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A Survey on Subject Matter Eligibility

Few areas of patent law are as unsettled as subject matter eligibility. What is considered patentable varies greatly across jurisdictions and nuances in claim language can make otherwise ineligible subject matter, eligible. The October 2018 issue of Sterne Kessler's Global Patent Prosecution Newsletter includes information on subject matter eligibility in the US and a number of foreign jurisdictions – with a highlight on eligibility issues in artificial intelligence.

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HOW TO DO THE TWO-STEP IN THE UNITED STATES: THE CURRENT STATE OF PATENT-ELIGIBLE SUBJECT MATTER

By Rebecca Lindhorst

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By: David Haars

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In the wake of the Supreme Court's *Mayo* and *Alice* decisions, uncertainty has surrounded what inventions are patent eligible in the United States. In *Mayo* and *Alice*, the Supreme Court developed a two-step test to determine patent eligibility. Step one determines if the invention is directed to a law of nature, natural phenomenon, or abstract idea. If so, the second step determines if there is an inventive concept sufficient to ensure the patent amounts to significantly more than the ineligible concept itself.[i] While this test has led to uncertainty in what inventions remain patent eligible, post-*Mayo*/*Alice* case law has begun to shed light on what is patent eligible in the United States. The current state of patent eligibility in the technology areas most impacted by the *Mayo*/*Alice* two-step are outlined below.

Plant and Animal Claims

Claims directed to plants and animals are generally patent ineligible in the United States. The Federal Circuit has held that even cloned animals are ineligible because the "claimed clones are exact genetic copies of patent ineligible subject matter."[ii] Exceptions exist, however, for certain plant patents. The Plant Patent Act provides protection for plants that are asexually reproducing, distinct, and new.[iii] While the Supreme Court has held that newly developed plant breeds are eligible for utility patents under 35 U.S.C. § 101[iv], it is important to note that this decision was pre-*Mayo*/*Alice*.

Compositions Comprising Products Found in Nature

There have been a limited number of decisions addressing composition of matter claims under § 101 since the *Mayo* and *Alice* decisions. The underlying rationale in the decisions thus far have held that compositions of matter are ineligible unless they have "markedly different" characteristics from any composition found in nature.[v] While the genomic form of a gene is

ineligible under § 101, certain complementary DNA (cDNA) forms encoding the gene are eligible if they do not exist in nature.[vi] Following this decision, the Federal Circuit has held that single-stranded DNA primers are also patent ineligible.[vii]

Diagnostic Method and Method of Treatment Claims

Diagnostic method claims have faced frequent and difficult eligibility challenges post-*Mayo*/*Alice*. Courts have consistently held diagnostic method claims ineligible when they recite the general steps of: (1) take a sample; (2) measure/analyze/detect/determine the presence of a biomarker; and (3) reach a conclusion/diagnosis.[viii] A recent Federal Circuit decision, *Vanda Pharmaceuticals v. West-Ward Pharmaceuticals*, held that a diagnostic claim which also recited an administration step is patent eligible.[ix] This decision is consistent with statements by both the Supreme Court and the Federal Circuit that method of treatment claims are generally patent eligible.[x] In light of the *Vanda* decision, the USPTO issued a memo to the examining corps in line with the court's holding explaining that method of treatment claims that apply natural relationships should be considered patent eligible and that it is not necessary for method of treatment claims to include non-routine or unconventional steps to be patent eligible.[xi] While the Federal Circuit denied West-Ward's petition for rehearing *en banc*, West-Ward may still file a petition for writ of certiorari to the Supreme Court. Consequently, it is too early to fully determine the impact these recent developments will have on the eligibility of diagnostic methods.

