

# FULL DISCLOSURE

## Patent Prosecution Update

June 2014

### An Update on Subject Matter Eligibility in the United States

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In covered business method post-grant proceeding *Liberty Mutual Insurance Co. v. Progressive Casualty Insurance Co.*, the Patent Trial and Appeal Board (PTAB) of the U.S. Patent and Trademark Office (USPTO) held all of the challenged claims of U.S. Patent No. 6,064,970 ("the '970 patent") unpatentable as obvious under 35 U.S.C. § 103(a).

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## An Update on Subject Matter Eligibility in the United States

by Elizabeth A. Doherty, Ph.D.

The past three months have been a busy period for those following the U.S. patent eligibility law. Recent examination guidance published by the U.S. Patent and Trademark Office (USPTO) may affect patent applications with composition or method claims in a variety of chemical, materials science, and biological arts. The Federal Circuit's recent decision in *In re Roslin Institute* (Edinburgh), No. 2013-1407 (Fed. Cir. May 8, 2014), also provides information about how the U.S. courts may consider patent eligibility of composition claims in the wake of recent U.S. Supreme Court case law. We provide an update of recent events to help practitioners keep an eye on this unsettled area of law. A more detailed article on the USPTO *Guidance* is also included in this edition of *Full Disclosure*.

As readers of *Full Disclosure* may recall, in 2012 and 2013 the U.S. Supreme Court issued two key decisions concerning patent eligibility. In *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 566 U.S. \_\_\_, 132 S. Ct. 1289 (2012), the Court held that a correlation between the concentration of a biomarker in a patient and the efficacy of a drug treatment was a law of nature. The Court concluded that, while an application of such a law of nature may be patent eligible, the claim-at-issue was, in effect, drawn to the correlation itself and was not patent eligible. *Id.* In *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. \_\_\_, 133 S. Ct. 2107 (2013), the Court addressed the patent eligibility of composition claims drawn to certain isolated genomic DNA and cDNA segments. The Court held that the claims drawn to isolated genomic DNAs were not patent eligible because the claimed sequences were the same as the naturally occurring gene sequences. *Id.* But the Court found the claims drawn to cDNAs patent eligible because the claimed cDNA sequences differed from the naturally occurring gene sequences due to the removal of introns. *Id.*

On March 4, 2014, the USPTO published new guidance for examination of the subject matter eligibility of product and process claims in view of the *Mayo* and *Myriad* cases. The document is entitled *Guidance For Determining Subject Matter Eligibility Of Claims Reciting Or Involving Laws of Nature, Natural Phenomena, & Natural Products* ("Guidance"), and is available at [http://www.uspto.gov/patents/law/exam/myriad-mayo\\_guidance.pdf](http://www.uspto.gov/patents/law/exam/myriad-mayo_guidance.pdf). The March 2014 *Guidance* is for use in subject matter eligibility determinations of all claims reciting or involving laws of nature, natural principles, natural phenomena, and/or natural products, which the *Guidance* collectively terms "judicial exceptions" to patentability. *Guidance* at 1-2. The USPTO also noted that earlier guidance concerning claims reciting abstract ideas remains unchanged by the March 4 *Guidance*. *Id.* at 1.

In particular, while the *Myriad* decision concerned certain isolated DNA segments, the USPTO noted that its *Guidance* applies to claims that recite or involve a variety of natural products. *Id.* at 3. Examples may include "chemicals derived from natural sources (e.g., antibiotics, fats, oils, petroleum derivatives, resins, toxins, etc.); foods (e.g., fruits, grains, meats and vegetables); metals and metallic compounds that exist in nature; minerals; natural materials (e.g., rocks, sands, soils); nucleic acids; organisms (e.g., bacteria, plants and multicellular animals); proteins and peptides; and other substances found in or derived from nature." *Id.*

According to the *Guidance*, if a claim involves, or may involve, a so-called "judicial exception" to patentability, such as a law of nature, a natural phenomenon, or a natural product, the claim is patent

eligible if “the claim as a whole is significantly different than the judicial exception(s).” *Id.* The *Guidance* provides a multifactor analytical framework designed to assist examiners in answering whether the claim recites something “significantly different” than a judicial exception. *Id.* at 3-5. If the claim is drawn to a product or composition, the factors assess whether there are sufficient structural differences between the claimed product and a natural product to render the claimed product “markedly different” from the natural product. In the case of method claims, the factors are aimed at, for example, determining whether the claim elements or steps impose limits on claim scope, provide specific instructions on how to apply or use the judicial exception(s), or add features that are more than well understood, conventional, or routine in the relevant field of study. *Id.* The *Guidance* then notes that “if the totality of the relevant factors weigh[s] toward eligibility, the claim qualifies as eligible subject matter,” but “[i]f the totality of the relevant factors weighs against eligibility, [then] the claim should be rejected.” *Id.* at 4.

The *Guidance* provides a handful of examples to illustrate the analysis, one of which includes a hypothetical claim to a “[p]urified amazonic acid,” a chemical isolated from the leaves of a tree found in the Amazon rainforest and known to have therapeutic effects for treating breast cancer. *Id.* at 7, Example B, claim 1. That claim is concluded to be ineligible for patenting because the amazonic acid is structurally identical to the amazonic acid found in leaves and the claim does not provide other distinguishing features. *Id.* In contrast, a hypothetical claim to a “[p]urified 5-methyl amazonic acid,” a derivative created in the laboratory with additional therapeutic functions, is considered patent eligible, because the claimed compound is “markedly different [in structure]” from what exists in nature. *Id.* at 7-8, Example B, claim 2.

If the claim to the purified amazonic acid is considered ineligible for patenting, what about methods of using that compound? The USPTO considers a hypothetical claim to “[a] method of treating colon cancer, comprising: administering a daily dose of purified amazonic acid to a patient suffering from colon cancer for a period of time from 10 days to 20 days . . . [at a daily dose of] about 0.75 to about 1.25 teaspoons of amazonic acid” to be patent eligible, because the claim as a whole recites something “significantly different” than the natural product by adding specific limitations as to the patient population (colon cancer, not breast cancer), administration schedule, treatment duration, and dosage. *Id.* at 7-9, Example B, claim 3. The *Guidance* does not consider a simpler method claim drawn to amazonic acid in colon cancer that omits the treatment schedule and/or dosage range limitations, however. Indeed, the example claims of the *Guidance* as a whole tend to be either relatively broad or relatively narrow in scope, which leaves uncertainty about how the USPTO will evaluate claims with a scope in between these extremes.

