The Patent Office Clarifies the Ban on Patenting Naturally-Derived Drugs and Other Products

Law of Life Newsletter

Firm Alert

Since the very beginning of America’s revolutionary patent system, inventors in the life sciences have been granted patents for discovering and purifying natural products. It was taken as a given that a purified natural product could be patented, so long as that natural product had never existed in a purified state before. Classic examples include Louis Pasteur’s patent for a pure yeast culture, Jokichi Takamine’s patent for adrenaline, and Selman Waksman’s numerous patents for natural antibiotics such as streptomycin. However, last year the U.S. Supreme Court banned the patenting of purified DNA in its landmark decision Association for Molecular Pathology v. Myriad Genetics, 569 U.S. 12 (2013) (commonly known as “Myriad”). This abrupt reversal of age-old law left many wondering if the ban extends to all naturally occurring substances, such as drugs from natural sources, biomarkers, DNA molecules, antibodies, enzymes, cultures, PCR primers, and nutrients.

The USPTO’s First Response to Myriad

It is the duty of the United States Patent and Trademark Office (USPTO) to ascertain whether an invention for which one seeks a patent is eligible for a patent. In response to the Myriad ban, the USPTO issued a set of guidelines to its patent examiners in March of 2014. The March guidelines were controversial and widely criticized. They created a complex approach in which examiners must answer 16 questions and weigh the answers of each against one another to determine whether an invention falls under the Myriad ban. The March guidelines also contained odd and surprising conclusions, such as that gunpowder is a “natural product” that could not have been patented when it was invented (had there been a patent system). In sum the March
guidelines provided no clarity to the regulated public as to what life sciences inventions apart from DNA are subject to the Supreme Court’s new ban.

The USPTO Reconsiders its Initial Approach

The USPTO took these criticisms to heart, and on December 16th it revoked the March guidelines and published a set of proposed new guidelines in the Federal Register (Fed. Reg. vol. 79, No. 241, p. 74618). The public has been given until March 16, 2015, to submit comments to the new guidelines. In light of such comments the USPTO may revise the guidelines before making them final. The USPTO’s guidelines are not laws; if challenged in a court of law the court will give them no deference. However, as most patent applicants prefer to avoid recourse to the courts in pursuit of a patent, whatever guidelines are adopted in final form will have a deep impact on the ability of life sciences companies to obtain patent protection for their inventions.

Natural Products Must Pass a Three-Step Test

The USPTO has replaced the 16-question analysis with a more straightforward three-step test, illustrated in a simple flowchart. The first step is to determine whether the invention in a given patent claim meets the requirement actually found in the Patent Act that one may only patent a process, machine, manufacture, or composition of matter. This is a clear and simple test, as anything composed of matter is a “composition of matter,” and anything that involves one or more defined human actions is a “process.” If the patent claim is in one of these categories, then the next step is to determine whether the invention is subject to one of the judge-made bans on patenting.

In the context of the life sciences, the second step will address whether any part of the invention involves a natural substance. This test really has two sub-parts. The first sub-part merely involves identifying a substance in the invention that can be considered natural. The second sub-part is determining whether the natural substance in the invention is somehow “markedly different” from how it is found in nature. The guidance states that the marked difference must be a difference in structure, function, or another property. Importantly, the guidance clearly states that a purified natural substance can be patented if the purified form is markedly different from the natural form in
one of these three ways. Examples of the marked difference are a difference in pharmacological function, a difference in structure, a difference in chemical properties, a difference in physical properties, or a difference in “form.” If the invention is “markedly different” from what is natural, then the ban does not apply. If it is not, then a third step must be performed.

The third is determining whether the invention as a whole is something “significantly more” than the natural substance. The term “significantly more” is inherently subjective, but is further defined to mean that the use of the natural substance is limited so that not all possible uses of the substance are patented. Examples of such limited uses are provided, including an improvement to a pre-existing technology, use of the substance with a particular machine, use of the substance in a transformation of a physical thing to another state or thing, use in a way that is not conventional and well-understood, and use in a specific useful application. Merely stating that the invention is intended for a specific field of use is not sufficient to overcome the ban.

Specific Examples of Patent Claims for Natural Substances

The guidance contains several specific examples of inventions involving natural substances, and provides opinions in each case as to whether the example violates the *Myriad* ban. One example is of a specific machine that is coated with a natural mineral. Because the mineral is used with a specific machine, the invention is “significantly more” than just the mineral, and the ban does not apply.

Another example is of a bacterium that has been genetically modified (GM) to contain two hydrocarbon metabolic pathways. Although the bacterium is a natural product, the GM bacterium has a markedly different function from the bacterium found in its natural state: the GM bacterium can metabolize two hydrocarbons, whereas the natural bacterium can only metabolize one. The GM bacterium also has a markedly different structure than a natural bacterium, by virtue of having the genes for the two metabolic pathways. Thus the ban does not apply.
Another example provided is the invention in the *Myriad* case, which was an isolated DNA molecule encoding the BRCA1 protein. In that case, the Supreme Court decided that the invention is banned from patenting. The molecule is a “composition of matter” as permitted by the Act (step 1). As a type of molecule that occurs in nature it is a “natural product;” the Court found that the isolated DNA is not “markedly different” from the natural DNA, because it has the same structure and serves the same function. Finally, there is no limitation on how the DNA can be used, so the invention is not “significantly more” than just the natural DNA. Therefore the guidance reaches the conclusion that it is banned from patenting.

**What Should Life Sciences Inventors Do?**

The new guidance is an improvement in that it creates an understandable framework for applying the *Myriad* ban. However, this does not change the underlying fact that the United States may now be the most hostile country in the world to life sciences inventions. New difficulties will be encountered for inventions in the areas of drugs, biologics (including antibodies and vaccines), dietary supplements, food additives, enzymes, nutrients, primers for PCR, and biomarkers. Several of these have been interpreted as banned from patenting by lower court decisions since *Myriad*.

However, one should not necessarily forgo attempts to protect such inventions for the following reasons.

Countries outside of the United States have not shown any interest in following the U.S.’s lead in creating this new patenting ban. Although the United States remains the world’s largest market in terms of nominal GDP, the European Union (EU) as a whole exceeds the GDP of the U.S. In sum, the EU, mainland China, and Japan have a GDP that is slightly less than twice that of the United States. These foreign markets remain quite lucrative and permit purified natural substances to be patented, so consider retaining the ability to claim these types of inventions in foreign countries. Based on the increased patenting risk in the U.S., consider shifting research focus to problems that are consequential in major markets outside of the U.S., and away from problems that are unique to the U.S. or primarily of consequence in the U.S.
Instead of patenting, certain types of inventions can be protected as trade secrets. As the U.S. weakens its patent laws, trade secrecy is becoming a more popular form of IP protection for all types of inventions. The *Myriad* ban is yet another push in the direction of secrecy for life sciences inventions.

Before patenting, publishing, or presenting newly identified genes or other useful natural substances, serious consideration should be given to maintaining the invention in strict secrecy until its commercial potential can be ascertained, so that patent applications can be filed for all commercially viable, artificially modified, forms. For drugs, biologics, and medical devices, trade secrecy is generally impractical, because of the need to obtain regulatory approval from the U.S. Food and Drug Administration. If the substance could be useful in an industry outside of those which have governmentally mandated rules of public disclosure, then consideration should be given to maintaining the invention as a permanent trade secret.