.S.C. § 101 provides: “Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.” Not everything is patentable. To be patentable, as required by Section 101, an invention must fall into one of four categories: (1) a process such as a process of manufacture or a method of use, (2) a machine such as typewriter which has moving parts, (3) an article of manufacture such as a hammer which does not have moving parts, or (4) a composition of matter such as a pharmaceutical drug. The general purpose of the statutory classes of subject matter is to limit patent protection to the field of applied technology, what the Constitution calls “the useful arts.”

Products may be one of machines, manufactures, or compositions of matter. A machine is “a concrete thing, consisting of parts or of certain devices and combinations of devices.” *Burr v. Duryee*, 68 U.S. (1 Wall.) 531, 570 (1863). A manufacture is “the production of articles for use from raw or prepared materials by giving to these materials new forms, qualities, properties or combinations, whether by hand-labor or by machinery.” *Chakrabarty*, 447 U.S. at 308 (quoting *American Fruit Growers, Inc. v. Brogdex Co.*, 283 U.S. 1, 11 (1931)). Compositions of matter include “all compositions of two or more substances and . . . all composite articles, whether they be the results of chemical union, or of mechanical mixture, or whether they be gases, fluids, powders or solids.” *Chakrabarty*, 447 U.S. at 308 (quoting *Shell Development Co. v. Watson*, 149 F. Supp. 279, 280 (D.D.C. 1957), *aff’d per curiam*, 252 F.2d 861 (D.C. Cir. 1958)).

For the definition of a process, see 35 U.S.C. § 100(b) (defining a “process” to encompass “[a] process, art or method, and includes a new use of a known process, machine, manufacture, composition of matter, or material.”). *See also Diamond v. Diehr*, 450 U.S. 175, 183-84 (1981) (quoting *Cochrane v. Deener*, 94 U.S. 780, 787-88 (1877), “A [statutory] process is a mode of treatment of certain materials to produce a given result. It is an act, or a series of acts, performed upon the subject-matter to be transformed and reduced to a different state or thing. . . . The process requires that certain things should be done with certain substances, and in a certain order, but the tools to be used in doing this may be of secondary consequence.”).

Whether a patent can be obtained for an invention that recites patentable subject matter depends, Section 101 tells us, on whether the invention meets the other “conditions and requirements of this title.” Thus, the patentable subject matter question necessarily precedes other statutory questions--such as whether the subject matter is novel (Section 102), would have been non-obvious to an artisan at the time of the invention (Section 103), or complies with non-art requirements (Section 112)--which need not be assessed when there is no patentable subject matter. Note, however, that a rejection of patent claims based on one of the other patentability requirements can achieve the same policy goal of refusing to grant a period of exclusivity for a particular subject matter.

C. Judicial Exceptions

The U.S. Supreme Court has identified three categories of subject matter that are unpatentable as “exceptions” to statutory subject matter:

1. Laws of Nature such as Newton’s discovery of the law of gravity or Einstein’s celebrated law $E = mc^2$;
2. Natural Phenomena including those reflected in claims that recite nothing but the physical characteristics of a form of energy, such as a frequency, voltage, or the strength of a magnetic field, or define energy or magnetism per se (other examples are a method of how grass grows or a new mineral discovered in the earth); and
3. Abstract Ideas such as the idea for a bid or a bubble hierarchy without some claimed practical application, or disembodied data structures or computer programs that are collections of information and are merely expressions of abstract ideas.

State Street Bank & Trust Co. v. Signature Financial Group, Inc., 149 F.3d 1368, 1373 (Fed. Cir. 1998) (citing *Diehr*, 450 U.S. at 185). “Section 101 has also been interpreted to exclude inventions deemed to be immoral, such as (until 1977) gambling machines, or devices deemed to be scientifically impossible, such as perpetual motion machines.” *Tol-O-Matic, Inc. v. Proma Produkt-Und Marketing Gesellschaft m.b.H.*, 945 F.2d 1546, 1552 (Fed. Cir. 1991). “All that the law requires is that the invention should not be frivolous, or injurious to the well-being, good policy, or good morals of society. The word *useful* therefore is incorporated into the act in contradistinction to mischievous or immoral.” *In re Nelson*, 280 F.2d 172, 178-79 (CCPA 1960) (emphasis in original) (citing *Lowell v. Lewis*, 15 Fed. Cas. 1018, No. 8568 (C.C. Mass. 1817) (Story, J.)).

D. Statutory Exceptions

Congress has determined that certain types of inventions are ineligible for patent protection. For example, patents are prohibited for “any invention or discovery which is useful solely in the utilization of special nuclear material or atomic energy in an atomic weapon.” 42 U.S.C. § 2181(a). Similarly, patents are unavailable to private applicants “for any invention which appears to the Commissioner of Patents to have significant utility in the conduct of aeronautical and space activities” in the absence of compliance with certain statutory requirements. 42 U.S.C. § 2457. *See generally* 1 D. Chisum, Patents § 1.06 (2007).

Another limitation on patentable subject matter concerns inventions for which publication or disclosure might be detrimental to the national security. 35 U.S.C. §§ 181-88 (the Invention Secrecy Act). The government may withhold a patent for such an invention and order that the invention be kept secret. 35 U.S.C. § 181. Unauthorized disclosure of an invention that is subject to a secrecy order can result in abandonment of the invention and forfeiture of rights. 35 U.S.C. § 182.

