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Gene Patents: A Brief Overview of Intellectual Property Issues

John R. Thomas
Visiting Scholar

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Summary

In the past, the U.S. courts upheld gene patents that met the criteria of patentability defined by the Patent Act. However, the practice of awarding patents on genes came under scrutiny by some scientists, legal scholars, politicians, and other experts. In June 2013, the Supreme Court ruled in *Association for Molecular Pathology v. Myriad Genetics, Inc.* that genomic DNA was ineligible for patenting under 35 U.S.C. §101 due to the "product of nature" doctrine. However, the Court adopted the view that cDNA could be patented. The *Myriad* holding attempts to provide inventors and firms with incentives to conduct R&D while recognizing that patent proprietors might obtain too much control over medical practice and future research.

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Patents

The Patent Act of 1952, codified in Title 35 of the United States Code, defines current patent law. According to section 101, one who "invents or discovers any new and useful process, machine, manufacture, or any composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title." To be patentable, an invention must be useful, novel, and nonobvious. The requirement of usefulness, or utility, is satisfied if the invention is operable and provides a tangible benefit. To be judged novel, the invention must not be fully anticipated by a prior patent, publication, or other knowledge within the public domain. A nonobvious invention must not have been readily within the ordinary skills of a competent artisan at the time the invention was made. The invention must be fully described. Once the United States Patent and Trademark Office (USPTO) issues a patent, the owner enjoys the right to exclude others from making, using, selling, offering to sell, or importing into the United States the patented invention. Generally, the term of a patent is 20 years from the date the application was filed. In the process of obtaining a patent, the information associated with the patent is published and made available to the public.

Gene Patents

In a June 2013 decision, the Supreme Court of the United States ruled in *Association for Molecular Pathology v. Myriad Genetics, Inc.,*[1] that genomic DNA was ineligible for patenting under 35 U.S.C. §101 because of the "product of nature" doctrine. Products of nature (preexisting substances found in the wild) may not be patented, *per se*. However, the courts have also determined that such a product of nature may be patentable if significant artificial changes are made. By purifying, isolating, or otherwise altering a naturally occurring product, an inventor may obtain a patent on the product in its altered form.[2]

Adopting the view that isolated and purified genomic DNA satisfied this exception to the "product of nature" doctrine, the USPTO issued over 50,000 patents relating at least in part to DNA.[3] However, some experts believed that the decision to patent human genes misconstrued the "product of nature" principle. In their view, the fact that scientists have isolated a gene is a "technicality" that did not allow genes to be patented.[4]

The Supreme Court decision in *Myriad* reflects this latter position. The litigation commenced on May 12, 2009, when the Association for Molecular Pathology and 19 other plaintiffs, including individual physicians, patients, and researchers, filed a lawsuit against the USPTO, Myriad Genetics, Inc., and the Directors of the University of Utah Research Foundation. The plaintiffs challenged several patents owned by Myriad that claim isolated human genes known as BRCA1 and BRCA2.[5] Certain alterations or mutations in these genes are associated with a predisposition

[1] 569 U.S. ___, 106 USPQ2d 1972 (2013).

[2] Diamond v. Chakrabarty, 417 U.S. 303 (1980).

[3] See Guyan Lian, "Molecules or Carriers of Biological Information: A Chemist's Perspective on the Patentability of Isolated Genes," 22 Albany Law Journal of Science and Technology (2012), 133.

[4] See, for example, Eileen M. Kane, "Splitting the Gene: DNA Patents and the Genetic Code," 71 Tennessee Law Review (2004), 707.

[5] For example, claim 1 of U.S. Patent No. 5,747,282 recites: "An isolated DNA coding for a BRCA1 polypeptide, said (continued...)

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to breast and ovarian cancers. Due to its intellectual property rights, Myriad was the sole commercial provider of genetic testing related to breast and ovarian cancer associated with the BRCA1 and BRCA2 genes. The plaintiffs asserted that Myriad's gene patent claims were invalid because, in their view, human genes are naturally occurring products that do not constitute patentable subject matter.

