



BIOTECHNOLOGY & PHARMACEUTICAL

BRINKS
HOFER
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& LIONE®

THE BIOPHARMA GROUP

Life-improving innovations in biotechnology and pharmaceuticals require intellectual property counsel with unique technical and legal expertise to protect the assets upon which companies are established and flourish. The BioPharma Group at Brinks Hofer Gilson & Lione includes attorneys and agents who counsel a diverse list of clients, from start-ups to prestigious academic institutions to global corporations, on the ever-evolving law of intellectual property in the United States and throughout the world. Our BioPharma Group members hold wide-ranging science and engineering degrees, many at the advanced level, and have extensive industry work experience in scientific disciplines such as:

- organic chemistry
- biophysics
- molecular biology
- immunology
- genetics
- pharmacology
- medical devices

The BioPharma Group successfully litigates biotech, Hatch-Waxman, and related patent claims in federal district court, and has won several prominent Federal Circuit appeals. We also obtain patents in diverse fields, including genetic microarrays and tissue engineering, and represent clients in interferences and reexaminations relating to receptors and gene therapy. We further unite technology and business by crafting licenses and agreements necessary to protect intellectual assets. We apply our legal, science and business skills to develop effective solutions that meet our client objectives.

■ BIOTECH, HATCH-WAXMAN AND PATENT LITIGATION

We conduct validity and infringement reviews in connection with Paragraph IV certifications for Abbreviated New Drug Applications or 505(b)(2) applications, and we defend clients in Hatch-Waxman, biotech, and related patent litigation. Biotechnology and pharmaceutical clients have selected BioPharma Group litigators to represent them in matters such as:

Edwards Lifesciences LLC, et al. v. Cook Incorporated, et al.

(Fed. Cir. 2009). Brinks successfully defended long-time client, Cook Incorporated, against claims of patent infringement by Edwards Lifesciences LLC and EndoGAD Research Pty Limited. The Federal Circuit affirmed the district court's finding of summary judgment that Cook Incorporated devices do not infringe Edwards' and EndoGAD's patents for endovascular devices to treat aneurysms.

Chiron Corporation v. Genentech, Inc.

(Fed. Cir. 2004). Brinks represented Genentech at the Federal Circuit in the appeal of a jury verdict that Chiron's asserted patent is invalid and Genentech's revolutionary breast cancer drug Herceptin® does not infringe. The Federal Circuit affirmed the verdict.

In Re Omeprazole Patent Litigation

(Fed. Cir. 2003). Brinks represented a generic pharmaceutical manufacturer before the Federal Circuit in an appeal of a district court finding of patent infringement. The patents at issue related to omeprazole used in the treatment of gastric disorders.

■ INTERFERENCES AND REEXAMINATIONS

The BioPharma Group has significant experience in interferences and reexaminations. Some recent examples include:

Genentech, Inc. v. ZymoGenetics, Inc.

(2008-2010). Members of the BioPharma Group represented Genentech, Inc. The interference related to technology involving nucleic acids encoding the Type-1 Cytokine Receptor GLM-R.

Nabel v. Finkel

(1998-2003). Members of the BioPharma Group represented the University of Michigan, assignee of the Nabel patent application. The interference related to gene therapy, specifically a method of treating restenosis with thymidine kinase.

U.S. Patent No. 5,661,133

Expression of a Protein in Myocardium by Injection of a Gene

U.S. Patent No. 4,670,444

7-Amino-1-Cyclopropyl-4-Oxo-1, 4-Dihydro-Quinoline and Naphthyridine-3-Carboxylic Acids and Antibacterial Agents Containing these Compounds

■ PATENT EVALUATIONS

While details of patent evaluations are confidential, BioPharma Group attorneys opine on patents for large and small pharmaceutical and biotechnology companies, as well as for venture capitalists. These projects range from evaluating a single competitor's patent to evaluating large portfolios of acquisition or investment targets, together with freedom to operate studies.

■ LICENSES AND OTHER AGREEMENTS

BioPharma Group attorneys also negotiate and draft agreements for clients, ranging from licensing a single patent to the formation of complex joint ventures. The technologies have ranged from discovery platforms to new chemical entities to diagnostic applications.

■ PATENT PROSECUTION

The BioPharma Group prosecutes and obtains United States and foreign patents for a wide variety of biotechnological and pharmaceutical inventions. Recent examples include:

09/863,293, Pub. No. 2010-0048557

Shielding Device

12/522,280, Pub. No. 2010-0041109

Corynebacterium Glutamicum variety producing L-Arginine and Method for Fabricating the Same

12/488,406, Pub. No. 2010-0035875

Triazolopyridine Jak Inhibitor Compounds and Methods

10/600,180, Pub. No. 2009-0215854

Antimicrobial Compositions, Products and Methods Employing the Same

11/869,512, Pub. No. 2009-0035339

Methods of Inactivating Viruses

11/113,505, Pub. No. 2005-0271711

Therapeutic Antimicrobial Compositions and Methods

WO 2010/011828

Automated Oligosaccharide Synthesizer

WO 2009/014639

Biomarkers for Pre-Diabetes, Cardiovascular Diseases, and Other Metabolic-Syndrome Related Disorders and Methods Using the Same

WO 2009/015336

Controlled Release Interferon Drug Products and Treatment of HCV Infection Using the Same

U.S. Patent No. 7,683,176

Triazolyl Pyridyl Benzenesulfonamides

U.S. Patent No. 7,649,011

Inhibitors of Human Tumor-Expressed CCXCKR2

U.S. Patent No. 7,470,771

Secreted and Transmembrane Polypeptides and Nucleic Acids Encoding the Same

U.S. Patent No. 7,456,015

Tetracycline-Regulated Adeno-Associated Viral (AAV) Vectors for Gene Delivery to the Nervous System

U.S. Patent No. 7,435,557

Methods of Identifying Inhibitors of GTP Cyclohydrolase I and II

U.S. Patent No. 7,195,780

Nanoparticle Delivery System

U.S. Patent No. 6,936,254

Method of Inducing Fetal Hemoglobin Synthesis

U.S. Patent No. 6,867,194

Enzyme Activated Nitric Oxide Donors

U.S. Patent No. 6,818,016

Methods for Coating Stents with DNA and Expression of Recombinant Genes from DNA Coated Stents in Vivo

U.S. Patent No. 6,734,288

Antibodies Against a Secreted Polypeptide that Stimulates Release of Protophyllan from Cartilage

U.S. Patent No. 6,610,540

Low Oxygen Culturing of Central Nervous System Progenitor Cells

U.S. Patent No. 6,592,871

HCV Peptide Antigens and Methods for the Determination of HCV

U.S. Patent No. 6,200,601

Softgel Capsule Containing DHA Antioxidants

■ HEALTH CARE BILL

The "Patient Protection and Affordable Care Act," signed into law on March 23, 2010, provides a new regulatory scheme for the approval of biosimilar versions of branded biologic drugs ("biosimilars") and establishes complex procedures dictating how patent litigation on biosimilars is carried out. BioPharma Group attorneys understand these changes and are prepared to advise pharmaceutical clients about the Act's impact upon their businesses.

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