E. PTO Guidelines

As of October 2005, the United States Patent and Trademark Office (PTO) has issued interim guidelines for patent examiners to determine if a given claimed invention meets the statutory requirements of being a useful process, manufacture, composition of matter, or machine (Section 101). PTO, Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility, Official Gazette Notices (November 22, 2005). These guidelines assert that a process, including a process for doing business, must produce a concrete, useful, and tangible result in order to be patentable. It does not matter whether the process is within the traditional technological arts or not.

II. The Federal Circuit’s General Approach

The legislative history for Section 101 supports a broad construction of the statutory provision. The Committee Reports accompanying the 1952 Patent Act inform us that Congress intended statutory subject matter to “include anything under the sun that is made by man.” The Supreme Court has noted that “the language of § 101 is extremely broad . . . [and] is a dynamic provision designed to encompass new and unforeseen inventions.” *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int’l, Inc.*, 534 U.S. 124, 130, 135 (2001). The U.S. Court of Appeals for the Federal Circuit, which acquired exclusive appellate jurisdiction over patent cases in 1982, has consistently reinforced the view that there are very few exceptions to the broad categories of patentable subject matter listed in Section 101. “We have come a long way from the days when judges frowned on patents as pernicious monopolies deserving scant regard. Today, patents are the backbone of much of the national economy, and, as this court has recently held, virtually anything is patentable.” *Hughes Aircraft Co. v. United States*, 148 F.3d 1384, 1385 (Fed. Cir. 1998) (citing *State Street*, 149 F.3d at 1368).

III. The LabCorp. Case

In *Metabolite Laboratories, Inc. v. Laboratory Corp. of Am. Holdings*, 370 F.3d 1354 (Fed. Cir. 2004), the Federal Circuit affirmed the district court judgment of infringement and rejected the accused infringer's arguments that "claim 13 is invalid on grounds of indefiniteness, lack of written description and enablement, anticipation, and obviousness." *Id.* at 1365. Neither the Federal Circuit nor the district court mentioned a challenge to the patent on the ground that its claims recited nonstatutory subject matter under Section 101. The Supreme Court initially granted certiorari to address whether claim 13 of Metabolite's asserted patent, U.S. Patent No. 4,940,658, which claims a correlation between an elevated level of homocysteine and a deficiency in vitamin B12 in humans, was invalid under Section 101 as claiming unpatentable natural phenomena.

The pending *LabCorp.* case drew much attention. Many amicus curiae filed briefs with the Supreme Court. *See* 1 D. Chisum, Patents, § 1.03[2][e] at n.71 (2007) (listing the amicus). Nevertheless, split 5-3 (Chief Justice John Roberts Jr. recused), the Supreme Court dismissed the petition for certiorari as improvidently granted because the issue had not been properly raised or briefed in the district and appellate courts. *Laboratory Corp. of Am. Holdings v. Metabolite Laboratories, Inc.*, 126 S. Ct. 2921 (June 22, 2006).

IV. The Federal Circuit's Specific Approach

Absent the current views of the Supreme Court, a "generalist" court, the debate continues about whether the patent system, as currently administered and enforced, adequately reflects the careful balance embodied in the patent laws. Studies have shown that the arguments of the opposing sides in the debate may gain or lose strength depending upon the specific industry. *See, e.g.*, Federal Trade Commission, To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy, ch. 3, p. 1 (Oct. 2003) (collecting evidence that "issues of fixed cost recovery, alternative appropriability mechanisms, and relationships between initial and follow-on innovation" vary by industry); D. Burk & M. Lemley, Policy Levers in Patent Law, 89 Va. L. Rev. 1575, 1577-89 (2003) ("Recent evidence has demonstrated that this complex relationship [between patents and innovation] is . . . industry-specific at each stage of the patent process"). The Federal Circuit, a specialist court with respect to patents, nevertheless insists that it "accords the same treatment to all forms of invention." *Eolas Technologies, Inc. v. Microsoft Corp.*, 399 F.3d 1325, 1339 (Fed. Cir. 2005), *cert. denied*, 126 S. Ct. 568 (2005). Regardless, an overview of the Federal Circuit's Pre-*LabCorp.* decisions on subject matter eligibility is perhaps most logically and usefully done by focusing on each of the controversial subject matter areas highlighted above. *See also AT&T Corp. v. Microsoft Corp.*, 414 F.3d 1366, 1370 (Fed. Cir. 2005) ("We reject this theory of liability as it fails to account for the realities of software distribution. '[T]he appellate process is not a mere academic exercise,' Rosemount, Inc. v. Beckman Instruments, Inc., 727 F.2d 1540, 1543 (Fed. Cir. 1984), and we cannot disregard the nature of the relevant technology and business practices underlying a particular litigation.").

A. Mathematical Algorithms & Software

Algorithm-related claims may or may not be patentable because they may or may not constitute statutory subject matter. Commentators have written often on the subject of the patentability of software. See 1 D. Chisum, *Patents*, § 1.03[6] at n.200 (2007). Two U.S. Supreme Court cases in the 1970's, *Gottshalk v. Benson*, 409 U.S. 63 (1972), and *Parker v. Flook*, 437 U.S. 584 (1978), found mathematical algorithms to be unpatentable--at least to the extent that they are merely abstract ideas.