The U.S. District Court for the Southern District of New York sided with the plaintiffs and held that Myriad's gene patent claims were invalid under 35 U.S.C. §101.[6] Judge Sweet reasoned that Myriad's claimed isolated DNA was not "markedly different from native DNA as it exists in nature" and therefore could not be patented.[7] Following an appeal, the Federal Circuit reversed this holding.[8] The Court of Appeals reasoned that "isolated" DNA is not merely "purified" DNA—rather, it has been "manipulated chemically so as to produce a molecule that is markedly different from that which exists in the body."[9] Under this reasoning, human genes consist of patentable subject matter.

The Supreme Court subsequently agreed to hear the *Myriad* case but did not issue a ruling in the matter. Rather, on March 26, 2012, the Court vacated the judgment and remanded the matter back to the Federal Circuit with instructions to reconsider the appeal. The Federal Circuit responded by once again holding that both isolated DNA and cDNA were patent eligible.[10] The Supreme Court then granted *certiorari*.[11]

Justice Thomas, writing for the Court, initially observed that Myriad had neither created nor altered the generic information encoded in the BRCA1 and BRCA2 genes. Rather, Myriad had discovered the precise location and genetic sequence of those genes. According to Justice Thomas, then, "Myriad did not create anything. To be sure, it found an important and useful gene, but separating that gene from its surrounding genetic material is not an act of invention."[12] The Supreme Court also was unimpressed that Myriad claimed DNA that had been isolated from the human genome through the severing of chemical bonds, with a non-naturally occurring molecule as a result. According to Justice Thomas, "Myriad's claims are simply not expressed in terms of chemical composition, nor do they rely in any way on the chemical changes that result from the isolation of a particular section of DNA."[13]

The Court took a more favorable view of cDNA, however. Observing that "cDNA retains the naturally occurring exons of DNA, but it is distinct from the DNA from which it was derived," Justice Thomas concluded that cDNA did not constitute a "product of nature" and therefore could be patented.

(...continued)

polypeptide having the [following] amino acid sequence…."

[6] 702 F. Supp. 2d 181, 94 USPQ2d 1683 (S.D.N.Y. 2010).

[7] Ibid., at 232, 94 USPQ2d at 1722.

[8] 653 F.3d 1329, 99 USPQ2d 1398.

[9] Ibid., at 1352, 99 USPQ2d at 1415.

[10] 689 F.3d 1323 (Fed. Cir. 2012).

[11] 568 U.S. ___ (2012).

[12] 106 USPQ2d at 1979.

[13] Ibid., at 1980.

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Justice Thomas also found it important to note what the *Myriad* opinion did not implicate. The case involved neither an innovative method of manipulating genes while searching for the BRCA1 and BRCA2 genes, the Court explained, nor new applications of knowledge about those genes. The Court also indicated that it had not considered the patentability of DNA in which the order of the naturally occurring nucleotides has been altered. Instead, the Court "merely [held] that genes and the information they encode are not patent eligible under §101 simply because they have been isolated from the surrounding genetic material."[14]

The opinion of Justice Thomas was joined in full by seven of his colleagues. Justice Scalia contributed a one-paragraph concurring opinion that joined the judgment of the Court and all of its opinion except those portions "going into fine details of molecular biology."[15] Justice Scalia found himself "unable to affirm those details on my own knowledge or even my own belief."[16] This shortcoming did not prevent him from concluding that isolated genomic DNA was identical to its natural state, however, while cDNA could be patented because it was a synthetic creation not found in nature.

Shortly after the Supreme Court issued its ruling, Myriad Genetics, Inc. and other plaintiffs commenced patent infringement litigation against certain genetic testing service providers.[17] Although the Supreme Court invalidated Myriad's claims on genomic DNA, Myriad asserted claims toward other genetic technologies. These claims recite in part, among other subject matter, a "method for detecting a germline alteration in a BRCA1 gene,"[18] an "isolated DNA coding for a BRCA1 polypeptide,"[19] a "method for screening germline of a human subject for an alteration of a BRCA1 gene,"[20] and a "pair of single-stranded DNA primers."[21] This litigation may provide further guidance as to the patentability of gene-related inventions in the wake of the Supreme Court's decision.

Legal Issues

The *Myriad* holding is expected to make it difficult for inventors to protect early, gene-related discoveries through the patent system. In particular, how the courts will apply the decision to other biologic products, including antisense DNA, microRNA, nucleic acids, proteins, and stem cells remains to be seen. However, the Supreme Court appears to approve of patent claims drawn to chemical modifications of naturally occurring substances, particularly if that modification endows the substance with a new property. For example, even slightly altered genes would appear to comprise patentable subject matter. As the USPTO explained in a memorandum released hours after the *Myriad* case issued:

[14] Ibid., at 1981.

