

Patenting life

Recent legal challenges affect biotechnology patents

The U.S. Supreme Court's *Diamond v. Chakrabarty* decision in 1980 held that a natural bacterium modified to digest different hydrocarbons in oil spills was patentable. Since *Chakrabarty*, the courts expanded on what types of modified natural products are patent eligible, which has led to significant growth in the biotechnology industry. However, the courts have recently reversed their direction.

In 2012, the Supreme Court in *Mayo v. Prometheus* determined that a diagnostic method for altering the dosage of a drug based on a patient's metabolite levels was not patentable. The next year, the Supreme Court in *Molecular Pathology vs. Myriad Genetics* found that an isolated human gene was not patentable, i.e., it was not "markedly different" than nature.

After these decisions, the U.S. Patent and Trademark Office (USPTO) published its own guidelines interpreting these cases.

"While not binding on the courts, the USPTO guidelines affect the patent prosecution process and extend the recent hard stance taken by the courts on patent eligibility," says Scott Frederick Peachman, an associate attorney at Fay Sharpe LLP.

These developments, coupled with the change in the U.S. to a substantially first-to-file country, can make things difficult for companies that are unprepared.

Smart Business spoke with Peachman about what biotechnology companies should know.

How has the legal landscape changed?

There are two key statutes affected by these decisions. First, patent eligibility has been narrowed for biotechnology inventions. Second, the USPTO has pushed to compel applicants to describe a biotechnology invention in great detail.

Under the new patent eligibility



SCOTT FREDERICK PEACHMAN
Associate Attorney
Fay Sharpe LLP

(216) 363-9000
speachman@faysharpe.com

Insights Legal Affairs is brought to you by **Fay Sharpe LLP**

requirements, modifications involving mere isolation of a natural product or mutation of a few nonessential amino acids in a protein are unlikely to produce products that are 'markedly different' than nature. The bar on patent eligibility will stand. However, if you modify a natural product enough to confer a new function or structure, it is more likely to be eligible for patenting.

Genes are still patentable if they are converted to complementary DNA, but the result in *Myriad* may cause some companies to protect their genes using trade secrets as opposed to patents.

What trends could be affected?

One promising industry for biotechnology is personalized medicine — genomic therapies and optimized diagnostics. This burgeoning industry will look towards *Prometheus*, which involved a personalized diagnostic method, and the USPTO guidelines before filing patent applications directed to new diagnostic methods.

Pharmaceutical companies are losing patent exclusivity on many blockbuster drugs and are considering filing patent applications on biologic products, such as therapeutic antibodies and DNA vaccines, to replace lost revenue. The pharmaceutical industry will look towards *Myriad* and the USPTO guidelines before filing patent applications directed to new biologics.

How can biotechnology businesses adjust?

Businesses need to look carefully at how these laws are developing. A patent eligibility rejection is challenging because the merits of the invention, such as its novelty or non-obviousness, cannot be used to overcome it. Additionally, the USPTO examiners are skeptical with respect to whether you have explained your invention well enough or whether you have demonstrated that it works the way you say it does. Spend your time considering the practical applications of your discovery, and then include examples to show adequate written description and enablement.

Biotechnology patent applications are getting really complex because of all these new considerations, but there is also pressure to file quickly because of our substantially first-to-file system. Biotechnology companies have to weigh the speed to file against having enough information to pass the various hurdles imposed by the courts and the USPTO.

A misstep in the patent drafting process could affect investor confidence down the road, and ultimately, funding. However, a properly executed patent strategy can take these concerns into account when drafting a patent application which, after being granted by the USPTO, may become a vital protective or revenue generating asset in the biotechnology industry. ●