
If the two extensions and the Stephens EFP are approved, they would exempt a limited number of federally permitted commercial fishing vessels from requirements of the HMS FMP pertaining to non-authorized gear types. The EFPs would authorize up to 13 DSBG vessels to fish year-round in areas within the EEZ off the U.S. West Coast. Aside from the exemption described above, vessels fishing under an EFP would be subject to all other regulations implementing the HMS FMP, including measures to protect sea turtles, marine mammals, and seabirds. The three applicants requested EFP issuance for two fishing seasons or the 2017 and 2018 calendar years.

The Council suggested NMFS impose requirements on the Stephens EFP consistent with one of the existing EFPs, including, but not limited to:

1. 30 percent observer coverage on each vessel’s fishing trips;
2. fishing only in federal waters; and
3. the operator of the fishing vessel operating under a DSBG EFP must actively tend all gear at all times and maintain the gear within sight (typically within 2–4 nautical miles of the gear) of the EFP participant fishing vessel.

NMFS is seeking public comment on the extension of the two existing EFPs, as well as the Stephens EFP application and the Council’s recommended conditions.

In accordance with NOAA Administrative Order 216–6, appropriate National Environmental Policy Act documents will be completed prior to the issuance of the EFPs. Additionally, NMFS will consider all applicable laws, including Section 7(a)(2) of the Endangered Species Act (16 U.S.C. 1531 et seq.), to determine if the proposed action is likely to jeopardize the continued existence and recovery of any endangered or threatened species or result in the destruction or adverse modification of critical habitat.

Authority: 16 U.S.C. 1801 et seq.

Emily H. Menashes,
Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

DEPARTMENT OF COMMERCE
Patent and Trademark Office
[Docket No.: PTO–P–2016–0041]

Notice of Roundtables and Request for Comments Related to Patent Subject Matter Eligibility

AGENCY: United States Patent and Trademark Office, Department of Commerce.

ACTION: Notice of public roundtables and request for comments related to patent subject matter eligibility.

SUMMARY: The United States Patent and Trademark Office (“USPTO”) seeks public input on patent subject matter eligibility in view of recent decisions by the Supreme Court and Court of Appeals for the Federal Circuit. The USPTO remains interested in feedback from members of the public to improve the USPTO’s existing subject matter eligibility guidance and training examples. The USPTO is also interested in facilitating a discussion among members of the public regarding the legal contours of eligible subject matter in the U.S. patent system. The USPTO will be facilitating these discussions by hosting two roundtable events. The first roundtable will begin at 8:00 a.m., EST on December 5, 2016, and the second roundtable will begin at 1:00 p.m., EST on January 18, 2017.

DATES: The meeting dates are:
1. November 14, 2016, 1 p.m. to 5 p.m., Alexandria, VA.
2. December 5, 2016, 8 a.m. to 5 p.m., Stanford, CA.
3. January 18, 2017, 8 a.m. to 5 p.m., Alexandria, VA.

ADDRESSES: The meeting locations are:
2. Paul Brest Hall, 555 Salvatierra Walk, Stanford University, Stanford, California 94305.

Writed comments are due by January 18, 2017.

Written Comments: The USPTO continues to accept comments on its subject matter eligibility guidance and training examples on an ongoing basis. Those comments, as well as any written comments on the topics for discussion in Roundtable 1, should be sent by electronic mail message via the Internet addressed to 2014 interim_guidance@uspto.gov. Because comments will be made available for public inspection, information that is not desired to be made public, such as an address or phone number, should not be included in the comments.