[15] Ibid.

[16] Ibid.

[17] See Alanna Byrne, "Myriad sues competitors over genetic testing," *Inside Counsel* (July 11, 2013).

[18] U.S. Patent No. 5,709,999, claim 6.

[19] U.S. Patent No. 5,747,282, claim 6.

[20] U.S. Patent No. 5,753,441, claim 7. Claim 7 is a dependent claim that incorporates claim 1 of the `441 patent, from which the recited language is quoted.

[21] U.S. Patent No. 5,837,492, claim 29.

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> As of today, naturally occurring nucleic acids are not patent eligible merely because they have been isolated. Examiners should now reject product claims drawn solely to naturally occurring nucleic acids or fragments thereof, whether isolated or not, as being ineligible subject matter under 35 U.S.C. §101. Claims clearly limited to non-naturally-occurring nucleic acids, such as a cDNA or a nucleic acid in which the order of the naturally occurring nucleotides has been altered (e.g., a man-made variant sequence), remain eligible. Other claims, including method claims, that involve naturally occurring nucleic acids may give rise to eligibility issues and should be examined under the existing guidance ... [22]

Firms that employ cDNA to develop novel therapeutic proteins stand to benefit from the *Myriad* case. Still, one wonders if the Court neglected to recall its earlier holding in *Mayo v. Prometheus*[23] that that conventional or obvious pre-solution activity does not transform an unpatentable law of nature into a patent-eligible application of such law. cDNA is derived from DNA and is identical to DNA except that the non-coding regions have been removed—a choice dictated by natural laws and not the inventor. Further, the production of cDNA is reportedly well-understood and routine. Arguably, then, no scientific distinction pertinent to patent eligibility exists between genomic DNA and cDNA. Under *Myriad*, however, DNA is not patentable subject matter but cDNA may be patented.

Ethical Issues

Gene patents have been subject to a longstanding debate. Although the Supreme Court declared that genomic DNA may not be patented, it held that cDNA fulfills the requirements of 35 U.S.C. §101. In addition, the USPTO has issued other sorts of gene-related inventions, including those relating to genetic screening methods, polypeptides, DNA primers, and other technologies. As a result, the debate on gene patents potentially remains active. Some of its main contours are outlined below.

An often held belief is that gene patents permit outsiders ownership of another person's genetic makeup, often without their knowledge or consent.[24] This concern led to complaints that patients no longer control their own bodies and doctors are being constrained from testing for various diseases.[25] Professor Lori Andrews argues that patents hinder access to testing procedures because "gene-patent holders can control any use of 'their' gene; they can prevent a doctor from testing a patient's blood for a specific genetic mutation and can stop anyone from doing research to improve a genetic test or to develop a gene therapy based on that gene."[26] This perceived constraint on research and testing options is an issue to opponents of gene patents.[27] According to Dr. Debra Leonard, patents on "specific genetic information limits the medical use of the

[22] USPTO, Memorandum from Andrew H. Hirshfeld, Deputy Commissioner for Patent Examination Policy, to the Patent Examining Corps (June 13, 2013) (available at http://www.patentlyo.com/files/myriad_20130613.pdf).

[23] 566 _U.S. _, 132 S. Ct. 1289 (2012). See also CRS Report R42815, *Mayo v. Prometheus: Implications for Patents, Biotechnology, and Personalized Medicine*, by John R. Thomas.

[24] Michael Crowley, "They Own Your Body," *Readers Digest*, August 2006, available at http://www.rd.com.

[25] Debra G.B. Leonard, "Medical Practice and Gene Patents: A Personal Perspective," *Academic Medicine*, December 2002, 1388.

[26] Lori B. Andrews, "Genes and Patent Policy: Rethinking Intellectual Property Rights," *Nature Reviews*, October 2002, 804.

[27] John F. Merz, "Disease Gene Patents: Overcoming Unethical Constraints on Clinical Laboratory Medicine," *Clinical Chemistry*, 45:3, 1999, 324.