Software and Business Method Claims

Software and business method patents have faced significant challenges since the *Mayo*/*Alice*decisions. Software claims, are not *per se* ineligible, however software claims that merely gather, analyze, and output data are patent ineligible.[xii] Software claims can be patent eligible when they are directed to an improvement in the way computers operate.[xiii] Additionally, claims which recite specific limitations to overcome deficits or problems in the prior art have been found patent eligible.[xiv] Based on these holdings, to be patent eligible software claims must recite specific steps to obtain a desired result rather than recite merely the result itself.[xv]

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[i] Mayo Collaborative Services v. Prometheus Laboratories, Inc., 566 U.S. 66 (2012); Alice Corp. Pty. Ltd. v. CLS Bank Int'l., 134 S. Ct. 2347 (2014).
[ii] In re Roslin Institute (Edinburgh), 750 F.3d 1333, 1337 (Fed. Cir. 2014).
[iii] 35 U.S.C. §§ 161–62 (2012).
[iv] J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc., 534 U.S. 124 (2001).
[v] Natural Alternatives Int'l v. Allmax Nutrition, Inc., 258 F. Supp. 3d 1170 (S.D. Cal. 2017); *Myriad*, 569 U.S. 576; *In re BRCA1*, 774 F.3d 755; *In re Roslin*. 750 F.3d 1333.
[vi] Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576 (2013).
[vii] In re BRCA1 and BRCA2-Based Hereditary Cancer Test Patent Litigation, 774 F.3d 755 (Fed. Cir. 2014).
[viii] *See e.g*. *In re BRCA1*, 774 F.3d 755; Ariosa Diagnostics, Inc. v. Sequenom, Inc., 809 F.3d 1282 (Fed. Cir. 2015); Genetic Technologies Ltd. V. Merial LLC, 818 F.3d 1369 (Fed. Cir. 2016); Cleveland Clinic Foundation v. True Health Diagnostics LLC, 859 F.3d 1352 (Fed. Cir. 2017).
[ix] Vanda Pharm. v. West-Ward Pharm., 887 F.3d 117 (Fed. Cir. 2018).
[x] *Myriad*, 569 U.S. at 596; Rapid Litigation Management Ltd. V. CellzDirect, Inc., 827 F.3d 1042, 1049 (Fed. Cir. 2016).
[xi] Memorandum from USPTO on Recent Subject Matter Eligibility Decision: *Vanda Pharmaceuticals Inc. v. West-Ward Pharmaceuticals* (June 7, 2018), https://www.uspto.gov/sites/default/files/documents/memo-vanda-20180607.PDF.
[xii] *See e.g*., Electric Power Group v. Alstom, 830 F.3d 1350 (Fed. Cir. 2016).

[xiii] *See e.g.*, Enfish, LLC v. Microsoft Corp., 822 F.3d 1327 (Fed. Cir. 2016).
[xiv] *See e.g.*, Core Wireless v. LG Electronics, 880 F.3d 1356 (Fed. Cir. 2018); Thales Visionix v. United States, 850 F.3d 1343 (Fed. Cir. 2017); McRo, Inc. v. Bandai Namco Games America, Inc., 837 F.3d 1299 (Fed. Cir. 2016).
[xv] Finjan, Inc. v. Blue Coat Systems, Inc., 879 F.3d 1299 (Fed. Cir. 2018).

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As evidenced recently in the United States, it may be difficult to tell what categories of inventions are eligible for patent protection in foreign jurisdictions. To further complicate issues, standards of eligible subject matter can differ from country to country. What follows is a survey of patent eligible subject matter in various jurisdictions.

A sampling of subject matter eligibility outside of the US is provided below. Certain categories of subject matter are excluded as patent ineligible in all countries discussed, such as scientific discoveries, purely intellectual activities, laws of nature, and mathematical equations; other categories are excluded as culture-specific, such as inventions "against public morality" or "against Sharia law". Microorganisms can be claimed in all of the jurisdictions included here, and are therefore excluded, as are certain categories of subject matter mentioned in only one foreign jurisdiction, such as the explicit exclusion of methods of horticulture and agriculture in India and personal skills in Japan.

The features of subject matter eligibility discussed may be nuanced in certain jurisdictions because this is an evolving area of the law across the globe.

Methods of Treating Humans

Methods of treatment in humans varies widely by jurisdiction.

Methods of treatment are patent eligible in Australia and Russia.

Europe: Article 53(c) prohibits the patenting of methods for treatment of a human by surgery or therapy and diagnostic methods practiced on a human. However, it is permissible to patent products, such as substances or compositions, for use in any of these methods – for example,

composition X for use in a method of therapy, diagnosis or surgery.

