

Patent "Evergreening": Issues in Innovation and Competition

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Summary

"Patent evergreening" is a potentially perjorative term that generally refers to the strategy of obtaining multiple patents that cover different aspects of the same product, typically by obtaining patents on improved versions of existing products. Although the patent system allows improvement patents to be obtained in any industry, evergreening is said to be most common in the pharmaceutical industry.

Some observers believe that the availability of so-called continuation applications at the U.S. Patent and Trademark Office (USPTO) may promote evergreening practices. USPTO regulations that would have restricted the availability of continuation applications have been struck down by the courts on the grounds that the regulations exceeded the agency's statutory authority to promulgate. Others believe that the Hatch-Waxman Act, specialized legislation that governs the resolution of patent disputes between brand-name and generic drug companies, may also encourage evergreening in the pharmaceutical industry. However, 2003 amendments to the Hatch-Waxman Act may have mitigated some of these concerns.

Critics of evergreening assert that the ability to obtain multiple patents on a product, over a period of many years, effectively extends the term of exclusivity that the patent holder obtains. They further assert that this practice is abusive, impedes the introduction of generic medications, and has a negative effect upon public health in the United States.

Other observers believe that the term "evergreening" is itself inappropriate. In their view, sound intellectual property policy allows innovators to obtain patents on improvement inventions. Most technological advance occurs incrementally, they observe, and many improvement patents cover advances that are of considerable practical significance to patients and other consumers. In addition, patents on improvements may not impede the ability of competitors to market products that were covered by expired patents on original technologies. Finally, the developer of the "original" product is not always the same entity as the developer of "improvement" technologies. The ability of any innovator to obtain a patent upon an improvement invention is said to promote competition.

Should Congress conclude that the current situation is satisfactory, then no action need be taken. If Congress wishes to intervene, however, a number of options present themselves. Congress may wish to consider the regulation of continuation applications or the introduction of statutory provisions that more directly address the perceived problem of evergreening. In addition, more generalized reform of the patent system may address concerns over evergreening. Current bills before the 111th Congress would potentially introduce a broad range of reforms in an effort to improve the patent system, and would perhaps respond to criticisms of evergreening practices.

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Introduction

Legislative interest in the interaction between intellectual property and public health has been evidenced by considerable discussion of a number of bills in the 111th Congress. Some of this legislation would establish marketing exclusivities for biologic medicines alongside an expedited marketing approval pathway for follow-on products.[1] The 111th Congress has also sustained consideration of proposals that would introduce a broad range of reforms to the patent system[2] and further discussed settlements of patent disputes that potentially delay the market entry of generic drugs.[3]

Another persistent issue at the intersection of patents and public health is the practice of "evergreening."[4] Also known as "stockpiling," "layering," "life-cycle management," or "line extension,"[5] evergreening generally consists of obtaining multiple patents that cover different aspects of the same product. This approach is said to be most common in the pharmaceutical industry, where patents cover such aspects of drugs as their active ingredient, formulations, methods of medical treatment, method of manufacturing, and chemical intermediates.[6] Critics of evergreening assert that the ability to obtain multiple patents on a product, over a period of many years, effectively extends the term of exclusivity that the patent holder obtains.[7] They further assert that this practice is abusive, impedes the introduction of generic medications, and has a negative effect upon public health in the United States.[8]

Other observers believe that the term "evergreening" is perjorative and misdescribes longstanding intellectual property policy that allows innovators to obtain patents on improvement inventions.[9] In their view, improvements upon previously patented inventions may be of great medical significance. As well, all patents have been reviewed by the U.S. Patent and Trademark Office (USPTO) and are presumptively valid,[10] whether some observers choose to characterize them as

[1] *See* CRS Report RL33901, *Follow-On Biologics: Intellectual Property and Innovation Issues*, by Wendy H. Schacht and John R. Thomas.

[2] *See* CRS Report R40481, *Patent Reform in the 111th Congress: Innovation Issues*, by Wendy H. Schacht and John R. Thomas.

[3] U.S. House of Representatives, Committee on the Judiciary, Hearing on Pay to Delay: Are Patent Settlements That Delay Generic Drug Market Entry Anticompetitive? (June 3, 2009).

[4] *See* Sarah Harding, "Perpetual Property," 61 *Florida Law Review* (2009), 285.

[5] *See* Michael Enzo Furrow, "Pharmaceutical Patent Life-Cycle Management After *KSR v. Teleflex*," 63 *Food and Drug Law Journal* (2008), 275.

[6] *See* Bryan Mercurio, "The Impact of the Australia-United States Free Trade Agreement on the Provision of Health Services in Australia," 26 *Whittier Law Review* (2005), 1051.

[7] *See* Sarah Beth Myers, "A Healthy Solution for Patients and Patents: How India's Legal Victory Against A Pharmaceutical Giant Reconciles Human Rights with Intellectual Property Rights," 10 *Vanderbilt Journal of Entertainment and Technology Law* (2008), 763.

