New guidance from the US Patent & Trademark Office identifies limitations on what can be claimed

Are your claims patent eligible?

As a leader in biofuel production, the US presents a key market for developing and protecting technology to convert biomass to biofuels. Patents, and their exclusionary rights, provide an important tool for commercialising biofuels and other bio-products, or otherwise participating in the bio-based economy. The US has seen a significant change in several aspects of its patent laws over the last several years, however, creating an impetus to review patent portfolios currently protecting or being built around these technologies.

One area of significant change has been in 'subject matter' or patent eligibility under 35 U.S.C. § 101. Section 101 generally establishes the patent-eligible statutory classes of invention, which include processes, machines, manufacture, and compositions of matter. Historically, the only limitations (or exceptions) placed on the eligibility of claims that fall within these classes have been that the claim must not be directed solely to a law of nature, a natural phenomenon, or an abstract idea. Despite most, if not all, inventions including elements of these exceptions within their scope, US courts and the US Patent and Trademark Office (USPTO) did not enforce section 101 as a threshold requirement until recently.

Significant to the industry, the Supreme Court ruled as patent ineligible claims encompassing isolated DNA molecules having a naturally-occurring sequence in its June 2013 Association for Molecular Pathology v. Myriad Genetics Inc. decision. While leaving room for the patent eligibility of claims encompassing DNA molecules that have been modified by the hand of man, e.g. complementary DNA (cDNA), the Myriad decision swept away scores of granted patent claims to isolated, naturally-occurring DNA molecules.

In its wake, lower courts have begun the formidable task of defining the bounds of what biotechnology-related patent claims remain patent eligible. And, the USPTO recently issued guidance, including examples, for determining if a claim that encompasses a naturally-occurring phenomenon (or product of nature) is patent eligible. These examples extend well beyond patent claims to isolated DNA molecules and are a must read for anyone in the bio-based economy seeking US patent protection. This article provides an introduction to the USPTO's section 101 examination guidance and highlights several relevant examples.

Subject matter eligibility examination at the USPTO

In determining subject matter eligibility, the patent examiner makes an initial determination of whether a patent claim falls within one of the four statutory classes of invention under section 101: process, machine, manufacture, and composition of matter (Figure 1, step 1). If the claimed invention falls within a statutory class, she then proceeds to apply the two-step test established by the Supreme Court in its 2012 Mayo Collaborative Services v. Prometheus Laboratories decision.

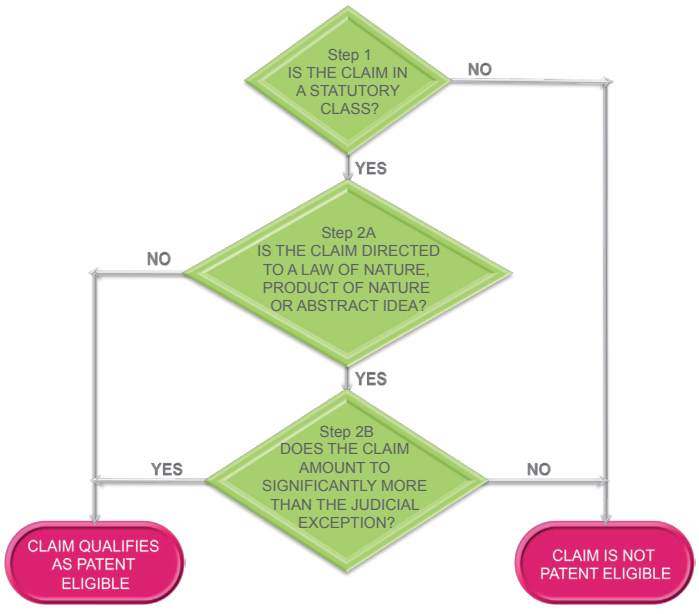

Figure 1: USPTO examination scheme for patent eligibility

First, the patent examiner determines whether the patent claim encompasses or recites an exception to patent eligibility, i.e. a law of nature, a natural phenomenon, or an abstract idea (Figure 1, step 2A). Products of nature include both naturally occurring products and man-made products that are not 'markedly different' from naturally occurring counterparts. Under this step, the examiner must determine if there is any marked difference between a claimed product and its naturally occurring counterpart.

Second, the patent examiner determines whether the claim includes an element or combination of elements in addition to the judicial exception so that the patent claim, when viewed as a whole, amounts to significantly more than the exception (Figure 1, step 2B). If the patent claim as a whole does not 'tie up,' i.e. prevents others from using the recited exception, then the claim is likely patent eligible. Under Step 2B, the patent examiner is to consider the additional claim elements individually and as an ordered combination.

Patent eligibility of claims reciting a 'nature based product', which is the USPTO's term for a product

that needs the marked differences examination, will turn in most cases on the outcome of the step 2A analysis. Step 2B is largely geared towards examination of claims that recite a law of nature or an abstract idea.

In the abstract, this two-step inquiry can seem quite complicated, particularly for patent claims that encompass products of nature. Fortunately, the USPTO provided guidance in its recent examples to illustrate how it will determine patent eligibility of claims reciting such products. The examples discussed below illustrate where those in the bio-based economy may encounter application of the test.

"Keeping a close eye on this developing area of US patent law is critical to … a strong patent portfolio"

Of biocatalysts and their products

Biofuel production generally involves the enzymatic conversion of a starting molecule (e.g. a sugar) present in a renewable starting composition (e.g. corn stover extract), into a fuel molecule (e.g. ethanol), present in an output composition. The fuel molecule is then isolated from the output composition.