Roundtable 1: Exploring the Legal Contours of Patent Subject Matter Eligibility

Instructions and Information on Roundtable 1: Roundtable 1 will be held on November 14, 2016, at the United States Patent and Trademark Office, Madison Building, Madison Auditorium, 600 Dulany Street, Alexandria, Virginia 22314. The roundtable will begin at 1:00 p.m., Eastern Standard Time (“EST”) and end at 5:00 p.m., EST. The roundtable will also be available via webcast enabling individuals who cannot attend in person to watch the roundtable via the Internet in real time. The agenda and webcast information will be available before the roundtable on the USPTO’s Roundtable 1 Web page www.uspto.gov/patent/notice-roundtables-and-request-comments-related-patent-subject-matter-eligibility. On-line registration will be available from that Web page, and attendees may register at the door. Attendees are encouraged to register on-line before the roundtable.

Written Comments: The USPTO continues to accept comments on its subject matter eligibility guidance and training examples on an ongoing basis. Those comments, as well as any written comments on the topics for discussion in Roundtable 1, should be sent by electronic mail message via the Internet addressed to 2014 interim_guidance@uspto.gov. Because comments will be made available for public inspection, information that is not desired to be made public, such as an address or phone number, should not be included in the comments.

Roundtable 2: Exploring the Legal Contours of Patent Subject Matter Eligibility

Instructions and Information on Roundtable 2: Roundtable 2 will be held on December 5, 2016, at Paul Brest Hall, 555 Salvatierra Walk, Stanford University, Stanford, California 94305. The roundtable will begin at 8:00 a.m., Pacific Standard Time (“PST”) and end
at 5:00 p.m. PST. The roundtable will also be available via webcast enabling individuals who cannot attend in person to watch the roundtable via the Internet in real time. The agenda and webcast information will be available before the roundtable on the USPTO’s Roundtable 2 Web page [www.uspto.gov/patent/laws-and-regulations/comments-public/notice-roundtables-and-request-comments-related-patent. On-line registration will be available from that Web page, and attendees may register at the door. Attendees are encouraged to register on-line before the roundtable.

Written Comments: For those wishing to submit written comments on the topics to be addressed by Roundtable 2, the deadline for receipt of those comments for consideration by the USPTO is January 18, 2017. Written comments should be sent by electronic mail message via the Internet addressed to 101Roundtable2@uspto.gov.

Because comments will be made available for public inspection, information that is not desired to be made public, such as an address or phone number, should not be included in the comments.

1. Background

As the world’s most innovative economy, the United States relies heavily on intellectual property to support economic growth and business development. The U.S. patent system is a critical piece of the nation’s robust system of intellectual property rights. To obtain patent protection, the requirement of subject matter eligibility under 35 U.S.C. 101 must be satisfied. Over the past six years, the Supreme Court has issued a series of decisions—Bilski, Mayo, Myriad, and Alice—that have significantly impacted patent eligibility law and continue to generate substantial public debate. These cases are briefly summarized below.

Bilski, decided in 2010, involved a business method for hedging risk. In analyzing patent eligibility, the Supreme Court recognized that section 101 specifies four independent categories of inventions or discoveries that are eligible for patent protection (processes, machines, manufactures, and compositions of matter), but judicial precedent provides three specific exceptions to patent eligibility for laws of nature, physical phenomena, and abstract ideas. The Court rejected the view of the U.S. Court of Appeals for the Federal Circuit (“Federal Circuit”) that the so-called “machine or transformation test” is the exclusive test for assessing patent eligibility of a process. Under that test, a process claim is patent eligible provided it is (1) tied to a particular machine or apparatus, or (2) transforms a particular article into a different state or thing. The Court explained that although the machine or transformation test “is a useful and important clue,” it is “not the sole test for deciding whether an invention is a patent-eligible process.” The Court held that the claims at issue were invalid because they were directed to the unpatentable abstract idea of hedging risk in the energy market and added only token post-solution components, namely, use of well-known random analysis techniques to establish inputs. The Court observed that hedging is a long prevalent fundamental economic practice, and that allowing the patent claims “would pre-empt use of [risk hedging] in all fields” and “effectively grant a monopoly over an abstract idea.” The Court, however, left open the possibility that at least some business methods are patent eligible. Following Bilski, the Supreme Court in Mayo addressed a method for optimizing drug dosages for treatment of autoimmune diseases in humans. The inventors discovered the relationship between the concentration of a metabolite in the blood and the likelihood that a dosage of a drug will be ineffective or harmful. Assessing the second step, the Court determined that the claims did not do “significantly more” than describe this natural relationship, i.e., the additional elements considered separately and as an ordered combination did not “transform the nature of the claim” into “a patent-eligible application” of the judicial exception. At issue in Myriad was the patent eligibility of claims to isolated DNA (genes) associated with an increased risk of breast cancer, and synthetic DNA created from RNA known as complementary DNA (cDNA). The Supreme Court held that the isolated genes “fell squarely within the law of nature exception.” While acknowledging that claims to a product “with markedly different characteristics from any found in nature” may be patent eligible, the Court explained that Myriad’s claims to isolated genes lacked such characteristics because they do not rely on any chemical changes resulting from isolation, and are not even expressed in terms of chemical composition. The Court did, however, rule that the claimed cDNAs were patent eligible because they differed from naturally occurring DNA by the absence of intron regions (i.e., non-coding nucleotide sequences).

