Patentable Subject Matter After *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*

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Abstract

The United States Supreme Court delivered its much-anticipated judgment in the case of *Mayo Collaborative Services v. Prometheus Laboratories, Inc.* on March 20, 2012. The judgment has triggered a spate of commentary from legal scholars and legal practitioners supporting and opposing the decision. One point about which there is unanimity is that the Supreme Court's judgment is of great significance inasmuch as it reconfigures the law relating to subject matter patent eligibility. The *Mayo v. Prometheus* case involved patents on a medical process for determining the appropriate level of dosage of synthetic drugs called thiopurines for individuals having certain autoimmune-related sicknesses. The judgment is bound to be of great significance to the biotechnology and pharmaceutical industries and will have an effect on the provision of health care and the development of medical diagnostic techniques. It could also have important consequences for other process patents such as computer-based business method and software-related patents. Extending the doctrines and principles relating to subject matter patent eligibility laid down in leading precedents, the U.S. Supreme Court clarified the standards relating to the exclusion of patent eligibility under Section 101 of the U.S. Patent Act. This essay sets out the development of the U.S. Supreme Court's jurisprudence relating to subject matter patent-eligibility and the contours of such eligibility as they have now taken shape in the wake of the Court's judgment in *Mayo v. Prometheus*. Due to the transnational repercussions of patent law, the essay sets out the position in law relating to subject matter patent eligibility in the two other major areas in respect of patent law, namely, Japan and the member states of the European Patent Organisation. Finally, the paper sets out some personal observations and comments regarding the judgment.

Companies achieve competitive advantage through acts of innovation. They approach innovations in its broadest sense, including both new technologies and new ways of doing things. They perceive a new basis for competing or find better means for competing in old ways. Innovation can be manifested in a new product design, a new production process, a new marketing approach, or a new way of conducting training.

Michael E. Porter[1]

Michael E. Porter, The Competitive Advantage of Nations, Harvard Business Review, March 1990.

I. Introduction:

The United States Supreme Court delivered its much anticipated judgment in the case of *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*[2] on March 20, 2012. The judgment has triggered considerable commentary from legal scholars and legal practitioners supporting and opposing the decision. One point about which there is a general consensus is that the Supreme Court's judgment is of great significance in shaping the continually evolving contours of subject matter patent-eligibility. The *Mayo v. Prometheus* case involved patents on a medical diagnostic process for determining the appropriate level of dosage of synthetic drugs called thiopurines for individuals having certain autoimmune related illnesses. The judgment is expected to have repercussions on the biotechnology and pharmaceutical industries and also have consequences on the development of medical diagnostics and the provision of health care. It could also have an effect on computer-based business method and software-related patents and the continuing validity of process patents in a host of other fields. Extending the doctrines and principles relating to subject-matter eligibility as laid down in the leading cases of *Gottschalk v. Benson*, *Parker v. Flook*, *Diamond v. Diehr*, and *Bilski v. Kappos*, clarified the standards governing the exclusion of "laws of nature" from patent eligibility under Section 101 of the U.S. Patent Act.

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[1] Michael E. Porter, *The Competitive Advantage of Nations*, Harvard Business Review, March-April 1990, at page 75.

[2] *Mayo Collaborative Services, et al. v. Prometheus Laboratories, Inc.* Slip Opinion, cited as 566 U.S. ____ (2012). Available at: http://www.supremecourt.gov/opinions/11pdf/10-1150.pdf.

Patent law is one species of the larger category of intellectual property law. Patent law has ramifications that go beyond the rights of patent-holders. Its purpose is to serve as an incentive to spur innovation and creativity with the ultimate aim that that will in turn benefit society at large. Under patent law, innovators are granted the exclusive right to the use of their inventions for a specified period of time in exchange of which the innovator is obliged to disclose the details of the invention. By doing this, the law recognizes the moral and economic rights that flow to the innovator as the fruits of his or her labor. At the same time, it promotes the interests of society because of the social benefit that accrues and the economic productivity that is enhanced as a result of the creation of new products and designs. It further serves the societal interest by means of the dissemination of knowledge regarding the invention and the freedom to use that knowledge after the lapse of the inventor's exclusive right at the end of the stipulated period. But these benefits have to be balanced at all times with the anti-competitive effects and the resultant costs to society that flow from the grant of exclusive rights.

Article 7 of the World Trade Organization's Agreement on Trade Related Aspects of Intellectual Property Rights sets out the aims of the regime of intellectual property rights thus:

> The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.[3]

Innovation is one of the vital engines of economic growth and international competitiveness. As Michael Porter, a world authority on competitiveness has pointed out in the lines that serve as the epigraph to this essay, innovation takes many forms. However, not all inventions are patentable. Different jurisdictions have different laws regarding what innovations are patentable and what innovations are excluded from the province of patentable subject matter. The determination as to what should be

[3] Article 7, Objectives, Agreement on Trade Related Aspects of Intellectual Property Rights (the TRIPS Agreement). Available at: http://www.wto.english/tratop_e/trips_e/t_agm2_e.htm.

included within the domain of patentable subject matter is made on the basis of a balance between a nation's larger economic interests and moralistic considerations. Due to the transnational effects of patent laws, such differences assume greater than normal significance. It is these transnational effects that have lent the impetus for the drive to effectuate harmonization of each component of intellectual property laws among the nations of the world.[4] This movement has been proceeding within the realm of patent law along separate tracks for procedural matters and substantive matters.