Gottshalk involved “a method of programming a general purpose digital computer to convert signals from binary-coded decimal form into pure binary form.” 409 U.S. at 65. Solving the conversion problem required use of an “algorithm,” that is, “a generalized formulation for programs to solve mathematical problems of converting one form of numerical representation to another.” *Id.* Noting that ideas are not patentable, the Supreme Court held the claimed invention nonstatutory because “[t]he mathematical formula involved . . . ha[d] no substantial practical application except in connection with a digital computer, which means . . . the patent would wholly pre-empt the mathematical formula and in practical effect would be a patent on the algorithm itself.” *Id.* at 71-72.

Parker also addressed the patentability of a mathematical algorithm run on a general-purpose computer and, once again, the Supreme Court held the process unpatentable. In this case, the claimed invention updated alarm limits for catalytic conversion processes. 437 U.S. at 585. The Court recognized that “[a]n ‘alarm limit’ is a number,” just as a percentage or a profit or a price is a number. *Id.*

Three years after *Parker*, the Supreme Court stressed that it “is now commonplace that an application of a law of nature or mathematical formula to a known structure or process may well be deserving of patent protection.” *Diamond v. Diehr*, 450 U.S. 175, 187-88 (1981). In *Diehr*, the Supreme Court affirmed the potential patentability of an industrial process that included as one of its steps the use of a mathematical formula and a programmed digital computer to do calculations. The Court distinguished *Parker* and *Gottshalk* as addressing improper attempts to patent new mathematical formulae or algorithms in the abstract.

Later, the Federal Circuit adopted the Freeman-Walter-Abele test of its predecessor court, the CCPA, to extract and identify mathematical algorithms. *In re Freeman*, 573 F.2d 1237 (CCPA 1978), *In re Walter*, 618 F.2d 758 (CCPA 1980), *In re Abele*, 684 F.2d 902 (CCPA 1982). This test was articulated as follows:

First, the claim is analyzed to determine whether a mathematical algorithm is directly or indirectly cited. Next, if a mathematical algorithm is found, the claim as a whole is further analyzed to determine whether the algorithm is applied in any manner to physical elements or process steps, and if it is, it passes muster under § 101.

In Re Pardo, 684 F.2d 912, 915 (CCPA 1982) (emphasis added).

Throughout the 1990s, the Federal Circuit chipped away at the “physical elements or process steps” requirement of the Freeman-Walter-Abele test while avoiding a specific disavowal of the test. The Federal Circuit affirmed the PTO’s rejection of claims as directed to nonstatutory subject matter (namely, a mathematical algorithm) in *In re Grams*, 888 F.2d 835 (Fed. Cir. 1990). The applicant’s claim 1 recited the combination of a physical step of gathering data with an algorithm consisting of analyzing the data to ascertain an abnormal condition in an individual. Eschewing the two-part *Walter* test as an exclusive test, the court held: “Whether section 101 precludes patentability in every case where the physical step of obtaining data for the algorithm is the only other significant element in mathematical algorithm-claiming claims is a question we need not answer. Analysis in that area depends on the claims as a whole and the circumstances of each case.” *Id.* at 840. The court concluded that the applicants were “in essence, claiming the mathematical algorithm.”

Reaching the opposite conclusion in *In re Iwahashi*, 888 F.2d 1370 (Fed. Cir. 1990), the court held that the PTO erred in rejecting the applicant’s claim on the ground of nonstatutory subject matter. Specifically, the PTO erroneously found that the claim, directed to an auto-correlation unit for providing auto-correlation coefficients for use as feature parameters in pattern recognition, merely recited a mathematical algorithm. The court emphasized the importance of claim language: “The claim as a whole certainly defines apparatus in the form of a combination of interrelated means and we cannot discern any logical reason why it should not be deemed statutory subject matter as either a machine or a manufacture as specified in § 101. The fact that the apparatus operates according to an algorithm does not make it nonstatutory.” *Id.* at 1375.

In *Arrythmia Research Technology Inc. v. Corazonix Corp.*, 958 F.2d 1053 (Fed. Cir. 1992), the Federal Circuit reversed the district court’s summary judgment invalidating the patent’s claims under Section 101. The transformation of electrocardiograph signals from a patient’s heartbeat by a machine through a series of mathematical calculations constituted a practical application of an abstract idea (a mathematical algorithm, formula, or calculation) because it corresponded to “a useful, concrete and tangible result”--the condition of a patient’s heart. The court expressly noted that the Freeman-Walter-Abele test “is not the only test for statutory subject matter” and “that failure to meet that test may not always defeat the claim.” *Id.* at 1058.

Similarly, in *In Re Allapat*, 33 F.3d 1526 (Fed. Cir. 1994) (in banc), the Federal Circuit reversed the PTO’s rejection of claims for nonstatutory subject matter under Section 101. Data transformed by a machine through a series of mathematical calculations to produce a smooth waveform display on a rasterizer monitor constituted a practical application of an abstract idea (a mathematical algorithm, formula, or calculation) because it produced “a useful, concrete and tangible result”--the smooth

waveform. Thus, the claimed subject matter “as a whole” recited a machine, which is one of the four categories of patentable subject matter listed in Section 101.