Two weeks after publication of the *Guidance*, on March 19, 2014, the USPTO published a set of slides used in its examiner training program on patent eligibility, entitled *Evaluating Subject Matter Eligibility Under 35 USC § 101: March 2014 Update*. The slides are available at [http://www.uspto.gov/patents/law/exam/myriad-mayo\\_slides\\_20140319.pdf](http://www.uspto.gov/patents/law/exam/myriad-mayo_slides_20140319.pdf). Practitioners should review the slides as well as the *Guidance* because the slides provide additional instructions to examiners beyond what is included in the *Guidance*, as well as additional claim examples. On April 16, 2014, the USPTO held a public presentation with a further slide presentation intended in part to clarify some of the thinking behind a few of the example claims in the *Guidance*. This presentation may be downloaded at [http://www.uspto.gov/patents/announce/myriad-mayo\\_bcp\\_20140416.pdf](http://www.uspto.gov/patents/announce/myriad-mayo_bcp_20140416.pdf).

Then, on May 9, 2014, the USPTO held a public forum at which several organizations and individual practitioners provided their views of the USPTO’s *Guidance*. Presentations from that meeting may be downloaded at <http://www.uspto.gov/patents/announce/myriad-mayo.jsp>. The USPTO is also currently accepting comments from the public on the *Guidance*. Comments may be submitted until June 30, 2014, on-line at the above web address. Whether public comments will influence the USPTO to change any aspects of the *Guidance* and, if so, how, remains unclear at present.

It is important to note that the USPTO *Guidance* reflects the USPTO’s analysis of the Supreme Court case precedent, and is not binding on U.S. courts. It remains to be seen whether courts will agree with the USPTO’s position. Only when the U.S. courts hear further cases concerning patent eligibility, including cases stemming from appeals of USPTO claim rejections, will it become clear whether the

U.S. courts agree with the USPTO's interpretation of *Mayo* and *Myriad*. This could take several years. In the meantime, however, patent applicants in the chemical and biopharmaceutical industries have to grapple with the new examination strategy of the USPTO. Thus, applicants should consider adapting claim drafting and disclosure strategies for new U.S. patent applications to meet the requirements for patent eligibility outlined in the new USPTO *Guidance*. In addition, applicants may also review relevant claims in pending U.S. patent applications and take appropriate action to amend claims as necessary.

While it may take some time for courts to substantially weigh in on the patent eligibility debate, on May 8, 2014, one day before one of the USPTO's public forums on the *Guidance*, the Federal Circuit issued a decision regarding the patent eligibility of the Roslin Institute's claims drawn to certain cloned mammals. *In re Roslin Institute*, No. 2013-1407 (Fed. Cir. May 8, 2014). The Roslin Institute is the creator of Dolly the Sheep—the first mammal ever cloned from an adult somatic cell. *Id.*, slip op. at 2. The Roslin Institute's claims recited, inter alia, a "live-born clone of a pre-existing, non-embryonic, donor mammal, wherein the mammal is selected from cattle, sheep, pigs, and goats." *Id.* at 3 (citation omitted). The court considered the claimed clones to be "exact genetic copies of patent ineligible subject matter" and "[a]ccordingly . . . not eligible for patent protection." *Id.* at 8. The court further noted that, while the Roslin Institute argued that there were environmental factors leading to phenotypic differences between its clones and their donor mammals, and that there were also differences in the mitochondrial DNA of the cloned mammals, those differences were not expressed in the claims. *Id.* at 9-10. According to the court, "[The Roslin Institute's] claims do not describe clones that have markedly different characteristics from the donor animals of which they are copies." *Id.* at 11. In view of this decision, as well as the USPTO *Guidance*, when drafting composition claims, patent applicants should consider ensuring that their specifications include a basis to add limitations to the claims that illustrate structural differences between the claimed subject matter and any natural products from which the claimed subject matter is derived.

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## PTAB Holds Challenged Claims Unpatentable as Obvious over a Combination of References

by Theresa M. Weisenberger

In covered business method post-grant proceeding *Liberty Mutual Insurance Co. v. Progressive Casualty Insurance Co.*, the Patent Trial and Appeal Board (PTAB) of the U.S. Patent and Trademark Office (USPTO) held all of the challenged claims of U.S. Patent No. 6,064,970 (“the ‘970 patent”) unpatentable as obvious under 35 U.S.C. § 103(a). CBM2012-00002, Paper 66 (Jan. 23, 2014). The PTAB found that the Challenger met its burden of proving, by a preponderance of the evidence, each of the three grounds of invalidity on which the PTAB instituted the review. Because this is the first decision in which the PTAB held claims invalid based on a combination of references, the PTAB’s analysis in its Final Written Decision might impact further obviousness challenges in other post-grant proceedings at the USPTO. However, as this was only a decision of one panel, how much of an impact this decision will have on other panels is yet to be determined.

Claim 4 of the ‘970 patent, which is illustrative of the other challenged claims, covers “[a] method of insuring a vehicle operator for a selected period based upon operator driving characteristics during the period.” The claimed methods comprise two main components. First, a base insurance premium is calculated based on an initial collection of information associated with an operator that is related to motor vehicle characteristics or driving characteristics. Second, this base insurance premium is adjusted according to information collected by monitoring the vehicle operator’s driving characteristics.

Based primarily on the disclosure of the ‘970 patent itself, the PTAB found that the “level of ordinary skill in the art is high.” *Id.* at 16. The challenged claims require actuarial knowledge that underlies calculating risk to value insurance premiums as well as some level of expertise in telematics. The PTAB found that the background section of the ‘970 patent reflected the level of ordinary skill. First, the level of ordinary skill includes a thorough understanding of using the principle of actuarial classes to determine vehicle insurance costs. Further, the background section disclosed that vehicle tracking systems were known in the art and that these systems could be modified to obtain the desired types of information relevant to determine the cost of insurance. This disclosure of the ‘970 patent was corroborated with evidence that companies during the time of the alleged invention were already developing vehicle telematics systems that monitored exactly the type of data relevant for adjusting insurance premiums. Thus, the PTAB concluded that the level of ordinary skill included “knowledge of determining insurance premiums using monitored vehicle data.” *Id.* at 18. In addition, the PTAB held that one of ordinary skill would possess knowledge of the “basic principles, standards, and practices of insurance premium determination,” as such knowledge was likewise disclosed in the background of the ‘970 patent. *Id.* at 18-19.