After the present introduction, part II of this essay sets out the development of the U.S. Supreme Court's jurisprudence relating to subject matter patent eligibility and the contours of such eligibility as they have now taken shape in the wake of the Court's judgment in *Mayo v. Prometheus*. Part III sets out the present international situation in respect of subject-matter patent eligibility with specific reference to the patentability of medical diagnostic methods similar to those at issue in the *Mayo* case. Of particular importance is the presently prevailing situation in Japan and the member states of the European Patent Organization. Part IV sets out a few brief personal observations regarding the judgment in *Mayo v. Prometheus*. Finally, the essay ends with a conclusion.

II. An Outline of the Jurisprudence Relating to Subject Matter Patent-Eligibility in the United States:

Patent Law in the United States is based upon one of the enumerated powers of the U.S. Congress under Article 1 of the U.S. Constitution. Specifically, Article 1, Section 8, Clause 8 of the U.S. Constitution states: "The Congress shall have power... To promote the Progress of Science and useful Arts, by securing for limited Times to

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[4] See, e.g., the remarks of David Kappos, the Director of the USPTO at the World Intellectual Property Symposium, on Sept. 22, 2011. "Promoting Innovation & Creativity: The America Invents Act and a Global Call for Harmonization":

> The public must have confidence that the patent system is striking the right balance between incentives to innovate and access to those new innovations. Through global synergy and collaboration, we have a unique opportunity, right away, to meet these challenges --- and I believe it is imperative we do that, and act by moving towards a more standardized global patent system.

Available at: http:www.uspto.gov/news/speeches/2011/kappos_wipo.jsp).

Authors and Inventors the exclusive Right to their respective Writings and Discoveries." The U.S. Supreme Court has said that this clause "reflects a balance between the need to encourage innovation and the avoidance of monopolies which stifle competition without any concomitant advance in the 'Progress of Science and useful Arts.'" [5]

The U.S. Patent Act is contained in Title 35 of the United States Code. Sections 101, 102, 103, and 112 set out the requisites for patent eligibility.[6]

Section 101 describes patentable subject matter as the discovery or invention of "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof."[7] Section 102 sets out "novelty" as one of the conditions for patent eligibility. Section 103 adds the further condition that the claimed subject matter should not have been obvious at the pertinent time "to a person having ordinary skill in the art."[8] Section 112 requires that the patent application should clearly describe the claimed invention and "the manner and process of making and using it."

Section 101 defines the scope of what counts as patentable subject matter. It is commonly viewed as serving the function of a gatekeeper screening the category of

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[5] *Bonito Boats v. Thunder Craft Boats*, 489 U.S. 141, 146 (1989).

[6] For the purposes of this paper, the definition of "process" is also important. Section 100 (b) defines it thus: "The term 'process' means process, art or method, and includes a new use of a known process, machine, manufacture, composition of matter, or material."

[7] The previous Patent Act contained the word "art" which was replaced by the word "process" in the Patent Act of 1952. Prior to the change, in the 1876 case of *Cochrane v. Deener,* 94 U.S. 780, 780 (1876), the U.S. Supreme Court had described process as "a mode of treatment of certain materials to produce a given result," and that "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."

[8] In an important recent judgment relating to the scope of the obviouness inquiry, the U.S. Supreme Court observed in *KSR International Company v. Teleflex Inc., et al.*, 550 U.S. 398, as follows:

> We build and create by bringing to the tangible and palpable reality around us new works based on instinct, simple logic, ordinary inferences, extraordinary ideas, and sometimes even genius. These advances, once part of our shared knowledge, define a new threshold from which innovation starts once more. And as progress from higher levels of achievement is expected in the normal course, the results of ordinary innovation are not the subject of exclusive rights under the patent laws.

claims that will be admitted for patent consideration.[9] For example, as early as 1852, the U.S. Supreme Court had observed in *Le Roy v. Tatham* that an abstract principle was unpatentable.[10]

Following is a list of some of the most significant cases relating to subject matter patent-eligibility after the enactment of the U.S. Patent Act of 1952.

1. *Gottschalk v. Benson* :[11]

This case involved a patent application for a algorithm-based method whereby binary-coded decimal numerals were converted to pure binary numerals, without the method being tied to any specific apparatus, machinery, or technology. The U.S. Supreme Court was required to decide whether the claimed method was a patentable process under Section 101 of the U.S. Patent Act. Based upon an extensive review of the case law, the Court noted that "[p]henomena of nature, though just discovered, mental processes, and abstract intellectual concepts are not patentable, as they are the basic tools of scientific and technological work,"[12] unless there was a consequent "application of the law of nature to a new and useful end."[13] In the present case the process claim was too abstract and wide-ranging, and the grant of a patent would be tantamount to a patent on the algorithm, which would run afoul of the proscription against the patenting of an idea.

2. *Parker v. Flook* :[14]

The case involved the patent-eligibility of a method based upon a mathematical formula, whereby appropriate alarm limits could be updated in certain industrial settings. The Court relied upon *Gottschalk v. Benson*, which it read as having held that a mathematical formula was akin to a law of nature and therefore could not be the subject matter of a patent.[15] In this case, since the mathematical formula was assumed

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[9] See Mark A. Lemley, Michael Risch, Ted Sichelman & R.Polk Wagner, *Life After* Bilski, 63 Stanford Law Review 1315, at 1326.

[10] *Le Roy v. Tatham*, 55 U.S. (14 How). 156 (1852).

[11] *Gottschalk v. Benson*, 409 U.S. 63 (1972).

[12] *Id.*,at 67.

[13] *Id.*, quoting the opinion of the U.S. Supreme Court in *Funk Bros. Seed Co. v. Kalo Co.*, 333 U.S. 127, 130.

[14] *Parker v. Flook,* 437 U.S. 584 (1978).

