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A Guide to Biotechnology Patent Law

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Research Guides

A Guide to Biotechnology Patent Law

Guide Information

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Guide Index

Home
Primary Sources
Secondary Sources
Computerized Research
Interest Groups

Home

Overview

This research guide is intended for use by those interested in biotechnology law. This research guide combines sources that will be most helpful to those new to the field of patent law, specifically in the area of biotechnology.

Biotechnology is broadly defined as the use of biological processes and organisms for the manufacture of products that are used to improve human health. The biotechnology field has grown rapidly over the past three decades since the Supreme Court found that living organisms where patentable subject matter in *Diamond v. Chakrabarty*. This year marks the ten year anniversary of the sequencing of the initial draft of the human genome. The past decade has seen a continued explosion of genetic information available to scientists and patients. Due to the rapid advancement of these genetic technologies, both the patent laws and regulatory laws seek ways to evolve and keep up with this dynamic area of science.

This research guide is an attempt to compile important statutes, regulations, and cases relevant to the field of biotechnology law and patent prosecution. In addition, there are a number of links to important resources for searching prior art in the field of biotechnology. Finally, there are links to recent law review articles and blogs that give an overview of current issues of interest to the biotechnology patent prosecutor.

About the author

Donald Prather is a part-time law student at Georgia State University College of Law. Prior to his interest in patent law, he obtained a Ph.D. in Genetics from Harvard University and began working as a scientist at the Centers for Disease Control and Prevention. He continues to work at CDC in the technology transfer office where he combines his interests in biotechnology and intellectual property law.

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Back to Top

Primary Sources

Statutes

The laws that regulate patents are found in Title 35 of the United States Code. These statutes are based on the Patent Act of 1952.

Title 35 of the United States Code

The United States Code on the Cornell Legal Information Institute is currenlty updated through February 2011. However, on September 16, 2011, President Obama signed the America Invents Act, the first major patent reform Act in nearly sixty years.

America Invents Act

Thus, patent practitioners will need to be familiar with both the "old" and "new" patent laws, since many of the changes in the patent laws take effect on different dates.

Regulations

The regulations that govern patents are found in Title 37 of the Code of Federal Regulations.

Title 37

Manual of Patent Examining Procedure (MPEP)

This lengthy manual sets for the detailed rules for patent prosecution by the United States Patent and Trademark Office.

Manual of Patent Examining Procedure

The manual is broken up into 27 chapters. There is one chapter that specifically addresses biotechnology (Chapter 2400).

Chapter 2400

Selected Biotechnology Cases

Association for Molecular Pathology, et al. v. U.S. Patent and Trademark Office, et al. (the Myriad case)

653 F.3d 1329 (Fed. Cir. 2011)

All eyes of the biotechnology community are waiting to see if the Supreme Court will grant cert in what has become commonly known as the Myriad case. On July 29, 2011, the Federal Circuit reversed the District Court, and found that isolated DNA was indeed patentable subject matter. The lawsuit involves a fight over patents covering two genes, BRCA1 and BRCA2, which are associated with susceptibility to breast cancer. The central issue in the case, whether isolated DNA is patentable subject matter, goes to the heart of the biotechnology industry. Passionate advocates on both sides of the debate will certainly flood the Court with amicus briefs, should the Supreme Court decide to hear the case.

Prometheus Laboratories, Inc. v. Mayo Collaborative Services

628 F.3d 1347 (Fed. Cir. 2010)

This case will be heard by the Supreme Court in the upcoming session. The case involves a method patent for administering a drug (thiopurine drugs to treat gastrointestinal and other autoimmune diseases), measuring the drug level in a patient, and adjusting the dose based on the results. The Federal Circuit had ruled the claims were valid under the machine-or-transformation test and thus were patentable subject matter under 35 U.S.C. § 101. The biotechnology community will be following this decision closely, in light of the Supreme Court's ruling in *Bilski v. Kappos.* In addition, the Court may address the dissent from *LabCorp v. Metabolite, Inc.*, when the Supreme denied cert in a similar case.

Classen Immunotherapies, Inc. v. Biogen Idec

2011 WL 3835409 (Fed. Cir. 2011)

In another case remanded to the Federal Circuit after the Supreme Court's decision in *Bilski v. Kappos*, the court held that two of the three patents with medical method claims recite patentable subject matter under 35 U.S.C. § 101. The court held that the practical inclusion of an immunization step allowed the claims to pass through the "coarse eligibility filter of § 101." The federal circuit also reversed the district court in regards to the "safe harbor" provision of 35 U.S.C. § 271(e)(1) , finding that the safe harbor is limited to obtaining premarket approval for generic medicines, and thus does not shelter the post-approval activities with approved vaccines.