In *In re Warmerdam*, 33 F.3d 1354 (Fed. Cir. 1994), the Federal Circuit held that the PTO properly rejected patent claims 1-4 and 6 under Section 101. Warmerdam’s claims 1-4 recited a method for controlling the motion of objects and machines to avoid collision with other objects by generating bubble hierarchies through the use of a particular mathematical procedure. The court found that the claimed method did nothing more than manipulate basic mathematical constructs and concluded that “taking several abstract ideas and manipulating them together adds nothing to the basic equation.” *Id.* at 1360. Claim 6 recited: “A data structure generated by the method of any of Claims 1 through 4.” This claim failed to recite patentable subject matter, per the court, because the “data structure” of claim 6 “is nothing more than another way of describing the manipulation of ideas contained in claims 1-4.” *Id.* at 1361-62 n.8. Commenting on the Freeman-Walter-Abele test, the court stated: “An alternative to creating these arbitrary definitional terms which deviate from those used in the statute may lie simply in returning to the language of the statute and the Supreme Court’s basic principles as enunciated in *Diehr*, and eschewing efforts to describe nonstatutory subject matter in other terms.” *Id.* at 1359.

In 1996, having listened to the debate and considered the case law as then developed, the PTO adopted a new set of “Examination Guidelines for Computer-Related Inventions,” 61 Fed. Reg. 7,478 (effective on March 19, 1996) (“Examination Guidelines”); see 1 D. Chisum, *Patents*, § 1.03[6][h] at n.417 (2007). The Examination Guidelines state: “Office personnel will no longer begin examination by determining if a claim recites a ‘mathematical algorithm.’ Rather, they will review the complete specification” specifically to “identify and understand any practical application asserted for the invention.” Moreover, “when a claim reciting a mathematical algorithm is found to define non-statutory subject matter the basis of the § 101 rejection must be that, when taken as a whole, the claim recites a law of nature, a natural phenomenon, or an abstract idea.” There is no fourth classification of non-statutory subject matter.

B. Business Methods

Patents on business methods (most recently, patents for tax reduction strategies) have proven to be a particularly controversial type of statutory subject matter. They have been criticized because the patents granted are perceived as being too broad, perhaps due to the difficulties in searching for prior art and recruiting suitably qualified patent examiners who have historically had a science background rather than a business background. Patent applications for business methods are also subject to delays in prosecution at the PTO and other patent offices. J. Young, *Analysis & Perspective: Business Method Patents*, 74 Patent, Trademark & Copyright J. (BNA) 322 (July 13, 2007) (the average pendency time from application filing to first PTO Office Action is

3.6 years for business method patents in Class 705). For commentary on the debate, *see* 1 D. Chisum, Patents, § 1.03[5] at n.140 (2007).

In *In Re Schrader*, 22 F.3d 290 (Fed. Cir. 1994), the Federal Circuit panel upheld a decision of unpatentability by the PTO. The patent claimed a method for competitive bidding on a number of related items such as continuous tracts of land. Judge Pauline Newman dissented. Judge Newman's dissent had significant influence on the drafters of the Examination Guidelines. The Examination Guidelines cite the dissent several times and conclude: "Office personnel have had difficulty in properly treating claims directed to methods of doing business. Claims should not be categorized as methods of doing business. Instead such claims should be treated like any other process claims, pursuant to these Guidelines when relevant." Examination Guidelines, 61 Fed. Reg. at 7,479. The Examination Guidelines provide some practical advice as to how to draft allowable patent applications covering "business methods." Simply stated, the application should be drafted in a manner such that it is "computer related." "Computer-related inventions" are defined to include any invention implemented in a computer or employing computer readable media.

A seminal case in the area of patentable subject matter in general, and business methods in particular, is *State Street Bank & Trust Co. v. Signature Financial Group, Inc.*, 149 F.3d 1368 (Fed. Cir. 1998). In *State Street*, the subject matter was U.S. Patent No. 5,193,056 titled "Data Processing System for Hub and Spoke Financial Services Configuration." The '056 patent, owned by Signature Financial Group, contains means plus function claims directed to a data processing system for implementing an investment structure for use in administering mutual funds. State Street Bank was managing mutual funds in a manner likely to be found to infringe the '056 patent. Following unsuccessful license negotiations, State Street brought a declaratory judgment action asserting that the '056 patent was invalid.

The district court granted a partial summary judgment motion holding the patent claims invalid for failing to claim statutory subject matter under Section 101. In reaching this conclusion the district court held that the claimed subject matter fell into one or both of the "mathematical algorithm" or "business method" exceptions to statutory subject matter. More specifically, the court noted that the claimed invention did not involve any physical transformation of numbers. *State Street Bank and Trust Co. v. Signature Financial Group, Inc.*, 927 F. Supp. 502, 516 (D. Mass. 1996).

A unanimous Federal Circuit panel (Judges Rich, Plager, and Bryson) overturned the summary judgment finding of invalidity. The opinion by Judge Rich begins with an affirmation of the broad nature of Section 101 by citing Congressional reports stating that Section 101 was intended to extend patentable subject matter to "anything under the sun that is made by man." Moreover, courts should not read limitations into the patent laws which were not expressed by Congress. *State Street*, 149 F.3d at 1373 (citing S. Rep. No. 1979, 82nd Cong., 2d Sess. 5 (1952), and quoting *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980)).

The court reasoned that previous “mathematical algorithm” cases had merely found that: “Unpatentable mathematical algorithms are identifiable by showing that they are merely abstract ideas constituting disembodied concepts or truths that are not ‘useful.’” *Id.* at 1373. “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.’” The court then held:

[T]ransformation of data, representing discrete dollar amounts, by a machine through a series of mathematical calculations into a final share price, constitutes a practical application of a mathematical algorithm, formula or calculation, because it produces “a useful, concrete and tangible result”—a final share price momentarily fixed for recording and reporting purposes and even accepted and relied upon by regulatory authorities and in subsequent trades.

