

Current Issues in Patentable Subject Matter: Business Methods, Tax Planning Methods, and Genetic Materials

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Summary

Congressional interest in the patent system has grown in recent years, tracking increasing recognition of the importance of intellectual property to innovative U.S. industries. One of the areas of interest is the topic of patentable subject matter—that is, the sorts of inventions for which patents may be obtained. In particular, patents on business methods, tax planning methods, and genetic materials have proven controversial. Legislation introduced in recent sessions of Congress would restrict the availability of patents in these fields. None of these bills has been enacted.

The patent statute currently provides that patents may be obtained on any invention that is a process, machine, manufacture, or composition of matter. The range of patentable subject matter under this provision has been characterized as extremely broad. The courts have nonetheless concluded that certain subject matter, including abstract ideas, mathematical algorithms, laws of nature, and mental processes may not be patented no matter how innovative they might be. They have reasoned that these inventions comprise the fundamental tools of scientific research, and that allowing them to be privately appropriated might interfere with future advancement.

Business method patents relate to a method of administering, managing, or conducting a business or organization. Tax planning method patents concern a method of reducing or deferring taxes. The 2010 decision of the U.S. Supreme Court in *Bilski v. Kappos* addressed whether particular methods are patentable, although opinions vary as to the conclusiveness of the Courts' ruling.

Patents claiming the products of biotechnology, and in particular genetic materials, have also led to considerable debate. Genetic material patents cover such technologies as DNA sequences, amino acid sequences, individual mutations known to cause disease, and testing kits for detecting genetic mutations. Since the 1980 decision of the Supreme Court in *Diamond v. Chakrabarty*, the U.S. Patent and Trademark Office (USPTO) has viewed genetic materials and related technologies as patentable. However, the March 29, 2010, district court opinion in *Association for Molecular Pathology v. USPTO* cast doubt upon the patentability of isolated DNA. Proceedings in the so-called "Myriad" litigation were pending as of the date this report issued.

Numerous arguments have been advanced in opposition to patents on business methods, tax planning methods, and genetic materials. Some commentators believe that business method patents ultimately discourage competition, that tax strategy patents provide undesirable innovation incentives, and that patents on genetic materials lead to deleterious effects on healthcare and medical research. Other experts assert that these concerns are overstated, and further contend that the patent system provides a powerful incentive for innovation, investment, and public disclosure of technology across many fields of endeavor.

Several legislative options present themselves. If Congress decides the current rules with respect to patent eligibility are appropriate, then no action need be taken. Other possibilities include amendments to the Patent Act either to bar the issuance of patents in particular disciplines, or to limit the ability to enforce certain kinds of patents. The desire to comply with certain international agreements, in particular the WTO Agreement on Trade-Related Aspects of Intellectual Property (TRIPS), may restrict certain legislative alternatives.

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Introduction

Recent congressional discussion of patent system reform has included consideration of provisions that would restrict the sorts of inventions for which patents may be obtained. Legislation introduced in the 111th Congress would have prevented the patenting of tax planning methods,[1] while one hearing regarding patent reform focused in part upon the propriety of patenting business methods.[2] Legislation introduced in previous sessions of Congress would have banned patents relating to genetic materials as well.[3] None of this legislation has been enacted.

Under current law, one of the requirements to obtain a patent is that the invention must consist of a "process, machine, manufacture, or composition of matter."[4] The courts and the U.S. Patent and Trademark Office (USPTO) have understood this language to allow an expansive range of patentable subject matter.[5] Patents have therefore been obtained upon diverse inventions, including living organisms, genetic materials, tax avoidance strategies, insurance methods, and marketing techniques.[6] Some observers believe that recent judicial opinions have narrowed the extent of patentable subject matter, however.[7]

The proper scope of patentable subject matter has been the subject of an often impassioned debate. Among other concerns, critics believe that business method patents are unnecessary to promote innovation,[8] that tax strategy patents conflict with public policy,[9] and that patents on generic materials raise ethical concerns.[10] However, other observers believe that the patent system has served as a fair and effective mechanism for promoting advances in a broad range of disciplines.[11] In their view, arbitrary restrictions upon the patent incentive are inappropriate.[12]

[1] H.R. 1265, § 303; H.R. 2584, §1; S. 506, § 303.

[2] U.S. House of Representatives, Committee on the Judiciary, Hearing on H.R. 1260, the "Patent Reform Act of 2009," April 30, 2009.

[3] See, e.g., The Genomic Research and Accessibility Act, 110th Congress, H.R. 977. This legislation was not enacted.

[4] 35 U.S.C. § 101 (2006). If an invention is judged to fall within one of these four categories of patentable subject matter, then it must meet other standards in order to be subject to a patent. In particular, the invention must not have been obvious to a person of ordinary skill in the art at the time it was made. 35 U.S.C. § 103(a) (2006).

[5] See Ryan Hagglund, "Patentability of Human-Animal Chimeras," 25 *Santa Clara Computer & High Technology Law Journal* (2008-2009), 51.

[6] See Dana Remus Irwin, "Paradise Lost in the Patent Law? Changing Visions of Technology in the Subject Matter Inquiry," 60 *Florida Law Review* (2008), 775.

[7] See Scott D. Locke & William D. Schmidt, "Business Method Patents: The Challenge of Coping with An Ever Changing Standard of Patentability," 18 *Fordham Intellectual Property, Media and Entertainment Law Journal* (2008), 1079.

[8] See Leo J. Raskind, "The *State Street Bank* Decision: The Bad Business of Unlimited Patent Protection for Methods of Doing Business," 10 *Fordham Intellectual Property, Media & Entertainment Law Journal* (1999), 61.

[9] See Tinna C. Otero, "Banning Tax Strategy Patents—Should We Listen to the Tax Practitioners?," 48 *Jurimetrics Journal* (2008), 309.

[10] See Michele Westhoff, "Gene Patents: Ethical Dilemmas and Possible Solutions," 20 *Health Lawyer* no. 4 (2008), 1.

[11] See Christopher A. Harkins, "Throwing Judge Bryson's Curveball: A Pro Patent View of Process Claims as Patent-Eligible Subject Matter," 7 *John Marshall Review of Intellectual Property Law* (2008), 701.

[12] See Kevin Schubert, "Should *State Street* Be Overruled? Continuing Controversy Over Business Method Patents," 90 *Journal of the Patent and Trademark Office Society* (2008), 461.

