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THE USPTO ISSUES GUIDELINES FOR SUBJECT MATTER ELIGIBILITY IN VIEW OF THE SUPREME COURT'S MYRIAD AND PROMETHEUS DECISIONS

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The U.S. Supreme Court's decisions in *Molecular Pathology v. Myriad Genetics, Inc.* (*Myriad*) and *Mayo Collaborative Services v. Prometheus Laboratories* (*Prometheus*), and its subsequent interpretations of 35 U.S.C. §101, have sparked tremendous controversy in the biotech industry. Similarly, the USPTO's interpretation of the Supreme Court's rulings as represented in its *Guidance* has not been without controversy. In last month's issue of *IP Buzz*, **we summarized and highlighted the key points of the guide**. In this month's article, we will discuss the guide's potential implications for inventors and legal service providers.

As touched upon in last month's article, the USPTO's *Guidance* in view of *Myriad* and *Prometheus* has been received with mixed reviews from the biotech and legal professions. On one hand, professionals appreciate that the USPTO was placed in a difficult position and the prompt issuance of a *Guidance* to instruct examiners on claims comprising natural products and/or natural laws. Proponents believe that the *Guidance* will be refined as the USPTO has made it clear that it is willing to accept feedback from the community.

However, proponents for the *Guidance* seem to be in the minority, with many biotech and legal professionals criticizing the USPTO's interpretation of the Supreme Court's rulings. Critics contend that the *Guidance* in effect goes beyond what the Supreme Court actually ruled in the recent patent eligibility cases. They point out that the Supreme Court limited the scope of its decisions and cautioned against over-interpretation, while the *Guidance* appears to be less measured and contrary to the Office's previous practices.

For instance, there are many previously issued patents pertaining to isolated enzymes, chemicals, naturally occurring antibiotics, and other "products of nature." However, based on the *Guidance*, it would appear that *none* of the following are patent-eligible subject matter: isolated chemical compound from crude oil useful as a lubricant, isolated chemical compound from plant useful as a drug, isolated antibiotic produced by bacteria, isolated protein from animal useful to cure/ameliorate human disease, and isolated plant/human genes/proteins (unless claimed as cDNA). In particular, the *Guidance* seems to call into question the longstanding Office policy of considering highly purified natural products as being patent eligible. In *Myriad*, the Supreme Court sidestepped this problem by indicating that their decision necessarily applied only to DNA and that DNA was unusual because DNA can be viewed as information as well as a chemical compound.

Regardless of one's views concerning the *Guidance*, inventors and patent practitioners must now try to adopt methods of ensuring meaningful patent protection for intellectual property that can be interpreted as containing a "product of nature" or as involving a "natural law." In the case of protecting intellectual property that might contain a "product of nature" (as understood by an examiner), one might consider including multiple claims having varying degrees of modifications to the naturally occurring product. At the same time, if one is to apply for a patent in Europe, it is important to keep in mind that European patent law thus far remains unchanged in view of *Myriad*. As such, although Europe forbids the patenting of particular human genes or elements, one *can* still claim such a gene or element so long as an industrial application for the gene or element is disclosed in the application. In summary, if claiming a product that might contain a "product of nature," it would be advisable to include broad claims that might be allowable in Europe (or other foreign patent offices) as well as subsequent claims with further modifications to the product.

Similarly, when protecting intellectual property involving a "law of nature," for U.S. filings, one must take care to: 1) limit the claim(s) to a particular application of the natural law, 2) not preempt all uses of the natural law, and 3) include unconventional steps that integrate the natural law into the claimed process

which applies it. It is also advisable to keep one's claim(s) as broad as possible when filing in Europe (or other foreign patent offices), while still obeying the particular laws of the European Patent Office (EPO). For example, although in *Prometheus* the Supreme Court ruled that diagnostic patents based solely on the application of a natural law are no longer patentable in the U.S., the EPO holds that an invention involving the practical application of a discovery or theory is patentable (with certain limitations pertaining to interaction with and treatment of a human/animal body). As such, a claim to the diagnostic invention at the center of *Prometheus* was previously allowed by the EPO as an *in vitro* method for determining the efficacy of a treatment. Thus, it is important to determine if one's product can be interpreted to contain a "law of nature" and appropriately adjust one's claims for prosecution in the U.S. versus abroad.

Going forward, it will be interesting to see how the *Guidance* impacts the types of patents and claims applied for by inventors both inside and outside the biotechnology industry, as the concepts of "natural products" and "laws of nature" extend not just to chemicals and biological matter. Ultimately, the *Guidance* is simply an administrative tool that has no force of law. The implications of the Supreme Court's decisions and the impact of this *Guidance* will undoubtedly take many years to unfold and will inevitably be shaped by litigation and judicial decisions. For instance, it seems likely to the authors that should the USPTO deny patentability of natural products based on isolation and purity, the courts may not uphold such a denial. Similarly, court challenges to the validity of currently existing purified natural product patents are not likely to succeed, at least on *Myriad* grounds. There has not been sufficient time for any of possible approaches suggested above to demonstrate success (or failure) during prosecution of a patent application. These points are presented for discussion purposes and not as suggested actions.