The framing of the level of ordinary skill to span two separate fields of study—insurance pricing and telematics—strengthened the Challenger’s obviousness arguments. For example, the PTAB agreed that a person of ordinary skill would have found it obvious to combine a reference directed to insurance pricing (*Florida Guide*), with a reference discussing vehicle telematics equipment (*Kosaka*), even if the latter reference only made a passing reference to insurance. Furthermore, the PTAB reiterated throughout the Final Written Decision that “prior art references must be ‘considered together with the knowledge of one of ordinary skill in the pertinent art.’” *Id.* at 19 (quoting *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994)). Although the Patent Owner read the prior art references much more narrowly

than the Challenger, the PTAB explained that “it is proper to take into account not only specific teachings of the reference but also the inferences which one skilled in the art would reasonably be expected to draw therefrom.” CBM2012-00002, Paper 66 at 19-20 (quoting *In re Preda*, 401 F.2d 825, 826 (C.C.P.A. 1968)). In other words, an obviousness analysis does not require precise teachings, since inferences and creative steps a person of ordinary skill in the art would employ factor into the analysis as well. See *id.* at 20.

The PTAB considered such inferences and creative steps when evaluating how a person of ordinary skill would understand the *Black Magic* reference, which concerned the use of so-called “black box” data recorders in vehicles. The Challenger relied upon *Black Magic* to disclose “a time and location of vehicle operation and a corresponding log of vehicle speed for the time and location,” as recited by the claims. *Id.* at 41. The Patent Owner argued that the phrase “time and distance travelled” teaches only recording the distance and duration of a trip, not the time of day during which data are recorded. *Id.* at 41-42. The PTAB dismissed the Patent Owner’s argument as too literal, focusing on “whether there should be a comma between the words ‘time’ and ‘and.’” *Id.* at 42. The proper inquiry requires considering *Black Magic*, as a whole, “from the perspective of one of ordinary skill in the art.” *Id.* This perspective includes “basic knowledge of the functionality of black box data recorders and GPS satellite technology,” including correlating data points such as speed with absolute time and location. *Id.* at 43. Such functionality, the PTAB found, is consistent with the purpose of black box recorders. *Id.* Thus, the PTAB found the Patent Owner’s reading of *Black Magic* overly narrow.

The PTAB’s decision provides insight for future parties to post-grant proceedings addressing obviousness challenges. First, tying the level of ordinary skill to the background of the challenged patent will strengthen the challenger’s position, especially for patents with more detailed backgrounds. Second, arguments that may successfully convince the PTAB that the prior art does not disclose a claimed element in an anticipation argument may not be as successful when addressing obviousness grounds. It is not enough to rely on the explicit disclosures of the references without the context of the general knowledge of one of ordinary skill in the art. Finally, post-grant challenge petitioners should consider challenging claims on obviousness bases even when the ground is predicated on a single reference, as the inferences and creative steps of a person of ordinary skill can supplement less-detailed disclosures.

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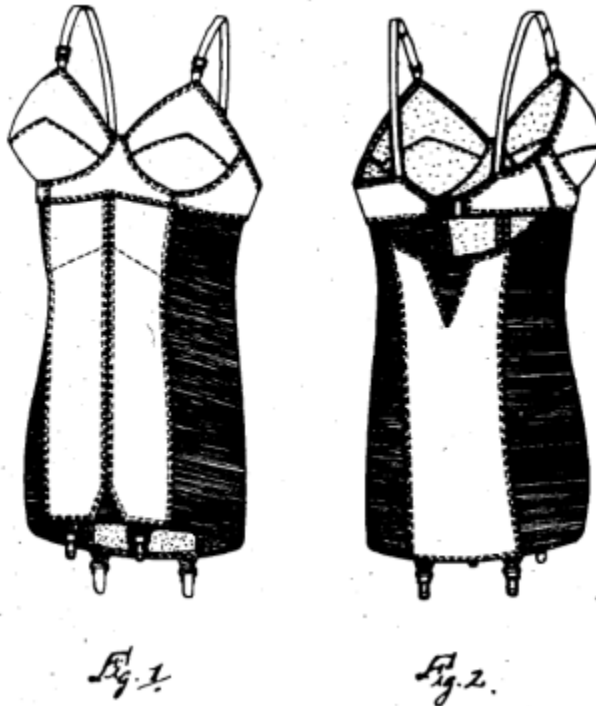
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## Design Patents

### *Inconsistent Girdles Present Major Hurdles: Poor-Quality Drawings Lead to Invalid Design Patents*

by Elizabeth D. Ferrill

Welcome to Full Disclosure's inaugural column on design patents (or industrial design rights, as they are known in many parts of the world). In this new addition to the newsletter, we hope to highlight recent design patent decisions as well as items of interest to design patent practitioners and to provide practical tips to those involved in developing innovative industrial design as well as those who seek to protect them with intellectual property rights.



U.S. Design Patent No. 141,993  
issued Aug. 7, 1945

You can probably tell this article is about girdles. And we will get there. But first, we need to back up a bit. One of the hardest things for applicants to appreciate is the paramount importance of quality drawings for a U.S. design patent application. Using drawings not specifically created with U.S. design patent filing requirements in mind—perhaps those filed with another intellectual property office—often fail to comply with U.S. practice.

The United States has an *examination* system for design rights, as opposed to a *registration* system like many other parts of the world. A U.S. Patent and Trademark Office (USPTO) design patent examiner focuses primarily on the drawings, which are therefore the root of many rejections.

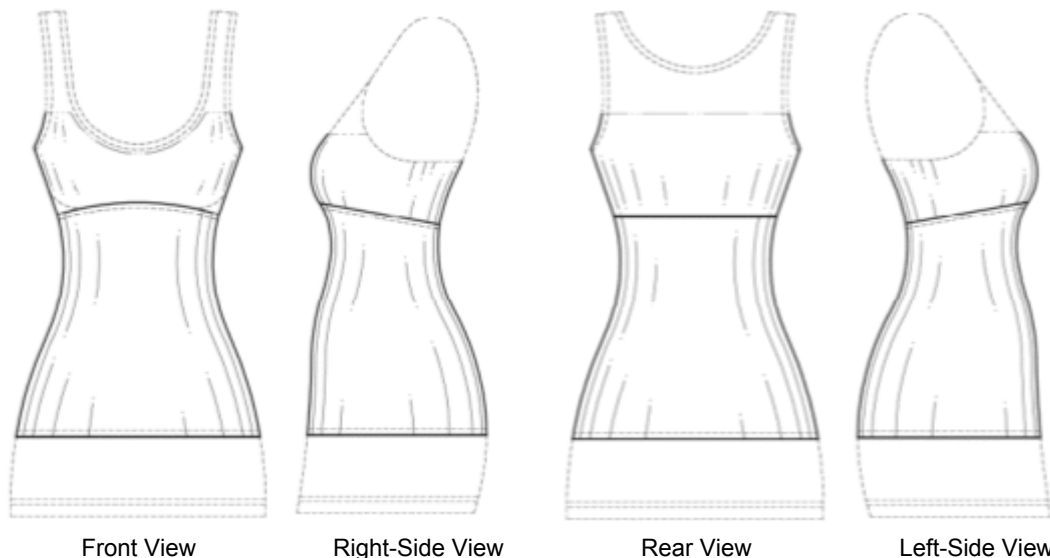
The USPTO Manual of Patent Examining Procedure (MPEP) states that the “necessity for good drawings in a design patent application cannot be overemphasized.”<sup>1</sup> Well-executed drawings will show the design