This report introduces the current debate concerning the appropriate range of patentable subject matter. It begins by providing an introduction to the patent system. It then reviews the ongoing discussion concerning the merits of business method and tax planning method patents. The current controversy concerning patents on genetic materials is then reviewed. The report then provides a broader discussion of innovation policy concerns that arise as policy makers consider the appropriate range of patentable subject matter. A summary of congressional issues and options concludes the report.

Fundamentals of the Patent System

The U.S. Constitution confers upon Congress the power "To promote the Progress of ... useful Arts, by securing for limited Times to ... Inventors the exclusive Right to their ... Discoveries."[13] In accordance with the Patent Act of 1952,[14] an inventor may seek the grant of a patent by preparing and submitting an application to the USPTO. USPTO officials known as examiners then determine whether the invention disclosed in the application merits the award of a patent.[15]

USPTO procedures require examiners to determine whether the invention fulfills certain substantive standards set by the patent statute. To be patentable, the invention must be novel, or different, from subject matter disclosed by an earlier patent, publication, or other state-of-the-art knowledge.[16] In addition, an invention is not patentable if "the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains."[17] This requirement of "nonobviousness" prevents the issuance of patents claiming subject matter that a skilled artisan would have been able to implement in view of the knowledge of the state of the art.[18] The invention must also be useful, a requirement that is satisfied if the invention is operable and provides a tangible benefit.[19]

Even if these requirements of novelty, nonobviousness, and utility are met, an invention is not patentable unless it falls within at least one category of patentable subject matter. According to section 101 of the Patent Act of 1952, an invention which is a "process, machine, manufacture, or composition of matter" may be patented.[20] The range of patentable subject matter under this statute has been characterized as "extremely broad."[21] The courts and USPTO have nonetheless concluded that certain subject matter, including abstract ideas and laws of nature, is not patentable under section 101.[22] This report further discusses this legal standard below.

[13] Article I, Section 8, Clause 8.

[14] P.L. 82-593, 66 Stat. 792 (codified at Title 35 of the United States Code).

[15] 35 U.S.C. § 131 (2006).

[16] 35 U.S.C. § 102 (2006).

[17] 35 U.S.C. § 103(a) (2006).

[18] See KSR International Co. v. Teleflex Inc., 550 U.S. 398 (2007).

[19] See In re Fischer, 421 F.3d 1365, 1371 (Fed. Cir. 2005).

[20] 35 U.S.C. § 101 (2006).

[21] In re Comiskey, 554 F.3d 967 (Fed. Cir. 2009).

[22] See In re Bilski, 545 F.3d 943 (Fed. Cir. 2008) (*en banc*).

In addition to these substantive requirements, the USPTO examiner will consider whether the submitted application fully discloses and distinctly claims the invention.[23] In particular, the application must enable persons skilled in the art to make and use the invention without undue experimentation.[24] In addition, the application must disclose the "best mode," or preferred way, that the applicant knows to practice the invention.[25]

If the USPTO allows the patent to issue, its owner obtains the right to exclude others from making, using, selling, offering to sell, or importing into the United States the patented invention.[26] Those who engage in those acts without the permission of the patentee during the term of the patent can be held liable for infringement. Adjudicated infringers may be enjoined from further infringing acts.[27] The patent statute also provides for an award of damages "adequate to compensate for the infringement, but in no event less than a reasonable royalty for the use made of the invention by the infringer."[28]

The maximum term of patent protection is ordinarily set at 20 years from the date the application is filed.[29] At the end of that period, others may employ that invention without regard to the expired patent.

Patent rights do not enforce themselves. Patent owners who wish to compel others to respect their rights must commence enforcement proceedings, which most commonly consist of litigation in the federal courts. Although issued patents enjoy a presumption of validity, accused infringers may assert that a patent is invalid or unenforceable on a number of grounds. The Court of Appeals for the Federal Circuit (Federal Circuit) possesses nationwide jurisdiction over most patent appeals from the district courts.[30] The Supreme Court enjoys discretionary authority to review cases decided by the Federal Circuit.[31]

Patents on Business and Tax Planning Methods

The Patent Act of 1952 allows a patent to issue upon a "process," which the statute defines to mean a "process, art, or method."[32] Process patents claim a series of steps that may be performed to achieve a specific result. Process patents typically relate to methods of manufacture or use.[33] A process patent may claim a method of making a product, for example, or a method of using a chemical compound to treat a disease.

[23] 35 U.S.C. § 112 (2006).

[24] See Invitrogen Corp. v. Clontech Labs., Inc., 429 F.3d 1052, 1070-71 (Fed. Cir. 2005).

[25] See High Concrete Structures, Inc. v. New Enterprise Stone and Lime Co., 377 F.3d 1379, 1382 (Fed. Cir. 2004).

[26] 35 U.S.C. § 271(a) (2006).

[27] 35 U.S.C. § 283 (2006). *See* eBay Inc. v. MercExchange L.L.C., 126 S.Ct. 1837 (2006).

[28] 35 U.S.C. § 284 (2006).

[29] 35 U.S.C. § 154(a)(2) (2006). Although the patent term is based upon the filing date, the patentee obtains no enforceable legal rights until the USPTO allows the application to issue as a granted patent. A number of Patent Act provisions may modify the basic 20-year term, including examination delays at the USPTO and delays in obtaining marketing approval for the patented invention from other federal agencies.

[30] 28 U.S.C. § 1295(a)(1) (2006).

[31] 28 U.S.C. § 1254(1) (2006).

[32] 35 U.S.C. § 100(b) (2006).

[33] See In re Pleuddemann, 910 F.2d 823, 826 (Fed. Cir. 1990).

Although the statutory term "process" is broad, courts and the USPTO have nonetheless established certain limits upon the sorts of processes that may be patented. In particular, abstract ideas, mathematical algorithms, mental processes, and scientific principles have been judged not to be patentable.[34] The Supreme Court has described these sorts of inventions as the "basic tools of scientific and technological work"[35] that should be "free to all men and reserved exclusively to none."[36] As explained by Supreme Court Justice Stephen Breyer, this rule "reflects a basic judgment that protection in such cases, despite its potentially positive incentive effects, would too severely interfere with, or discourage, development and the further spread of future knowledge itself."[37]

In recent years, two controversial categories of process patents have been identified. The first of these, business method patents, have been defined to include "a method of administering, managing, or otherwise operating a business or organization, including a technique used in doing or conducting business."[38] The second, tax strategy patents, have been defined as "a plan, strategy, technique, or scheme that is designed to reduce, minimize, or defer, or has, when implemented, the effect of reducing, minimizing, or deferring, a taxpayer's tax liability."[39] This report discusses these two sorts of process patents in turn.