[15] *Id.*, at 589.

to be part of the prior art, the Court[16] held that the mere addition of some non-inventive subsequent activity could not make it patentable under Section 101 of the U.S. Patent Act (35 U.S.C. 101).[17]

3. *Diamond v. Chakrabarty* :[18]

This case involved the patentability of a genetically engineered bacterium. The question at issue was whether a living micro-organism could be validly interpreted as a patentable manufacture or a composition of matter within the meaning of 35 U.S.C. 101. After reviewing the relevant case law and the legislative history of the germane legal provisions, the Court held that the micro-organism in question was patentable subject matter as it was a product of human invention and not a natural phenomenon.[19]

4. *Diamond v. Diehr* :[20]

This case involved a patent on an industrial process which employed the use of a mathematical formula as one of the steps in the process. Clarifying the Court's previous opinions in *Gottschalk v. Benson* and *Parker v. Flook*, the Court held that the mere presence of a mathematical formula as one step in a process claim does not invalidate the claim. The claimed process must be considered in its totality. If the process performs a patentable function, then it is patentable subject matter not with standing the use of

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[16] The opinion of the Court was written by Justice Stevens. Justices Brennan, White, Marshall, Blackmun, and Powell joined in the opinion.

[17] Three Justices dissented. Justice Stewart's dissenting opinion, joined in by Chief Justice Burger and Justice Rehnquist considered the claimed process as falling within the bounds of subject-matter patentability under Section 101.

[18] *Diamond v. Chakrabarty*, 447 U.S. 303 (1980).

[19] The opinion of the Court contained a widely cited statement that "[t]he Committee Reports accompanying the 1952 Act inform us that Congress intended statutory subject matter to 'include anything under the sun that is made my man.' "Id. at 309. The opinion of the Court was written by Chief Justice Burger, with Justices Stewart, Blackmun, Rehnquist and Stevens joining in. Justice Brennan dissented, with Justices White, Marshall, and Powell joining in his dissenting opinion.

[20] *Diamond v. Diehr,* 450 U.S. 175 (1981). Justice Rehnquist wrote the opinion of the Court, with Chief Justice Burger, and Justices Stewart, White and Powell joining in. Justice Stevens dissented, with Justices Brennan, Marshall, and Blackmun joining in Justice Stevens's dissenting opinion.

the mathematical formula.[21].

5. *Laboratory Corp. of America Holdings v. Metabolite Laboratories, Inc.* :[22]

It will be useful to mention here a case where a similar question was involved and in which a certiorari had been granted but was later dismissed by a majority of the Court without going into the merits of the case. However, three Justices dissented stating that a resolution of the question at issue would benefit medical practitioners and researchers and members of the general public that seek proper health care. Justice Breyer wrote the dissenting opinion, with Justices Stevens and Justice Souter joining. The dissenting Justices were of the view that the claimed process in the case was unpatentable as it was merely a "natural phenomenon." Of particular significance was the policy consideration that the dissenting judgment sought to canvass. According to the dissenting view, if the patent in that case were not held invalid, it would

> leave the medical profession subject to the restrictions imposed by this individual patent and others of its kind. Those restrictions may inhibit doctors from using their best medical judgment; they may force doctors to spend unnecessary time and energy to enter into license agreements; they may divert resources from the medical task of health care to the legal task of searching patent files for similar simple correlations; they may raise the cost of healthcare while inhibiting its effective delivery.[23]

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[21] The Court made particular reference to Justice Stone's opinion in *Mackay Radio & Telegraph Co. v. Radio Corp. of America*, 306 U.S.86 (1939) as taking the Court "a long way" to the resolution of the issue in the case. The Court quoted Justice Stone's following observation: "While a scientific truth, or the mathematical expression of it, is not a patentable invention, a novel and useful structure created with the aid of knowledge of scientific truth may be." *Diamond v. Diehr*, 450 U.S. 175, at 190 (1981).

[22] *Laboratory Corp. of America Holdings v. Metabolite Laboratories, Inc.*, 548 U.S. 124 (2006), 126 S.Ct. 2921.

[23] *Id.*, at 138. In the penultimate paragraph of the dissenting opinion, Justice Breyer makes a percipient reference to specialists and generalists and the varying opinions among both groups regarding the adequacy of the current patent system in the United States. The opinion cites the need to preserve the "careful balance" referred to by the Court in *Bonito Boats Inc. v. Thunder Craft Inc.*, 489 U.S. 141,146 (1989). In that judgment the Court had stated: "From their inception, the federal patent laws have embodied a careful

6. *Bilski v. Kappos* :[24]

This case involved a claimed method for efficient buying and selling when trading in the energy market.[25] The United States Court of Appeals for the Federal Circuit had departed from the test that it had earlier used to determine patentability under Section 101 of the U.S. Patent Act.[26] In its stead, the Federal Court postulated the "machine-or-transformation" test as the only test for determining patentability under Section 101,[27] and on that footing held the claimed method to be subject matter that was ineligible for patent protection. On appeal, the U.S. Supreme Court held that though it was an important factor to be considered, the machine-or-transformation test was not the only test for determining patent-eligibility of processes under Section 101.[28] The Court also refused to exclude business methods from the ambit of patentable subject matter under

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balance between the need to promote innovation and the recognition that imitation and refinement through imitation are both necessary to invention itself, and the very lifeblood of a competitive economy."

[24] *Bilski v. Kappos*, Slip opinion, 561 U.S. ____ (2010), available at : http:www.supremecourt.gov/opinions/09pdf/08-964.pdf.