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Id. at 601.

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Id. at 604.

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Id. at 602.

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Id. at 604.

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Id. at 612.

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Id. at 611–12.

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Id. at 606–07.

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Myriad, 133 S. Ct. at 1294–95.

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Id. at 1294.

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Id.

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Id. at 1305.

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Id. at 1296–98; see Alice, 134 S. Ct. at 2355 (summarizing two-part test in Mayo).
Finally, in Alice, the Court reaffirmed the Mayo two-step framework and applied it to claims reciting a computer-implemented process, system, computer, and computer-readable medium for mitigating settlement risk.\(^{28}\) Under step one of the framework, the Court concluded that the claims were directed to the abstract idea of intermediated settlement.\(^{29}\) In assessing step two, the Court considered whether the claim elements, individually or as an ordered combination, “transform the nature of the claim into a patent-eligible application.”\(^{30}\) The Court referred to the second step as “a search for an inventive concept—i.e., an element or combination of elements that is sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the ineligible concept itself.”\(^{31}\) Looking at the claims at issue, the Court concluded that mere means of a technical process, including the means of a technical process, including the steps of receiving, analyzing, and outputting data, are not patent eligible.\(^{32}\)

On the other hand, the Mayo two-step test has generally raised the bar for patent eligibility in all fields of technology. In the wake of these cases, the Federal Circuit has issued several decisions applying the Supreme Court test to a broad spectrum of subject matter, from the life sciences to computer-related inventions (including business methods).\(^{36}\) Although most of the Federal Circuit decisions have held claims to be patent ineligible, several of the decisions have held claims to be patent eligible.\(^{37}\) In addition, the USPTO has issued and updated guidance documents to aid the public and patent examiners in understanding how these cases apply to the patent examination process. In light of the changing landscape regarding subject matter eligibility in the United States, the USPTO is interested in inviting public discussion on these issues to help refine, if necessary, its guidance and to obtain views on the legal contours of subject matter eligibility.

2. Topics for Public Comment and Discussion At Roundtable 1: USPTO Subject Matter Eligibility Guidelines

The USPTO has issued a series of guidance documents and training materials available at www.gpo.gov/fdsys/pkg/FR-2016-05-06/pdf/2016-71487.pdf. The most recent documents include the May 2016 Life Sciences examples and three memoranda to the Patent Examining Corps: The May 4, 2016 memorandum titled “Formulating a Subject Matter Eligibility Rejection and Evaluating the Applicant’s Response to a Subject Matter Eligibility Rejection”; the May 19, 2016 memorandum titled “Recent Subject Matter Eligibility Decisions (Enfish, LLC v. Microsoft Corp. and TLI Communications LLC v. A.V. Automotive, LLC); and the July 14, 2016 memorandum titled “Recent Subject Matter Eligibility Rulings (Rapid Litigation Management v. CellzDirect and Sequenom v. Ariosa).” The USPTO remains interested in feedback from interested stakeholders or members of the public to improve the USPTO’s subject matter eligibility guidance and training examples, and is already accepting comments on those documents.\(^{39}\) For discussion at Roundtable 1, the Office is particularly seeking views and comments on the following:

