Patent Reform: Issues in the Biomedical and Software Industries

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Summary

The Leahy-Smith America Invents Act, P.L. 112-29, passed Congress following several years of legislative debate over patent reform. This attention to patent policy reflects a recognition of the increasing importance of intellectual property to U.S. innovation. Patent ownership is perceived as an incentive to the technological advancement that leads to economic growth. As such, the number of patent applications and grants has grown significantly, as have the type and breadth of inventions that can be patented.

Along with the expansion in the number and range of patents, there were growing concerns over whether the current system was working efficiently and effectively. Several studies recommended patent reform and various bills were introduced in recent congresses that would make significant alterations in current patent law. Other experts maintained that major changes in existing law were unnecessary and that, while not perfect, the patent process was adapting to technological progress.

The patent laws provide a system under which all inventions are subject to the same requirements of patentability regardless of the technical field in which they arose. However, inventors and innovative companies in different industries often hold divergent views concerning the importance of patents, reflecting varying experiences with the patent system. Innovators in the biomedical sector tend to see patent protection as a critically important way to prohibit competitors from appropriating the results of a company's research and development efforts. Typically only a few, often one or two, patents cover a particular drug. In contrast, the nature of software development is such that inventions often are cumulative and new products generally embody numerous patentable inventions. As a result, distinct industries may react differently to the patent reform legislation enacted by Congress.

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Introduction

Following several years of congressional debate over patent reform, P.L. 112-29, the Leahy-Smith America Invents Act was passed in September 2011.[1] This attention to patent policy reflects a recognition of the increasing importance of intellectual property to U.S. innovation. Patent ownership is perceived as an incentive to the technological advancement that leads to economic growth. As such, the number of patent applications and grants have grown significantly as have the type and breath of inventions that can be patented. In 1980, 104,329 utility patent applications were received at the U.S. Patent and Trademark Office (USPTO); by 2010, this number had more than quadrupled to 456,106 applications. During the same time period, the number of U.S. utility patents granted grew from 61,819 to 219,614.[2]

Along with the expansion in the number and range of patents, there were growing concerns over whether the patent system was working efficiently and effectively. Several recent studies (including those by the National Academy of Sciences and the Federal Trade Commission)[3] recommended patent reform. While some experts maintained that major alterations in existing law were unnecessary and that, while not perfect, the patent process was adapting to technological progress, Congress arguably made the most significant changes to the patent statute since the 19th century when it enacted P.L. 112-29.

Among other provisions, the Leahy-Smith America Invents Act introduces into U.S. law a first-inventor-to-file priority rule, an infringement defense based upon prior commercial use, and assignee filing. The legislation prevents patents from claiming or encompassing human organisms, limits the availability of patents claiming tax strategies, and restricts the best mode requirement. The statute also makes notable reforms to administrative patent challenge proceedings at the U.S. Patent and Trademark Office (USPTO) and to the law of patent marking. Along with numerous other changes to patent laws and procedures, these reforms were intended to modernize the U.S. patent system and to improve its fairness and effectiveness.

The discussion of patent reform led to the emergence of several, often opposing, points of view. While the patent laws provide a system under which all inventions are treated the same regardless of the technical field, the varying experiences of companies in different industries often give rise to differing views concerning the importance and role of patents. Innovators in biomedical industries tend to see patent protection as critically important as a way to prohibit competitors from appropriating the results of a company's research and development efforts. Typically only a few, often one or two, patents cover a particular drug. In contrast, the nature of software development is such that inventions tend to be cumulative and new products generally embody numerous patentable inventions. Acknowledging these differences, this report explores the relationships between patents and innovation and looks at the role of intellectual property in the biomedical and software industries, two sectors where U.S. investment in research and

[1] For a detailed discussion of P.L. 112-29 see CRS Report R42014, *The Leahy-Smith America Invents Act: Innovation Issues*, by (name redacted) and (name redacted).