[25] Claim 1 of the patent at issue as quoted in the Supreme Court opinion is as follows:

> Claim 1 consists of the following steps:
> "(a) initiating a series of transactions between said commodity provider and consumers of said commodity wherein said consumers purchase said commodity at a fixed rate based upon historical averages, said fixed rate corresponding to a risk position of said consumers;
> "(b) identifying market participants for said commodity having a counter-risk position to said consumers; and
> "(c) 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." App. 19-20.

Bilski v. Kappos, id., at internal page 2 of the opinion of the Court (Slip opinion).

[26] The then prevailing test was whether the claimed process had the effect of producing a "useful, concrete, and tangible result." This test was propounded and used by the Federal Court in *State Street Bank & Trust Co. v. Signature Financial Group, Inc.* 149 F. 3d 1368, 1373 (1998) and *AT&T Corp. v. Excel Communications, Inc.*, 172 F. 3d 1352, 1357 (1999).

[27] Under the machine-or-transformation test, a process would be patentable if "(1) it is tied to a particular machine or apparatus, or (2) it transforms a particular article into a different state or thing." 545 F. 3d, at 954.

[28] The Court reasoned that the machine-or-transformation test, although appropriate for the Industrial Age, was anachronistic for the Information Age inasmuch as it "would create

Section 101.[29] Instead, the Court followed the principle laid down in *Gottschalk v. Benson*, *Parker v. Flook*, and *Diamond v. Diehr* and held the claimed method in this case to be ineligible for a patent as it was, in essence, no more than an abstract idea.[30]

7. *Mayo Collaborative Services v. Prometheus Laboratories, Inc.* :[31]

This case involved two patents on a process whereby doctors could determine the appropriate level of dosage of synthetic drugs called thiopurines to be administered for individuals with certain autoimmune problems. The process was embodied in a thiopurine metabolites test kit. The metabolite levels in the individual's blood stream that resulted from the metabolism of a given dose of thiopurine drug served as a pointer regarding the calibration of subsequent dosage. The claimed process involved the ascertainment of the metabolite levels as a consequence of the initial ingesting of a given dose of the thiopurine drug, and a specification of the standards above and below which metabolite levels showed a need for adjustment of the subsequent dosage.[32] Prometheus Laboratories, Inc. was the sole license holder of the patents. The

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uncertainty as to the patentability of software, advanced diagnostic medicine techniques, and inventions based on linear programming, data compression, and the manipulation of digital signals. *Bilski v. Kappos*, slip opinion, 561 U.S. __ (2010), internal page 9, 130 S.Ct. 3218.

[29] The issue of the patentability of business methods had been catapulted into prominence since the judgment of the United States Court of Appeals for the Federal Circuit in the case of *State Street Bank & Trust Co. v. Signature Financial Group, Inc.,* 149 F.3d 1368 (Fed. Cir. 1998). While refusing to accept the excludability of business methods from the ambit of patent-eligible subject matter, the Court of Appeals stated: "Since the 1952 Patent Act, business methods have been, and should have been, subject to the same legal requirements for patentability as applied to any other process or method [internal footnote omitted]." 149 F.3d 1368 at 1375. The Court of Appeals later reiterated this view in *AT&T Corp. v. Excel Communications, Inc.*, 172 F.3d 1352 (1999).

[30] *Bilski v. Kappos* reiterated the principle that a patentable claim must fall outside the category of unpatentable subject matter, namely, abstract ideas, laws of nature, and natural phenomena, that had been so designated by the Court's precedents. *Bilski v. Kappos,* 130 S.Ct. 3218, 3225 (2010). (The majority opinion stated: "The Court's precedents provide three specific exceptions to Sectio 101's broad patent-eligibility principles: 'laws of nature, physical phenomena, and abstract ideas.'"

[31] *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 566 U.S. ____ (2012) (slip opinion), *supra* note 2.

[32] Claim 1 of one of the patents at issue as quoted by the Court in its judgment reads as follows:

petitioner Mayo Collaborative Services, Inc.'s contention was that doctors routinely checked individual reactions to drug dosages and made appropriate adjustments, and hence, the claimed process was patent-ineligible as it merely sought the exclusive right to use a technique of medical diagnosis that was commonplace in the medical profession and involved no innovation.

The District Court held that the claimed process was based upon correlations between metabolite levels and drug dosages which were natural phenomena and hence ineligible for patent protection. On appeal, the U.S. Court of Appeals for the Federal Circuit reversed. The U.S. Court of Appeals reasoned that the initial act of ingesting the thiopurine drug and the checking of the resultant metabolite level which were steps in the claimed process involved a certain transformative aspect in respect of the human body. This, according to the Court of Appeals rendered the process patentable under the "machine-or-transformation test" and also circumscribed its ambit sufficiently to meet the requirements of Section 101 of the U.S. Patent Act. Upon the application of *Mayo Collaborative Services*, the U.S. Supreme Court granted certiorari, and remanded the case to the Federal Court for reconsideration in light of its holding in *Bilski v. Kappos* that the "machine-or-transformation" test was an important factor to be considered but was not dispositive regarding patent-eligibility. Upon remand, the Federal Court reaffirmed its judgment. The U.S. Supreme Court once again granted Mayo's petition for certiorari, and went on to hold by a unanimous decision that the claimed process was in essence a statement of a law of nature and hence ineligible for

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"A method of optimizing therapeutic efficacy for treatment of an immune-mediated gastrointestinal disorder, comprising:
"(a) administering a drug providing 6-thioguanine to a subject having said immune-mediated gastrointestinal disorder, and
"(b)determining the level of 6-thioguanine in said subject having said Immune-mediated gastrointestinal disorder,
"wherein the level of 6-thioguanine less than about 230 pmol per 8+108 red blood cells indicates a need to increase the amount of said drug subsequently administered to said subject and
"wherein the level of 6-thiogunine greater than about 400 pmol per 8+108 red blood cells indicates a need to decrease the amount of said drug subsequently administered to said subject." '623 patent, col. 20, Il. 10-20, 2 App. 16.