Id. The court then rejected the Freeman-Walter-Able test as having “little, if any, applicability to determining the presence of statutory subject matter” after *Diehr* and *Chakrabarty*. *Id.* at 1374. The court concluded by saying that a patent claim may contain statutory subject matter “even if the useful result is expressed in numbers, such as a price, profit, percentage, cost, or loss.” *Id.* at 1375. Thus, the Federal Circuit firmly held that there is no requirement whatsoever that an invention show any physical transformation of matter or a process in order to be patentable.

The Federal Circuit was equally clear in overruling the district court’s reliance on the “business method exception,” citing with approval both Judge Newman’s dissent in *Schrader* and the PTO Examination Guidelines. The court pronounced, “[w]e take this opportunity to lay this ill-conceived [business method] exception to rest.” *State Street* at 1375. The court went on to state that “[w]hether the claims are directed to subject matter within § 101 should not turn on whether the claimed subject matter does ‘business’ instead of something else.” *Id.* at 1377.

Thus, pursuant to *State Street*, performance by a machine of a mathematical algorithm, formula, or calculation is patentable if it produces a “useful, concrete and tangible result.” *State Street* at 1373 (means plus function limitations recite a machine). The key question now may be whether the claimed invention is a “practical application” of an algorithm or business method. See Box 13 of PTO “Examination Procedures for Computer-Related Inventions.”

In *AT&T Corp. v. Excel Communications, Inc.*, 172 F.3d 1352 (Fed. Cir. 1999), the Federal Circuit applied *State Street* to find statutory subject matter in a claimed process that uses telephone subscribers’ and call recipients’ primary interexchange carriers (PICs) as data, applies Boolean algebra to those data to determine the value of the PIC indicator, and applies that value through switching and recording mechanisms to produce a signal useful for billing purposes—a useful, concrete, tangible result achieved without pre-empting other uses of the mathematical principle. The district court had concluded that the method claims implicitly recited a mathematical algorithm, expressed the view that the only physical step in the claims involved data-gathering for the

algorithm, and, on summary judgment, held all of the method claims at issue invalid for failure to qualify as statutory subject matter. The Federal Circuit reversed and remanded, stating: “Because § 101 includes processes as a category of patentable subject matter, the judicially-defined proscription against patenting of a ‘mathematical algorithm,’ to the extent such a proscription still exists, is narrowly limited to mathematical algorithms in the abstract.” *Id.* at 1356.

In response to concerns raised by the debate about business method patents, Congress enacted 35 U.S.C. § 273(a)(3) in 1999. Section 273(a)(3) created a “prior user” defense. The defense limits liability for infringement of patents claiming methods of “doing or conducting business.”

C. Biological Subject Matter

One of the most controversial patentable subject matter areas has been biological material, including genetic material and living organisms (plants and animals). The literature on the topic is vast. *See* 1 D. Chisum, Patents, § 1.02[7] at n.189 (2007). A true product of nature cannot be patented, even if the claimant is the first person to discover or identify the product. A patent may recite, however, the process of using the new product of nature. U.S. Patent and Trademark Office, Manual of Patent Examining Procedure § 706.03(a) (2005) (MPEP). Moreover, claim limitations such as “non-human” and “non-natural” can be used to avoid rejection under Section 101. *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1329 (Fed. Cir. 2003).

In the late 1970s, scientists began filing patent applications disclosing and claiming the techniques and products of biotechnology. These applications raised a serious issue concerning statutory subject matter for claims to genetically altered living organisms. In *Diamond v. Chakrabarty*, 447 U.S. 303, 308 (1980) (claims directed to bacteria that had been genetically modified to enable them to digest oil and, therefore, to be useful in environmental protection against oil spills), the Supreme Court resolved the issue, holding that a living, genetically altered microorganism constituted patentable subject matter as either a manufacture or a composition of matter. The Court stated: “In choosing such expansive terms as ‘manufacture’ and ‘composition of matter,’ modified by the comprehensive ‘any,’ Congress plainly contemplated that the patent laws would be given wide scope.” *Id.* at 308. *See also J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int’l, Inc.*, 534 U.S. 124, 131 (2001) (noting with approval that the PTO “has issued some 1,800 utility patents for plants, plant parts, and seeds pursuant to 35 U.S.C. § 101”).

The Federal Circuit has followed the Supreme Court’s lead. In *In re Lundak*, 773 F.2d 1216, 1219 n.1 (Fed. Cir. 1985), the appellate court stated: “it is the public interest in the progress of the useful arts that is benefited as new technologies evolve. An interpretation of the statute to deny patent rights in microbiological inventions would be contrary to law. . . . The PTO must continue to adapt its procedures to facilitate the advance of science and technology.”

Newly developed plant breeds fall within the terms of Section 101, and neither the Plant Patent Act, 35 U.S.C. §§ 161-64, nor the Plant Variety Protection Act, 7 U.S.C. § 2321 et seq., limit the scope of subject matter patentable under Section 101. *J.E.M. Ag Supply Inc. v. Pioneer Hi-Bred Int'l Inc.*, 534 U.S. 124, 145 (2001) (applied in *Monsanto Co. v. McFarling*, 363 F.3d 1336 (Fed. Cir. 2004)). In *Animal Legal Defense Fund v. Quigg*, 932 F.2d 920 (Fed. Cir. 1991), the Federal Circuit held that animal rights advocate organizations, farmers, and animal husbandry organizations lacked standing to seek judicial review of the PTO's 1987 notice, 1077 Official Gazette 24 (April 21, 1987), that it "now considers non-naturally occurring, non-human multicellular organisms, including animals, to be patentable subject matter." The court supported its holding by stating, "The Notice clearly corresponds with the interpretations of Section 101 set out by the Board . . . in reliance on *Chakrabarty*"