[2] U.S. Patent and Trademark Office, *U.S. Patent Statistics, Calendar Years 1963-2010*, available at http://www.uspto.gov/web/offices/ac/ido/oeip/taf/us_stat.pdf .

[3] National Research Council, National Academy of Sciences, *A Patent System for the 21st Century*, (Washington, National Academies Press, 2004) and Federal Trade Commission, *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy*, October 2003, available at http://www.ftc.gov.

development (R&D) has led to market leadership, a strong export position, and contributed to the Nation's economic growth.

Patents and Innovation

Patent law is based upon the Patent Act of 1952, codified in Title 35 of the United States Code. According to the statute, 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."[4] Patents are issued by the United States Patent and Trademark Office (USPTO), generally for a term of 20 years from the date of filing. The patent grants its owner the right to exclude others from making, using, selling, offering to sell, or importing into the United States the patented invention. To be afforded patent rights, an invention must be judged to consist of patentable subject matter, possess utility, and be novel and nonobvious. The application must fully disclose and distinctly claim the invention for which protection is sought.

The grant of a patent does not necessarily provide the owner with an affirmative right to market the patented invention. For example, pharmaceutical products are also subject to marketing approval by the Food and Drug Administration (FDA).[5] Federal laws typically require that pharmaceutical manufacturers demonstrate that their products are safe and effective in order to bring these drugs to the marketplace. USPTO issuance of a patent and FDA marketing consent are distinct events that depend upon different criteria.[6]

Patent ownership is perceived to be an incentive to innovation, the basis for the technological advancement that contributes to economic growth. Patent title provides the recipient with a limited-time monopoly over the use of his discovery in exchange for the public dissemination of information contained in the patent application. Award of a patent is intended to stimulate the investment necessary to develop an idea and bring it to the marketplace embodied in a product or process, although it does not guarantee that the patent will generate commercial benefits. The requirement for publication of the patent is expected to stimulate additional innovation and other creative means to meet similar and expanded demands in the marketplace.

Innovation produces new knowledge. However, innovation typically is costly and resource intensive. Studies demonstrate that the rate of return to society as a whole generated by investments in research and development leading to innovation is significantly larger than the benefits that can be captured by the person or organization financing the work.[7] Some estimate that the social rate of return on R&D spending is over twice that of the rate of return to the inventor. Ideas often are easily imitated as the knowledge associated with an innovation is

[4] 35 U.S.C.§101.

[5] For more information see CRS Report R41114, *The Hatch-Waxman Act: A Quarter Century Later*, by (name red acted) and (name redacted), and CRS Report RL30756, *Patent Law and Its Application to the Pharmaceutical Industry: An Examination of the Drug Price Competition and Patent Term Restoration Act of 1984 ("The Hatch-Waxman Act")*, by (name redacted) and (name redacted).

[6] For more information see CRS Report RL33288, *Proprietary Rights in Pharmaceutical Innovation: Issues at the Intersection of Patents and Marketing Exclusivities*, by (name redacted).

[7] For a list of relevant research in this area see Council of Economic Advisors. *Supporting Research and Development to Promote Economic Growth: The Federal Government's Role*, October 1995, 6-7.

dispersed and adapted to other products and processes that, in turn, stimulate growth in the economy. Patents permit novel concepts or discoveries to become "property" when reduced to practice and therefore allow for control over their use.

Issuance of a patent furnishes the inventor with a limited-time exclusive right, the benefits of which are mitigated by other factors, particularly the requirements for information disclosure, the length of the patent, and the scope of rights conferred. The process of obtaining a patent places the concept on which it is based in the public domain. In return for a monopoly right to the application of the knowledge generated, the inventor must publish the ideas covered in the patent. As a disclosure system, the patent can, and often does, stimulate other firms or individuals to invent "around" existing patents to provide for parallel technical developments or meet similar market needs.

