

December 18, 2014

Practice Group:

*IP Procurement and
Portfolio
Management*

IP Litigation

Patent Office Issues New Examination Guidelines for Subject Matter Eligibility

U.S. IP Procurement and Portfolio Management Alert

By Aaron J. Morrow, Mark G. Knedeisen, Christopher G. Wolfe

Introduction

On December 16, 2014, the United States Patent and Trademark Office (PTO) published new guidelines¹ for determining patent eligibility under 35 U.S.C. § 101.² These guidelines do not have the force of law, but nevertheless establish the specific procedures that the Examiners apply during examination of patent applications. These guidelines are effective immediately, supersede previous guidelines regarding nature-based products, and supplement previous guidelines regarding abstract ideas. Based on Supreme Court decisions, the new guidelines set forth an analytical framework that is designed to “promote[] examination efficiency and consistency across all technologies” and is particularly relevant for patents directed to natural products, software, and business methods.

Background

Under U.S. patent law, only new and useful processes, machines, articles of manufacture, and compositions of matter are eligible for patenting. 35 U.S.C. § 101. However, even if a patent claim falls within one of the listed categories, it is not patent eligible if it is directed to a law of nature, natural phenomenon, or abstract idea. The eligibility requirement is in addition to the well-known requirements that an invention be novel and nonobvious to be patentable. See 35 U.S.C. §§ 102-103.

The Supreme Court has decided several cases recently that help define the scope of these judicially recognized exceptions. In *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. ___, 132 S.Ct. 1289 (2012), the Supreme Court employed a two-part framework (now referred to as the “*Mayo* two-part framework”) to determine whether a patent claim is ineligible for falling into one of the exceptions. The first step is to determine whether the claim is directed to one of the exceptions, *i.e.*, a law of nature, natural phenomenon, or an abstract idea. If not (and the claim falls into one of the statutory patent-eligible categories of § 101), the claim is patent eligible. If the claim is directed to one of the judicially recognized exceptions, the second part of the analysis examines whether the claim recites additional elements that amount to “significantly more” than the judicial exception. Using this framework, the Supreme Court concluded that the claimed method at issue in *Mayo* of assisting doctors who use thiopurine drugs to treat patients with autoimmune diseases was

¹ 2014 Interim Guidance on Patent Subject Matter Eligibility, 79 FR 74618, pp. 74618 -74633 (December 16, 2014) available at <https://www.federalregister.gov/articles/2014/12/16/2014-29414/2014-interim-guidance-on-patent-subject-matter-eligibility>

² 35 U.S.C. § 101 states as follows: “Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.”

Patent Office Issues New Examination Guidelines for Subject Matter Eligibility

patent ineligible because it was directed toward a natural law. One year later, the Supreme Court similarly concluded that a patent claim directed to isolation of a naturally occurring DNA segment was a patent-ineligible product of nature. See *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. ___, 133 S. Ct. 2107 (2013) (the patent also claimed a non-naturally occurring DNA segment, which the Supreme Court found patent eligible).

In the 2014 term, the Supreme Court applied the *Mayo* two-part framework in *Alice Corp. v. CLS Bank*, 573 U.S. ___, 134 S.Ct. 2347 (2014) relating to the abstract idea exception, which is often an issue for software and business method inventions. The patent at issue in *Alice* related to computer systems for mitigating settlement risk for financial transactions. First, the Supreme Court determined that even though the claims at issue were directed to one of the categories in § 101 (*i.e.*, methods and machines), they fell within the abstract idea exception because the concept of intermediate settlement is “a fundamental economic practice long prevalent in our system of commerce.” Second, the Supreme Court determined that the claims did not recite significantly more than applying the abstract idea, even though they recited computer systems for performing the intermediate settlement, because the functions performed by the generically claimed computer were “well-understood, routine, [and] conventional.”

The *Alice* decision followed a 2010 decision, *Bilski v. Kappos*, 561 U.S. 593 (2010), where the Supreme Court found that a claim directed to hedging risk was also a patent-ineligible abstract idea. So far the Supreme Court has not precisely defined what constitutes an abstract idea by choosing “not [to] labor to delimit the precise contours . . .,” *Alice*, 134 S.Ct. at 2357, although it has provided examples, namely “preexisting, fundamental truths that exist in principle apart from any human action” and “fundamental economic practices long prevalent in our system of commerce.” Neither the *Alice* nor *Bilski* decisions recognized a *per se* excluded category of subject matter, such as software or business methods; nor did they impose any special requirements for their eligibility. Since the *Alice* decision, however, many lower courts and the PTO in post-issuance proceedings have found software patent claims invalid.³

Following the *Mayo*, *Myriad*, and *Alice* decisions, the PTO issued earlier guidelines for its Examiners. In March 2014, the PTO issued guidelines for natural products based on *Mayo* and *Myriad*. These guidelines required that the Examiner consider whether the claim recites or involves a nature-based product. If the answer was “yes” or “maybe,” the Examiner was required to subject the claim to further analysis using a factor-based weighing test strongly focused on whether structural differences are present in the claimed nature-based product relative to its naturally occurring form. These guidelines also provided several example claims in an attempt to illustrate how the factor-based weighing test should be applied.