D. Printed Subject Matter

Historically, "printed matter" alone did not constitute a "manufacture" and, therefore, did not fall within the classes of patentable subject matter. Printed matter could constitute an element of a patentable claim, however, if the claim recited a feature of physical structure or a relation between the printed matter and the physical structure. The line between the general rule and its exception proved difficult to draw. *See* 1 D. Chisum, Patents, § 1.02[4] (2007). Federal Circuit decisions recognize the exception and question the general rule. *See, e.g., In re Lowry*, 32 F.3d 1579 (Fed. Cir. 1994) (reversing the PTO's rejection under Section 103, which had refused to accord patentable weight to the recited "printed matter").

Rather than rejecting printed subject matter as unpatentable under Section 101, the Federal Circuit tends to measure claims reciting such subject matter against the standards of novelty or obviousness. *See, e.g., In re Beauregard*, 53 F.3d 1583 (Fed. Cir. 1995) (vacating PTO rejection of computer program product claims on the basis of printed matter doctrine because computer programs embodied in a tangible medium, such as a floppy disk, are patentable subject matter under 35 U.S.C. § 101 and must be examined under 35 U.S.C. §§ 102 & 103). In *In re Gulack*, 703 F.2d 1381, 1385 (Fed. Cir. 1983), the Federal Circuit examined printed subject matter against the relevant art, under Section 103, and stated that the differences "between an invention and the prior art cited against it cannot be ignored merely because those differences reside in the content of the printed matter."

In *In re Ngai*, 367 F.3d 1336 (Fed. Cir. 2004), the Federal Circuit distinguished *Gulack*: "In Gulack, [703 F.2d 1381,] the Board rejected a claim directed to a circular band designed for mathematical and educational purposes. The invention consisted of '(1) a band, ring, or set of concentric rings; (2) a plurality of individual digits imprinted on the band or ring at regularly spaced intervals; and (3) an algorithm by which the appropriate digits are developed. Id. at 1387. The rejection was premised upon the fact that a circular band with items printed upon it was well known in the art. See id. at 1384. We reversed, finding that the numbers printed on the band had a functional relationship to the band itself. The . . . 'digits are related to the band in two ways: (1) the band

supports the digits; and (2) there is an endless sequence of digits--each digit residing in a unique position with respect to every other digit in an endless loop. Thus, the digits exploit the endless nature of the band.’ *Id.* at 1386-87. . . . This case however, is dissimilar from Gulack. There the printed matter and the circularity of the band were interrelated, so as to produce a new product useful for ‘educational and recreational mathematical’ purposes. Here, addition of a new set of instructions [describing a patentable method] into a known kit does not interrelate with the kit in the same way as the numbers interrelated with the band. . . . Here, the printed matter in no way depends on the kit, and the kit does not depend on the printed matter. All the printed matter does is teach a new use for an existing product.”

E. Medical Methods

Whether medical methods constitute patentable subject matter has long been controversial. The early “ether” case suggested that a surgical method as such was not patentable. *Morton v. New York Eye Infirmary*, 17 F. Cas. 879 (no. 9865) (S.D.N.Y. 1862) (claims reciting a process of using ether in surgery to eliminate sensitivity to pain did not encompass patentable subject matter). Later decisions refused, however, to exclude all medical treatment methods from patentability. Unlike in many other countries, therapeutic methods of treating humans are generally patentable in the U.S.

The Federal Circuit has been relatively quiet in this area, perhaps because the PTO and Congress have been active. A PTO notice of hearings provides the flavor of the debate on patents for therapeutic and diagnostic methods. PTO, “Notice of Hearings and Request for Comments on Issues Relating to Patent Protection for Therapeutic and Diagnostic Methods,” 61 Fed. Reg. 10,320 (March 13, 1996). *See also* 1 D. Chisum, Patents, § 1.03[3] (2007). In response to concerns raised by medical professionals over patents issued on surgical techniques, Congress enacted 35 U.S.C. § 287(c) in 1996. Section 287(c) renders inapplicable remedies against patent infringement by medical practitioners and related health entities for performance of a medical activity.

V. The Controversy Continues

As of 2003, the PTO has been rejecting business method patents that do not make use of “technology” (most often non-computer-related applications) on the basis of, among other cases, *In Re Schrader*, 22 F.3d 290 (Fed. Cir. 1994). In *Ex Parte Lundgren*, Appeal No. 2003-2088 (Bd. Pat. App. & Inter. Sept. 28, 2005) (3-2 decision), however, the PTO held that “technology arts” is not the test for patentable subject matter under Section 101. The application claimed a method for compensating a manager responsible for reducing the margin of prices over costs, reducing incentives for industry collusion, or reducing incentives for coordinated special interest lobbying. The examiner concluded that the invention is an economic theory expressed as a mathematical algorithm with no disclosure or suggestion of a computer, an automated means, or an apparatus of any kind, placing the invention and its practical application “outside the technological arts.” The Board held that the examiner incorrectly applied a separate “technological arts” test to the

patentable subject matter requirement of Section 101. This decision seemed to open the door for business methods that are not machine implemented.

