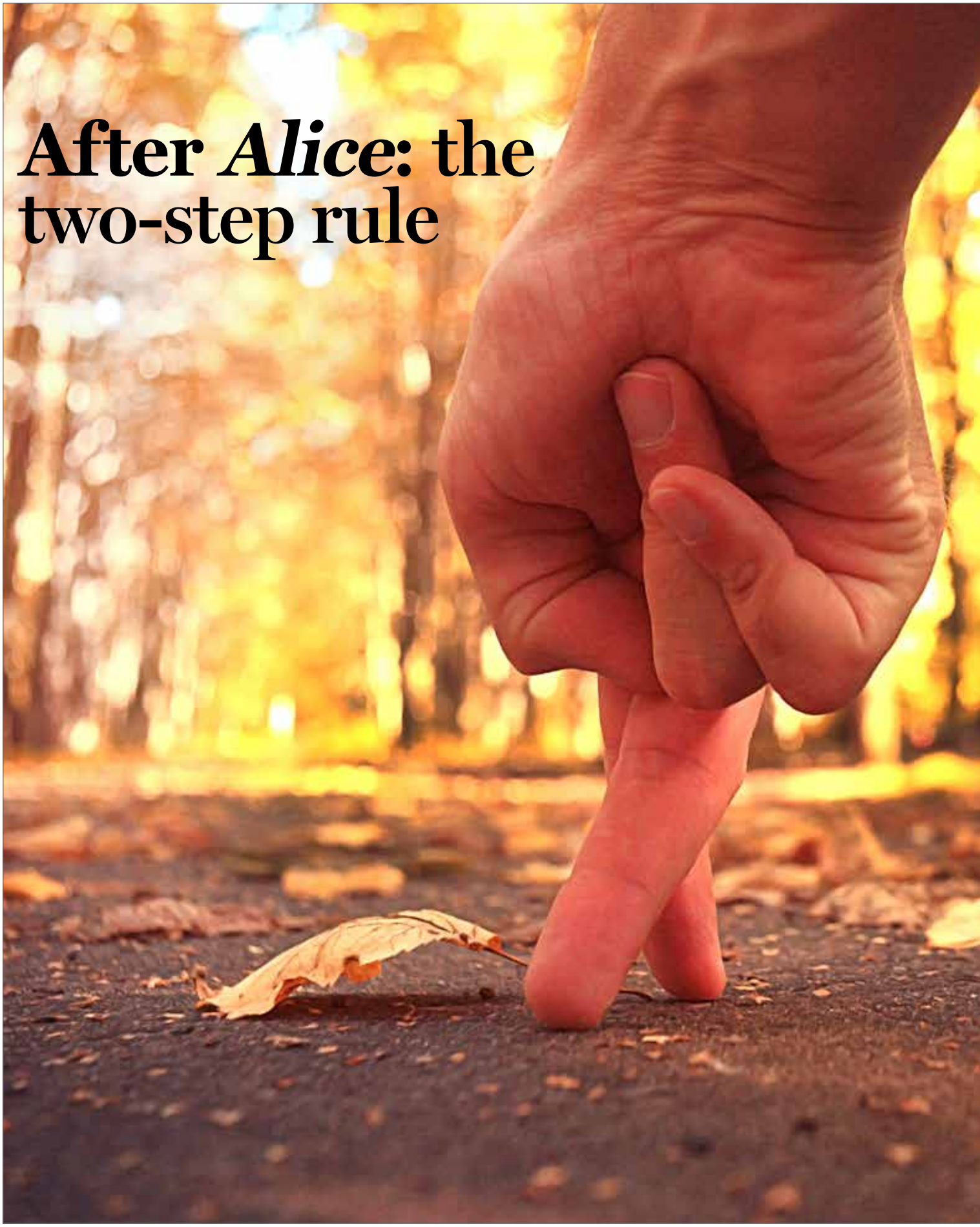
After *Alice*: the two-step rule



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Existing portfolios should be carefully reviewed and care must be taken in drafting new patent applications to withstand section 101 scrutiny in the US, as **Judith Kim**, director, and **Scott Schaller**, of counsel, at Sterne Kessler Goldstein & Fox, describe.