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information and impedes or prevents widespread research on the disease, the traditional pathway by which medical knowledge is advanced and shared."[28]

However, other experts disagree. As noted by Dr. Jorge Goldstein and Attorney Elina Golod, the courts have consistently "taken the position that a person does not own any tissues or cells once they are outside the person's body."[29] Attorneys Lee Bendekgey and Dr. Diana Hamlet-Cox found no evidence of patients unable to utilize existing genetic tests because of patents. Instead, they maintain, it is a financial issue associated with the cost of health care and/or an issue of profits for the doctor or clinical geneticist wishing to administer tests patented by other inventors.[30] Similarly, Professor Iain Cockburn found "there is little quantitative evidence thus far of a negative impact of patents on scientific research activity.... "[31] From his perspective, the disclosure obligations of the patent system may better serve the objective of encouraging the diffusion of knowledge and raising social returns than the chief legal alternative, trade secret protection.[32]

Economic Issues

Actual experience and cited studies suggest that companies which do not control the results of their investments—either through ownership of patent title, exclusive license, or pricing decisions—tend to be less likely to engage in related R&D. Patents can provide an economic incentive for companies to pursue further development and commercialization. Studies indicate that research funding accounts for approximately one-quarter of the costs associated with bringing a new product to market. According to *The Economist*, "A dollar's worth of academic invention or discover requires upwards of $10,000 of private capital to bring [it] to market."[33] Patent ownership is seen as a way to encourage the additional, and often substantial investment necessary for new goods and services, particularly in the case of small business. In an academic setting, the possession of title to inventions is expected to provide motivation for the university to license the technology to the private sector for commercialization in anticipation of royalty payments.

While various analyses indicate that the value of patents differs across industries and between firms of different maturation levels within a sector,[34] the pharmaceutical industry perceives patents as critical to protecting innovation. Several studies over the years have demonstrated the important role patents play in the pharmaceutical sector. Of the 18 major manufacturing industries

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[28] *Medical Practice and Gene Patents: A Personal Perspective*, 1388.

[29] Jorge A. Goldstein and Elina Golod, "Human Gene Patents," *Academic Medicine*, December 2002, Part 2, 1321.

[30] Lee Bendekgey and Diana Hamlet-Cox, "Gene Patents and Innovation," *Academic Medicine*, December 2002, Part 2, 1378

[31] Iain M. Cockburn, Blurred Boundaries: Tensions Between Open Scientific Resources and Commercial Exploitation of Knowledge in Biomedical Research, April 30, 2005, 15, available at http://people.bu.edu/cockburn/cockburn-blurred-boundaries.pdf

[32] Ibid., 11.

[33] "Innovation's Golden Goose," *The Economist (US)*, December 14, 2002, available at http://www.economist.com/node/1476653?story_id=1476653.

[34] Stuart J.H. Graham, Robert P. Merges, Pam Samuelson, and Ted Sichelman, "High Technology Entrepreneurs and the Patent System: Results of the 2008 Berkeley Patent Survey," *Berkeley Technology Law Journal*, April 16, 2010, 1255, available at http://www.btlj.org/data/articles/24_feature.pdf.

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analyzed by Richard Levin and his colleagues, only drug companies rated product patents the most effective means of ensuring that firms can capture the profits associated with their innovations.[35] Later research by Professor Wesley Cohen et.al demonstrated that patents were considered the most effective method to protect inventions in the drug industry, particularly when biotechnology is included.[36] A recent paper by several professors at the Berkeley School of Law, University of California, found that there were "substantial differences between the health-related sectors (biotechnology and medical devices), in which patents are more commonly used and considered important, and the software and Internet fields, in which patents are reported to be less useful."[37] These studies reinforce earlier work by the late Professor Edwin Mansfield that indicated 65% of pharmaceutical inventions would not have been brought to market without patent protection in contrast to the 8% of innovations made in other industries.[38]