Patents may also provide a more socially desirable outcome than its chief legal alternative, trade secret protection. Trade secrecy guards against the improper appropriation of valuable, commercially useful information that is the subject of reasonable measures to preserve its secrecy.[8] Taking the steps necessary to maintain secrecy, such as implementing physical security and enforcement, imposes costs that may ultimately be unproductive for society.[9] Also, while the patent law obliges inventors to disclose their inventions to the public,[10] trade secret protection requires firms to conceal them. The disclosure obligations of the patent system may better serve the objective of encouraging the diffusion of advanced technological knowledge. Patents may also prevent unproductive expenditures of time and money associated with R&D that duplicates other work.

The patent system thus has dual policy goals—providing incentives for inventors to invent and encouraging inventors to disclose technical information.[11] Disclosure requirements are factors in achieving a balance between current and future innovation through the patent process, as are limitations on scope, novelty mandates, and nonobviousness considerations.[12] Patents often give rise to an environment of competitiveness with multiple sources of innovation, which is viewed by some experts as the basis for technological progress. This is important because, as Professors Robert Merges and Richard Nelson found in their studies, in a situation where only "a few organizations controlled the development of a technology, technical advance appeared sluggish."[13]

Not everyone agrees that the patent system is a particularly effective means to stimulate innovation. Some observers believe that the patent system encourages industry concentration and presents a barrier to entry in some markets.[14] They suggest that the patent system often converts

[8] American Law Institute, Restatement of Unfair Competition Third §39, 1995.

[9] David D. Friedman, et al., "Some Economics of Trade Secret Law," 5 *Journal of Economic Perspectives*, 1991, 61.

[10] 35 U.S.C. §112 (2000).

[11] Robert P. Merges, "Commercial Success and Patent Standards: Economic Perspectives on Innovation," *California Law Review*, July 1988, 876.

[12] Kenneth W. Dam, "The Economic Underpinnings of Patent Law," *Journal of Legal Studies*, January, 1994, pp. 266-267. Scope is determined by the number of claims made in a patent. Claims are the technical descriptions associated with the invention. In order for an idea to receive a patent, the law requires that it be "new, useful [novel], and nonobvious to a person of ordinary skill in the art to which the invention pertains."

[13] Robert P. Merges and Richard R. Nelson, "On the Complex Economics of Patent Scope," *Columbia Law Review*, May 1990, 908.

[14] See (name redacted), "Collusion and Collective Action in the Patent System: A Proposal for Patent Bounties," (continued...)

pioneering inventors into technological suppressors, who use their patents to block subsequent improvements and thereby impede technological progress.[15] Others believe that the patent system too frequently attracts speculators who prefer to acquire and enforce patents rather than engage in socially productive activity such as bringing new products and processes to the marketplace.[16]

Some experts argue that patents do not work as well in reality as in theory because they do not confer perfect appropriability. In other words, they allow the inventor to obtain a larger portion of the returns on his investment but do not permit him to capture all the benefits. Patents can be circumvented and infringement cannot always be proven. Thus, patents are not the only way, nor necessarily the most efficient means, for the inventor to protect the benefits generated by his efforts. A study by Yale University's Richard Levin and his colleagues concluded that lead time, learning curve advantages (e.g., familiarity with the science and technology under consideration), and sales/service activities were typically more important in exploiting appropriability than were patents. That was true for both products and processes. However, patents were found to be better at protecting products than processes. The novel ideas associated with a product often can be determined through reverse engineering—taking the item apart to assess how it was made. That information then could be used by competitors if not covered by a patent. Because it is more difficult to identify the procedures related to a process, other means of appropriation are seen as preferable to patents, with the attendant disclosure requirements.[17]

An analysis of the literature in this area performed for the World Intellectual Property Organization[18] highlights several conclusions concerning the use of patents that mirror much of the above discussion. The research surveyed indicates that "lead time and secrecy seem to be the most relevant appropriability devices for most sectors" and that while patents may not be the most effective means to protect inventions, they are still utilized by firms in all industries. There is a consensus that "disclosure and ease of inventing-around are the most important reasons for not patenting." At the same time, "patents are more relevant as an appropriability mechanism for product than for process innovations and for some sectors such as chemicals (especially pharmaceuticals), some machinery industries and biotechnology."