In *Ex Parte Bilski*, Appeal No. 2002-2257 (Bd. Pat. Appeals & Interferences Sept. 26, 2006), however, the PTO characterized *Lundgren* as declining to establish a separate “technology arts” test but as not eliminating a “technology” requirement for patents, which is contained within the definition of the statutory classes. The PTO held that only methods which recite a transformation of physical subject matter or data from one state or thing to another, and are not a law of nature, physical phenomenon, or abstract idea, are statutory processes. *Bilski*’s claim in U.S. Patent Application No. 08/833,892 recited a method of managing the consumption risk costs of a commodity sold by a commodity provider at a fixed price. The Board held the recited subject matter nothing but a disembodied abstract idea, rather than a practical implementation of the concept.

Examiner training materials, released in 1998 in connection with the 1996 Examination Guidelines for Computer-Related Inventions, 61 Fed. Reg. 7,478, make repeated references to the need for the invention to be in the “technological arts.” See <http://www.uspto.gov/web/offices/pac/compexam/examcomp.htm>. The Examination Guidelines are expected to be revised.

Meanwhile, the application of Section 101 is under scrutiny in several PTO appeals pending before the court. The *Bilski* case has been appealed to the Federal Circuit, Federal Circuit Appeal No. 07-1130, and oral argument has been set for October 1, 2007. Three other pending cases before the Federal Circuit are also noteworthy.

In *In re Nuijten*, Federal Circuit Appeal No. 06-1371, the PTO rejected the claims of U.S. Patent Application No. 09/211,928. The claims recite a signal with embedded supplemental data. The PTO refused to issue a patent, because the claim is directed to an abstract idea, unless the applicant included a limitation directed to a specific mode of transmission (e.g., smoke signal, electromagnetic, etc.). *Nuijten* argues that bare signals should be patentable subject matter under Section 101. The Federal Circuit heard oral argument on February 5, 2007, and a decision is expected soon.

In *In re Comiskey*, Federal Circuit Appeal No. 06-1286, the court heard oral argument on January 12, 2007, and requested supplemental briefing on patentable subject matter issues. The claims of U.S. Patent Application No. 09/461,742 involve a method of handling arbitration that does not require any machine assistance. Section 101 was not raised by the examiner, Board, or PTO Solicitor; rather, the Federal Circuit raised the issue sua sponte. During the appeal, the PTO representative indicated that, if *Comiskey* were successful in the current appeal on the issue of obviousness, then the PTO would likely raise Section 101 issues on remand.

Finally, *In re Ferguson*, Federal Circuit Appeal No. 07-1232, remains in the briefing stage. At issue is U.S. Patent Application No. 09/387,823, which apparently includes method claims reciting a marketing “paradigm.” It can be anticipated that

significant changes in the test for patentable subject matter under Section 101 may result from these cases now on appeal.

VI. Foreign Approaches

As stated above, different jurisdictions have come to different views as to what subject matter can be patented and what cannot. Outlined below are the approaches taken by the European Patent Convention (EPC) (available at <http://www.european-patent-office.org/legal/epc.html>) and by the 1994 Agreement on the Trade-Related Aspects of Intellectual Property (available at http://www.wto.org/english/tratop_e/trips_e/t_agm0_e.html). These approaches are outlined for purposes of illustrative comparison to the approach of United States law.

A. The European Patent Convention

Unlike the four-category approach of Section 101 under U.S. patent law, the EPC offers little positive guidance defining what subject matter qualifies for protection under the patent law. Article 52(1) of the EPC provides generally that “European patents shall be granted for any inventions which are susceptible of industrial application, which are new and which involve an inventive step.” Article 57 defines that “an invention shall be considered as susceptible of industrial application if it can be made or used in any kind of industry, including agriculture.”

Also unlike U.S. patent law, the EPC excludes a non-exhaustive list of classes that do not qualify as inventions and, therefore, are not patentable subject matter. In particular, Article 52(2) excludes as not inventions “(a) discoveries, scientific theories and mathematical methods; (b) aesthetic creations; (c) schemes, rules and methods for performing mental acts, playing games or doing business, and programs for computers; [and] (d) presentations of information.” The exclusions apply, however, only insofar as the excluded subject matter is claimed “as such.” EPC Article 52(3). With respect to computer-related inventions, pressure from the computer industry led to an early revision of the strict approach that the European Patent Office (EPO) originally intended to take on the question of patentability of computer-related inventions.

Thus, for example, the relevant EPO Technical Board of Appeal has held that there is no per se prohibition against the grant of patents for computer product media bearing a computer program or even a computer program element comprising computer program code as long as the object of the program is to produce a technical effect beyond the mere running of the program. The Board saw no distinction between claiming a program indirectly as a computer-controlled method or apparatus and claiming the program itself. The Board stated: “a computer program claimed by itself is not excluded from patentability if the program, when running on a computer or loaded into a computer, brings about, or is capable of bringing about, a technical effect which goes beyond the ‘normal’ physical interactions between the program (software) and the computer (hardware) on which it its run.” Decision on Case T 1173/97 (1999).

Methods of doing business are grouped with methods of performing mental acts and rules for playing games as being unpatentable under Article 52(2)(c). Following developments in the United States, however, the EPO has indicated that it would accept claims to business methods provided that such claims are closely linked to a technical problem of some sort. Claims to abstract business methods will be rejected on the ground that they are excluded by EPC Articles 52(2) and (3), because they are methods of doing business “as such.” Claims for computer-implemented business methods should be treated in exactly the same way as any other computer-implemented invention. Finally, claims for other implementations of business methods should be treated using the same scheme for examination as for computer implementations.