1. Suggestions to how to improve the Office’s subject matter eligibility guidance, particularly the three recent memoranda discussed above;
2. Comments on the May 2016 Life Sciences examples and their effect on prosecution of patent applications in the life sciences, and suggestions of additional examples, or technology areas in which examples would be helpful;
3. Suggestions on how best to make examiners aware of newly issued judicial decisions, and how best to incorporate recent decisions holding claims eligible, such as Enfish, Bascom, Rapid Litigation Management, and McRO, into the Office’s subject matter eligibility guidance; and
4. Concerns on how the Office’s subject matter eligibility guidance and training examples, or how court decisions, are being applied by examiners.

3. Topics for Public Comment and Discussion At Roundtable 2: Exploring the Legal Contours of Patent Subject Matter Eligibility

The public is invited to submit comments on any topics related to patent subject matter eligibility under 35 U.S.C. 101 that they deem relevant. This roundtable event is not seeking additional input on the examiner guidance and training examples referenced above. Instead, the USPTO is seeking to promote conversation on how the current section 101 jurisprudence is evolving; what the optimum legal contours for patent eligibility should be; and how best to achieve these goals. Specifically, the USPTO would like to facilitate discussion and create a public record with relevant information on the actual or perceived impact of existing law on particular technology areas, and the effects on investment in research and development, and innovation generally. The USPTO would appreciate comments on whether developments in patent-eligibility law should be left primarily to the courts or whether other administrative initiatives are desirable. In addition, the USPTO would appreciate comments on whether legislative changes are desirable and, if so, views on the elements of such changes.

\(^{28}\) Alice, 134 S. Ct. at 2355, 2352.

\(^{29}\) Id. at 2355–57.

\(^{30}\) Id. at 2355 (quoting Mayo, 132 S. Ct. at 1294).

\(^{31}\) Id. (internal quotation marks omitted).

\(^{32}\) Id. at 2357–60.

\(^{33}\) Id. at 2360.

\(^{34}\) Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions, 1998 O.J. (L 213) 18 (Art. 5(2)) provides “[a]n element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element.”

\(^{35}\) See, e.g., In re Roslin Inst (Edinburgh), 750 F.3d 1333 (Fed. Cir. 2014); Univ. of Utah Research Found. v. Amby Genetics Corp., 774 F.3d 755 (Fed. Cir. 2014); Ariosa Diagnostics, Inc. v. Sequenom, Inc., 798 F.3d 1371 (Fed. Cir. 2015); Genetic Techs., Ltd. v. Merial LLC, 818 F.3d 1369 (Fed. Cir. 2016); Rapid Litigation Mgmt. Ltd. v. CellzDirect, Inc., 827 F.3d 1042 (Fed. Cir. 2016).


\(^{37}\) DDR Holdings, 773 F.3d 1245; Enfish, 822 F.3d 1327; Bascom, 827 F.3d 1341; Rapid Litigation, 827 F.3d 1042; McRO, Inc., 827 F.3d 1042.


To facilitate the launch of this data-gathering exercise, the USPTO is particularly interested in receiving views and comments on questions presented below. However, the tenor of the questions should not be taken as an indication that the USPTO is predisposed to any particular views, positions, or actions. The USPTO also invites the public to share their views and insights on other aspects of patent subject matter eligibility that are not addressed in the questions.