In June 2014, the PTO issued guidelines based on the *Alice* decision. These guidelines cemented that the Examiners are to apply the *Mayo* two-part framework for patent claims that implicate abstract ideas. However, since the Supreme Court did “not labor to delimit the precise contours” of an abstract idea, the guidelines only provided examples from case law

³ See *e.g.*, *buySafe, Inc. v. Google, Inc.*, No. 2013-1575 (Fed. Cir. 2014); *Planet Bingo, LLC v. VKGS LLC*, Case No. 2013-1663 (Fed. Cir. 2014); *Digitech Image Tech., LLC v. Elec. For Imaging, Inc.*, 758 F.3d 1344 (Fed. Cir. 2014); *U.S. Bancorp v. Retirement Capital Access Management Co.*, CBM2013-00014 (PTAB 2014); *SAP America, Inc. v. Lakshmi Arunchalam*, CBM2013-00013 (PTAB 2014); *but see DDR Holdings, LLC v. Hotels.com, LP*, Case No. 2013-1505 (Fed. Cir. 2014) (claims patent eligible).

Patent Office Issues New Examination Guidelines for Subject Matter Eligibility

of abstract ideas and listed generally types of claim limitations from *Alice* that may be enough to qualify as “significantly more” when recited in a claim with an abstract idea to transform the claim’s patent eligibility.

The new December 2014 guidelines supersede the March 2014 guidelines regarding nature-based products and supplement the June 2014 guidelines regarding abstract ideas. Regarding natural products, the new guidelines are significantly less restrictive relative to the previous guidelines. With respect to abstract ideas, the guidelines attempt to provide clarification by citing and summarizing relevant court decisions. Subject matter eligibility is an obstacle to patentability even if the invention is novel and non-obvious, so these new guidelines merit consideration for applicants and practitioners in any technology area.

Natural Products Guidelines

The guidelines regarding natural products include a noteworthy change in how claims are analyzed to determine patent eligibility. The approach established by the previous guidelines required that a factor-balancing test be performed for a claim if the claim “recites or involves” a natural product. In contrast, the new guidelines seemingly retract the broad applicability of this language by replacing “recites or involves” with “directed to.” The new guidelines also present a “streamlined” analysis in which a claim that clearly does not completely foreclose use of the natural product does not need to be subjected to a full analysis of patent eligibility.

In addition, the new guidelines explicitly state that a claim directed to a natural product is first analyzed to determine whether the claimed nature-based product has markedly different characteristics based on structure, function, and/or properties. The claim is further scrutinized to determine if it includes meaningful additional elements only if the nature-based product recited by the claim does not have markedly different characteristics.

This evaluation approach is also less strict than that established by the previous guidelines because functionality is considered in the analysis of “markedly different.” The new guidelines explicitly state:

[t]his revised analysis represents a change from prior guidance, because now changes in functional characteristics and other non-structural properties can evidence markedly different characteristics, whereas in the March 2014 Procedure only structural changes were sufficient to show a marked difference.

The impact of this change is readily seen in an example given in the new guidelines; contrary to the previous guidelines, which prohibited patent eligibility of naturally occurring compounds that were merely recited as “purified” or “isolated” in the claim, the new guidelines state that a purified or isolated naturally occurring product will be patent eligible when there is a resultant change in characteristics that shows it is markedly different from the naturally occurring form.

Another important shift in the analysis of natural products under the new patent eligibility guidelines is related to combinations of natural products. The new guidelines establish that the combination as a whole must be assessed to determine if it is markedly different from a product of nature. Under the old guidelines, evaluation of a combination of natural products was performed by individually comparing each component part to its naturally occurring form, and the presence of other natural products in the combination was not given consideration.

Patent Office Issues New Examination Guidelines for Subject Matter Eligibility

Yet another change presented by the new natural product guidelines is concerned with method claims. The previous patent eligibility framework was more lenient regarding method claims relative to product claims but nevertheless required that a factor-weighting test be applied to method claims reciting or involving a product of nature. In the new guidelines, a method claim directed to a natural product is not even subjected to the initial analysis of whether the claim is markedly different; instead, a process claim is now considered patent eligible unless it is written in such a way that it is not different from a product claim. The new guidelines provide an example of such a claim, “a method of providing an apple,” which shows that a method claim must be completely lacking in additional recitations in order to be ineligible for a patent.

The natural products guidelines also provide several example claims with corresponding application of the new framework. These examples demonstrate that the new guidelines are a scaled-back approach relative to the previous guidelines. For example, the new guidelines discuss a product claim reciting “a beverage composition comprising pomelo juice and an effective amount of an added preservative.” This claim is patent eligible under the new guidelines because the property of slower spoiling, which is contributed by the preservative, is markedly different from properties of the juice by itself in nature. Under the previous guidelines, such a claim was typically considered ineligible because the individual components of the combination were analyzed separately, and some preservatives are natural products. As another example, a method claim reciting “a method of treating breast or colon cancer, comprising administering an effective amount of purified amazonic acid to a patient suffering from breast or colon cancer” is patent eligible under the new guidelines. The claim does not even require an analysis of “markedly different” because the claim is focused on a process of practically applying the product to treat a particular disease. Under the previous guidelines, such a claim was typically rejected as patent ineligible unless it also recited a dosage and/or a time period of administration.