Business Method Patents

Prior to 1998, some courts had held that methods of doing business were not patentable subject matter under § 101 of the Patent Act. For example, the Court of Appeals for the First Circuit held that:

> [A] system for the transaction of business, such, for example, as the cafeteria system for transacting the restaurant business, or similarly the open-air drive-in system for conducting the motion picture theatre business, however, novel, useful, or commercially successful is not patentable apart from the means for making the system practically useful, or carrying it out.[40]

The Federal Circuit revisited the issue in 1998, however, and in its well-known decision in *State Street Bank & Trust Co. v. Signature Financial Group* held that no business method exclusion from patentability existed.[41] The patent at issue in that case concerned a data-processing system for implementing an investment structure known as a "Hub and Spoke" system.[42] This system allowed individual mutual funds ("Spokes") to pool their assets in an investment portfolio

[34] See Laboratory Corp. of America Holdings v. Metabolite Laboratories, Inc. 548 U.S. 124 (2006) (opinion of Justice Breyer, dissenting from dismissal of writ of certiorari as improvidently granted) (hereinafter "LabCorp.").

[35] Gottschalk v. Benson, 409 U.S. 63, 67 (1972).

[36] Funk Brothers Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 130 (1948).

[37] LabCorp., *supra*, at 128.

[38] Business Method Patent Improvement Act, H.R. 5364, 106th Cong., § 2 (2000). This legislation was not enacted.

[39] H.R. 1908, 110th Cong., § 10(b)(2)(A) (2008). In a portion of the definition not quoted above, the legislation expressly explained that "the use of tax preparation software or other tools used solely to perform or model mathematical calculations or prepare tax or information returns" was not considered a "tax planning method." This legislation was not enacted.

[40] Lowe's Drive-In Theaters, Inc. v. Park-In Theaters, Inc., 174 F.2d 547, 552 (1st Cir. 1949).

[41] 149 F.3d 1368 (Fed. Cir. 1998).

[42] See U.S. Patent No. 5,193,056.

("Hub") organized as a partnership. According to the patent, this investment regime provided the advantageous combination of economies of scale in administering investments coupled with the tax advantages of a partnership.[43] The patented system purported to allow administrators to monitor financial information and complete the accounting necessary to maintain this particular investment structure. In addition, it tracked "all the relevant data determined on a daily basis for the Hub and each Spoke, so that aggregate year end income, expenses, and capital gain or loss can be determined for accounting and tax purposes for the Hub and, as a result, for each publicly traded Spoke."[44]

Litigation arose between Signature, the patent owner, and State Street Bank over the latter firm's alleged use of the patented invention. Among the defenses offered by State Street Bank was that the asserted patent claimed subject matter that was not within one of the four categories of statutory subject matter,[45] and hence was invalid. The district court sided with State Street Bank.[46] The trial judge explained:

> At bottom, the invention is an accounting system for a certain type of financial investment vehicle claimed as [a] means for performing a series of mathematical functions. Quite simply, it involves no further physical transformation or reduction than inputting numbers, calculating numbers, outputting numbers, and storing numbers. The same functions could be performed, albeit less efficiently, by an accountant armed with pencil, paper, calculator, and a filing system.[47]

The trial court further relied upon "the long-established principle that business 'plans' and 'systems' are not patentable."[48] The court judged that "patenting an accounting system necessary to carry on a certain type of business is tantamount to a patent on the business itself."[49] Because the court found that "abstract ideas are not patentable, either as methods of doing business or as mathematical algorithms,"[50] the patent was held to be invalid.

Following an appeal, the Federal Circuit reversed. The court of appeals concluded that the patent claimed not merely an abstract idea, but rather a programmed machine that produced a "useful, concrete, and tangible result."[51] Because the invention achieved a useful result, it constituted patentable subject matter even though its result was expressed numerically.[52] The Federal Circuit further explained that:

> Today, we hold that the transformation 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

[43] 149 F.3d at 1370.

[44] Id.

[45] 35 U.S.C. § 101 (2006) (identifying processes, machines, manufactures, and compositions of matter as patentable subject matter).

[46] 927 F. Supp. 502 (D. Mass. 1996).

[47] Id. at 515.

[48] Id.

[49] Id. at 516.

[50] Id.

[51] 149 F.3d at 1373.

[52] Id. at 1375.

> recording and reporting purposes and even accepted and relied upon by regulatory authorities and in subsequent trades.[53]

The court of appeals then turned to the district court's business methods rejection, opting to "take [the] opportunity to lay this ill-conceived exception to rest."[54] The court explained restrictions upon patents for methods of doing business had not been the law since at least the enactment of the 1952 Patent Act. The Federal Circuit then concluded that methods of doing business should be subject to the same patentability analysis as any other sort of process.[55]

Following *State Street Bank,* numerous patents that arguably claim business methods have issued from the USPTO.[56] Katherine Strandburg, a member of the faculty of the New York University School of Law, has characterized business method patents as involving four categories: "(1) 'back office' or administrative operational methods; (2) customer service operational methods; (3) methods of providing personal or professional service; and (4) intangible 'products.'"[57] Several of these patents have been the subject of litigation in the federal courts.[58]

Patents on methods of doing business have attracted controversy. Some observers believe that such patents are appropriate supporters of the costly research and development efforts that occur in our service-oriented, information-based economy.[59] Others believe that business method patents are unnecessary to promote innovation and may raise unique concerns over competition.[60] A subsequent portion of this report will review this debate.

Congressional reaction to the patenting of business methods has to this point been limited. In 1999, Congress enacted the First Inventor Defense Act as part of the American Inventors Protection Act.[61] That statute provides an earlier inventor of a "method of doing or conducting business" that was later patented by another to assert a defense to patent infringement in certain circumstances.

In enacting the First Inventor Defense Act, Congress recognized that some firms may have operated under the impression that business methods could not be patented prior to the *State Street Bank* decision. As a result, they may have maintained their innovative business methods as trade secrets. Having used these trade secrets in furtherance of their marketplace activities for a period of time, however, these firms may be unable to obtain a patent upon their business method. Further, should a competitor later independently invent and patent the same business method, the trade secret holder would potentially be liable for patent infringement. Following the

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[53] Id. at 1373.

[54] Id. at 1375.