Role of Patents in Biomedical R&D

Research demonstrates that the value of patents is differs across industries and between firms of different maturation levels within a sector.[19] The pharmaceutical industry perceives patents as

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University of Illinois Law Review, 2001, 305.

[15] *On the Complex Economics of Patent Scope*, 839.

[16] Elizabeth D. Ferrill, "Patent Investment Trusts: Let's Build a Pit to Catch the Patent Trolls," *6 North Carlina Journal of Law and Technology*, 2005, 367.

[17] 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), 254.

[18] Andres Lopez, "Innovation and Appropriability, Empirical Evidence and Research Agenda," in *The Economics of Intellectual Property*, World Intellectual Property Organization, January 2009, 21, available at http://www.wipo/int/export/sites/www/ip-development/en/economics/pdf/wo_1012_e.pdf.

[19] 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.

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 analyzed by Richard Levin and his colleagues, only drug companies rated product patents the most effective means of insuring that firms can capture the profits associated with their innovations.[20] Later research by Professor Wesley Cohen and his colleagues demonstrated that patents were considered the most effective method to protect inventions in the drug industry, particularly when biotechnology is included.[21] 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."[22] 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.[23]

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.[24] 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."[25] 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.[26]

The costs associated with imitating pharmaceuticals "are extremely low relative to the innovator's costs for discovering and developing a new compound."[27] Studies by Dr. Joseph DiMasi of Tufts University and others indicate that the capitalized cost of bringing a new drug (defined as a "new molecular entity" rather than a new formulation of an existing pharmaceutical product) to the point of marketing approval was $802 million (2000 dollars).[28] Additional research done by analysts at the Federal Trade Commission found the costs to be even higher; between $839

[20] *Appropriating the Returns for Industrial Research and Development*, 255 and 257.

[21] 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.

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

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

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

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

[26] 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.

[27] 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.

[28] Joseph A. DiMasi, Ronald W. Hansen, and Henry G. Grabowski. "The Price of Innovation: New Estimates of Drug Development Costs," 22 *Journal of Health Economics*, 2003. Capitalized cost includes the "time cost" associated with an investment and the cost of testing drug products that fail.

million and $868 million (2000 dollars).[29] Later work argues that it now takes over $1 billion to bring a new drug to market.[30] At the same time, the total capitalized costs appear to be growing at an annual rate of 7.4% above general price inflation.[31]

A large portion of new drug costs (in terms of money and time) are associated with the size and breath of clinical trials necessary to obtain FDA marketing approval. According to a study supported by the Federal Reserve Bank of Boston, only 10% of potential drug candidates reach the human trial phase and only a small portion of these actually reach the market.[32] In research presented at a conference sponsored by the Federal Reserve Bank of Dallas, Duke University's Henry Grabowski found that only 1% of drug compounds reach the human trial stage and 22% of those entering clinical trials receive FDA approval.[33] Professor Iain Cockburn notes that "as drug discovery became more science-intensive, ... it became not just more expensive but also more difficult to manage."[34] Furthermore, returns to new drug introductions vary widely and the median new drug does not bring in sufficient profits to cover the costs of bringing the product to the marketplace.[35] According to research by Professors Grabowski, John Vernon, and DiMasi, only 34% of new drugs (new chemical entities) introduced generated profits that equaled the industry average R&D cost.[36]

The significant costs of pharmaceutical R&D, coupled with the uncertainty of the clinical trial process, lend consequence to patents in this area because "the disparity between the investments of innovators and those of imitators is particularly large in pharmaceuticals—almost as large as when software pirates simply copy the diskettes of an innovator."[37] While the capitalized cost of developing a new drug to the point of market approval is about $1 billion, it takes only between $1 million and $2 million to obtain approval for a generic version of the pharmaceutical.[38] This difference is a result of the costs associated with clinical trials needed to demonstrate the safety and efficacy of a new drug, data that could be utilized by generic companies if not protected by a patent.[39] A generic company does not have to fund these studies to get FDA marketing approval; under the provisions of the Hatch-Waxman Act generic firms only have to prove that their product is "bioequivalent" to the innovator drug.[40]

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[29] Christopher P. Adams and Van V. Brantner, *Estimating the Costs of New Drug Development: Is it Really $802m?*, Federal Trade Commission, December 2004, available at http://media.romanvenable.net/images/drugCost.pdf.