Board of Trustees of Leland Stanford Junior Univ. v. Roche Molecular Systems, Inc.

131 S.Ct. 2188 (2011)

The Supreme Court affirmed the Federal Circuit's finding that the Bayh-Dole Act does not automatically vest ownership of patent rights with a university when the research was federally funded. While this case was closely watched by the technology transfer community, ultimately the case is likely to have little impact, or lasting effect. Instead, this case highlights the importance of having solid employee contracts between the university and researchers making it clear that university researchers will assign all rights over to the university, and for universities to be much more vigilant about agreements that the researchers sign with collaborating partners.

In re Kubin
561 F.3d 1351 (Fed. Cir. 2009)

In April 2009, *In re Kubin* was decided by the Court of Appeals for the Federal Circuit and upheld the Board of Patent Appeals and Interference's finding that patent claims are not patentable when: conventional techniques are used to make an invention, there are a finite number of ways to arrive at the new invention, and there is a reasonable expectation of success of the invention. More specifically, the court held that claims to the deoxyribonucleic acid (DNA) sequence were "obvious" in light of the prior discovery of the protein and because of the availability of a highly specific and commercially available monoclonal antibody. *In re Kubin* has potentially large implications for biotechnology patents, because the court has raised the nonobviousness threshold of 35 U.S.C. § 103 by extending the flexible obviousness test as discussed in *KSR International Co. v. Teleflex Inc.* to biotechnology patent applications.

Back to Top

Secondary Sources

Biotechnology Law Review Articles

How to Claim a Gene: Application of the Patent Disclosure Requirements to Genetic Sequences
P. Brian Giles, Georgia State University Law Review: Vol. 27: Iss. 3, Article 6
This article discusses the difficulties in trying to claim a genetic sequence. Specifically, there is a tension between the scope of the claim and possibly overreaching with a genus claim because that may in turn fail to satisfy the patent disclosure requirements of 35 U.S.C. 112, which requires an adequate written description of the invention and must enable one to make and use the invention. The author suggests identifying sequences by percent identity without including a functional limitation.

Things You Should Care About in the New Patent Statute

Mark Lemley, SSRN Working Paper Series, 2011.

With the passage of the new patent reform act (America Invents Act), a number of changes have been made to the patent laws. This paper provides a quick overview of twenty of those changes, discusses the implications of those changes, provides the effective date of each change, and importantly discusses the some of the ambiguities created by the new law. While these changes are not specific to biotechnology, patent prosecutors in the biotechnology field must understand the changes in the new law in order to counsel their clients on appropriate patent prosecution strategies.

The Impact of Human Gene Patents on Innovation and Access: A Survey of Human Gene Patent Litigation
Christopher Holman, UMKC Law Review, Vol. 76, p. 295, 2007.

With the Myriad case making it to the Federal Circuit, and potentially to the Supreme Court, the interest in gene patents has increased significantly. The author looks at lawsuits that have been filed to determine the impact of gene patents on genetic testing. The author concludes that the effect on genetic testing and genetic research has been minimal, and the main place gene patents have been involved in litigation is in the area of biotechnology-derived protein therapeutics.

Books

- Biotechnology and the patent system : balancing innovation and property rights by Barfield, Claude E.
  Call Number: KF3133.B56 B37 2007
  ISBN: 0844742562
  Publication Date: 2007Good general book that discusses the biotechnology industry and the importance of intellectual property rights in biotechnology.
- A Guide to Biotechnology Law and Business by Bohrer, Robert
  Call Number: KF3133.B56 B64 2007
  ISBN: 1594600872
  Publication Date: 2007This book provides an overview of the relevant cases in biotechnology law, but also provides a lot more information geared toward the interest of biotechnology businesses. This book goes into more detail about what biotechnology companies would be interested in, including FDA law and financing of biotechnology companies.
- 2011 Federal Circuit Yearbook by Gale Peterson and Derrick Pizarro

Call Number: KF3157.A152 F43
ISBN: 1402414560
Publication Date: 2011Good source for yearly updates on federal circuit case law that affects patent law. While not strictly limited to biotechnology, this book gives a good short review of relevant cases broken up into sections based on different areas of patent law. Since this book is published each year, this series is a good source for patent law evolution in the Federal Circuit.