Impact of Judicial Interpretation of Section 101

1. How has the Supreme Court’s interpretation of 35 U.S.C. 101 in the past several years affected the enforcement of patents and the development of subject-matter-eligibility law? In your response please:
   a. Identify the scope of the problem, including specific examples;
   b. Identify any legal and/or technical inaccuracies;
   c. suggest possible changes and/or solutions to any problems with section 101; and
   d. provide explanations and/or any legal, policy, or economic analyses supporting your comments.

Statutory Categories of Patentable Subject Matter

To be eligible for patent protection, an invention must comply with section 101 of the Patent Act, which limits entitlement to a patent to “whoevers invents or discovers any new and useful process, machine, manufacture, or composition of matter.” The four categories of invention enumerated in the statute—process, machine, manufacture, and composition of matter—exhaust the possible types of inventions for which a patent may be obtained.

2. Should the patent statute be amended to further define the statutory categories of invention, i.e., process, machine, manufacture, and composition of matter? If so, please identify possible legislative changes, including which sections of title 35 should be amended, e.g., sections 100 or 101.

Exceptions to Patentable Subject Matter

The Supreme Court has articulated three exceptions to patent eligibility under section 101: Laws of nature, natural phenomena, and abstract ideas.

3. Do you think there should be exceptions to patentable subject matter?
   a. If no, how should section 101 or other patentability provisions operate to address subject matter currently considered to fall within judicial exceptions?
   b. If yes, please explain whether the judicial exceptions are sufficient in scope and if not, please identify other exceptions that should be included in the determination of patent eligible subject matter.

4. Should the patent statute be amended to define the judicial exceptions? If so, please suggest possible legislative changes, including which sections of title 35 should be amended, e.g., sections 100 or 101.

5. If you identified other exceptions in your response to 3(b), please suggest possible legislative changes, including which sections of title 35 should be amended, e.g., sections 100 or 101.

6. Other jurisdictions, e.g., Europe and Japan, provide examples of subject matter that does not qualify as an invention or discovery for purposes of patent eligibility. For example, in Europe, scientific theories, methods for performing mental acts, computer programs per se, and presentations of information are not regarded as inventions.
   a. Do you think that title 35 should be amended to revise the definition for the term “invention” and/or provide a definition for the term “discovery” along with specific examples of subject matter that should not be treated as an invention and/or discovery?
   b. If so, please suggest possible legislative changes, including which sections of title 35 should be amended, e.g., sections 100 or 101.

7. Does the concept of preemption, either separately or in the context of the Mayo two-step framework, capture useful insight in guarding against the issuance of overly broad patents? If so, please suggest possible legislative changes to capture those insights.

Patentable Subject Matter in the Life Sciences

8. What does the term “discovery” in sections 100 and 101 mean, and to what extent should a “discovery” be eligible for a patent? Please provide specific examples.
9. What does the term “invention” in sections 100 and 101 mean, and to what extent should a non-naturally occurring product of human ingenuity qualify as an “invention” to be eligible for a patent? Please provide specific examples.
10. To what extent should products that have been isolated from their natural surroundings as a result of human ingenuity be eligible for a patent? Please provide specific examples as well as scientific explanations and/or legal analyses to support your response.

11. To what extent should a “diagnostic method” be eligible for a patent? Please provide specific examples.
12. Are there lines that can or should be drawn scientifically or legislatively between different types of compositions of matter for purposes of obtaining patent protection (e.g., between human genes and genes of other species)?
13. What particular inventions or specific types of technologies that should be patent eligible are not patent eligible, or are likely to be challenged as patent ineligible, under Mayo/Myriad? Please provide specific examples and explain why you believe claim drafting strategies will not be sufficient to avoid patent eligibility problems.

Process Patents and the Machine or Transformation Test

14. Should patents be available for methods that do not involve a machine or a transformation? If so, please provide specific examples.
15. If you support some form of “machine or transformation test,” please identify the best expression of such a test.
   a. Should incorporation of the use of a general purpose computer be enough to satisfy the “machine” part of the test? If not, what more should be required?
   b. Should a transformation that occurs in the human body as a result of a claimed process be enough to satisfy the “transformation” part of the test? If not, what more should be required?