[30] Christopher Paul Adams and Van Vu Brantner, "Spending on New Drug Development," *Health Economics*, (published online 26 Feb.2009) Epub ahead of print.

[31] *The Price of Innovation: New Estimates of Drug Development Costs*, 180.

[32] Carrie Conway, "The Pros and Cons of Pharmaceutical Patents," *Regional Review*, Federal Reserve Bank of Boston, March 2003, available at http://www.findarticles.com.

[33] Henry G. Grabowski, "Patents, Innovation, and Access to New Pharmaceuticals," *Journal of International Economic Law*, 2002, 851.

[34] Iain Cockburn, "The Changing Structure of the Pharmaceutical Industry," *Health Affairs*, January/February 2004, 15.

[35] Henry G. Grabowski, "Patents and New Product Development in the Pharmaceutical and Biotechnology Industries," *Science and Cents: Exploring the Economics of Biotechnology*, Proceedings of a 2002 Conference, Federal Reserve Bank of Dallas, pp. 95-96 available at http://www.dallasfed.org/research/pubs/science/grabowski.pdf and Henry Grabowski, John Vernon, and Joseph A. DiMasi, "Returns on Research and Development for 1990s New Drug Introductions," 20 *Pharmacoeconomics*, 2002.

[36] *Returns on Research and Development for 1990s New Drug Introductions*, 23.

[37] *The Economics of Human Gene Patents*, 1352.

[38] *Patents, Innovation, and Access to New Pharmaceuticals*, 852.

[39] *The Economics of Human Gene Patents*, 1352.

[40] For more information see CRS Report RL30756, *Patent Law and Its Application to the Pharmaceutical Industry: An*
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While patents are designed to spur innovation, some experts maintain that certain patents, particularly those on research tools[41] in biotechnology, hinder the innovation process. Professors Rebecca Eisenberg and Richard Nelson argue that ownership of research tools may "impose significant transaction costs" that result in delayed innovation and possible future litigation.[42] It 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 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.[43]

Eisenberg and her colleague at the University of Michigan Law School, Michael Heller, contend that in the future scientists might need to obtain numerous patent licenses in order to undertake basic research.[44] Similar concerns were expressed by Harold Varmus, President of Memorial Sloan-Kettering and formerly the Director of the National Institutes of Health. In July 2000 prepared testimony, he spoke to being "troubled by widespread tendencies to seek protection of intellectual property increasingly early in the process that ultimately leads to products of obvious commercial value, because such practices can have detrimental effects on science and its delivery of health benefits."[45]

However, other experts dispute this assertion. A study by Professors John Walsh, Ashish Arora, and Wesley Cohen found that although there are now more patents associated with biomedical research, and on more fundamental work, there is little evidence that work has been curtailed due to intellectual property issues associated with research tools.[46] Scientists are able to continue their 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 of the report, 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."

Later research by Cohen, Walsh, and Charlene Cho found that "only 1% of academic researchers (i.e., those in universities, non-profits and government labs) report having to delay a project, and none abandoned a project due to others' patents, suggesting that neither anti-commons nor

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Examination of the Drug Price Competition and Patent Term Restoration Act of 1984 ("The Hatch-Waxman Act"), by (name redacted) and (name redacted).

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

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

[43] Ibid.

[44] Michael A. Heller and Rebecca S. Eisenberg, "Can Patents Deter Innovation? The Anticommons in Biomedical Research," 280 *Science*, 1998, 698-701.