Patent-eligible subject matter in the US includes four statutory categories defined in title 35, section 101 (§101) of the US code as "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof".

Laws of nature, natural phenomena, and abstract ideas have been held by the US Supreme Court to be implicit exceptions to patent-eligible subject matter under §101, with the exceptions rationalised as a means to prevent the monopolisation of the basic scientific and technological tools required for future innovation. These judicial exceptions arguably did not play a large role in US prosecution or enforcement of biotechnology and pharmaceutical patents until recent years.

Instead, innumerable patents were issued with claims directed to, for example, isolated genes, isolated biological products, and diagnostic tests, in the decades before the Supreme Court's holdings in *Mayo Collaborative v Prometheus Labs (Mayo)* and *Association for Molecular Pathology v Myriad (Myriad)*.

But the holdings in those cases, subsequent decisions by the US Court of Appeals for the Federal Circuit and non-binding examination guidelines from the US Patent and Trademark Office (USPTO) have altered expectations regarding patent-eligible subject matter and have introduced a need to reassess both mature and developing patent portfolios.

In *Mayo*, the methods at issue recited "administering" a drug to a subject, "determining" the level of a metabolite, and "wherein" clauses that correlated specific levels of the metabolite with a need to increase or decrease the drug amount. The Supreme Court unanimously held that the methods were patent-ineligible and invalid.

The court found that the claimed correlation depended only on the natural process of drug metabolism and was therefore a law of nature exempt from patent eligibility. Based on the facts of the case, the court found that the remaining steps, when taken alone or in combination, added nothing significant to the natural law.

The court stated that a process reciting a law of nature is patentable only if it recites "additional features that provide practical assurance that the process is more than a drafting effort to monopolise the law of nature itself".

In *Myriad*, the court unanimously held that a naturally-occurring DNA segment is a patent-ineligible product of nature, and does not become patent-eligible based simply on isolation from the genome. The court reasoned that the claimed "isolated" DNAs fell within the law of nature exception because they were directed to the same genetic information as the natural sequences and did not rely on any chemical changes that result from isolation.

In contrast, the court unanimously held that complementary DNAs (cDNAs) that have been synthetically modified to omit non-coding sequences found in nature are sufficiently different from natural sequences for patent eligibility.

The Supreme Court most recently discussed the analysis for determining patent eligibility under §101 in *Alice Corp v CLS Bank*. The *Alice* ruling spelled out Mayo's determination of patent eligibility as a two-part test: (1) determine whether the claims are directed to a patent-ineligible concept; and (2) determine whether the claim's elements, considered both individually and as an ordered combination, transform the nature of the claims into a patent-eligible application.

Discussing *Mayo*, the court noted that a claim that simply recites conventional steps at a high level of generality does not


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supply the necessary inventive concept for transforming the claim into patent-eligible subject matter under the second step.

In *In re Roslin Institute (Edinburgh)*, decided before *Alice*, the Federal Circuit held that the cloned animals at issue were not patent-eligible subject matter because nothing in the claims or specification suggested a relevant difference between the clones and the naturally occurring donor animals.

In *University of Utah Research v Ambry Genetics Corporation*, the Federal Circuit held that the DNA primers and diagnostic methods at issue were not patent-eligible subject matter. The court reasoned that the primers, even if synthetic, could not be distinguished from the patent-ineligible isolated DNA of *Myriad* and that a primer's function of binding to cDNA is not fundamentally different from DNA's natural properties.

The method claims recited a step of "comparing" the sequence of a subject's gene with a corresponding wild-type sequence to identify any alterations, along with techniques for comparing the sequences.

Applying the first step of the test, cleared up in the *Alice* ruling, the court found that the methods were directed to patent-ineligible abstract ideas by claiming the mental processes of "comparing" sequences and determining alterations.

Under the second step of the test, the court found that the remainder of each claim's elements, considered alone or in combination, only required comparisons by well-understood, routine, and conventional techniques. While discussed in terms of the first step of the analysis, the court noted that the claims lacked any limitation on the number or purpose of the comparisons that would prevent the building blocks of scientific research from being improperly monopolised.

