AMP V. MYRIAD

Supreme Court: *Association for Molecular Pathology v. Myriad Genetics, Inc.* (June 13, 2013)—In a unanimous ruling, the Supreme Court ruled that the genes Myriad Genetics had isolated were products of nature and ineligible for patent protection, but that synthesized DNA molecules remained eligible. The Court noted that its ruling does not involve method claims, patents on new applications of knowledge about the genes at issue, or the patentability of DNA where the naturally occurring nucleotide sequence has been altered .....[Opinion]

BIOLOGICS PRICE COMPETITION AND INNOVATION ACT (BCPIA)

Biologics Price Competition and Innovation Act.....[Legislation]

- FDA Biosimilars Website with links to resources.....[Website]
- FDA Draft Guidance for Industry: Clinical Pharmacology Data to Support a Demonstration of Biosimilarity to a Reference Product (May 2014).....[FDA Guidance]
- FDA Draft Guidance for Industry: Formal Meetings Between the FDA and Biosimilar Biological Product Sponsors or Applicants (March 2013)..... [FDA Industry Guidance]
- FDA Draft Guidance: Biosimilars: Questions and Answers ("Q&A") Regarding Implementation of the Biologics Price Competition and Innovation Act of 2009 (February 2012) .....[FDA Biosimilars Q&A]
- FDA Draft Guidance: Scientific Considerations in Demonstrating Biosimilarity to a Reference Product (February 2012).....[FDA Scientific Considerations]
- FDA Draft Guidance: Quality Considerations in Demonstrating Biosimilarity to a Reference Protein Product (February 2012) .....[FDA Quality Considerations]

ISSUES IN PERSONALIZED MEDICINE

- FDA Guidance for Industry: Clinical Pharmacogenomics: Premarket Evaluation in Early-Phase Clinical Studies and Recommendations for Labeling (January 2013) ..... [Guidance]
- FDA Draft Guidance for Industry: Enrichment Strategies for Clinical Trials to Support Approval of Human Drugs and Biological Products (December 2012) .... [Draft Guidance]
- FDA Draft Guidance for Industry and Food and Drug Administration Staff – In Vitro Companion Diagnostic Devices (July 14, 2011) ..... [Draft Guidance]
- FDA's List of Approved Companion Diagnostics (last updated August 26, 2013) .....[List]

SAFE HARBOR

Section 271(e)(1) of the Patent Act (Title 35 of the U.S. Code) provides that "[i]t shall not be an act of infringement to … use … or import into the United States a patented invention … solely

for uses reasonably related to the development and submission of information under a Federal law which regulates the … use … of drugs."

- ***Momenta v. Amphastar* (Federal Circuit, Aug. 3, 2012)**. In an enoxaparin ANDA case, holding that defendant's tests of a drug that can be comprised of a range of different molecules for purposes of FDA submission do fall under the safe harbor.....[Opinion]
- ***Merck KGaA v. Integra Lifesciences I, Ltd.* (Supreme Ct., 2005)**. Holding that experimentation not ultimately the subject of an FDA submission, or the use of patented compounds in experiments that are not ultimately submitted to the FDA, may in certain circumstances remain exempted from infringement under § 271(e)(1), and remanding for evidentiary review under the proper standard.....[Opinion]

KEY CASES, REPORTS & STATUTES

- ***FTC v. Actavis, Inc.* (Supreme Ct., June 17, 2013)—**Holding that reverse payment settlements of patent litigations are not immune from antitrust liability.....[Opinion]
    - *Reversing: FTC v. Watson Pharmaceuticals* (11th Cir., April 25, 2012)—Holding that a reverse payment settlement agreement generally is "immune from antitrust attack so long as its anticompetitive effects fall within the scope of the exclusionary potential of the patent."[Opinion]
- ***Association for Molecular Pathology v. Myriad Genetics, Inc.* (Supreme Ct., June 13, 2013)**—In a unanimous ruling, the Supreme Court ruled that the genes Myriad had isolated were products of nature and ineligible for patent protection, but that synthesized DNA molecules remained eligible. The Court noted that its ruling does not involve method claims, patents on new applications of knowledge about the genes at issue, or the patentability of DNA where the naturally occurring nucleotide sequence has been altered.....[Opinion]
- ***Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Act) (21 U.S.C. § 355)***—Creates special procedures for identifying and resolving patent disputes between brand-name and generic drug manufacturers, including requiring prospective generic manufacturers to assure the FDA that it will not infringe brand-name patents .....[Public Law 98-417] [21 U.S.C. § 355]