clearly and completely so that, as the USPTO puts it, “nothing regarding the design sought to be patented is left to conjecture.”<sup>2</sup>

As a result, the United States has strict requirements for design patent drawings. The drawings must be clear and typically have surface shading to show any three-dimensional contours of the design. Technically, while photographs are permitted, the USPTO regulations express a preference for line drawings. In practice, examiners often require photographs to be redrawn as line drawings because of the USPTO’s limited ability to reproduce photographs in high quality in the final patents. Also, the USPTO encourages applicants to file as many drawing views as necessary to “sufficiently” show the design. A design, for example, claiming many concave elements on different sides may need additional views to adequately disclose the shape of these elements—in other words, the more high-quality drawings, the merrier.

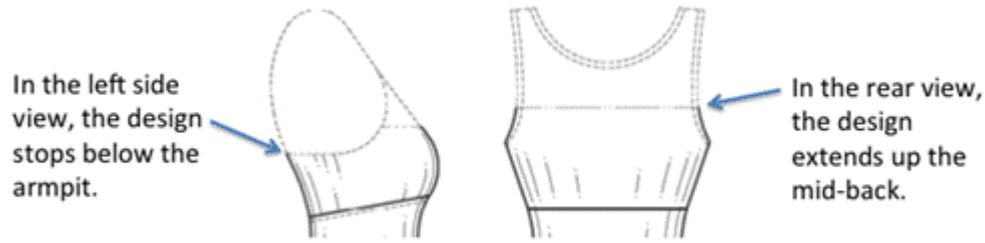
In some cases, poor-quality drawings will prolong prosecution while the applicant corrects the drawings, making it much more expensive to get the patent issued. In the worst-case scenario, deficient drawings may sink the application entirely for failure to comply with the definiteness (clarity) requirements of 35 U.S.C. § 112. This happens when the examiner requires corrections to the drawings that may not be possible without adding “new matter”—meaning details not present in the original drawings. In that case, the applicant would need to file a new application, losing the original filing date.

This brings us back to the case of the inconsistent girdle drawings, recently decided in New York City—*Times Three Clothier, LLC v. Spanx, Inc.*<sup>3</sup> Plaintiff Times Three Clothier, whose product goes by the name Yummie Tummie®, filed suit against defendant Spanx, makers of a celebrity-beloved line of shapewear. Times Three Clothier alleged infringement of its three design patents directed to “garments”—essentially modern-day girdles. Spanx fired back that the design patents were invalid as indefinite (lacking clarity). For two of the design patents, the court agreed with Spanx and invalidated the patents. As shown below, the court found U.S. Design Patent No. 666,384 (“the ‘384 patent”) to “suffer[] from a fatal inconsistency”<sup>4</sup>:



Can’t see it? It is important to know that “solid” lines are part of the claimed design and “broken” (or dashed) lines are not. With that in mind, look more closely at the bust line of the left-side view as compared to the rear view:





The claimed portion of the rear view extends higher up the wearer’s back than the claimed portion of the side view. In short, the drawings are inconsistent. The court determined that it could not resolve this problem in favor of the patent owner because doing so “would materially alter the ‘subject matter covered by the exclusive rights of the patent.’”<sup>5</sup> Its hands tied, the court declared the ’384 patent “insolubly ambiguous,” and thus invalid.<sup>6</sup>

This case is unusual—but only because this patent emerged from the USPTO allowing a court to render this decision. A recent study showed that, of rejections to pending design patent applications, the USPTO rejected 91.53% of the applications because the drawings lacked clarity or definiteness.<sup>7</sup> This strongly suggests that the USPTO is catching most of these drawing issues before the design patents issue.

The best advice for applicants is to follow the USPTO’s suggestion and hire a professional draftsman that specializes in preparing design patent drawings.<sup>8</sup> Provide this draftsman with high-quality photographs of a product embodying the design or with CAD files of the product. If feasible, send that draftsman a sample article. While your drawing fees will be higher, you will likely save money in the long run by reducing or even eliminating much of the back-and-forth with the USPTO on the road to getting your design patent.

If you file first in another country, especially one with only a registration system, then it may seem unnecessary to spend the extra money to get high-quality drawings. But if you think you might file in the United States and wish to claim priority to the earlier filing, then it still makes sense to retain a professional draftsman. With proper planning, you may be able to largely reuse the same set of figures with only minor alterations throughout the world.

One other important note is that, while the USPTO encourages as many figures as needed, many parts of the world take the opposite view. For instance, the European Union (Office for Harmonization in the Internal Market) limits the number of drawings for each embodiment to only seven figures. And South Korea has a limit on how many perspective views can be included in a single application. This can make filing an application in the United States that was first filed elsewhere challenging in some circumstances. You should consult competent counsel to help you navigate all of these issues.

<sup>1</sup> MPEP ¶ 15.48 (9th ed. Mar. 2014).

<sup>2</sup> *Id.*

<sup>3</sup> No. 13-cv-02157, Dkt. 58 (S.D.N.Y. Apr. 29, 2014).

<sup>4</sup> *Id.*, slip op. at 21.

<sup>5</sup> *Id.* at 22 (quoting *Ancor Techs., Inc. v. Apple, Inc.*, 744 F.3d 732, 737 (Fed. Cir. 2014)).