Mayo Collaborative Services v. Prometheus Laboratories, Inc., 566 U.S. ____ (2012) (slip opinion), at internal page 6.

patent-protection. As the Court put it:

> Prometheus' patents set forth laws of nature— namely, relationships between concentrations of certain metabolites in the blood and the likelihood that a dosage of a thiopurine drug will prove ineffective or cause harm.... While it takes a human action (the thiopurine drug) to trigger a manifestation of this relation in a particular person, the relation itself exists in principle apart from any human action. The relation is a consequence of the ways in which thiopurine compounds are metabolized by the body — entirely natural processes. And so a patent that simply describes that relation sets forth a natural law.
>
> The question before us is whether the claims do significantly more than simply describe these natural relations. To put the matter more precisely, do the patent claims add ***enough*** to their statements of the correlations to allow the processes they describe to qualify as patent-eligible processes that *apply* natural laws? We believe that the answer to this question is no.[33]

Holding the process claim to be invalid, the Court reversed the judgment of the U.S. Court of Appeals.

The Supreme Court's opinion is bound to have wide-ranging repercussions for the pharmaceutical industry, the medical profession, and the general public seeking medical help. The wide array of amicus briefs in support of both petitioners as well as respondents testifies to the expected repercussions of the Supreme Court's judgment.[34] The judgment could , inter alia, have a marked influence on the development of the biotechnology industry and personalized medicine whereby treatment is calibrated to meet the specific needs of each individual seeking treatment.[35] The judgment could

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[33] *Id.* at internal page 8.

[34] In the Supreme Court there were seven amicus briefs in support of Mayo Collaborative Services, fifteen in support of Prometheus Laboratories, and six in support of neither party. Justice Breyer has observed elsewhere that amicus briefs, more than the parties' briefs, indicate the wide public policy implications of the cases before the Court. See Stephen G. Breyer, *Genetic Advances and Legal Institutions*, 28 (4 Supplement) J.L. Med. & Ethics 23-28 (2000).

[35] See, for example: Brief for Arup Laboratories, Inc. and Laboratory Corporation of

potentially affect the computer and software industry, too.[36]

The day after the Supreme Court's judgment, the United States Patent and Trademark Office issued a memorandum to guide the Patent Examining Corps in determining patent subject matter eligibility in the light of *Mayo v. Prometheus*.[37] This was supplanted by a more detailed, memorandum seeking to serve guidance "for examination of process claims in which a law of nature, a natural phenomenon, or naturally occurring relation or correlation ... is a limiting element or step."[38] The new interim procedure lists three inquiries to be made for determining subject matter patent

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America Holdings (D/B/A Labcorp) as Amici Curiae in Support of Petitioners, at page 4. ("The preemptive effects of such patents on research, medical services and the growing field of personalized medicine are profound."). Also see: Brief of the Biotechnology Industry Organization as Amicus Curiae In Support of Respondent. The brief states, inter alia, (at page 5):

> The progress of the biotechnology industry over the 30 years of its existence has demonstrated that patent protection is an essential driver of innovation. The role that patents have played for this industry and which they must play to encourage innovation in the field of personalized medicine, is exactly the role that the Patent Clause envisions....Using section 101 to broadly exclude entire categories of new and useful inventions from patent eligibility would be antithetical to this basic purpose.

Available at SCOTUS blog, http://www.scotusblog.com/case-files/cases/mayo-collaborative-services-v-prometheus-laboratories-inc/

[36] See, for example, Brief of SAP America, Inc. as Amicus Curiae In Support of Affirming the Federal Circuit's Opinion. The Brief states, at page 2:

> The software and computer industries are a vital part of today's Information Age economy and these industries depend on patent protection for growth and innovation. A decision regarding the scope of 35 U.S.C. Section 101 as applied to medical diagnostic processes could have far-reaching effects in all technology areas, including software and other computer-related technologies.

[37] United States Patent and Trademark Office Memorandum dated March 21, 2012, available at: http://www.uspto.gov/patents/law/exam/mayo_prelim_guidance.pdf.

[38] United States Patent and Trademark Office Memorandum dated July 3, 2012. Subject: *2012 Interim Procedure for Subject Matter Eligibility Analysis of Process Claims Involving Laws of Nature.* Available at: http://www.uspto.gov/patents/law/exam/2012_interim_guidance.pdf. The guidelines for evaluation of process claims that involved abstract ideas as opposed to laws of nature continued to be the earlier issued *Interim Guidance for Determining Subject Matter Eligibility for Process Claim in View of Bilski v. Kappos*, 75 Fed.Reg.43922, July 27, 2010 *(2010 Interim Bilski Guidance)*.

eligibility under Section 101. The third inquiry requires the presence of additional elements that apply the law of nature so that the claimed process is "significantly more than the natural principle itself." This points to a considerably heightened level of scrutiny for examining process claims that are based upon laws of nature or naturally occurring phenomena.

Also of great interest to date are the Supreme Court's rulings on petitions for certiorari in two significant cases involving subject matter patentability under Section 101 of the U.S. Patent Act. In both cases, the Court granted certiorari, vacated the judgment of the U.S. Court of Appeals for the Federal Circuit, and remanded the cases to the Federal Court for further consideration in view of the judgment in *Mayo v. Prometheus*.[39]

The first of these is *The Association of Molecular Pathology, et al. v. Myriad Genetics, Inc., et al.* in which the Court made its ruling on March 26, 2012. The case involves the patentability of isolated human DNA. Although the claim relates to a composition of matter and not a process as in *Mayo v. Prometheus*, it could reasonably be adjudged as a claim on a natural phenomenon and therefore patent-ineligible.