[45] U.S. Congress, House Committee on the Judiciary, Subcommittee on Courts and Intellectual Property, *Hearings on Gene Patents and Other Genomic Inventions*, July 13, 2000, available at http://www.house.gov/judiciary/seve0713.htm.

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

restrictions on access were seriously limiting academic research."[47] In addition to finding that patents did not interfere with ongoing R&D, the authors found that patents had "significantly less" impact on what projects were actually pursued than lack of funding, time constraints, or scientific competition. However, "respondents doing research on drugs and therapies were ... somewhat more likely to report that unreasonable terms demanded for research inputs were an important reason for them not to pursue a project."[48]

Role of Patents in the Software Industry

Over the past 25 years, there has been a demonstrable and sustained increase in the number of software patents granted in the United States. Research by James Bessen and Robert Hunt for the Federal Reserve Bank of Philadelphia noted that the 1,000 software patents issued annually in the early 1980s[49] had increased to an annual total of 5,000 by 1990. Today over 20,000 software patents are granted each year. While software patents comprised approximately 2% of all patents awarded in the early 1980s, they now account for approximately 15% of the total number of U.S. patent issued each year.[50]

Experts differ as to their assessment of the role of patents in promoting innovation in the computer software sector. This discussion centers around the issue of whether the increase in the number of patents is a result of inventive behavior generated by intellectual property protection or a result of changes in law during the 1980s and 1990s that made patents on software easier to obtain. Some experts argue that patent protection is not a significant factor in the development of computer software programs. Other analysts maintain that they play an important role in generating new technologies, particularly for small firms in the marketplace.

The nature of software development is such that inventions often are cumulative and new products generally embody numerous patentable inventions. This has led to what has been described by some observers as a

> poor match between patents and products in the [software] industry: it is difficult to patent an entire product in the software industry because any particular product is likely to include dozens if not hundreds of separate technological ideas.[51]

This situation may be augmented by the multiplicity of patents often associated with a finished computer product that utilizes the software. It is not uncommon for thousands of different patents (relating to hardware and software) to be embodied in one single computer. In addition, ownership of these patents may well be fractured among hundreds or thousands of different individuals and firms.

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[47] Wesley M. Cohen and John P. Walsh, *Real Impediments to Academic Biomedical Research*, NBER, May 15, 2007, 12 and forthcoming in *Innovation Policy and Economics*, Vol. 7, available at http://nber15.nber.org/books_in_progress/innovation8/cohen-walsh6-19-07.pdf. See also John P. Walsh, Charlene Cho, and Welsely Cohen, "View from the Bench: Patents and Material Transfers," *Science*, 23 September 2005, 2002-2003.

[48] Ibid., 13.

[49] There is no official USPTO category for "software" patents; Bessen and Hunt use their own definition.

[50] James Bessen and Robert M. Hunt, *An Empirical Look at Software Patents*, Working Paper No. 03-17/R, Federal Reserve Bank of Philadelphia, March 2004, p. 3, available at http://www.phil.frb.org and Robert Hunt and James Bessen, "The Software Patent Experiment," *Q3 2004 Business Review*, 24, available at http://www.phil.frb.org.

[51] Ronald J. Mann, "Do Patents Facilitate Financing in the Software Industry?," *Texas Law Review*, March 2005, 979.

Studies by Bessen and Hunt explored the characteristics of software patents and determined that most are not owned by software companies but by large manufacturing companies. They found that

> Firms in just three manufacturing industries (machinery, electronics, and instruments) alone accounted for 66 percent of software patents [yet] ... Firms outside the manufacturing sector employed 90 percent of computer programmers, but together they accounted for only 25 percent of software patents.[52]

This data leads the authors to the conclusion that patents may not be closely tied to the development of new software technologies. Ownership of such patents is concentrated in sectors that have large patent portfolios and use them for strategic purposes.[53] Instead, they believe that companies are utilizing patents as a means to protect or leverage their investments rather than to generate more innovation through R&D spending.[54]

In industries where innovation is sequential and complementary, as with software and computers, some experts argue that strong patents interfere with the innovation process.[55] Inventions in these sectors typically are built upon earlier technologies and are integrated into existing systems. Commentators pose that patents inhibit or prevent enhancements to existing products because the patent owner may not have the interest or capability necessary to generate improvements at the same time that other firms cannot advance the technology without infringing on the original patent.