EPC Article 52(4) further excludes “methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body.” The exclusion does not apply, however, to any “substance or composition for use in [such] a method” even if previously known for some other purpose as long as that purpose was not a method of treatment or diagnosis practiced on a human or animal body. EPC Article 54(5). The prohibition against medical inventions has been narrowly construed in several cases. The Appeal Board has reasoned that the purpose of Article 52(4) is to ensure that a medical caretaker can practice freely without fear of patent infringement. Thus, if the patent claim does not restrict the caretaker in selecting appropriate medical action then the claim does not fall within the exclusion. *See, e.g.*, Decision on Case T 385/86 (1988) (upholding as patentable a non-invasive method for determining pH or temperature in a particular area of a body by magnetic resonance because the results obtained could not be used directly by a physician to make a diagnosis).

EPC Article 53(b) excludes patents “in respect of . . . plant or animal varieties or essentially biological processes for the production of plants or animals” but adds that the exclusion “does not apply to microbiological processes or the products thereof.” Also relevant to biological inventions is EPC Article 53(a), which excludes from patentable subject matter inventions whose publication or exploitation would be contrary to *ordre public* or morality. In 1998, the European Union adopted a directive requiring that its member states harmonize their laws relating to the patenting of biotechnological inventions, and the EPO adopted relatively complex rule changes in response to the directive. For a discussion of the patentability of biological subject matter under the EPC, see W. Cornish, Intellectual Property: Patents, Copyrights, Trade Marks and Allied Rights 216-31 (4th ed. 1999).

More generally, Professor Cornish notes that the exclusions and limitations in the EPC represent a fairly conservative consensus of European opinion on the topic of patentable subject matter in 1973. Developments have shown that the rules have been and will continue to be amended in response to changes in the United States and elsewhere, and as technology advances, concerning the patenting of computer-related inventions, methods of doing business, medical inventions, and biological inventions.

B. The TRIPS Agreement

The initial world trade accord called the General Agreement on Tariffs and Trade (GATT) was completed in Geneva in 1947. The Uruguay Round of GATT began in Uruguay in 1986 and was completed in Geneva in 1993. On April 15, 1994, the United States and 107 other countries became signatories to the agreement, which included Trade-Related Aspects of Intellectual Property Rights (TRIPS), effective on July 1, 1995. The World Trade Organization (WTO) was created by the Uruguay Round of negotiations; became effective on January 1, 1995; is located in Geneva, Switzerland; and, as of January 1, 2007, included 150 countries. TRIPS is binding on countries that are members of the WTO, and a WTO Council for TRIPS monitors the operation of the agreement and governments' compliance with it.

TRIPS recognizes that widely varying standards in the protection and enforcement of intellectual property rights and the lack of a multilateral framework of principles, rules, and disciplines addressing international trade had been a growing source of tension in international economic relations. Rules and disciplines were needed to cope with these tensions. To that end, TRIPS addresses the applicability of basic GATT principles and those of relevant international intellectual property agreements; the provision of adequate intellectual property rights; the provision of effective enforcement measures for those rights; multilateral dispute settlement; and transitional arrangements.

Part I of TRIPS sets out general provisions and basic principles, notably a national-treatment commitment under which the nationals of other members must be given treatment no less favorable than that accorded a member's own nationals with regard to the protection of intellectual property. TRIPS also contains a most-favored-nation clause, a novelty in an international intellectual property agreement, under which any advantage a member gives to the nationals of another country must be extended immediately and unconditionally to the nationals of all other members, even if such treatment is more favorable than that which it gives to its own nationals.

Part II addresses each intellectual property right in succession. The patent portion of TRIPS is Section 5 of Part II. Article 27 in Section 5 of Part II of TRIPS addresses "patentable subject matter." Paragraph 1 of Article 27 states (emphasis added):

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

Thus, like the EPC and unlike the four-category approach of Section 101 under U.S. patent law, TRIPS offers little positive guidance defining what patentable subject qualifies for protection under the patent law.

Paragraphs 2 and 3 of Article 27 of TRIPS permit member countries to “exclude from patentability” certain inventions. The list of permissible exclusions includes many but not all of the exclusions under the EPC. Specifically, Paragraph 2 states:

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

Paragraph 3 includes among the list of excluded subject matter “(a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;” and “(b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.”

Notably missing from the TRIPS provisions are the EPC Article 52(2) exclusions of “(a) discoveries, scientific theories and mathematical methods; (b) aesthetic creations; (c) schemes, rules and methods for performing mental acts, playing games or doing business, and programs for computers; and (d) presentations of information”--all, of course, “as such.”

VII. Conclusion

It is often difficult to reach a satisfactory compromise to resolve a deep-seated policy debate. This is especially true of issues that trigger emotional and ethical, as well as substantive, positions. (The debate about abortion comes to mind.) The debate about patentable subject matter may be one of these issues, and a compromise test or standard may satisfy no one completely. To date, the patent law has sought to sail between the dangers of over-protection and diminished incentive to invent by establishing rules that bring certain types of inventions within the scope of patentability while excluding others.

It would appear that “almost anything under the sun that is made by man” can be patented by paying careful attention to the Federal Circuit and PTO rules, i.e., by properly claiming the invention. There are few business methods, for example, that are not at least partially implemented in a computer or that do not use computer readable media. And it is clear that business methods implemented on a computer are now

protectable as long as the method is otherwise novel, nonobvious, and meets the requirements of Section 112 (enablement, written description, best mode, etc.).