The second is *WildTangent v. Ultramercial*,[40] in which the Court made its ruling on May 21, 2012. The patent in this case involves a claimed process for a specific mode of distributing copyrighted content on the internet.[41]

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[39] At the time of writing this, a few other petitions for certiorari relating to patent-eligibility remain pending. Among these are *Fort Properties v. American Master Lease*, *Accenture Global v. Guidewire* and *Bancorp Services v. Sun Life*.

[40] The judgment of the U.S. Court of Appeals for the Federal Circuit is reported at 657 F.3d 1323

[41] Claim 1 of the patent at issue as quoted in the judgment of the U.S. Court of Appeals for the Federal Circuit is as follows:

> A method for distribution of products over the Internet via a facilitator, said method comprising the steps of:
>
> a first step of receiving, from content provider, media products that are covered by intellectual property rights protection and are available for purchase, wherein each said media product being comprised of at least one of text data, music data, and video data;
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> a second step of selecting a sponsor message to be associated with the media product, said sponsor message being selected from a plurality of sponsor messages, said second step including accessing an activity log to verify that the total number of times which the sponsor message has been previously presented is less than the number of transaction cycles contracted

III. The International Position Relating to Patent Subject Matter Eligibility:

The fostering of industrial innovation is an important factor in achieving and promoting competitiveness in the global arena. Intellectual property rights, and patent rights in particular, play a vital role in shaping a culture in which creativity and innovation can thrive. As one of the Amicus Curiae briefs in the case has accurately stated:

> The United States has been historically, and remains currently, a leader in innovation. Manufacturing, chemistry, electronics, biotechnology, and computer software are just a few of the technological fields that have seen tremendous commercial development within the United States. The Patent Laws of the United States have accommodated and fostered innovation in and development of all these technologies, and have helped the United States to achieve and maintain its position in the

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by the sponsor of the sponsor message;
a third step of providing the media product for sale at an Internet website;
a fourth step of restricting general public access to said media product;
a fifth step of offering to a consumer access to the media product without charge to the consumer on the precondition that the consumer views the sponsor message;
a sixth step of receiving from the consumer a request to view the sponsor message, wherein the consumer submits said request in response to being offered access to the media product;
a seventh step of, in response to receiving the request from the consumer, facilitating the display of a sponsor message to the consumer;
an eighth step of, if the sponsor message is not an interactive message, allowing said consumer access to said media product after said step of facilitating the display of said sponsor message;
a ninth step of, if the sponsor message is an interactive message, presenting at least one query to the consumer and allowing said consumer access to said media product after receiving a response to said at least one query;
a tenth step of recording the transaction event to the activity log, said tenth step including the total number of times the sponsor message has been presented, and
an eleventh step of receiving payment from the sponsor of the sponsor message displayed.
657 F.3d 1323 at 1324, 1325.

global economy.[42]

Because of the transnational effects of patent law, and the benefit to free trade and other aspects of international cooperation that can flow from harmonization of patent laws among the nations of the world, efforts have been made in this direction since 1883. Some of the principal international treaties relating to harmonization are the Paris Convention for the Protection of Industrial Property, the Convention Establishing the World Intellectual Property Organization, the Patent Cooperation Treaty, the Convention On the Unification Of Certain Points of Substantive Law On Patents for Invention, the Convention On the Grant Of European Patents, and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), the Patent Law Treaty and the Substantive Patent Law Treaty.

The most important of the international treaties relating to intellectual property rights is the TRIPS agreement which is administered under the aegis of the World Trade Organization.

The Scope of patentable subject matter under the TRIPS agreement is contained in Article 27 in the chapter entitled: "Part II Standards Concerning the Availability, Scope and Use of Intellectual Property Rights." Sub-clause 3 (a) of Article 27 specifically makes "diagnostic, therapeutic and surgical methods for the treatment of humans and animals" excludable from the ambit of patentable subject matter.[43] So also, the

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[42] Brief of Amici Curiae Association Internationale Pour La Protection De La Propriete Intellectuelle and International Association For the Protection Of Intellectual Property (U.S.) In Support of Neither Party, at pages 3 and 4. Available at SCOTUS blog, supra note 34.

[43] The entire Article 27 of the TRIPS agreement states as follows:

> 1.Subject to the provisions of paragraphs 2 and 3, patents shall be 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.
>
> For the purposes of this Article, the terms "inventive step" and "capable of industrial application" may be deemed by a Member to be synonymous with the terms "non-obvious" and "useful" respectively.
>
> 2. Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary

Handbook of the World Intellectual Property Organization lists "methods of treatment for humans or animals, or diagnostic methods practiced on humans or animals," as among the items that are excludable from the ambit of patentable subject matter.[44]

Following is a description of the scope of subject matter patent-eligibility in Japan and the member states of the European Patent Organization.

1. Subject matter patent eligibility in Japan:

The important factors for determining subject matter patent eligibility in Japan are

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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.

3. Members may also exclude from patentability:

(a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;

(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.

Available at http://www.jpo.go.jp/shiryou_e/s_sonota_e/fips_e/trips/ta/chap3.htm.

[44] See Article 2.7 of the *WIPO Intellectual Property Handbook: Policy, Law and Use,* available at http://www.wipo.int/export/sites/www/about-ip/en/iprm/pdf/ch2.pdf.

The entire Article 2.7 reads as follows:

2.7 In order to be eligible for patent protection, an invention must fall within the scope of patentable subject matter. Patentable subject matter is established by statute, and is usually defined in terms of the exceptions to patentability, the general rule being that patent protection shall be available for inventions in all fields of technology (see Article 27.1 of the TRIPS Agreement).