<sup>6</sup> The district court would presumably make the same decision after the U.S. Supreme Court’s recent holding in *Nautilus, Inc. v. Biosig Instruments, Inc.*, No. 13-369 (U.S. June 2, 2014) [[click here](#)]. In this case, the Supreme Court overturned the “insolubly ambiguous” test in favor of a test asking, in light of the specification and the prosecution history, whether the claim “fail[s] to inform, with reasonable certainty, those skilled in the art about the scope of the invention.” *Id.*, slip op. at 1.

<sup>7</sup> Jason J. Du Mont and Mark D. Janis, *Virtual Designs*, 17 *Stan. Tech. L. Rev.* 50 (2014).

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## Rule Review

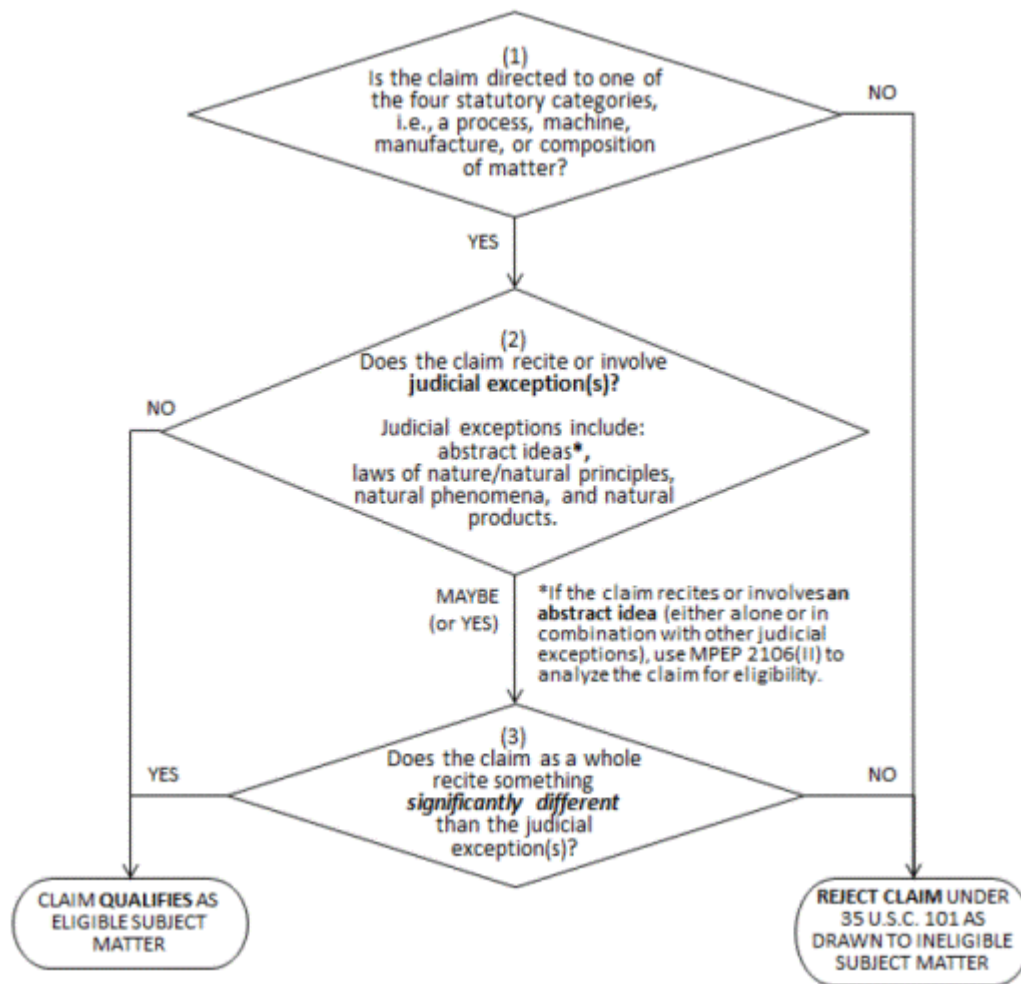
### *“Natural” Exceptions to Subject Matter Eligibility: New USPTO Guidance*

by Elliot C. Cook

As the law evolves concerning exceptions to patentable subject matter under 35 U.S.C. § 101, so does the guidance applicable to patent examiners. Accordingly, based on the Supreme Court’s recent pronouncements of the judicial exceptions to patent eligibility for laws of nature, natural principles, natural phenomena, and natural products, the U.S. Patent and Trademark Office (USPTO) issued [Guidance For Determining Subject Matter Eligibility Of Claims Reciting Or Involving Laws of Nature, Natural Phenomena, & Natural Products](http://www.uspto.gov/patents/law/exam/myriad-mayo_guidance.pdf) (“*Guidance*”) ([http://www.uspto.gov/patents/law/exam/myriad-mayo\\_guidance.pdf](http://www.uspto.gov/patents/law/exam/myriad-mayo_guidance.pdf)), on March 4, 2014. The *Guidance* will impact the work of both examiners and practitioners.

The *Guidance* accounts for the Supreme Court’s decisions in *Ass’n. for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. \_\_\_, 133 S. Ct. 2107 (2013), and *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 566 U.S. \_\_\_, 132 S. Ct. 1289 (2012). While the *Guidance* applies to all claim types (i.e., machine, composition, manufacture, and process claims), it only applies to claims reciting or involving laws of nature, natural phenomena, and natural products, which the *Guidance* recognizes as “judicial exceptions” to patentability. *Guidance* at 1-2. The *Guidance* does not, for example, apply to the “abstract idea” exception to patent eligibility. *Id.* at 1. The *Guidance* supersedes the prior June 13, 2013, USPTO memorandum titled “Supreme Court Decision in *Association for Molecular Pathology v. Myriad Genetics, Inc.*”

The *Guidance* is comprised of four parts. Part I focuses on the overall process for determining the eligibility of inventions that claim or involve natural laws, phenomena, and products. To illustrate the process, a flowchart is provided representing a process of asking whether an invention: (1) is directed to one of the four statutory categories of patentability (i.e., a process, machine, manufacture, or composition of matter); (2) claims or involves a judicial exception to such categories of subject matter (i.e., an abstract idea, law of nature, natural principle, natural phenomenon, or natural product); and (3) recites, as a whole, something “significantly different” than such judicial exceptions. The flowchart is reproduced below:



*Id.* at 2.