Put simply, the patent-ineligible composition claims in the cases were found to lack any relevant limitations that would distinguish them from natural counterparts. And the patent-ineligible method claims in the cases were all found to be directed to natural laws/phenomena or abstract ideas without any unconventional limitations that would avoid an improper monopoly over them. From now on, the two-step test outlined in the *Alice* ruling controls determination of patent eligibility.

USPTO guidance

The USPTO continues to hone its guidance on subject matter eligibility based on case law, and issued the 2014 interim guidance on patent subject matter eligibility. While the guidance is not legally binding, the USPTO examiners use it as their guide for examination of patent applications.

In line with *Alice*, the guidance sets out a two-step process for determining subject matter eligibility for claims directed to laws of nature, natural phenomena, and abstract ideas. Step one says the claimed invention "must be directed to one of the four statutory categories".

Step two says it "must not be wholly directed to subject matter encompassing a judicially recognised exception". Step two itself is a two-part analysis from *Alice* (also called the '*Mayo* test').

The first component of step two requires the identification of the judicial exception in the claim. Examples of laws of nature and natural phenomena include:

- An isolated DNA *(Myriad)*;
- A correlation that is the consequence of how a certain compound is metabolised by the body *(Mayo)*;
- Electromagnetism to transmit signals; and
- The chemical principle underlying the union between fatty elements and water (see *Tilghman v Proctor*).

Abstract ideas include fundamental economic practices, certain methods of organising human activities, an idea 'of itself', and mathematical relationships/formulas.

To determine whether a claim that includes a nature-based product limitation recites a "product of nature" exception, the "markedly different" characteristics analysis is used. Examples of marked difference include: biological or pharmacological functions or activities; chemical and physical properties; phenotype; and structure and form, whether chemical, genetic or physical.

If a claim includes a nature-based product that has markedly different characteristics, the claim does not recite a "product of nature" exception and is patent-eligible unless the claim recites another exception. If the claim includes a product that has no markedly different characteristics from the product's naturally occurring counterpart, the claim is directed to an exception and must proceed to the second part of step two.

In this second component of step two, a claim directed to a judicial exception is analysed to determine whether the elements of the claim, considered individually and as an ordered combination, are sufficient to ensure that the claim as a whole amounts to significantly more than the exception itself—a search for an "inventive concept".

The claim must include additional features to ensure that it describes a process or product that applies the exception in a meaningful way, such that it is more than a drafting effort designed to monopolise the exception. Examples qualifying as "significantly more" include:

- Improvements to another technology or technical field;
- Improvements to the functioning of a computer itself;
- Applying the judicial exception with, or by use of, a particular machine;

- Effecting a transformation or reduction of a particular article to a different state or thing;
- Adding a specific limitation other than what is well-understood, or routine in the field; and
- Adding unconventional steps that confine the claim to a particular useful application.

Examples that did not qualify as "significantly more" include:

- Adding the words "apply it" with the judicial exception or mere instructions to implement an abstract idea on a computer;
- Simply appending well-understood routine and conventional activities previously known to the industry;
- Adding insignificant extra solution activity to the judicial exception; and
- Generally linking the use of the judicial exception to a particular technological environment or field of use.

According to the USPTO's guidance, for a claim reciting a plurality of exceptions, if the claim fails under the second part of step two for one exception, the claim is ineligible. However, a claim, when viewed as a whole, which clearly does not seek to tie up any judicial exception such that others cannot practise it, does not need to proceed through the full analysis as its eligibility will be self-evident.

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The guidance provides six sample analyses based on Supreme Court decisions, and ends with a summary of court decisions.

The case law and guidance put a heavy burden on applicants to show subject matter patent eligibility, yet significantly narrow the scope of allowable claims. This burden will increase the costs and time required for drafting and prosecuting patent applications.

Existing portfolios should be carefully reviewed to determine whether US claims meet patent eligibility requirements and, if not, whether support exists for adding a limitation to avoid judicial exceptions. Care must be taken in drafting new patent applications to withstand §101 scrutiny in the US, while not unnecessarily limiting the applications for prosecution outside the US, where standards are different.

More back-up claims and support in the specification will be needed to further withstand the post-America Invents Act age of post-grant review, in which claims can be attacked based on §101. ■

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