Canada: In contrast to claims for a method of medical treatment, a claim for a use of a compound or device to medically treat a disorder may be valid, so long as the claim does not limit the skill and judgment of a physician. For example, "1. The use of compound X to treat disorder Y" is considered to be patent-eligible subject matter in Canada. Addition of dosing regimen information may be deemed to limit the skill of a physician.

Mexico: Therapeutic method claims are accepted when drafted as second medical use formats: “Swiss-style type” or “EPC2000 type”.

Brazil: Therapeutic method claims are accepted in a Swiss-type format. Limitations may be placed in claimed subject matter regarding dosing regimens as they may be seen to cover therapeutic methods of treatment.

Japan: Therapeutic method claims are accepted when drafted in Swiss-type format or "composition for use" format.

Israel: Medical methods are not permitted in Israel. However, examples of acceptable formats include “Use of X in the preparation of a medicament for use in treating disease Y”. This is contrasted with the unacceptable format: “Use of X in the treatment of disease Y.”

South Korea: Methods of treatment are ineligible, but composition claims such as “a pharmaceutical composition comprising product X for the treatment of disease Y” are eligible.

Gulf Cooperation Council (GCC): As with methods of diagnosis, methods of treatment in the human body are patent ineligible subject matter, but products used as a part of treatment are eligible.

Diagnostic Methods

Diagnostic Methods are patent eligible subject matter in Australia and Russia.

Diagnostic methods are patent ineligible subject matter in India.

Europe: Diagnostic steps performed on the human body are ineligible, but diagnostic tests performed on samples obtained from a human body may be patented.

Canada: Methods of data acquisition are statutory subject matter, provided claims do not include ineligible subject matter, such as methods of treatment.

China: Methods for the diagnosis of diseases are not patentable. However, (i) the method of acquiring information from a living human or animal body as the intermediate result only; (ii) the method of acquiring information by processing or detecting the tissues, body fluid or waste isolated from the human or animal body as the intermediate result only; and (iii) the method of processing the acquired information, are not considered to be methods for the diagnosis of diseases if the immediate purpose is not to obtain the diagnostic result of a disease or health condition.[1]

Japan: Compositions, devices, systems or kits for use in diagnosis to be practiced on the human body are industrially applicable and patentable subject matter.

South Korea: Inventions that include the human body as an essential element are deemed patent ineligible subject matter.

GCC: Methods of diagnosis applied to the human body are ineligible, but products used as a part of diagnosis are eligible.

Plants and Animals

Plants and animals are patent ineligible subject matter in Europe, Canada, China, South Korea, India, Russia, and the GCC, but are eligible subject matter in Australia and Japan.

Software

Software is patent ineligible subject matter in Europe, Russia, Argentina, Brazil (copyrightable protection allowed) and the GCC, but is eligible subject matter in Canada, Australia and Japan.

China: Software patents are per se patent ineligible (though copyrightable). However, these are distinguished from computer-related inventions, which recite a computer program as part of an apparatus claim. Claims must recite technical solutions, because non-technical solutions are ineligible subject matter.

South Korea: Patents for software are only eligible if recorded on a storage medium, the combination of software and hardware represent an improvement over the prior art, the combination has a technical result, and the combination constitutes a complete technical solution.

India: Previously, software was per se unpatentable if not claimed in conjunction with novel hardware. Currently, the novel hardware requirement has been dispensed with, and examiners look to the underlying substance of claims as a whole. Computer programs are still per se unpatentable, but Indian examiners are allowing descriptions of technical solutions in the form of programs to be patented.

Business Methods

Business methods are patent ineligible subject matter in Europe, Japan, Russia, and the GCC, but are eligible subject matter in Canada, Australia, and South Korea (if presented as a specific technology in combination with computer technology).

China: Business methods are per se ineligible unless they recite technical features, especially those of a physical nature.

Brazil: Business methods are patent ineligible. However, technical processes that improve the implementation of a business method is patent eligible.

India: As with computer programs, examiners in India are encouraged to look at the underlying substance of claims as a whole. Business methods are unpatentable subject matter, but "the mere presence of words such as 'enterprise', 'business' [or] 'business rules…' should not imply the claims are automatically ineligible.