Part II of the *Guidance* focuses on how examiners should judge whether an invention is “significantly different” than a judicial exception to patent eligibility, i.e., the third step in the overall process of Part I. According to the *Guidance*, a “significant difference” between a claimed invention and a judicial exception to patent eligibility (i.e., a natural product, law of nature, or natural phenomenon) may be shown where a claim includes elements in addition to the judicial exception that “practically apply” the judicial exception in a significant way, or when the claim includes features or steps demonstrating that the claimed subject matter is markedly different from what exists in nature. *Id.* at 3-4. The *Guidance* further provides a list of factors that examiners should consider in a balancing test to determine whether a claim represents a “significant difference” vis-à-vis a judicial exception to patent eligibility. *Id.* at 4-5.

Part III of the *Guidance* provides several examples of claims to illustrate how the process and analysis of Parts I and II should be applied. In a first example, a claim directed to a “stable energy-generating plasmid, which provides a hydrocarbon degradative pathway,” is deemed patent ineligible based on the above factors, but a claim directed to a “bacterium from the genus *Pseudomonas* containing therein at least two stable energy-generating plasmids, each of said plasmids providing a separate hydrocarbon degradative pathway,” is considered patent eligible based on Parts I and II of the *Guidance*. *Id.* at 5-6. A further example directed to a “fountain-style firework” is found to be patent eligible under the framework identified in Parts I and II of the *Guidance*. *Id.* at 9-10. Various other examples are provided and analyzed as well.

Finally, Part IV of the *Guidance* provides a “form paragraph” for examiners to use when rejecting a claim that recites or involves a natural law, principle, phenomenon, or product. *Id.* at 18. The form paragraph states: “[T]he claimed invention is not directed to patent eligible subject matter. Based upon an analysis with respect to the claim as a whole, claim(s) do not recite something significantly different than a judicial exception. The rationale for this determination is explained below . . . .” *Id.* (examiner notes omitted).

Because the *Guidance* took effect within the USPTO immediately upon its issuance on March 4, 2014, it

has started, and will continue, to affect examination of inventions directed to natural laws, principles, phenomena, and products. Practitioners in a variety of fields, including chemical, materials science, pharmaceutical, and biological inventions in particular, should give special attention to the *Guidance* when formulating new claims and preparing claim amendments. While the changes and clarifications within the *Guidance* are important to note, what the *Guidance* leaves unchanged is equally important. In particular, the *Guidance* is explicit in stating that “[t]here is no change to examination of claims reciting an abstract idea, which should continue to be analyzed for subject matter eligibility using the existing guidance in [MPEP § 2106\(II\)](#).” Thus, while the *Guidance* provides additional illumination for examiners and practitioners with respect to all types of claims reciting or involving natural laws, principles, phenomena, and products, it leaves untouched examination practices for other areas of compliance with 35 U.S.C. § 101, as well as other statutory requirements for patentability. For more information on the *Guidance* and how the USPTO intends for it to be applied, the USPTO issued a [presentation](#) dated March 19, 2014, which is available at the USPTO’s website.

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## EPO Practice

### *A View of the USPTO Myriad Guidance from Europe*

by Martin D. Hyden and Clara N. Jiménez

The approach for determining the presence of patentable subject matter in a claim by the European Patent Office (EPO) and the U.S. Patent and Trademark Office (USPTO) has differed for many years due to differences in legislation and judicial interpretation. However, this difference has recently become more marked in light of the [recent guidance issued by the USPTO](#) to the Patent Examining Corps for determining the patent eligibility of claims relating to products of nature and laws of nature following recent U.S. Supreme Court decisions, including *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. \_\_\_, 133 S. Ct. 2107 (2013), and *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 566 U.S. \_\_\_, 132 S. Ct. 1289 (2012).

Article 52 of the European Patent Convention (EPC) states that patents shall be granted for any inventions in all fields of technology, subject to certain conditions, but goes on to indicate that certain types of inventions shall not be regarded as patentable, including: “(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; [and] (d) presentations of information.” Under the decisions of the Boards of Appeal of the EPO, in order to be patentable, the subject matter claimed must therefore have a “technical character” or, to be more precise, involve a “technical teaching,” i.e., an instruction addressed to a skilled person as to how to solve a particular technical problem using particular technical means. Article 53 EPC also specifies exclusions for exploitation that would be contrary to morality or “ordre public,” plant or animal varieties, essentially biological processes, and methods of treating the human or animal body for therapy or diagnosis.

In the United States, what is patentable is defined by statute in 35 U.S.C. § 101, which states merely that a patent may be obtained for an invention comprised in one of the four recited statutory categories (process, machine, manufacture, or composition of matter). A claim that does not fall within one of these four categories cannot be the subject of a valid patent. Further interpretation of that statute has been left to the U.S. courts. The courts have further defined the four statutory categories to *exclude* certain subject matter (namely, abstract ideas, laws of nature/natural principles, natural phenomena, and natural products). The USPTO refers to these court-made exclusions as “judicial exceptions.”

The legislative noninventions of the EPC and the judicial exclusions of the United States have significant overlap. However, neither the EPC nor the decisions of the EPO Boards of Appeal have any exclusion corresponding to the USPTO’s new natural products exclusion. Instead, provided that there is a technical character, claims involving natural products will be assessed by the EPO for patentability (novelty, inventive step, etc.) in the usual manner.

Under the USPTO *Guidance*, for a claim involving a natural product to be patent eligible, the claimed product must be *both* non-naturally occurring *and* “markedly different” from naturally occurring products.

See [Guidance For Determining Subject Matter Eligibility Of Claims Reciting Or Involving Laws of Nature, Natural Phenomena, & Natural Products](#) “(Guidance)” ([http://www.uspto.gov/patents/law/exam/myriad-mayo\\_guidance.pdf](http://www.uspto.gov/patents/law/exam/myriad-mayo_guidance.pdf)) (Mar. 4, 2014). In particular, the *Guidance* is focused “in determining whether a claim reflects a significant difference from what exists in nature and thus is eligible [subject matter], or

whether a claim is effectively drawn to something that is naturally occurring,” and thus ineligible for patenting. *See id. at 1-2.*

While the Supreme Court’s *Myriad* decision related to human genomic and cDNA sequences, the *Guidance* is addressed to claims reciting “chemicals derived from natural sources (e.g., antibiotics, fats, oils, petroleum derivatives, resins, toxins, etc.); foods (e.g., fruits, grains, meats and vegetables); metals and metallic compounds that exist in nature; minerals; natural materials (e.g., rocks, sands, soils); nucleic acids; organisms (e.g., bacteria, plants and multicellular animals); proteins and peptides; and other substances found in or derived from nature.” *Id.* at 3. Thus, the *Guidance* seems to suggest that claimed subject matter demonstrating “technical character,” in the EPO sense, is now excluded from patenting in the United States, irrespective of issues of novelty, obviousness, etc.