Abstract Ideas

The new guidelines regarding abstract ideas are not significantly different from the June 2014 guidelines but, nonetheless, may lead to practical differences in examination outcomes.

First, the new guidelines tighten the application of the first part of the *Mayo* analysis. The June 2014 guidelines stated that a claim was directed to an abstract idea if the claim included an abstract idea or if an abstract idea was present in the claim. Because most any claim involves an abstract idea at some level, this approach made it very difficult to clear the first step of the *Mayo* analysis, even for claims that are clearly eligible. Under the new guidelines, the PTO adds a preemption factor to the first part of the *Mayo* analysis. Examiners are instructed to consider both whether a claim recites or describes an abstract idea and also whether the claim will “tie up” or preempt the abstract idea. Additionally, the streamlined analysis described above may also be applied to abstract ideas. Claims that may or may not be directed to an abstract idea may be considered eligible if the claim, “when viewed as a whole, clearly does not seek to tie up any [abstract idea] such that others cannot practice it.”

Second, the new guidelines encourage examiners and applicants to apply the *Mayo* analysis by analogy to previously decided Supreme Court and Federal Circuit cases. The new guidelines provide extensive bulleted lists of examples from prior cases for both parts of the *Mayo* framework, including 14 identified abstract ideas (first step of *Mayo*) and claim

Patent Office Issues New Examination Guidelines for Subject Matter Eligibility

elements that are and are not significantly more than an abstract idea or other judicial exceptions (second step of *Mayo*). Further, the new guidelines include an extensive section summarizing Supreme Court and Federal Circuit precedent on subject matter eligibility. Taken as a whole, these factors suggest that the PTO is encouraging applicants and examiners both to argue abstract-idea eligibility issues by analogy to prior case law.

Conclusions and Practice Tips

The new guidelines are very likely to reduce the number of non-statutory subject matter rejections for natural products. The new guidelines also provide a much larger set of examples relative to the prior guidelines, which should provide more certainty in whether a claim reciting a nature-based product is patent eligible or not. In this regard, the examples in the previous guidelines were, for the most part, extreme claims that left doubt with respect to where the line was drawn for eligibility. Therefore, the new guidelines should provide applicants and practitioners with more certainty about whether an invention is patent eligible and how to claim the invention such that the claims are not rejected under 35 U.S.C. § 101 or can easily overcome a rejection under this basis. Applicants and practitioners should reference the many example claims provided by the new natural products guidelines and identify the examples most similar to the invention. This approach can ensure that a newly drafted application contains subject matter that is patent eligible and can allow pending applications to have claim amendments that avoid or overcome patent eligibility rejections.

It is too soon to tell what substantive effect the new guidelines will have on the number of non-statutory subject matter rejections for software and business methods. It does appear that claims that clearly fail to preempt or tie up an abstract idea may be easier to move through the PTO than they were previously. Also, the extensive summaries of example claims and claim elements falling on both sides of the eligibility line give additional form to the eligibility analysis for abstract ideas that did not exist previously. When faced with an abstract idea-type rejection, applicants may consider arguments on lack of preemption and arguments based on analogies to the various examples in the guidelines.

Patent Office Issues New Examination Guidelines for Subject Matter Eligibility

Authors:

Aaron J. Morrow

aaron.morrow@klgates.com

+1.312.781.6043

Mark G. Knedeisen

mark.knedeisen@klgates.com

+1.412.355.6342

Christopher G. Wolfe

christopher.wolfe@klgates.com

+1.412.355.6798

K&L GATES

Anchorage Austin Beijing Berlin Boston Brisbane Brussels Charleston Charlotte Chicago Dallas Doha Dubai Fort Worth Frankfurt
Harrisburg Hong Kong Houston London Los Angeles Melbourne Miami Milan Moscow Newark New York Orange County Palo Alto Paris
Perth Pittsburgh Portland Raleigh Research Triangle Park San Francisco São Paulo Seattle Seoul Shanghai Singapore Spokane
Sydney Taipei Tokyo Warsaw Washington, D.C. Wilmington

K&L Gates comprises more than 2,000 lawyers globally who practice in fully integrated offices located on five continents. The firm represents leading multinational corporations, growth and middle-market companies, capital markets participants and entrepreneurs in every major industry group as well as public sector entities, educational institutions, philanthropic organizations and individuals. For more information about K&L Gates or its locations, practices and registrations, visit www.klgates.com.

This publication is for informational purposes and does not contain or convey legal advice. The information herein should not be used or relied upon in regard to any particular facts or circumstances without first consulting a lawyer.

© 2014 K&L Gates LLP. All Rights Reserved.