



## Follow-On Biologics: Is Your Product Patent Portfolio Ready?

*Law 360 March 23, 2010 by [Sukduang, Sanya](#), [Davies Ph.D.](#), [Jonathan R.](#)*

### **Leading the way for biotechnology IP protection**

As the research and scientific discoveries of the past decade have moved beyond the lab into the commercial application of biotechnology, explosive growth has occurred in related sectors that require intellectual property protection for survival. Finnegan has advised biotech pioneers on every aspect of intellectual property, including patenting groundbreaking advancements, enforcing patents in litigation, and defending against claims of infringement or ownership by others. In fact, Finnegan successfully represented Eli Lilly and Company in a lawsuit involving the first marketed product produced by biotechnology—human insulin. Finnegan has worked with its clients to develop and execute successful intellectual property strategies. We have provided counseling or litigation services in a range of technologies such as automated DNA sequencing, the cloning of Dolly the sheep, molecular mechanism infringement claims, protein therapies, and advancements in genetically modified crops designed to resist pests and disease.

Established biotech sectors such as human therapeutics, agriculture, diagnostic testing, and drug development have turned the promise of biotech into reality. But with success have come new challenges in the form of greater numbers of competitor patents, the prospect of generic biologics, complex joint development

and marketing collaborations, and potential fundamental changes to the U.S. patent system. The so-called third wave of the biotech movement is also developing new, biotech-based alternatives for materials and energy, environmental remediation, and more environmentally friendly manufacturing processes and raw ingredients. Finnegan has a proven track record of staying abreast of rapid advancements in science and changing legal issues in this fast-paced, multidisciplinary industry. Our depth of experience in the industry also brings rapid understanding of how intellectual property strategy fits in the overall strategy of the business.

### **Sophisticated industry advancements supported by IP**

Strong IP protection has been essential to the advancement of the biotech industry and remains key to its continued growth.

- More biotech companies than ever are developing human therapies that will be tomorrow's blockbuster drugs.
- The threat of bioterrorism and the rise of new infectious diseases have led to renewed interest in vaccines and antibiotics.
- The first generation of antibody-based therapies are in the marketplace and revolutionizing treatment in areas like arthritis and cancer.
- Genomic research has led to advanced discoveries in proteomic and cell-based research with expansive application in diagnosing, treating, and preventing disease and in moving the healthcare field toward a more targeted approach to treating patients.
- Diagnostics companies are using research to better identify and classify diseases and responses to therapeutic treatments.
- Pharmaceutical companies are partnering with biotech firms in drug-discovery efforts to find more effective, targeted, and less invasive ways to treat and prevent diseases.
- Scientists are using biotechnology to manufacture polymers for medical devices and industrial uses such as biodegradable plastics, vitamins, and enzymes, and to grow feed stocks for biofuels.

- Farmers are exponentially increasing yields using fewer resources with the planting of genetically modified crops.
- Labs are using biotechnology to perform more sophisticated chemical analyses for a wide range of applications.

Innovations and strong industry growth rates are anticipated for the remainder of the decade. To succeed, companies and organizations need a seasoned law firm to protect their most valuable IP assets.

### **Understanding the law, science, and technology**

Finnegan's mastery of IP law coupled with our backgrounds in biochemistry, chemistry, and molecular biology and experience in the industry provide us with the necessary resources and expertise to address the most complex biotech issues. Our experience in litigating complex biotechnology cases — both before the district courts — and on appeal is unparalleled in the field. More than half of Finnegan's lawyers who practice in the biotech industry hold doctorate degrees in molecular biology, biochemistry, immunology, or pharmacology. Thirty-four previously held positions in the industry or at universities. And, over 60 of our lawyers have served as patent examiners at the U.S. Patent and Trademark Office. Over the past two decades, Finnegan has provided a full range of services to the biotechnology industry, including:

- Drafting and prosecuting patents for high-value products and technologies.
- Assessing and navigating the dense patent thicket surrounding many new technologies.
- Writing opinions and providing ongoing counseling for new and existing technologies.
- Advocating for, and defending client interests in, complex patent interferences and reexamination proceedings at the U.S. Patent and Trademark Office.
- Litigating high-value current products in district and appellate courts.

- Conducting due diligence for mergers, acquisitions, licensing, and partnering opportunities.
- Structuring, drafting, and negotiating IP license agreements.
- Providing trademark prosecution and counseling services.

## **Global presence**

As emerging markets demand more sophisticated healthcare programs and as global markets and biotech investments expand, clients need a law firm that understands the industry's issues and concerns related to formulating and executing global IP strategies. Our experience, combined with our expanding presence in Asia, established base in Europe, and offices across the U.S. allow us to respond to our clients virtually around the clock. We regularly appear on behalf of our global clients in the International Trade Commission, courts throughout the U.S., and the U.S. Patent and Trademark Office.

## **A diverse client base**

We work with innovative clients of all sizes, including Fortune 100, Global 1000, and public and private organizations in the biotechnology industry:

- Akros Pharma, Inc.
- AstraZeneca
- BioArray Solutions Ltd, a division of Immucor, Inc.
- Celera Diagnostics
- CSL Behring GmbH
- Cubist Pharmaceuticals
- Cypress Bioscience, Inc.
- Eli Lilly and Company
- Emergent BioSolutions
- Five Prime Therapeutics
- Genzyme Corporation

- Geron Corporation
- Human Genome Sciences, Inc.
- sanofi-aventis
- Syngenta