[55] Id.

[56] See, e.g., John R. Allison & Emerson H. Tiller, "The Business Method Patent Myth," 18 *Berkeley Technology Law Journal* (2003), 987.

[57] Katherine J. Strandburg, "What If There Were a Business Method Use Exemption to Patent Infringement?," 2008 *Michigan State Law Review*, 245.

[58] See, e.g., Nicholas A. Smith, "Business Method Patents and Their Limits: Justifications, History, and the Emergence of a Claim Construction Jurisprudence," 9 *Michigan Telecommunications & Technology Law Review* (2002), 171.

[59] Thomas J. Scott, Jr. & Stephen T. Schreiner, "Planning for the Brave New World: Are Business Method Patents Going to Be Second Class Citizens?," 19 *Intellectual Property & Technology Law Journal* no. 6 (2007), 6.

[60] Andrew A. Schwartz, "The Patent Office Meets the Poison Pill: Why Legal Methods Cannot Be Patented," 90 *Journal of the Patent and Trademark Office* (2008), 194.

[61] P.L. 106-113, 113 Stat. 1536 (1999) (codified at 35 U.S.C. § 273(b) (2006)).

confirmation of the patenting of business methods by the *State Street Bank* court, the creation of the first inventor defense was intended to provide a defense to patent infringement in favor of the first inventor/trade secret holder.[62]

By stipulating that the first inventor defense applied only to a "method of doing or conducting business," Congress arguably recognized the validity of these sorts of patents.[63] The First Inventor Defense Act did not define the term "method of doing or conducting business," however, and to date no published judicial opinion addresses the precise scope of this defense.[64]

Tax Planning Method Patents

Although the *State Street Bank* opinion rejected a *per se* rule denying patents on business methods, the invention claimed by the Signature patent was arguably motivated by a desire to reduce tax liability.[65] In some sense, then, *State Street Bank* may be seen as the first tax patent case. Some commentators believe that the "increase in the number of tax strategy patents requested and approved by the [USPTO] came on the heels" of *State Street Bank*.[66]

Generally stated, tax planning method patents may be defined as those that disclose and claim a system or method for reducing or deferring taxes.[67] As of January 6, 2011, the USPTO identified 130 issued patents and 155 published applications under classification number 705/36T.[68] As the USPTO received 482,871 patent applications in 2009, and granted 191,927 patents during that year, it should be appreciated that tax strategy patents represent a very small share of that agency's workload.[69] Among the titles of the issued patents are:

- System and method for forecasting tax effects of financial transactions (U.S. Patent No. 7,305,353)
- Method and apparatus for tax efficient investment management (U.S. Patent No. 7,031,937)
- Method and apparatus for tax-efficient investment using both long and short positions (U.S. Patent No. 6,832,209)

[62] See generally David H. Hollander, Jr., "The First Inventor Defense: A Limited Prior User Right Finds Its Way Into U.S. Patent Law," 30 *American Intellectual Property Law Association Quarterly Journal* (2002), 37.

[63] See Rochelle Cooper Dreyfuss, "Are Business Method Patents Bad for Business?," 16 *Santa Clara Computer and High Technology Law Journal* (2000), 263.

[64] John R. Allison & Starling D. Hunter, "On the Feasibility of Improving Patent Quality One Technology At a Time: The Case of Business Methods," 21 *Berkeley Technology Law Journal* (2006), 729.

[65] See, e.g., Paul E. Schaafsma, "A Gathering Storm in the Financial Industry," 9 *Stanford Journal of Law, Business and Finance* (2004), 176.

[66] Meyer, *supra*, at 187.

[67] H.R. 1908, 110th Cong., § 10(b)(2)(A) (2008).

[68] It should be appreciated that some observers have criticized the USPTO classification system as unreliable. *See, e.g.,* John R. Allison and Mark A. Lemley, "The Growing Complexity of the United States Patent System," 82 *Boston University Law Review* (2002), 77. As a result, it is possible that some patents arguably directed towards tax strategies may presently be classified under different categories.

[69] USPTO, U.S. Patent Statistics, Calendar Years 1963-2009 (available at http://www.uspto.gov/web/offices/ac/ido/oeip/taf/us_stat.pdf).

> • Computerized system and method for optimizing after-tax proceeds (U.S. Patent No. 6,115,697)

Tax planning method patents have resulted in a lively discussion among interested parties. Some observers, and in particular tax professionals, have found tax planning method patents to be "ridiculous,"[70] "bizarre,"[71] and "deeply unsettling."[72] On the other hand, other commentators, including many patent professionals, believe both that concerns over tax patents are overstated, and that the patenting of tax strategies may lead to numerous positive consequences. This report will review this debate below.

In the 111th Congress, three bills have been introduced that would stipulate that patents may not be obtained on methods of tax planning.[73] H.R. 1265 and S. 506 define the excluded category of "tax planning invention[s]" to mean "a plan, strategy, technique, scheme, process, or system that is designed to reduce, minimize, determine, avoid, or defer, or has, when implemented, the effect of reducing, minimizing, determining, avoiding, or deferring, a taxpayer's tax liability or is designed to facilitate compliance with tax laws, but does not include tax preparation software and other tools or systems used solely to prepare tax or information returns."[74] H.R. 2584 would prevent any patent claiming a "tax planning method," which is defined similarly.[75] The legislation would apply to any application filed at the USPTO on or after the date of enactment.[76]

Bilski v. Kappos

Increasing public scrutiny of business and tax strategy patents in recent years has corresponded with heightened attention to patent eligibility issues by the USPTO and the courts. On June 28, 2010, the Supreme Court issued its decision in *Bilski v. Kappos* concerning patentable subject matter.[77] Bilski's application concerned a method of hedging risk in the field of commodities trading. In particular, his application claimed the following method:

> A method for managing the consumption risk costs of a commodity sold by a commodity provider at a fixed price comprising the steps of:
>
> initiating a series of transactions between said commodity provider and consumers of said commodity wherein said consumers purchase said commodity at fixed rate based upon historical averages, said fixed rate corresponding to a risk position of said consumer;
>
> identifying market participants for said commodity having a counter-risk position to said consumers; and

[70] Editorial, "Pay to Obey," *New York Times* (Oct. 31, 2006).

[71] David Nolte, "USPTO is Getting It Wrong on Tax Strategy Patents," (July 20, 2006) (available at http://www.expertclick.com/NewsReleaseWire/default.cfm?Action=ReleaseDetail&ID=13238).