Biotechnology Patent Law Treatises

- Biotechnology and the Federal Circuit by Burchfiel, Kenneth J.
  Call Number: KF3133.B56 B87 2010
  ISBN: 157018738X
  Publication Date: 2010This treatise gives really helpful analysis of the Federal Circuit decisions that are most relevant to the field of biotechnology.

Back to Top

Computerized Research

Biotechnology Prior Art Searches

One of the most important parts of practicing patent law is performing prior art searches. The sites listed here are the most common sites for beginning prior art searches.

Google Patents

Google has collected all the patent information that is publicly available from the United States Patent and Trademark Office. The site contains approximately 8 million patents and 3 million patent applications. The site is more user friendly than the USPTO site and allows you to download a PDF version of the patent.

United States Patent and Trademark Office

This is the official site for the United States Patent and Trademark Office (USPTO). This site gives you all the information necessary for prosecuting patents in the United States. There is a patent search function that allows searching of all issued patents and published patent applications. The search function is not very user friendly and thus requires more knowledge of what exactly you are searching for.

Public PAIR (Patent Application Information Retrieval)

This site within the USPTO website provides lots of detailed information regarding the patent prosecution history of each patent. This site provides lots of details including important dates, correspondence with the USPTO, schedule of fees due, patent term adjustments, and a listing of references for each patent.

PubMed

This is the primary site for searching for publications in the biomedical literature. It contains over 21 million citations to search various biomedical journals. This site is maintained by the National Center for Biotechnology Information (NCBI) at the National Institutes of Health (NIH). The resulting searches provide full text links to articles that are publicly available.

Biotechnology Blogs

Patently-O

Patently-O is the leading blog in the United States for patent lawyers. It is a blog operated by Professors Dennis Crouch, from the University of Missouri School of Law, and Jason Rantanen from the University of Iowa School of Law. It is not specific to biotechnology patent lawyers, and is updated constantly with detailed analysis of important cases, tips for patent prosecution, and reports patent-related statistics. In addition, the comments on this blog can actually be helpful as well, given that many practicing patent experts in the field follow this blog.

Patent Docs

This blog labels itself as a biotech and pharma patent news blog. The blog is run by Kevin E. Noonan (founding author and former husband of Supreme Court Justice Sonia Sotomayor) and Donald Zuhn, both partners with McDonnell Boehnen Hulbert & Berghoff LLP. This site reports new biotech and pharma cases filed that week. The site also arranges the post by patent law topics, and thus makes it easy to find posts relating to a particular biotech topic of interest.

Holman's Biotech IP Blog

This biotech blog is run by Professor Chris Holman from the University of Missouri-Kansas City School of Law. While there are only a handful of posts each month,

the posts are very informative. Thus, if there is a post on your topic of interest, then it will likely have a good detail of information as a starting point for further research.

The Genomics Law Report

This blog provides commentary in the specific area of genomics, personalized medicine and the law. The blog is run by attorney Dan Vorhaus, an associate with the firm Robinson, Bradshaw, & Hinson. This blog is very informative for those biotechnology scientists who are interested in genetic testing and provides commentary on recent cases and FDA issues related to genetic technologies.

Back to Top

Interest Groups

General Intellectual Property

American Intellectual Property Law Association (AIPLA)

AIPLA is one of the most popular intellectual property professional organizations. This website is geared more toward practicing intellectual property lawyers. The group is involved in intellectual property policy and advocacy, produces reports on intellectual property economic activity, and maintains a career center for information regarding careers in intellectual property law.

Intellectual Property Owners Association (IPO)

This is the website of the IPO trade association that represents owners of intellectual property (patents, trademarks, copyrights, and trade secrets). This group is composed of more than 10,000 intellectual property lawyers and in-house corporate counsel. IPO advocates for changes to the laws that increase certainty with regard to intellectual property issues in order to decrease unnecessary litigation. The site contains links to legislation, important cases and briefs, and provides a number of publications and intellectual property statistics.

Biotechnology Groups

Biotechnology Industry Organization (BIO)

BIO is the largest representative organization for the biotechnology and life sciences community. The group advocates for legislation on behalf of the biotechnology industry and files amicus briefs in appropriate cases. The group also puts on an annual trade show that is attended by more than 15,000 biotechnology professionals from around the globe.

Association of University Technology Managers (AUTM)

The Association of University Technology Managers is a group of more than 3500 technology transfer professionals. Due to the importance of universities as incubators of biotechnology research, this group represents a large group biotechnology lawyers, biotechnology licensing professionals, and emerging biotechnology companies.

Back to Top

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