Not everyone agrees with this assessment. Professor Robert Merges maintains that patents have not hindered innovation in the software industry and that the significant ownership of title to inventions by large companies in this sector has not resulted in the demise of small firms developing new technologies.[56] Analysis of software companies by Professor Ronald Mann indicates the importance of software patents to small companies, particularly later-stage start-ups firms. He notes that the software industry is comprised primarily of small businesses and "the data suggests a different picture, one in which software R&D is impressively robust."[57] Mann's research indicates that small firms spend proportionally more on software R&D than large companies. Research and development spending by software firms "tends to be relatively stable over time as a percentage of sales. Indeed, company size seems to be more important in explaining variations in R&D spending within the industry."[58]

Studies by Mann also indicate that the importance of software patents is dependent on where the firm is in its development process. Patents play a more significant role in later-stage start-up companies when firms can generate revenues through licensing.[59] At that point, "patents are

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[52] *The Software Patent Experiment*, 26.

[53] *An Empirical Look at Software Patents*, 4.

[54] *The Software Patent Experiment*, 26.

[55] James Bessen and Eric Maskin, "Sequential Innovation, Patents, and Imitation," *Massachusetts Institute of Technology Working Paper, Department of Economics*, January 2000, p. 2 available at http://www.researchoninnovation.org/patent.pdf.

[56] Robert P. Merges, "The Uninvited Guest: Patents on Wall Street," *Federal Reserve Bank of Atlanta Economic Review*, 4th Quarter 2003, 9.

[57] *Do Patents Facilitate Financing in the Software Industry?*, 1002.

[58] Ibid., 1003.

[59] Ibid., 985.

useful as "barter" in cross-licensing agreements that the firm enters if it reaches a sufficiently mature stage to be a significant player in the industry."[60] Patents may allow a firm to differentiate its areas of expertise and innovative activity.[61]

Patents enable a company to transform ideas into a tangible form of property that can provide value. This can be useful in negotiations for the acquisition of the firm. While intellectual property is important to some investors but not to others, it is considered a significant factor when a company is involved in acquisition negotiations or in an IPO.[62] It can prevent large companies from appropriating a small firm's technology. Bradford Smith and Susan Mann, writing in the University of Chicago Law Review, concur with the argument that patents are beneficial for small, software firms. They maintain that patents prevent larger companies from utilizing the technologies developed by small businesses while allowing these companies to attract venture capital.[63]

The multiplicity of patents involved in computer-related products has resulted in the extensive use of cross licensing in these industries such that one commentator argues: "licensing of software patents has become an industry unto itself."[64] Instead of promoting innovation, some experts maintain that the ownership of intellectual property has become an obstacle to the development and application of new ideas. The expansion in the number of patents associated with software is a consequence of the changes in patent law that make these patents easier to obtain, rather than an indication of increased innovative activity. There are indications, according to Bessen and Hunt, that patents are being substituted for increases in R&D.[65] The substitution occurs in industries that patent strategically but not in other sectors.[66] The propensity to patent software appears to be related to the utilization of the software by companies rather than to the R&D resources expended in developing the product.[67] This is of interest because a rationale behind the patent system is that it provides incentives for the additional investments necessary to bring a product to the marketplace.

Concerns have been expressed in the academic community that the propensity to patent and the extensive use of cross licensing has resulted in a "patent thicket" where ownership of patent title is used to block others from innovating. According to Bessen and Hunt, "This may have increased the attractiveness of a strategy that emphasizes patent rights over a strategy based on R&D."[68] However, other experts maintain that this might not be a true assessment of the situation. In an article for the Virginia Journal of Law and Technology, David Evans and Anne Layne-Farrar argue it is not clear that a patent thicket exists. "Other industries with long-standing histories of patenting could be categorized as having cumulative and sequential R&D, yet they do not display

[60] Ibid., 990.