The analytical framework set forth in the *Guidance* seeks to establish patentability by asking three questions:

1. Is the claimed invention directed to one of the four statutory patent-eligible subject matter categories: process, machine, manufacture, or composition of matter?
2. Does the claim recite or involve one or more judicial exceptions?
3. Does the claim as a whole recite something significantly different than the judicial exception(s)?

If the answer to the first question is “no,” the claim is not eligible for patent protection and should be rejected under 35 U.S.C. § 101. If the answer is “yes,” the examiner must then ask the second question, i.e., whether the claim recites or involves one or more judicial exceptions (including natural products). The *Guidance* offers examples of subject matter falling within the natural products’ judicial exception, e.g., “chemicals derived from natural sources (e.g., antibiotics, fats, oils, petroleum derivatives, resins, toxins, etc.); foods (e.g., fruits, grains, meats and vegetables); [and] metals and metallic compounds that exist in nature.” *Id.* at 3. If the answer is “yes,” or if it is unclear whether the claim involves a judicial exception, the examiner must proceed to the third question. *Id.* Under the third inquiry, the examiner must determine whether the claim, as a whole, recites something *significantly different* than the judicial exception.

With this as background, we now take a look at examples that illustrate the application of the USPTO *Guidance* and examine whether they would face a different fate in the EPO. The *Guidance* gives examples of the following situations and conclusions on patent eligibility. For some of the examples, the USPTO and the EPO would arrive at different conclusions regarding patentability. A claim reciting a purified product found in nature? – Possibly *not eligible* under the USPTO *Guidance*, if the claimed product is structurally unchanged from what is found in nature. *See Guidance* at 7-9, Example III.B, discussed in more detail below. In the EPO, if the natural product is capable of industrial application, it is potentially patentable; improved levels of purity are considered to be novel. A claim reciting a simple mixture of metallic elements (copper and tin are given in one example)? – Possibly *not eligible* under the USPTO *Guidance*, if each element is as found in nature so that the claimed composition is, in the view of the *Guidance*, merely the juxtaposition of two structurally unchanged natural products. *See* USPTO slide presentation of March 19, 2014, entitled *Evaluating Subject Matter Eligibility Under 35 USC § 101: March 2014 Update*, slides 44-45, available at [http://www.uspto.gov/patents/law/exam/myriad-mayo\\_slides\\_20140319.pdf](http://www.uspto.gov/patents/law/exam/myriad-mayo_slides_20140319.pdf). In contrast, in the EPO, a mixture of metallic elements having a technical effect, e.g., a mixture of iron and aluminum forming a thermite mixture, would be considered patent eligible. A claim to a beverage comprising fruit juice and a preservative? – Potentially *not eligible*, if a natural product can act as a preservative such that the claim, in the USPTO’s view, encompasses a mere mixture of two natural products, with neither product structurally changed from its natural form. In the EPO, this would be patent-eligible subject matter due to the technical character imparted by the preservative to the beverage. A gunpowder composition that encompasses a simple mixture of three naturally occurring materials is also considered by the USPTO ineligible, as each of the three materials is naturally occurring and not structurally changed by formation of the mixture. *See* USPTO slide presentation of April 16, 2014, entitled *Evaluating Subject Matter Eligibility Under 35 USC § 101*, slides 52-57, available at [http://www.uspto.gov/patents/announce/myriad-mayo\\_bcp\\_20140416.pdf](http://www.uspto.gov/patents/announce/myriad-mayo_bcp_20140416.pdf). In the EPO, this would be patent eligible based on its technical character.

In other instances, the analysis under the USPTO *Guidance* and the EPC arrive at the same conclusion. For example, an *alloy* of metallic elements is patent eligible according to the USPTO, as the crystalline form with both elements is not known in nature. USPTO March 19, 2014, slide presentation, slide 45. The same conclusion would be reached in the EPO.

The *Guidance* makes particular reference to the specific wording of the claims under consideration. In some cases, it may be possible to avoid the exclusion by simple changes to claim wording, e.g., changing the word “mixture” to “alloy.” However, in other cases, further claim limitations might be necessary to avoid the exclusion, e.g., defining how a claimed molecule differs structurally from its naturally occurring variant due to the process used to purify it. For instance, Example III.B of the *Guidance* provides three claims:

Claim 1 directed to “[p]urified amazonic acid.”

Claim 2, directed to “[p]urified 5-methyl amazonic acid.”

Claim 3, in turn, is directed to “[a] method of treating colon cancer, comprising: administering a daily dose of purified amazonic acid to a patient suffering from colon cancer for a period of time from 10 days to 20 days, wherein said daily dose comprises about 0.75 to about 1.25 teaspoons of amazonic acid.”

*Guidance* at 7. According to the Example, amazonic acid was not previously known to have activity in colon cancer but was known to be active against breast cancer. See *id.* at 7.

Under the USPTO *Guidance*, claim 1 does not qualify as patentable subject matter because the claim is a composition of matter that recites a naturally occurring chemical found in the leaves of Amazonian cherry trees, and the claim as a whole does not recite something “significantly different” than the natural product. *Id.* The claim also lacks features that demonstrate that the recited product is “markedly different” in structure from what exists in nature. *Id.*

In contrast, claim 2 is deemed to encompass patentable subject matter because the addition of the 5-methyl group renders the claimed product structurally different from the natural product. *Id.* at 8. The *Guidance* notes that, while the claim does not recite a functional difference, the presence of a functional difference resulting from the structural difference would make a stronger case for patent eligibility than the structural difference alone.

Claim 3 is also deemed to encompass patentable subject matter because the claim as a whole recites something “significantly different” than the natural product. *Id.* In discussing the factors in favor of subject matter eligibility, the *Guidance* notes that the specific dosage and treatment period limitations narrow the scope of the claims such that others are not substantially foreclosed from using amazonic acid in other ways.

In Europe, all three of these claims would fall outside the explicit exclusions of Article 52 EPC, but claim 3 would fall within the exclusions of Article 53 EPC (method of treatment). In the EPO, it is likely that the analysis of patentability for claims 1 and 2 would primarily focus on whether each of the claims has a concrete and technical character. In the case of claim 1, it is likely that the purified acid would qualify as patentable subject matter as it is provided in its purified state, instead of in its natural state. Similarly, the modification of the acid by addition of the methyl group in claim 2 would on its own have sufficient technical character to overcome the patentable subject matter threshold. With regard to claim 3, redrafting that claim as a second medical use claim covering amazonic acid for use in colon cancer may render it patent eligible in the EPO.