[72] Melone, *supra*, at 438.

[73] H.R. 1265, § 303; H.R. 2584, §1; S. 506, § 303.

[74] H.R. 1265, § 303(a); S. 506, § 303(a).

[75] H.R. 2584, §1(a).

[76] H.R. 1265, § 303(b); H.R. 2584, §1(b); S. 506, § 303(b).

[77] 130 S.Ct. 3218 (2010).

> initiating a series of transactions between said commodity provider and said market participants at a second fixed rate such that said series of market participant transactions balances the risk position of said series of consumer transactions.[78]

The USPTO rejected the application as claiming subject matter that was ineligible for patenting under section 101.

On appeal, the Federal Circuit characterized the "true issue before us then is whether Applicants are seeking to claim a fundamental principle (such as an abstract idea) or a mental process." The Federal Circuit explained:

> A claimed process is surely patent-eligible under § 101 if: (1) it is tied to a particular machine or apparatus, or (2) it transforms a particular article into a different state or thing.[79]

Applying this standard, the Federal Circuit concluded that Bilski's application did not claim patentable subject matter. The Court of Appeals acknowledged Bilski's admission that his claimed invention was not limited to any specific machine or apparatus, and therefore did not satisfy the first prong of the section 101 inquiry.[80] The Federal Circuit also reasoned that the claimed process did not achieve a physical transformation. According to Chief Judge Michel, "[p]urported transformations or manipulations simply of public or private legal obligations or relationships, business risks, or other such abstractions cannot meet the test because they are not physical objects or substances, and they are not representative of physical objects or substances."[81] As a result, the USPTO decision to deny Bilski's application was affirmed.

After agreeing to hear the case, the Supreme Court issued a total of three opinions, consisting of a plurality opinion for the Court and two concurring opinions. No single opinion was joined by a majority of Justices for all of its parts. The opinion for the Court, authored by Justice Kennedy, agreed that Bilski's invention could not be patented. But the plurality rejected the Federal Circuit's conclusion that the machine or transformation test was the sole standard for identifying patentable processes. Rather, that standard was deemed "an important and useful clue."[82] The Court also confirmed that laws of nature, physical phenomenon, and abstract ideas were not patentable subject matter.

The majority also rejected the assertion that business methods should not be considered patentable subject matter *per se*. In reaching this conclusion, Justice Kennedy pointed to the First Inventor Defense Act, which explicitly speaks to patents claiming a "method of doing or conducting business."[83] As he explained, the "argument that business methods are categorically outside of §101's scope is further undermined by the fact that federal law explicitly contemplates the existence of at least some business method patents."[84]

[78] 545 F.3d 943, 949 (Fed. Cir. 2008).

[79] *Id.* at 954.

[80] *Id.* at 962.

[81] *Id.* at 965.

[82] 130 S.Ct. at 3227.

[83] 35 U.S.C. § 273.

[84] 130 S.Ct. at 3228.

Justice Stevens, joined by Justices Breyer, Ginsburg, and Sotomayor, issued a lengthy concurring opinion on the day of his retirement from the Supreme Court. He agreed that the machine-or-transformation test was "reliable in most cases" but "not the exclusive test."[85] In his view, the Court should "restore patent law to its historical and constitutional moorings" by declaring that "methods of doing business are not, in themselves, covered by the statute."[86]

Justice Breyer also issued a concurring opinion that Justice Scalia joined in part. Justice Breyer identified four points on which all nine justices agreed: (1) the range of patentable subject matter is broad but not without limit; (2) the machine-or-transformation test has proven to be of use in determining whether a process is patentable or not; (3) the machine-or-transformation test is not the sole standard for assessing the patentability of processes; and (4) not everything that merely achieves a "useful, concrete, and tangible result" qualifies as patentable subject matter.[87]

Opinions vary upon the impact of *Bilski v. Kappos*, particularly with respect to tax strategy patents. Attorney Marvin Petry explains that "*Bilski* seems, once and for all, to have ended the tax practitioners' concern with tax strategy patents because it conclusively rejects tax strategy patents which were of significant concern, those that involve pure method steps...."[88] On the other hand, Ellen P. Aprill, a member of the faculty of Loyola Law School of Los Angeles, writes that *Bilski v. Kappos* "leaves us in a greater state of uncertainty than that which existed before it was decided." In her view, the Supreme Court ruling "demonstrates that for those who believe that tax strategies should not be patented, legislation is needed." Future developments will provide better perspectives upon the effect of the *Bilski* opinion upon business method and tax strategy patents.[89]

Patents on Genetic Materials

Controversy concerning patentable subject matter has not been confined to methods of doing business and tax planning methods. Patents claiming the products of biotechnology, and in particular genetic materials, have also led to considerable debate. In recent years, advances in biotechnology have resulted in a growing body of knowledge concerning the genetic material of living organisms. In turn, thousands of patents have been granted that assert rights in specific sequences of deoxyribonucleic acid (DNA)—the nucleic acid that contains the genetic instructions that all known living organisms use in order to develop and function.[90] Other patents claim related technologies, including individual mutations known to cause disease, testing kits for detecting genetic mutations, amino acid sequences (proteins), and the use of these proteins as medicines.[91]

[85] *Id.* at 3231.

[86] *Id.*

[87] *Id.* at 3258-59.

[88] Marvin Petry, "*Bilski v. Kappos: A New Chapter in Tax Strategy Patentability* ((Oct. 28, 2010) (available at http://www.lexisnexis.com/COMMUNITY/PATENTLAW/blogs/patentcommentary/archive/2010/10/28/bilski-v-kappos-a-new-chapter-in-tax-strategy-patentability.aspx).

[89] Ellen P. Aprill, "The Impact of *Bilski* on Tax Strategy Patents," TaxProfBlog (June 28, 2010) (available at http://taxprof.typepad.com/taxprof_blog/2010/06/aprill-bilski-.html).

[90] See Kevin T. Kelly, "Fragging the Patent Frags: Restricting Expressed Sequence Tag Patenting Using the Enablement-Commensurate-In-Scope-With-the-Claims Requirement," 17 *Texas Intellectual Property Law Journal* (2008), 49.

[91] See Eileen M. Kane, "Splitting the Gene: DNA Patents and the Genetic Code," 71 *Tennessee Law Review* (2004), (continued...)