Patentability of Business Methods

16. To what extent should an invention that involves a business method be eligible for a patent? Please provide specific examples.

Patentability of Software/Computer-Related Inventions

17. To what extent should an invention that involves computer software be eligible for a patent? Please provide specific examples.
18. What mechanisms, other than the judicial exceptions, can be used to prevent issuance of overly broad software or computer-related patents that cover wide swaths of economic activity? Do you think that other provisions of title 35 (enablement, written description, definiteness, novelty, non-obviousness) could be used more effectively to achieve this goal? If not, please explain why.

Roundtable 1: USPTO Subject Matter Eligibility Guidelines

Requests to Speak: Individuals interested in speaking at Roundtable 1 must complete the on-line registration
no later than October 26, 2016, and include their name, contact information (telephone number and email address), the organization(s) the person represents, if any, the topics they wish to address, and the approximate length of the presentation. To ensure a balanced array of views, there is the possibility that not all persons who wish to make a presentation will be able to do so given time constraints; however, the USPTO will do its best to try to accommodate as many persons as possible. Selected speakers will be notified thereafter. However, all members of the public are encouraged to submit written comments by electronic mail message via the Internet addressed to 101Roundtable2@uspto.gov.

The public is invited to speak at Roundtable 1 by appearing, in person, at the USPTO in Alexandria, Virginia or one of the following USPTO Regional Offices: the Midwest Regional Office, 300 River Place Drive, Suite 2900, Detroit, Michigan 48207; The Rocky Mountain Regional Office, 1961 Stout Street, Denver, Colorado 80224; the West Coast Regional Office, 26 S. Fourth Street, San Jose, California 95113; or the Texas Regional Office, 207 South Houston Street, Suite 159, Dallas, Texas 75202. Individuals requesting to speak at one of the aforementioned Regional Offices will be provided with the opportunity to speak at the roundtable and engage with USPTO representatives in Alexandria, Virginia in real time. If requesting to speak at this roundtable, please check the appropriate location when completing the on-line registration.

Public Availability of Transcripts and Public Comments: The transcript of Roundtable 1 and the written comments submitted on the USPTO’s subject matter eligibility guidance and training examples will be made available for public inspection upon request at the Office of the Commissioner for Patents, located at 600 Dulany Street, Madison East Building, Tenth Floor, Alexandria, Virginia and via address: http://www.uspto.gov.

Roundtable 2: Exploring the Legal Contours of Patent Subject Matter Eligibility

Requests to Speak: Individuals interested in speaking at Roundtable 2 must complete the on-line registration no later than November 14, 2016, and include their name, contact information (telephone number and email address), the organization(s) the person represents, if any, the topics they wish to address, and the approximate length of the presentation. To ensure a balanced array of views, there is the possibility that not all persons who wish to make a presentation will be able to do so given time constraints; however, the USPTO will do its best to try to accommodate as many persons as possible. Selected speakers will be notified thereafter. However, all members of the public are encouraged to submit written comments by electronic mail message via the Internet addressed to 101Roundtable2@uspto.gov.

The public is invited to speak at Roundtable 2 by appearing, in person, at Stanford University, Stanford, California or at one of the following USPTO Regional Offices: The Midwest Regional Office, 300 River Place Drive, Suite 2900, Detroit, Michigan 48207; the Rocky Mountain Regional Office, 1961 Stout Street, Denver, Colorado 80224; or the Texas Regional Office, 207 South Houston Street, Suite 159, Dallas, Texas 75202. Individuals requesting to speak at one of the aforementioned Regional Offices will be provided with the opportunity to speak at the roundtable and engage with USPTO representatives in Stanford, California in real time. If requesting to speak at this roundtable, please check the appropriate location when completing the on-line registration.