Patents may be particularly important in the pharmaceutical sector because of the relative ease of replicating the finished product. Imitation costs vary among industries. For example, while it is expensive, complicated, and time consuming to duplicate an airplane, it is relatively simple to chemically analyze a pill and reproduce it.[39] The degree to which industry perceives patents as effective has been characterized as "positively correlated with the increase in duplication costs and time associated with patents."[40] Other commentators note that patents are particularly important in this sector because of the relative ease of replicating the finished product. Costs associated with imitating a product "are extremely low relative to the innovator's costs for discovering and developing a new compound."[41] Early research in this area by Mansfield indicated that, in certain industries, patents significantly raise the costs incurred by nonpatent holders wishing to use the idea or invent around the patent—an estimated 40% in the pharmaceutical sector, 30% for major new chemical products, and 25% for typical chemical goods—and are thus viewed as significant. However, in other industries, patents have much smaller impact on the costs associated with imitation (e.g., in the 7%-15% range for electronics), and may be considered less successful in protecting resource investments.[42]

Opponents of gene patents argue that they restrain additional research because "there are no alternatives to a patented gene in diagnosis, treatment, and research,"[43] and owners require licensing fees.[44] However, despite what some experts claim to be a negative result of financial

[35] Richard C. Levin, Alvin K. Klevorick, Richard R. Nelson, and Sidney G. Winter. "Appropriating the Returns for Industrial Research and Development," *Brookings Papers on Economic Activity*, 1987, in *The Economics of Technical Change*, eds. Edwin Mansfield and Elizabeth Mansfield (Vermont, Edward Elgar Publishing Co., 1993), 255 and 257.

[36] Wesley M. Cohen, Richard R. Nelson, and John P. Walsh, *Protecting Their Intellectual Assets: Appropriability Conditions and Why U.S. Manufacturing Firms Patent (or Not)*, NBER Working Paper 7552, Cambridge, National Bureau of Economic Research, February 2000, available at http://www.nber.org/papers/w7552.

[37] *High Technology Entrepreneurs and the Patent System: Results of the 2008 Berkeley Patent Survey*, 1255.

[38] Edwin Mansfield, "Patents and Innovation: An Empirical Study," *Management Science*, February 1986, 173-181.

[39] Federic M. Scherer, "The Economics of Human Gene Patents," 77 *Academic Medicine*, December 2002, 1350.

[40] *Appropriating the Returns for Industrial Research and Development*, 269.

[41] Henry Grabowski, "Patents and New Product Development in the Pharmaceutical and Biotechnology Industries," *Duke University Economics Working Paper*, July 2002, available at http://www.econ.duke.edu/Papers/Other/Grabowski/Patents.pdf, 4.

[42] Edwin Mansfield, Mark Schwartz, and Samuel Wagner, "Imitation Costs and Patents: An Empirical Study," *The Economic Journal*, December 1981, in *The Economics of Technical Change*, 270.

[43] *Patents on Human Genes: An Analysis of Scope and Claims*, 1566.

[44] *They Own Your Body.*

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considerations in the biomedical research community,[45] others maintain that, at most, gene patents "prevent the doctors and clinical geneticists from performing these tests for profit, or in a way that competes with the patent holder, without reimbursement to the inventors of those tests."[46]

Some analysts assert that certain patents, particularly those on research tools[47] in biotechnology, hinder the innovation process. Professors Rebecca Eisenberg and Richard Nelson state that ownership of research tools may "impose significant transaction costs" that result in delayed innovation and possible future litigation.[48] They argue that patents also can stand in the way of research by others:

> Broad claims on early discoveries that are fundamental to emerging fields of knowledge are particularly worrisome in light of the great value, demonstrated time and again in the history of science and technology, of having many independent minds at work trying to advance a field. Public science has flourished by permitting scientists to challenge and build upon the work of rivals.[49]

Professor Arti Rai argues that "the most important research tools are fundamental research platforms that open up new and uncharted areas of investigation" that need further development by researchers in the field.[50] While acknowledging that patent protection on research tools has stimulated private investment in biotechnology and the development of new products and processes, Eisenberg writes that:

> Patents on research tools threaten to restrict access to discoveries that, according to the firm beliefs of scientists trained in the tradition of open science, are likely to have the greatest social value if they are widely disseminated to researchers who are taking different approaches to different problems.[51]

Other commentators dispute these assertions. F. Scott Kieff, then a member of the visiting faculty at Northwestern University School of Law, maintains that there was no such "norm" regarding open scientific access as opposed to intellectual property protection in the basic biological science community.[52] He notes that "experience shows that patents on inputs generally do not prevent the production of outputs" and that the availability of intellectual property protection has expanded the resources available in the biotechnology community and led to its success.[53] Bendekgey and Hamlet-Cox agree that there is no evidence that gene patents have caused a decrease in research as a whole in the biomedical arena or in gene therapies.[54]

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[45] *Medical Practice and Gene Patents: A Personal Perspective*, 1390.