The availability of patents pertaining to genetic technologies may be traced to the well-known decision of the U.S. Supreme Court in *Diamond v. Chakrabarty*.[92] That 1980 opinion held that a genetically engineered microorganism constituted patentable subject matter, qualifying as both a "composition of matter" or "manufacture" within the meaning of §101 of the Patent Act.[93] In so doing, the Supreme Court confirmed the traditional rule that "laws of nature, physical phenomenon, and abstract ideas have been held not patentable. Thus, a new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter." The Court reasoned that the traditional rule denying patents to "products of nature" was inapplicable to the invention before it, however. Chief Justice Burger explained:

> [T]he patentee has produced a new bacterium with markedly different characteristics from any found in nature and one having the potential for significant utility. His discovery is not nature's handiwork, but his own; accordingly it is patentable subject matter under § 101.[94]

As applied to genetic materials, the reasoning of *Diamond v. Chakrabarty* may be read to allow patents to issue where scientists have isolated these materials from their natural environment or produced through artificial techniques. As a result, patent claims directed towards DNA typically employ such terms as "isolated" or "recombinant" in order to reflect these conditions. Notably, this claim language restricts the scope of patent to isolated or artificially produced substances. As a result, the genes naturally possessed by humans and other living organisms are not included within the scope of proprietary rights.[95]

The March 29, 2010, decision of the District Court for the Southern District of New York in *Association for Molecular Pathology v. USPTO* cast serious doubt upon this reasoning, however.[96] Judge Sweet's lengthy opinion struck down several patents owned by Myriad Genetics claiming isolated DNA and various analytical methods:

> The claims-in-suit directed to "isolated DNA" containing human BRCA1/2 gene sequences reflect the USPTO's practice of granting patents on DNA sequences so long as those sequences are claimed in the form of "isolated DNA." This practice is premised on the view that DNA should be treated no differently from any other chemical compound, and that its purification from the body, using well-known techniques, renders it patentable by transforming it into something distinctly different in character. Many, however, including scientists in the field of molecular biology and genomics, have considered this practice a "lawyer's trick" that circumvents the prohibitions on the direct patenting of DNA in our bodies but which, in practice, reaches the same result. The resolution of these motions is based upon long recognized principles of molecular biology and genetics: DNA represents the physical embodiment of biological information, distinct in its essential characteristics from any other chemical found in nature. It is concluded that DNA's existence in an "isolated" form alters neither this fundamental quality of DNA as it exists in the body nor the information it encodes. Therefore, the patents at issue directed to "isolated DNA" containing

(...continued)

707.

[92] 447 U.S. 303 (1980).

[93] Id. at 308.

[94] Id. at 310.

[95] Roger Schechter & John Thomas, *Principles of Patent Law* (2d ed. 2004), 33.

[96] 702 F.Supp. 2d 181 (S.D.N.Y. 2010).

> sequences found in nature are unsustainable as a matter of law and are deemed unpatentable subject matter under 35 USC 101.
>
> Similarly, because the claimed comparisons of DNA sequences are abstract mental processes, they also constitute unpatentable subjct matter under Section 101.

Some observers believe that the broad language employed by Judge Sweet implies that virtually all gene patents are invalid under §101 as claiming unpatentable subject matter.[97] At the time this report goes to press, this litigation is the subject of an appeal to the Federal Circuit.

As with patents claiming business methods and tax strategies, patents pertaining to genetic materials are controversial.[98] Critics have asserted that genetic materials should remain accessible to all, rather than subject to intellectual property rights, and that such patents may depress research efforts and have a deleterious impact upon public health.[99] Other experts believe these critiques are overstated or misplaced, however.[100] In their view, patent rights in DNA are no more expansive or worthy of concern than for other sorts of inventions. This report reviews this debate below.

Congress has previously considered restricting patents relating to genetic materials. In the 110th Congress, Representative Becerra introduced the Genetic Research and Accessibility Act, H.R. 977. That bill would have provided:

> Notwithstanding any other provision of law, no patent may be obtained for a nucleotide sequence, or its functions or correlations, or the naturally occurring products it specifies.[101]

The proposed amendment would not have applied to a patent issued prior to the date of enactment of the Genetic Research and Accessibility Act.[102] This legislation was not enacted. As well, the Genomic Research and Diagnostic Disability Act of 2002 was introduced, but not enacted, in the 107th Congress.[103] That legislation would have created a research exemption from infringement for research on genetic sequence information and an infringement exemption for genetic diagnostic testing.

Innovation Policy Issues

The patenting of business methods, tax strategies, genetic materials, and other sorts of post-industrial technologies has raised controversy. Some observers have expressed concerns that these sorts of inventions should not be patented, no matter how innovative they might be. They believe that section 101 of the Patent Act, the provision governing patentable subject matter, should be

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[97] See Miri Yoon, "Gene Patenting Debate: The Meaning of *Myriad*," 9 *John Marshall Journal of Intellectual Property Law* (2010), 953.

[98] See CRS Report RS22516, *Gene Patents: A Brief Overview of Intellectual Property Issues*, by Wendy H. Schacht.

[99] Nuffield Council on Bioethics, The Ethics of Patenting DNA—A Discussion Paper (2002).

[100] R. Stephen Crespi, "Patenting and Ethics—A Dubious Connection," 85 *Journal of the Patent and Trademark Office Society* (2003), 31.

[101] H.R. 977, § 2(a).

[102] Id. at § 2(c).

[103] H.R. 3967.

interpreted, and if necessary amended, to exclude these sorts of inventions from patenting.[104] Others believe that these concerns are overstated. They further assert that the patenting of inventions of the Information Age, as well as biotechnologies, will be beneficial for innovation and competition.[105] This report reviews some of the primary arguments that have been raised in this debate.