2.8 Subject matter which may be excluded from patentability includes the following (see also Article 27.3 of the TRIPS Agreement). Examples of fields of technology which may be excluded from the scope of patentable subject matter includes the following:

discoveries of materials or substances already existing in nature;

- scientific theories or mathematical methods;
- plants and animals other than microorganisms, and essential biological processes for the production of plants and animals,

set out in the *Examination Guidelines for Patent Utility Model in Japan*.[45] Article 29 (1) of the Patent Act of Japan requires that in order to be patentable, an invention should be "industrially applicable." Among the inventions listed in the *Guidelines* as unpatentable are:

"(1) A law of nature as such...

(2) Mere discoveries and not creations...

(3) Those contrary to a law of nature...

(4) Those in which a law of nature is not utilized...

(5) Those not regarded as technical ideas...

(6) Those for which it is clearly impossible to solve the problem...

to be solved by any means presented in a claim."[46]

Among the "List of Industrially Inapplicable Inventions" are "methods of surgery, therapy or diagnosis of humans."[47] Further, "methods of diagnosis of humans" is listed among "types of methods considered to be classified as 'methods of surgery, therapy or diagnosis of humans."[48]

These provisions indicate that the sort of medical process at issue in *Mayo v. Prometheus* would be considered patent-ineligible subject matter.

2. The Member States of the European Patent Organization:

What constitutes patent-eligible subject matter is set out in Articles 52 and 53 of the *European Patent Convention*.[49] Article 52 describes the ambit of "Patentable Inventions" thus:

(1) European patents shall be granted for any inventions, in all fields of technology, provided that they are new, involve an inventive

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other than non-biological and microbiological processes;
- schemes, rules or methods, such as those for doing business, performing purely mental acts or playing games;
- methods of treatment for humans or animals (but not products for use in such methods).

[45] *Examination Guidelines for Patent and Utility Model in Japan*, available at http://www.jpo.go.jp/cgi/linke.cgi?url=/tetuzuki_e/t_tokkyo_e/1312-oo2_e.htm.

[46] *Examination Guidelines for Patent and Utility Model in Japan*, *Id.* at internal pages 1, 2, and 3.

[47] *Id.*, Clause 2.1 and Clause 2.1.1 at internal page 4.

[48] *Id.*, Clause 2.1.1.1 and Clause 2.1.1.1 (3) at internal pages 4 and 5.

[49] *The European Patent Convention*, available at http://www.epo.org/law-practice/legal-texts/html/epc/2010/e/ma1.html.

step and are susceptible of industrial application.

(2) The following in particular shall not be regarded as inventions within the meaning of paragraph 1:

(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;

(d) presentations of information.

(3) Paragraph 2 shall exclude the patentability of subject-matter or or activities referred to therein only to the extent to which a European patent relates to such subject-matter or activities as such.

Article 53 then lists the "Exceptions to patentability" thus:

European patents shall not be granted in respect of:

(a) inventions the commercial exploitation of which would be contrary to "ordre public" or morality; such exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States;

(b) plant or animal varieties or essentially biological processes for the production of plants or animals; this provision shall not apply to microbiological processes or the products thereof;

(c) methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body; this provision shall not apply to products, in particular substances or compositions, for use in any of these methods.

Article 53 (c) indicates that the patent at issue in *Mayo v. Prometheus* would not be considered to be patent eligible under the European Patent Convention.[50]

[50] It is important to note the Opinion of the Enlarged Board of Appeal at the European Patent Office delivered in December 2005, in Case G 0001/4, available at: http://www.epo.org/law-practice/case-law-appeals/pdf/g040001ex1.pdf. The Enlarged Board held that a diagnostic method will be excluded from patentability only if all the technical method steps that are constitutive for making the diagnosis must be performed on the human or animal body. If even one of the constitutive steps is not performed on the human or animal body, then the method is patentable under the *European Patent Convention*.

IV. Some Brief Comments and Observations About the Court's Opinion in *Mayo v. Prometheus*:

1. Justice Breyer's opinion pays attention, albeit in passing, to the international aspect of the issue.[51] Due to the forces of globalization, national patent laws have international ramifications. This has been one of the factors impelling the drive to bring about the international harmonization of patent laws. The U.S. Congress has implicitly recognized the importance of harmonization.[52] The opinion has the effect of bringing the U.S. law in respect of patentability of medical diagnostic techniques in closer alignment with that of most other countries.[53]

2. The Court's opinion is in keeping with the intent of Congress in enacting Section 287 (c) of the United States Patent Act, which exempts from liability medical practitioners who in performing a medical activity infringe a medical method patent.[54] Harmonization with international law and practices was at least one of the motivating

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[51] *Mayo v. Prometheus*, supra note 2, at pages 23 and 24 of the slip opinion, the opinion cites one of the Amicus Curiae briefs to the effect that "research leading to the discovery of laws of nature, is expensive; it 'ha[s] made the United States the world leader in this field'; and it requires protection." And later, the opinion cites another of the amicus curiae briefs for the information that "methods of medical treatment are not patentable in most of Western Europe."

[52] See, for example, Section 3 (p) of the "Leahy-Smith America Invents Act.," available at http://www.uspto.gov/aia_implementation/bills-112hr1249enr.pdf. With reference to the conversion to a "first inventor to file" system, the section expresses the "sense of Congress" that doing so would "promote harmonization of the United States patent system with the patent systems commonly used in nearly all other countries throughout the world ... and thereby promote greater international uniformity and certainty in the procedures used for securing the exclusive rights of inventors to their discoveries."

