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File, Protect, Update, Defend

Building a biotech patent portfolio in the changing patent landscape.

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Change is sweeping over the patent landscape, and those representing clients in the biotech field must update their patent portfolio strategies to keep pace. The Patent and Trademark Office (PTO) is retooling its requirements, the European Patent Office (EPO) is proposing major rule changes, and the U.S. Supreme Court is issuing far-reaching opinions that affect patent and licensing strategy. Taken together, these changes will redefine the life sciences patent landscape, affecting licensors, licensees, industry, and academia in various ways.

At the PTO, new director David Kappos sees his mission as improving patent quality and reducing the enormous backlog of over 1 million patent applications awaiting examination. Kappos's initiatives include decreasing the overall pendency of an application from 32 months to 20 months, reducing patent appeal pendency from seven months to three months, and decreasing reexamination pendency from over two years to one year.

Recent changes to European patent practice will also affect biotech companies. As of April 1, European divisional applications can no longer be filed at any time before grant, abandonment, or withdrawal of a patent case, but must now be filed within two years of the first EPO communication in the first-filed European application. As a result of this two-year time limit, biotech companies will no longer be able to prolong the patent life of a drug or pharmaceutical by continually filing multiple divisional applications.

Supreme Court decisions will further unsettle the patent landscape for biotech companies by redefining patentable subject matter. One case in particular, *In re Bilski*, could exclude certain life science technologies from even obtaining patent protection. While the claims in the Bilski patent relate to financial services, *Bilski*'s "machine or transformation" test for patentable subject matter affects innovations related to personalized medicine, particularly the use of pharmaceuticals and diagnostic testing. Under *Bilski*, a data-gathering step directed toward a fundamental principle, such as a natural phenomenon or algorithm, may fail the machine or transformation test and be insufficient for patent protection.

Bilski's impact can already be seen in *Classen Immunotherapies, Inc. v. Biogen*, in which the U.S. Court of Appeals for the Federal Circuit invalidated a patent directed to methods for determining an optimal immunization schedule, reasoning that the claim describes nothing more than a correlation between an immunization schedule and the presence of a chronic disorder.

Highly controversial human gene patents, particularly those related to genetic diagnostic testing, may also be impacted by *Bilski*. Many biotech companies have patent claims covering specific genes that may be responsible for certain types of cancer or hereditary diseases. Under *Bilski*, such patent claims may be seen as simply "comparing" naturally occurring genetic sequences, or "diagnosing" the presence of natural mutations, and may therefore be unworthy of patent protection.

To respond to this rapidly evolving patent environment, biotech companies need to develop an effective strategy for building high-value patent portfolios. Strategically building and maintaining a strong patent portfolio is critical for life sciences companies because the portfolio is often the driving force for important events in the company's life cycle, including venture capital investment, mergers and acquisitions, public offerings, strategic collaborations, joint ventures, and litigation. A strategic patent portfolio that is broad and flexible to withstand changes in the patent landscape ensures the greatest coverage of these assets.

Establish the broadest possible patent protection for the company's core technology. You can use broad patent protection both offensively to block competitors from the marketplace, and defensively to serve as a bargaining chip against potential patent infringement suits. To establish the broadest possible protection, you should file patents to cover all aspects of the core technology, including compounds, diagnostics, therapeutics, methods of treatment, use or manufacture, and any other aspects of the invention. As the core technology evolves, keep abreast of changes and make any incremental improvements needed to create a "picket fence" of protection around your core technology.

A strategic patent portfolio can also facilitate collaborations and acquisitions. Pfizer Inc's 2009 acquisition of Wyeth for \$68 billion enhanced Pfizer's patent-protected pipeline in key disease areas, such as Alzheimer's disease, inflammation, oncology, pain, and psychosis. According to the press release, acquiring Wyeth's strategic patented product portfolio offered Pfizer additional opportunities to generate revenue and promote innovation.

To further strengthen a patent portfolio and expand a company's global presence, your company should also file international patent applications. Although expensive, strategic patent filing in foreign countries can improve the commercial success of a product. To optimize international patent protection, biotech companies should file patent applications in countries with large markets for the product as well as countries where competitors' manufacturing facilities are located. A patent in these countries will protect the company against potential infringers who may wish to make, use, or sell the company's invention around the world.

In addition to establishing the broadest possible patents for the company's core technology, developing a strategic portfolio also requires finding ways to patent areas not already covered, known as white space. The amount of white space measures how crowded a particular area is with patents and patent applications, and thus how much room exists for new innovations. According to the amount of white space available,

biotech companies can develop an immediate strategy for building core technology and a future strategy for expansion. Biotech companies can also identify potential design-around opportunities or modifications to assure the broadest possible coverage for their products. By expanding their presence in the marketplace, biotech companies will be able to assert their patent rights against potential infringers, and will also have the option of granting licenses to competitors.

Cross-licensing with competitors is another way to enhance a patent portfolio. A cross-license is a mutual sharing of patents between companies without the exchange of license fees and with a promise not to sue. Cross-licensing opportunities arise when companies have overlapping patents, and practicing one patent would mean infringing the other company's patent. Companies can pool the relevant patents and divide the patent rights among themselves so that each party takes exclusive or nonexclusive rights to a particular field of use covered by the combined patents. Such cross-licenses can lower licensing fees, encourage earlier and lower litigation settlements, and promote innovation by preventing competitors from blocking one another's products. Generally, a company will seek rights to practice within its preferred field of use based on the commercial marketplace it desires to control, and grant other companies rights to a field it desires less.

In July 2009, for instance, Glaxo-SmithKline plc and Nuevolution A/S entered into a cross-license covering patented technologies for rapid synthesis and DNA tagging of small-molecule compounds to efficiently screen and identify important drug leads. Under the cross-license, GlaxoSmithKline obtained a nonexclusive license to Nuevolution's lead discovery technology, and Nuevolution obtained a nonexclusive license to GlaxoSmithKline's pharmaceutical technology.

Biotech companies have been on the cutting edge of innovation. With careful patent strategies, you can ensure that your company keeps its competitive edge as well. Be sure you have procedures in place to guarantee that your company builds and maintains high-value portfolios that will thrive in the changing patent landscape.

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