BIOTECH BRIEFINGS

- **Briefing Summer 2012**—This issue of the Biotech Briefing contains two articles. The first article, *Putting* Myriad *in Perspective*, authored by Professor Eileen M. Herlihy (New England Law School in Boston, Massachusetts), discusses the *Myriad* case on patentability of certain DNA based technologies and its similarities with early regulatory issues for recombinant DNA technologies. The second article, *Will Patents Matter in a Biosimilars Future?*, was authored by Dr. Kevin E. Noonan, Ph.D. (Partner with McDonnell Boehnen Hulbert & Berghoff LLP, Chicago, Illinois) and explores

intellectual property issues facing biological drug manufacturers following enactment of the Biologics Price Competition and Innovation Act. .....[Briefing]

- **Briefing Fall 2011**—This issue contains two articles on timely topics: whole genome sequencing, and *Stanford v. Roche*. The article on whole genome sequencing was authored by Gary Marchant (Professor of Law at the Sandra Day O'Connor College of Law, Arizona State University) and Rachel Lindor (Research Fellow at the Sandra Day O'Connor College of Law and Mayo Medical School). Sean O'Connor (Professor of Law at the University of Washington) authored the second article on the Supreme Court's recent decision in *Stanford v. Roche*. .....[Briefing]
- **Briefing Winter 2007/08 (4:2)**—This issue explores a range of issues: the rise of bioethics consulting to biotech corporations; the biosecurity implications of synthetic biology; an update on the joint development by two ABA sections on model legislation for assisted reproductive technology; and the medical, legal, and ethical issues raised by whole body CT scanning. .....[Briefing]
- **Briefing Fall 2007 (4:1)**—This issue contains the articles *"Who Owns Your Genes?" Event Illuminates Arguments For and Against DNA Patenting* (Shawna Williams); and *Ensuring Patent Protection in the Face of Freedom to Operate Issues: How a Long-Term Solution to a Short-Term Problem Could Be Detrimental* (Natalie J. Dean). .....[Briefing]
- **Briefing Fall/Winter 2006/07 (3:1)**—This issue contains the articles *Personalized Medicine & Pharmacogenomics* (Christina DeHayes); *Pharmacogenomics and Physician Liability* (Robert J. Milligan, Gary E. Marchant, and Brian Wilhelmi); and *Reach Through Royalties and the Patent Misuse Defense: Can a Tool Company Still Hit the Jackpot?* (Suzanne K. Nusbaum). .....[Briefing]
- **Briefing Summer 2006 (2:4)**— This issue contains four articles focusing on a different issue arising out of a clinical trial of a new monoclonal antibody in early 2006: *The Emergence of Pre-clinical and Exploratory Phase One Clinical Trials as a Focus of Drug Development Regulation* (Christina L. DeHayes); *Risk Management Applications from TGN 1412 Clinical Trial* (Steve Hall); *Life Sciences Companies and Liability Insurance for Clinical Trials Conducted Abroad* (David T. Case, Julia Reynolds Johnson, and Anand D. Nair); *Toward Ethical Standards of Informed Consent: How Much Disclosure in Human Clinical Trials?* (Alan R. Sharett). .....[Briefing]
- **Briefing Spring 2006 (2:3)**—This issue contains an article by Bruce Bunnell, a member of the Center for Gene Therapy at Tulane, on the impact of Hurricane Katrina on biomedical research at Tulane. Matthew Kleiman, a law student at Duke, and Nader Mousavi, a partner at Wilmer Hale, offer some thoughts on state open records laws and public/private research partnerships. Dan Pancamo, a committee vice-chair and counsel at Phelps Dunbar, revisits wrongful birth and wrongful life actions in light of the Human Genome Project. Richard Pearson, an associate at King & Spalding, offers a tutorial on drug delivery in the age of nanotechnology. .....[Briefing]

ROUNDTABLES

- **Regulatory & Policy Implications of Personalized Medicine & Pharmacogenomics (Monday, April 30, 2007)**: Event flyer and speaker biographies (Janet Woodcock, M.D., and Ellen J. Flannery). *The field of pharmacogenomics deals with the influence of individual genetic variations on drug response in patients. Pharmacogenomic research is helping to pave the way toward better diagnostic tools, safer and more effective treatments, and — ultimately — personalized medicine, with therapy choices on a patient-by-patient basis to maximize effectiveness and minimize side effects for each patient. The advent of personalized medicine will have implications for industry, health care providers, regulators, patients, researchers, and research subjects. In our first Roundtable, in October 2006, Dr. Francis Collins and Professor Toby Citrin spoke about the science of pharmacogenomics and some of the promise of personalized medicine. In this Roundtable, we invite you to learn about the regulatory and policy issues that will arise as researchers, industry, and government regulators move towards implementing a pharmacogenomic approach to medical care.* ..... [Flyer and Agenda]
- **Alan E. Guttmacher and Francis S. Collins, MD, PhD, Commentary: *Realizing the Promise of Genomics in Biomedical Research* (Sep. 21, 2005)**. ..... [Commentary]
- Links to further articles and resources on pharmacogenomics and personalized medicine from the *Personalized Medicine and Pharmacogenomics Roundtable* (Oct. 17, 2006). .....[Links]