Proponents of a broad notion of patentable subject matter assert that the patent system has traditionally offered a powerful incentive for innovation across many industries. For example, the chemical, electronics, manufacturing, telecommunications, and pharmaceutical industries are among those that have long sought and enforced patents. In the view of these commentators, the patent system will readily adapt to new fields of endeavor as well. Further, many inventions of the 21st century—including business methods and genetic inventions—are as subject to costly research and development efforts as more traditional technologies. Observers question why the patent incentive exists in one field of costly research and development and not in another.[106]

The patent system also provides the benefit of public disclosure. In order to obtain patent rights, inventors must fully disclose their inventions such that a skilled artisan could practice them without undue experimentation.[107] A patent system that denies protection to entire categories of inventions may cause inventors to conceal them as trade secrets. In contrast to patenting, trade secret protection does not result in the disclosure of publicly available information. Taking the steps necessary to maintain secrecy, such as implementing physical security measures, also imposes costs that may ultimately be unproductive for society.[108]

Another argument in favor of a broad notion of patentable subject matter is that distinguishing patentable and unpatentable inventions may at times prove difficult. For example, assessing whether a particular invention is sufficiently technologically embedded to constitute patentable subject matter may not constitute a straightforward, routine inquiry. Aware of the legal requirements to obtain a patent, lawyers may draft patent instruments in such as a way as to make software inventions appear to be hard-wired machines. Such artful claims drafting may ultimately make patents more difficult to read and interpret.[109]

Supporters of an expansive patent system also observe that patents have been identified as facilitators of markets. If inventors lack patent rights, they may have scant tangible assets to sell or license. In addition, an inventor might otherwise be unable to police the conduct of a contracting party. Any technology or know-how that has been disclosed to a prospective licensee might be appropriated without compensation to the inventor. The availability of patent protection decreases the ability of contracting parties to engage in opportunistic behavior. By lowering such transaction costs, the patent system may make transactions concerning information goods more

[104] See, e.g., Michael Moulton, "Effecting the Impossible: An Argument Against Tax Strategy Patents," 81 *Southern California Law Review* (2008), 631.

[105] See, e.g., Lucas Osbron, "Tax Strategy Patents: Why the Tax Community Should Not Exclude the Patent System," 18 *Albany Law Journal of Science and Technology* (2008), 325.

[106] See, e.g., Christopher A. Harkins, "Throwing Judge Bryson's Curveball: A Pro Patent View of Process Claims as Patent-Eligible Subject Matter," 7 *John Marshall Review of Intellectual Property Law* (2008), 701.

[107] 35 U.S.C. § 112 (2006).

[108] See Robert G. Bone, "A New Look at Trade Secret Law: Doctrine in Search of Justification," 86 *California Law Review* (1998), 241.

[109] See Fusco, *supra*.

feasible.[110] Categorical exclusion of certain sorts of inventions from the patent system may deny entire industries this potential benefit.

Studies have also indicated that entrepreneurs and small, innovative firms rely more heavily upon the patent system than larger enterprises. Large firms often possess a number of alternative means for achieving a proprietary interest in a particular technology. For example, trade secrecy, ready access to markets, trademark rights, speed of development, and consumer goodwill may to some degree act as substitutes for the patent system. However, individual inventors and small firms often do not have these mechanisms at their disposal. As a result, the patent system may enjoy heightened importance with respect to these enterprises.[111]

Legal experts also assert that patents do not provide the affirmative right to use the patented invention, but rather the right to exclude others from doing so. This perspective implies that the grant of patent neither implies government approval of an invention, nor allows meaningful control of a technology. As a result, the grant of a patent on, for example, a particular tax strategy, should not be deemed as an indication that the strategy is legally sound.[112] Similarly, disallowing patents on genetic materials would not necessarily suppress the technology as a general matter.[113]

Although these and other assertions weigh in favor of an ambitious scope of patentable subject matter, other observers are less optimistic. Some commentators believe that innovation in areas such as business methods, tax planning methods, and genetic materials has flourished even though the availability of patent rights has been uncertain. For example, the American Institute of Certified Public Accountants [AICPA] asserts that "[p]eople already have substantial incentives to comply with tax law and lower their taxes."[114] Under this line of reasoning, the patent incentive is unnecessary to promote a socially optimal level of innovation within these disciplines.

Other observers go further, believing that patents in these areas may not merely be unnecessary, but also socially detrimental. With respect to business methods, some commentators believe that these patents are commonly of such broad scope as to "effectively appropriate all possible solutions to a particular problem."[115] This extent of proprietary rights may limit the ability of others to design around the patented invention and ultimately discourage competition.[116]

With respect to tax strategy patents, some believe that an incentive to develop methods of lowering one's taxes is not socially desirable. William A. Drennan, a member of the law faculty at Southern Illinois University, contrasts the grant of tax strategy patents with recent Treasury

[110] Paul J. Heald, "Optimal Remedies for Patent Infringement: A Transactional Model," 45 *Houston Law Review* (2008), 1165; Paul J. Heald, "A Transaction Costs Theory of Patent Law," 66 *Ohio State Law Journal* (2005), 473.

[111] Michael J. Meurer, "Inventors, Entrepreneurs, and Intellectual Property Law," 45 *Houston Law Review* (2008), 1201.

[112] See, e.g., Osbron, *supra*.

[113] Robert P. Merges, "Intellectual Property in Higher Life Forms: The Patent System and Controversial Technologies," 47 *Maryland Law Review* (1998), 1051.

[114] AICPA, "Analysis and Legislative Proposals Regarding Patents for Tax Strategies" (February 28, 2007) (available at http://tax.aicpa.org) (hereinafter "AICPA Analysis").

[115] David Kappos *et al.*, "A Technological Contribution Requirement for Patentable Subject Matter: Supreme Court Precedent and Policy," 6 *Northwestern Journal of Technology and Intellectual Property* 152 (2008) at *57.

[116] See Alexandra Wilson, "Business Method Patents Gone Wild: Narrowing *State Street Bank* and Shifting to a European Perspective," 12 *Journal of Technology Law and Policy* (2007), 71.

Department Regulations that, in his view, "reduce the economic incentive to create tax loopholes."[117] Mr. Drennan thus explains:

> [O]ne government agency—the Treasury Department—is taking action to discourage loopholes. In contrast, the Patent Office (at the direction of the Federal Circuit) is providing a new incentive to create loopholes. Since the Treasury Department is in charge of the sound administration of the U.S. tax system, the Treasury Department's views on sound tax policy should be given greater weight than the view of the Patent Office on this subject.[118]

Other experts believe that tax strategy patents are inappropriate because they are said to inject private control over a system of public laws.[119] Under this view, a patent may potentially grant one individual the ability to prevent others from using a new tax provision. In turn, private actors may affect the ability of federal, state, and local governments to raise revenue, influence taxpayer behavior, and otherwise achieve the intended purposes of the tax laws.[120] These concerns were voiced by the AICPA in the following way:

> Tax strategy patents also preempt Congress's prerogative to have full legislative control over tax policy. Congress enacts tax law provisions applicable to various taxpayers and intends that taxpayers will be able to use them. Tax strategy patents thwart this Congressional intent by giving tax strategy patent holders the power to decide how select tax law provisions can be used and who can use them.[121]