Furthermore, note that claim 3 above includes numerical ranges related to dosage and treatment duration. If the simple use of amazonic acid in colon cancer had not been previously demonstrated and could not be expected from its previously known activity in breast cancer, a claim covering amazonic acid for use in colon cancer, without specifying the dose or treatment duration as in the USPTO example above, should be novel and have inventive step. Accordingly, in the EPO, it might not be necessary to add the dosage and treatment duration limitations if the claim is otherwise novel, has inventive step, and



is drafted in a patent-eligible format. Thus, there may be cases in which an applicant will narrow a U.S. process claim in ways that would not be necessary in the EPO merely to ensure that the claim satisfies the *Guidance*.

Thus, the application of the USPTO *Guidance* is likely to lead to more rejections for lack of patent-eligible subject matter in the United States. The application of the *Guidance* may also lead to some significantly divergent outcomes in the USPTO and EPO. Furthermore, applicants seeking to avoid patent eligibility rejection in the United States (for example, when claiming a natural product) should consider the implications of their strategy on inventive step at the EPO (where the corresponding claim is patent eligible).

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## At the Federal Circuit

### *“A” Does Not Always Encompass “One”—Federal Circuit Reads “Population” into a Claim*

by Adam M. Breier, Ph.D.

If a claim recites a composition for inducing a desired effect in “a patient” and also recites that it does not produce a certain side effect, one might expect that the claim refers to a single person. If the desired effect occurred in that patient and the side effect did not, would the claim be satisfied? The Federal Circuit decided it would not in *Braintree Laboratories, Inc. v. Novel Laboratories, Inc.*, \_\_\_ F.3d \_\_\_, 110 U.S.P.Q.2d 1525, 2014 WL 1584451 (Fed. Cir. 2014). The case concerned Braintree’s U.S. Patent No. 6,946,149 (“the ‘149 patent”), which claims a composition used to help prepare patients for colonoscopies. The Federal Circuit construed a claim in the ‘149 patent to require that a side effect not occur in a *population* of patients, even though the claim recited “a patient” (albeit in the preamble).

The colon needs to be visually clear during a colonoscopy. Therefore, patients typically drink several liters of a solution, such as an osmotic laxative, to purge the colon before the colonoscopy. An osmotic laxative may cause an electrolyte shift as a side effect. Asserted ‘149 patent claim 15 reads as follows, in relevant part:

A composition for inducing purgation of the colon of *a patient*, the composition comprising . . . [a] solution comprising an effective amount of [three types of salt], wherein the composition does not produce any *clinically significant electrolyte shifts* . . . .

Ex Parte Reexamination Certificate, ‘149 patent, col. 2, ll. 23-30 (emphases added).

The parties did not dispute that “a patient” should be imported from the preamble into the limitation of not producing any clinically significant electrolyte shifts. The district court had construed “a patient” as meaning “one or more patients” in granting summary judgment of infringement, and Braintree supported this construction on appeal. Novel argued against this construction because it would mean that a composition could satisfy this limitation as long as one patient experienced no clinically significant electrolyte shifts, even if 99 patients out of 100 did.

In an opinion by Judge Prost, the Federal Circuit agreed with Novel and interpreted “‘a patient’ to mean the general class of persons to whom the patented compositions are directed, i.e., a patient *population*.” *Braintree Labs.*, 110 U.S.P.Q.2d at 1530 (emphasis added). Interpreting “a patient” as one or more patients, the Court reasoned, “leads to the absurd result of infringement even if a composition causes clinically significant electrolyte shifts in a large percentage of patients,” but that the meaning of a patient population “is consistent with the invention the patentee intended to define and protect.” *Id.* (citation and internal quotation marks omitted). The Court noted that the specification stated the objective of finding “a well tolerated orally administered colonic purgative that . . . avoided the risks of upset of electrolyte balance *in patients*.” *Id.* at 1530-31 (quoting ‘149 patent, col. 4, ll. 45–48). The Court also noted other statements in the specification referring to “patients” or “people.” *See id.* at 1531.

As a result, the Court found a genuine dispute as to whether the accused product avoids producing any clinically significant electrolyte shifts in a patient population. Accordingly, the Court vacated the lower

court's finding on summary judgment that Novel infringed Braintree's claims and remanded the case back to the lower court for further proceedings. *Id.*

Dissenting, Judge Moore would have construed "a patient" as "one or more patients," in agreement with Braintree and the district court. *Id.* at 1536 (Moore, J., dissenting). The dissent noted that "a" has been construed many times, and the Court has repeatedly held that "a," when used in a "comprising" claim, means "one or more." *Id.* at 1537. "The exceptions to this rule are extremely limited: a patentee must evince a clear intent to limit 'a' or 'an' to 'one.'" *Id.* (quoting *01 Communique Lab., Inc. v. LogMeIn, Inc.*, 687 F.3d 1292, 1297 (Fed. Cir. 2012)). And "there is no plain meaning of 'a' that excludes the singular." *Id.* Furthermore, she pointed out that the specification only sometimes used the word "patients" and also used the singular, e.g., stating a "purpose" of avoiding undesirable effects "on *the recipient*" of the solution. *Id.* (quoting '149 patent, col. 3, ll. 32-38). Thus, Judge Moore concluded that Braintree's construction was correct.

Although it may be rare going forward for judges to decide that construing "a" to include "one" gives absurd results, it seems prudent for innovators to consider guarding against undesired interpretations of claims with limitations on what the subject matter achieves. For example, a claim explicitly reciting that a composition does not produce a side effect in *at least one* patient may be less susceptible to the kind of construction in *Braintree Laboratories*. Also, a claim preamble is considered limiting if it is "necessary to give life, meaning, and vitality" to the claim. *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305 (Fed. Cir. 1999) (citations omitted). Specifying the entity subject to a recited effect outside of a claim's preamble may reduce the risk of claim construction surprises related to this standard.

Additionally, obtaining a fallback claim that more specifically recites the basis for evaluating whether an effect occurred could have made the intended meaning clearer. Notably, such fallback claims might also be of increased value in light of the Supreme Court's recent rejection of the Federal Circuit's indefiniteness standard. [Nautilus, Inc. v. Biosig Instruments, Inc., No. 13-369 \(U.S. June 2, 2014\)](#). And, although perfect foresight is difficult to achieve, practitioners should avoid drafting specifications with language suggesting that a claimed invention involves an effect in a population rather than an individual.

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