[61] Ibid., 985.

[62] Ibid., 978.

[63] Bradford L. Smith and Susan O. Mann, "Innovation and Intellectual Property Protection in the Software Industry: An Emerging Role for Patents?," *University of Chicago Law Review*, winter 2004, 206.

[64] Mark H. Webbink, "A New Paradigm for Intellectual Property Rights in Software," *Duke Law and Technology Review*, 2005, 12 and 16.

[65] *The Software Patent Experiment*, 28-29.

[66] *An Empirical Look at Software Patents*, 34.

[67] *The Software Patent Experiment*, 27.

[68] Ibid., 30.

signs of innovation gridlock."[69] There are additional ways to prevent the use of patents to block innovation including the use of pro-competitive patent pools and antitrust enforcement.

Others agree that innovation in the software industry is not hindered by a patent thicket. In one study where actual software companies and investors were surveyed, the analyst found new companies were not concerned with existing patent portfolios as a barrier to their work as "none of the startup firms [interviewed] suggested a practice of doing prior art searches before beginning development of their products."[70] Because the software industry is so diverse, it is "difficult for any single patent or group of patents to control a major part of the whole industry."[71]

Concluding Observations

Innovators in the biomedical and software industries tend to exhibit divergent views on the value of patents. Patent protection is critically important to the pharmaceutical and biotechnology sectors as a way to prohibit competitors from appropriating the results of a company's research and development efforts. However,

> patents are not among the key means used to protect innovations in either the computer or semiconductor industries. In those two industries, firms rely more heavily on secrecy, lead time and complementary capabilities to protect their inventions.[72]

A difference between the role of patents in the biomedical community and their role in the computer software sector lies with the dissimilar composition of the respective products. Typically only a few, often one or two, patents cover a particular drug. In contrast, the nature of software development is such that inventions often are cumulative and new products generally embody numerous patentable inventions. While few companies other than those that manufacture drugs need to deal with the relevant pharmaceutical patents,

> computers are ubiquitous—and as a result, so is software authorship ... Thus, a patent on a drug creates potential liability for those companies in the pharmaceutical business, while a software patent creates potential liability for any company with its own website or software customizations, regardless of its business.[73]

The patent laws provide a system under which all inventions are subject to the same requirements of patentability regardless of the technical field in which they arose. The reforms embodied in the Leahy-Smith America Invents Act continue this approach. As a consequence, inventors and innovative companies in different industries, with varying patent experiences, may display diverse opinions on the changes to the patent law. According to Professor Brian Kahin, these distinct views of the patent reform issue reflect

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[69] David S. Evans and Anne Layne-Farrar, "Software Patents and Open Source: The Battle Over Intellectual Property Rights," *Virginia Journal of Law and Technology*, Summer 2004, 23.

[70] *Do Patents Facilitate Financing in the Software Industry?*, 1004.

[71] Ibid., 1007.

[72] *Protecting Their Intellectual Assets: Appropriability Conditions and Why U.S. Manufacturing Firms Patent (or Not)*, 8.

[73] Ben Klemens, *The Computer-Shaped Hole in the Patent Reform Act*, The Brookings Institution, July 28, 2005.

> the contrast between the discrete-product environment of pharmaceuticals and chemicals and the extreme complex-product environment associated with information technology.… In contract to the classic use of patents to exclude competitors in pharmaceuticals, … the large volume of patents relative to [information technology]products imposes a cost burden and makes the IT sector prone to inadvertent infringement and vulnerable to patent trolls.[74]

Thus, it remains to be seen how these identified differences might be affected by the patent reform legislation recently enacted by the U.S. Congress.

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[74] Brian Kahin, "Patents and Diversity in Innovation," *Michigan Telecommunications and Technology Law Review*, April 27, 2007, 390, available at http://www.mttlr.org/volthirteen/kahin.pdf.