[46] *Gene Patents and Innovation*, 1378.

[47] A biotechnology research tool is a cell line, reagent, or antibody used in research.

[48] Rebecca S. Eisenberg and Richard R. Nelson, "Public vs. Proprietary Science: A Fruitful Tension?," *Daedalus*, Spring 2002.

[49] Ibid.

[50] Arti Rai, "Genome Patents: A Case Study in Patenting Research Tools," *Academic Medicine*, December 2002, Part 2, 1369.

[51] Rebecca Eisenberg, "Why the Gene Patenting Controversy Persists," *Academic Medicine*, December 2002, Part 2, 1383.

[52] F. Scott Kieff, "Facilitating Scientific Research: Intellectual Property Rights and the Norms of Science – A Response to Rai and Heisenberg," *Northwestern University Law Review*, Winter 2001, 694.

[53] Ibid., 704.

[54] *Gene Patents and Innovation*, 1377, 1378.

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A study by Professors John Walsh, Ashish Arora, and Wesley Cohen found little evidence that work has been curtailed due to intellectual property issues associated with research tools.[55] Scientists are able to continue research by "licensing, inventing around patents, going offshore, the development and use of public databases and research tools, court challenges, and simply using the technology without a license (i.e., infringement)." According to the authors, private sector owners of patents permitted such infringement in academia (with the exception of those associated with diagnostic tests in clinical trials) "partly because it can increase the value of the patented technology."

A later analysis by Professors Walsh, Cohen, and Charlene Cho concluded that patents do not have a "substantial" impact upon basic biomedical research and that "none of [their] random sample of academics reported stopping a research project due to another's patent on a research input, and only about 1% of the random sample of academics reported experiencing a delay or modification in their research due to patents."[56] However, obtaining "tangible" research inputs (e.g., actual materials) appear to be more difficult because of competition, cost, and time issues.[57]

Concluding Observations

Congress has exhibited a strong and ongoing interest in facilitating the development of new, innovative pharmaceuticals for the marketplace while reducing the cost of drugs to consumers. To date, the U.S. system of research, development, and commercialization has had a clear impact on the pharmaceutical and biotechnology industries. Policies pertaining to funding for research and development (R&D), intellectual property protection, and cooperative ventures have played an important role in the economic success of these sectors.[58]

A critical component of many of these federal efforts concerns patents.[59] Patent ownership can provide an economic incentive for companies to take the results of research and make the often substantial investment necessary to bring new goods and services to the marketplace. The grant of a patent provides the inventor with a mechanism to capture the returns to his invention through exclusive rights on its practice for a limited time. In the pharmaceutical industry, patents are perceived as particularly important to innovation due, in part, to the ease of duplicating the invention. Now with the decision in *Myriad*, it remains to be seen what the effect may be on research and development in this area and on innovation in the health care arena.

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[55] John P. Walsh, Ashish Arora, Wesley M. Cohen, "Working Through the Patent Problem," *Science*, February 14, 2003, 1021.

[56] John P. Walsh, Charlene Cho, and Wesley Cohen, *Patents, Material Transfers and Access to Research Inputs in Biomedical Research*, September 20, 2005, 37, available at http://tigger.uic.edu/~jwalsh/WalshChoCohenFinal050922.pdf.

[57] Ibid., 2.

[58] Iain Cockburn, Rebecca Henderson, Luigi Orsenigo, and Gary P. Pisano, "Pharmaceuticals and Biotechnology," *U.S. Industry in 2000* (National Academy Press, Washington, 1999), 365.

[59] See CRS Report RL32076, *The Bayh-Dole Act: Selected Issues in Patent Policy and the Commercialization of Technology*, by Wendy H. Schacht, and CRS Report RL32324, *Federal R&D, Drug Discovery, and Pricing: Insights from the NIH-University-Industry Relationship*, by Wendy H. Schacht.

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Author Contact Information

John R. Thomas
Visiting Scholar
jrthomas@crs.loc.gov, 7-0975

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