A robust patent portfolio covering aspects of biofuel production will include composition claims directed to the biocatalyst, the input and output compositions, and method claims directed to various phases of biofuel production and extraction. Each of these types of claims may recite a nature based product and consequently will be examined for subject matter eligibility at the USPTO.

Claims to biocatalyst microorganisms

The US Supreme Court confirmed the patent eligibility of genetically modified microorganisms in its landmark Diamond v. Chakrabarty decision. A recombinant microorganism and its naturally occurring counterpart can have markedly different structural characteristics based on the mere presence of a transgene or if the transgene confers a new activity on the host cell. However, claim drafters must avoid capturing naturally occurring microorganisms within the scope of the claim. For example, a claim 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' would be patent eligible if no naturally occurring Pseudomonas contains two stable plasmids providing separate hydrocarbon degradative pathways. But if such a Pseudomonas exists in nature, or is later discovered, then the claim would not be patent eligible.

Claims to an isolated naturally occurring microorganism are not patent eligible. However, a claim to a mixture of bacterial species where the mixture has, for example, different host infectivity than the individual species in nature, may lead to a different result. Under the USPTO's examples, a claim to 'an inoculant for leguminous plants comprising a mixture of Rhizobium californiana and Rhizobium phaseoli' is patent eligible where (i) Rhizobium californiana and Rhizobium phaseoli do not occur together in nature, and (ii) the claimed inoculant infects a host plant that neither bacteria would infect in isolation.

Claims to renewable starting compositions

Production of biofuels or other renewable chemicals relies on some form of biomass as a starting material. Thus, claims to a starting composition will necessarily recite a nature-based product. Nevertheless, the claim may be patent eligible if the starting composition has markedly different characteristics compared to the naturally occurring source of the biomass.

For example, a claim to 'a beverage composition comprising pomelo juice and an effective amount of an added preservative' may be found patent eligible over the naturally occurring pomelo fruit, where a marked difference of the claimed composition is slower spoiling. Thus, careful comparison of the starting biomass' characteristics to that of the naturally occurring source materials may identify differences that could support the patent eligibility of claims to the starting biomass.

Claims to a product isolated by a process

Under a long standing principle of US patent law, the patentability of a product-by-process claim turns on the patentability of the product itself. The same principle applies in the patent eligibility examination. For example, a claim to a biofuel composition defined by the process of making it is patent eligible only if the biofuel composition itself is markedly different from a naturally occurring counterpart. If the biofuel composition does not have a naturally occurring counterpart, the examiner would compare the composition to its individual components as they occur in nature.

For example, a claim to 'a gunpowder composition comprising potassium nitrate, charcoal and sulfur' is patent eligible because of the marked difference between the explosivity of the gunpowder composition relative to the lack of explosivity of the individual components as they occur in nature. Thus, a careful comparison of the characteristics of a biofuel composition to that of its individual components as they occur in nature could identify

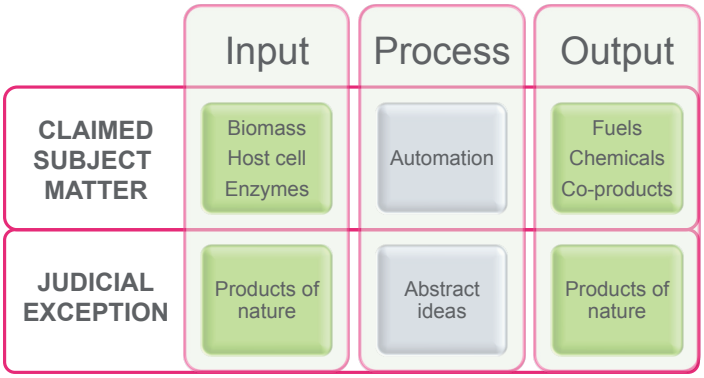

Figure 2: Typical patent claims and the judicial exceptions for biofuel production

marked differences that may support patent eligibility of a biofuel composition.

Processes not exempt

The USPTO applies the same two-part analysis to determine patent eligibility of process claims. However, a process claim that recites a product of nature exception is patent eligible when the claim as a whole focuses on a process of practically using the product of nature, and not on the product per se. For example, a claim to 'a method of treating cancer by administering amazonic acid' is patent eligible even if a claim to the amazonic acid itself is not. Similarly, a claim to a method for producing a biofuel using a naturally occurring enzyme or microorganism is likely patent eligible even if a claim to the enzyme or microorganism per se is not.

Generally, processes of producing a biofuel or bio-product using a product of nature qualify as patent eligible. And, extraction, distillation, and other processes to recover the biofuel or bio-product also qualify just the same. However, just because a claimed process includes steps of extraction or recovery, does not per se make the claim patent eligible. Where, for example, the claimed process includes an algorithm or mathematical formula, which qualifies as a law of nature or abstract idea, to control a step or the entire claimed process, the claim may not be patent eligible. The USPTO will apply the same two-step analysis to determine if such claims as a whole provide meaningful limits on the use of the algorithm or mathematical formula and qualify as patent eligible.

Conclusion

The USPTO's Examples for determining patent eligibility of claims that recite products of nature provide useful guidance for evaluating the viability of patent portfolios currently protecting or being built around production of biofuels and other bioproducts in the U.S. However, the scope of patent eligibility will continue to change as courts further define its boundaries. Keeping a close eye on this developing area of U.S. patent law is critical to the development and maintenance of a strong patent portfolio. ●

References:
1 See http://www.uspto.gov/patents/law/exam/mdc_examples_nature-based_products.pdf.

For more information:
This article was written by Directors, Jeremiah Frueauf and Deborah Sterling, Ph.D. and Associate Miklos Gaszner, Ph.D. Visit www.skgf.com