[53] See Brief of Amici Curiae Association Internationale Pour La Protection De La Propriete Intellectuelle And International Association for the Protection of Intellectual Property (U.S.) In Support of Neither Party, at A 16 ("Methods of medical treatment are only patentable subject matter in Australia and in the States. In all other reporting countries methods of medical treatment are not patentable.") Available at SCOTUS Blog, *supra* note 36.

[54] 35 U.S.C. 287©(1)-(2) (2004); Omnibus Consolidated Appropriations Act of 1996 Section 616, Pub. L. 104-208, 110 Stat., 3009 (codified as 35 U.S.C. Section 287 (c) (1994) Supp. II 1996 & Supp. IV 1998). The Bill in the Senate for the enactment of Section 287 (c) was entitled: "S.1334 –A bill to amend chapter 28 of title 35, United States Code, to provide form noninfringing uses of patents on medical and surgical procedures."

factors behind the enactment of 35 U.S. 287 (c).[55] The Court's opinion furthers this intent.

3. Intellectual Property laws and Competition law have antithetical concerns. While intellectual property laws serve to promote innovation and creativity, they tend to inhibit the sort of competition that competition law seeks to promote. At their core both serve the public good.[56] The Court's Opinion in *Mayo v. Prometheus* does not directly deal with the tension between intellectual property law and antitrust or competition law. However, it does take due cognizance of the negative effects of the exclusive nature of rights conferred by patent law. The Opinion notes:

> Patent protection is, after all, a two-edged sword. On the one hand, the promise of exclusive rights provides monetary incentives that lead to creation, invention, and discovery. On the other hand, that very exclusivity can impede the flow of information that might permit, indeed spur, invention, by for example, raising the price of using the patented ideas once created, requiring potential users to conduct costly and time-consuming searches of existing patents and pending patent applications, and requiring the negotiation of complex licensing arrangements.[57]

Even as it recognized these contradictory effects, the Court did not base its opinion on a resolution of this tension in this specific case because of the consequential difficulties that could result in cases of patents in other unrelated areas. By doing so, the Court deftly avoided obfuscating further the already contentious area of subject-matter patent eligibility.

4. The Court's "law of nature" rationale has the potential effect of rendering a large swath of innovations related to biotechnology and pharmaceuticals ineligible for

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[55] See U.S. Patent and Trademark Office, "Notice of Hearings and Request for Comments on Issues Relating to Patents Protection for Therapeutic and Diagnostic Methods," 61 Fed. Reg. at 103200-23.

[56] For a detailed discussion of the conflicting aims of intellectual property law and competition law, see: U.S. Dept of Justice and Federal Trade Comm'n, Antitrust Enforcement and Intellectual Property Rights: Promoting Innovation and Competition (2007). Available at: http://www.ftc.gov/reports/innovation/PO40101PromotingInnovationandCompetitionrpt0704.pdf.

[57] *Mayo v. Prometheus*, *supra* note 2, at internal page 23.

patent protection. The actual consequences of the Court's judgment will be known only after a passage of time. However, the intuitive response of most people is that the judgment is beneficial from the viewpoint of the provision of health care and thereby in the interest of the larger public good. It will also have the salutary effect of reining in an overgenerous grant of patents granted in recent years by the USPTO.

V. Conclusion:

Thus, the judgment of the U.S. Supreme Court in the case of *Mayo Collaborative Services v. Prometheus Laboratories, Inc.* is a major step in the Court's evolving jurisprudence relating to subject matter patent eligibility and particularly in the area of medical diagnostics. The judgment is likely to have a major impact on the biotechnology and pharmaceutical industries. It will also have a bearing on the provision of health care to individuals. Medical practice and the freedom of doctors to use therapeutic techniques that are most suited to the needs of the particular individual in need of such care will also be greatly enhanced. The *Mayo* ruling will also serve as an important precedent in the resolution of important biotechnology related cases presently pending before the courts. The outcome of those cases will be eagerly watched as the emerging doctrine relating to subject matter eligibility evolves and assumes a clearly delineated shape and form.

Mayo Collaborative Services v. Prometheus Laboratories, Inc. 判決後の特許可能な主題

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要　約

米国連邦最高裁は、2012年3月20日の*Mayo Collaborative Services v. Prometheus Laboratories, Inc.*の判例において、十分に予測された判決を打ち出した。その判決は、その決議の賛否両方の法学者や法実践者から多くの意見を引き起こした。一つ合意していた点は、主題特許可能性と関係のある法律を再構成するものである限り、最高裁の判決は非常に重要である、ということである。*Mayo v. Prometheus*のケースでは、自己免疫疾患治療のチオプリン（thiopurine）という合成薬の適切な投与量を決める、医学的な工程に特許が関わっている。判決は、バイオテクノロジーと製薬業界にとって、確かに大きな意味を持つものであり、ヘルスケアと医学的診断のテクニックの分野においても影響を持つものであろう。それはまた、コンピューターをベースにしたビジネス方法とソフトウエア関連の特許などの他の方法特許においても、重要なつながりを持ちうるものであろう。重要な判例となった主題特許可能性に関わる方針や原則を広げていくと、最高裁は米国特許法第101条の下、特許可能性の除外に関わる基準を明確化している。この論文では、*Mayo v. Prometheus*の判決にならって形作られてきた、主題特許可能性とそのような可能性の輪郭に関わる米国最高裁の法理の発展を述べている。特許法での国を超えた反響のために、この論文では特許法に関する2つの他の主な分野、つまり日本とEuropean Patent Organisationの加盟各国の主題特許可能性に関わる法律の立場を述べている。最後にこの論文ではその判決に関する個人的な所見や意見を述べている。