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[1] https://www.lifesciencesipreview.com/article/china-v-us-what-can-be-patented-in-the-life-sciences-field

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Artificial Intelligence (AI) has become one of the most important technologies of the 21st century. AI generally refers to a branch of computer science that simulates "intelligent" behavior in computers and has the potential to greatly affect nearly every aspect of our lives.

This article surveys subject-matter eligibility requirements of AI patent applications in the United States, Europe, and China.

United States

In the United States, the U.S. Patent and Trademark Office determines the subject matter eligibility of computer-implemented patent applications, including AI patent applications, based on Alice and its progeny. This framework inquires whether the claims at issue are directed to a patent-ineligible concept (e.g., law of nature, natural phenomena, or abstract idea), and if so, whether the claims include additional element(s) sufficient to ensure that the claims amount to significantly more than the ineligible concept itself. [[1]] The U.S. Court of Appeals for the Federal Circuit ("Federal Circuit") has provided guidance as to the patent eligibility of computer-implemented inventions, which also generally applies to AI inventions. [[2]] In particular, the Federal Circuit has indicated that claims directed to technical solutions to technical problems and claims rooted in computer technology may have a good basis for patent eligibility. [[3]] The Federal Circuit has also indicated that claims reciting features that improve computer performance (e.g., increased computing speed, reduced bandwidth requirements, and reduced storage requirements) and claims reciting graphical-user-interface features may be patent eligible subject matter. [[4]]

Europe

In Europe, the European Patent Office determines the patentability of computer-implemented patent applications, including AI patent applications, based on a pair of hurdles: an eligibility hurdle (Article 52 EPC), which requires the claimed subject matter to have a technical character; and a patentability hurdle (Articles 54, 56 EPC), which requires the claimed subject matter to contribute a technical solution to a technical problem. Each hurdle can provide obstacles to AI applications. With respect to the first hurdle, Article 52 lists subject matter that doesn't possess technical character, such as mathematical methods, methods for performing mental acts or doing business, and presentations of information. The second hurdle extends from the first hurdle and further requires that the claim portions contributing to the technical character must also provide an inventive step over the prior art; in other words, those claim portions that don't contribute to the technical character cannot contribute to the inventive step.

China

In China, the China National Intellectual Property Administration (CNIPA) determines subject-matter eligibility of patent applications, including AI patent applications, with respect to a technical solution, similar to the EPO. In April 2017, the CNIPA released revised Examination Guidelines that, among other things, describe patent eligibility for software claims in the form of "medium plus computer program process" claims and apparatus claims that recite a component implemented by a computer program. [[5]] Previously, software-related claims could include only process claims or "means plus function" claims. [[6]] In August 2017, the CNIPA also prioritized examination for Chinese patent applications directed to certain technical fields, including energy conservation, environment protection, new generation information technology, biotechnology, high-end equipment manufacturing, new energy, new materials, new energy vehicles, intelligent manufacturing, internet, big data, and cloud computing. As these changes are relatively new, their overall effect on the eligibility of AI and other computer-implemented inventions has yet to be determined.

Conclusion

As described above, the United States, Europe, and China determine the subject matter eligibility of AI-based patent applications generally within the existing frameworks developed for computer-implemented inventions within each respective jurisdiction. Though the frameworks may have similarities in these jurisdictions, patent applicants must remain cognizant of legal developments in subject matter eligibility and adapt their prosecution strategies accordingly.

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[1] *Alice Corp. v. CLS Bank International*, 134 S. Ct. 2347 (2014)
[2] *See Enfish v. Microsoft*, 822 F.3d 1327 (Fed. Cir. 2016), *McRO, Inc. v. Bandai Namco Games Am. Inc.*, 837 F.3d 1299 (Fed. Cir. 2016), and *Core Wireless Licensing S.A.R.L. v. LG Electronics, Inc.*, 880 F.3d 1356 (Fed. Cir. 2018)
[3] *Id.*
[4] *Id.*
[5]https://www.linkedin.com/pulse/china-lift-curbs-software-patents-april-1-2017-sipo-richard-huang?trk=v-feed&lipi=urn%3Ali%3Apage%3Ad_flagship3_feed%3BENVekQ%2BCg6VsppSOhezdTw%3D%3D
[6] *Id.*

accurate, and updated. Please consult your own lawyer regarding any specific legal questions.

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