Tax professionals have also expressed concerns over the impact of tax strategy patents upon their own practices, as well as taxpayers in general. Some observers believe that the burdens of investigating whether a taxpayer's planned course of action is covered by a tax strategy patent, determining whether the patent was providently granted by the USPTO, and potentially negotiating with the patent proprietor in order to employ the strategy, will be costly and impractical for many taxpayers.[122] Further, because compliance with the tax laws and its self-assessment system is obligatory for all citizens of the United States, the scope of this burden could be considerable.[123]

Several additional objections have arisen to patenting the inventions of genetic materials. Some individuals believe that patenting genetic materials devalues the worth and dignity of living beings. These commentators believe that such patents would allow individuals to obtain an ownership right in another sentient being. From this perspective, such a patent right is akin to slavery and morally wrong. Human genetic materials in particular are instead deemed to be the common heritage of humanity and therefore should be the subject of shared public ownership, rather than proprietary rights.[124]

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[117] Drennan, *supra*, at 280.

[118] Id.

[119] See Richard S. Marshall, "Tax Strategy Patents—Legislative, Judicial and Other Developments," 48 *Tax Management Memo* (2007), 243.

[120] Steve Seidenberg, "Taxation Innovation: Patent Office Receives Criticism for Issuing Patents on Tax Strategies," *Inside Counsel* (December 2006).

[121] AICPA Analysis, *supra*, at 5.

[122] Gary C. Bubb, "Patented Tax Strategies—Are You Serious?," *Rhode Island Lawyers Weekly* (August 20, 2007).

[123] Ellen P. Aprill, "Responding to Tax Strategy Patents," American Bar Association Annual Meeting (August 11, 2007), 7.

[124] Nuffield Council on Bioethics, "The Ethics of Patenting DNA: A Discussion Paper," 22 (2002).

Patents on genetic materials have also been said to lead to possible deleterious effects on healthcare and research related to healthcare. For example, some patents claim human genes that indicate susceptibility to a particular disease and diagnostic tests for detecting that gene. Observers question whether having only one proprietary diagnostic test for a particular disease lies in the public interest. They also suggest that patent rights over a gene that is linked to a particular disease might inhibit further research concerning that disease.[125]

Professors Heller and Eisenberg have also expressed the concern that the "tragedy of the anticommons" may lead to the underuse of patented genetic resources. In their view, too many overlapping intellectual property rights with respect to genetic materials may hinder research and development, and ultimately the exploitation of potential future products. For example, one enterprise might own a patent on a genomic DNA fragment, another on the corresponding protein, and yet another on a diagnostic test for a genetic disease. In this circumstance, multiple owners each have the right to exclude others and no one has an effective privilege of use. Development of a commercial product in this situation may prove difficult or impossible.[126]

Additional assertions have been made both in support of a broad scope of patentable subject matter, as well as in favor of restricting the scope of patenting. Unfortunately, no rigorous analytical method allows for study of the role the patent system plays in promoting innovation, investment, and competition. As a result, arguments for and against a broad scope of patentable subject matter are difficult to quantify. Determining the precise scope of patentable subject matter therefore remains a matter of legal reasoning, as informed by concerns over innovation and competition policy.

Congressional Issues and Options

If Congress decides that the current rules with respect to patent eligibility are satisfactory, then no action need be taken. Should Congress choose to take action, however, a number of options exist. One possibility is an amendment to section 101 of the Patent Act stipulating that certain subject matter is not patentable. Legislation introduced in the 111th Congress would take this step with respect to tax shelters,[127] while legislation in the 110th Congress would have done so with respect to nucleotide sequences.[128]

Another option is to allow patents on particular inventions to issue, but to limit the remedies available to proprietors of such patents. The Patent Act currently stipulates that damages and injunctions are not available for patent infringement caused by "a medical practitioner's performance of a medical activity" under certain circumstances.[129] This provision could potentially be amended to include other categories of inventions.

Other legislative responses are also possible. Congress could choose to track USPTO practices with respect to patents on business methods, tax strategies, or genetic materials. In this respect,

[125] Id. at 40.

[126] Michael A. Heller and Rebecca S. Eisenberg, "Can Patents Deter Innovation? The Anticommons in Biomedical Research," 280 *Science* (May 1, 1998), 698.

[127] H.R. 1265, § 303; H.R. 2584, §1; S. 506, § 303.

[128] Genomic Research and Accessibility Act, H.R. 977, § 2.

[129] 35 U.S.C. § 287(c) (2006).

commentators have proposed several reforms, including the hiring of USPTO examiners with expertise in taxation or other sensitive areas.[130] Congress could also encourage continued cooperation between the USPTO and other federal agencies, such as the IRS, with expertise in particular disciplines.

If legislation is contemplated, one international agreement that deserves consideration is the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights, commonly known as the TRIPS Agreement.[131] As a WTO member, the United States has committed to "give effect to the provisions of [the TRIPS] Agreement."[132] The TRIPS Agreement provides that "patents shall be available for any inventions, whether products or processes, in all fields of technology."[133] It further states that "patents shall be available and patent rights enjoyable without discrimination as to ... the field of technology."[134] The TRIPS Agreement additionally stipulates that WTO member states may exclude from patentability certain inventions, in particular "diagnostic, therapeutic and surgical methods for the treatment of humans and animals" and "plants and animals other than micro-organisms, and essentially biological processes for the production of plants and animals other than non-biological and microbiological processes."[135] Compliance with the TRIPS Agreement may place some limits on the ability of WTO member states to legislate with respect to patentable subject matter.

Concluding Observations

The topic of patentable subject matter has raised a surprisingly heated debate in many contexts, including business methods, tax strategies, and genetic materials. Many knowledgeable observers have voiced strong objections to patents in these fields on a number of grounds. However, other experts point to the lack of direct evidence that granting patents within these fields has persistently led to deleterious consequences, and instead believe that they potentially benefit society. Although the patenting of business methods, tax strategies, and genetic materials has generally been viewed on an individual basis, the policy issues raised in these debates share many common themes. Collectively, these debates may promote further inquiry into the sorts of inventions that may be appropriately patented.

[130] Aprill, *supra*, at 21.

[131] See Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, art. 66, para. 1, Legal Instruments—Results of the Uruguay Round vol. 31, 33 I.L.M. 81 (1994).

[132] Id. at Art. 1, § 1.

[133] Id. at Art. 27(1).

[134] Id.

[135] Id. at 27(3).

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