[8] *See* Christine S. Paine, Comment, Brand-Name Drug Manufacturers Risk Antitrust Violations by Slowing Generic Production Through Patent Layering, 33 *Seton Hall Law Review* (2003), 479.

[9] *See* GlaxoSmithKline Briefings, "Evergreening" (March 2007) (available at http://www.gsk.com/policies/GSK-and-evergreening.pdf) (hereinafter "Evergreening Briefing"). This report will nonetheless use the term "evergreening" due to its widespread usage.

[10] 35 U.S.C. § 282 (2006).

the result of "evergreening" practices or not.[11] In addition, competitors of the patent owner may be able to market inventions covered by expired patents without regard to subsequent patents. As a result, improvement patents may not have a significant negative impact upon generic competition.[12]

This report reviews the current debate regarding patent evergreening. It begins by introducing the patent system and the role of patents in innovation. It then introduces the concept of evergreening and identifies competing views concerning this practice. This report closes with congressional issues and options.

Patent Fundamentals

The U.S. Constitution confers upon Congress the power "To promote the Progress of ... useful Arts, by securing for limited Times to ... Inventors the exclusive Right to their ... Discoveries.... "[13] In accordance with the Patent Act of 1952,[14] an inventor may seek the grant of a patent by preparing and submitting an application to the USPTO. USPTO officials known as examiners then determine whether the invention disclosed in the application merits the award of a patent.[15]

USPTO procedures require examiners to determine whether the invention fulfills certain substantive standards set by the patent statute. An invention that constitutes a "process, machine, manufacture, or composition of matter" may be patented.[16] It must also be novel, or different, from subject matter disclosed by an earlier patent, publication, or other state-of-the-art knowledge.[17] In addition, an invention is not patentable if "the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains."[18] This requirement of "nonobviousness" prevents the issuance of patents claiming subject matter that a skilled artisan would have been able to implement in view of the knowledge of the state of the art.[19] The invention must also be useful, a requirement that is satisfied if the invention is operable and provides a tangible benefit.[20]

In addition to these substantive requirements, the USPTO examiner will consider whether the submitted application fully discloses and distinctly claims the invention.[21] In particular, the application must enable persons skilled in the art to make and use the invention without undue

[11] *See* Natalie Derzko, "The Impact of Recent Reforms of the Hatch-Waxman Scheme on Orange Book Strategic Behavior and Pharmaceutical Innovation," 45 *IDEA: The Journal of Law and Technology* (2005), 165.

[12] *See* Evergreening Briefing, *supra*.

[13] Article I, Section 8, Clause 8.

[14] P.L. 82-593, 66 Stat. 792 (codified at Title 35 of the United States Code).

[15] 35 U.S.C. § 131 (2006).

[16] 35 U.S.C. § 101 (2006).

[17] 35 U.S.C. § 102 (2006).

[18] 35 U.S.C. § 103(a) (2006).

[19] *See* KSR International Co. v. Teleflex Inc., 550 U.S. 398 (2007).

[20] *See* In re Fischer, 421 F.3d 1365, 1371 (Fed. Cir. 2005).

[21] 35 U.S.C. § 112 (2006).

experimentation.[22] In addition, the application must disclose the "best mode," or preferred way, that the applicant knows to practice the invention.[23]

If the USPTO allows the patent to issue, its owner obtains the right to exclude others from making, using, selling, offering to sell or importing into the United States the patented invention.[24] Those who engage in those acts without the permission of the patentee during the term of the patent can be held liable for infringement. Adjudicated infringers may be enjoined from further infringing acts.[25] The patent statute also provides for an award of damages "adequate to compensate for the infringement, but in no event less than a reasonable royalty for the use made of the invention by the infringer."[26]

The maximum term of patent protection is ordinarily set at 20 years from the date the application is filed.[27] At the end of that period, others may employ that invention without regard to the expired patent.

Patent rights do not enforce themselves. Patent owners who wish to compel others to respect their rights must commence enforcement proceedings, which most commonly consist of litigation in the federal courts. Although issued patents enjoy a presumption of validity, accused infringers may assert that a patent is invalid or unenforceable on a number of grounds. The Court of Appeals for the Federal Circuit (Federal Circuit) possesses nationwide jurisdiction over most patent appeals from the district courts.[28] The Supreme Court enjoys discretionary authority to review cases decided by the Federal Circuit.[29]

The Evergreening Controversy

Introduction to Evergreening

According to Janice Mueller, a member of the faculty of the University of Pittsburgh School of Law, and Donald Chisum, a retired member of the Santa Clara University Law School faculty, "evergreening refers to attempts by owners of pharmaceutical product patents to effectively extend the term of those patents on modified forms of the same drug, new delivery systems for the drug, new uses of the drug, and the like."[30] Various properties of a drug that are eligible for patenting include methods of manufacture, methods of medical treatment, chemical

[22] *See* Invitrogen Corp. v. Clontech Labs., Inc., 429 F.3d 1052, 1070-71 (Fed. Cir. 2005).

[23] *See* High Concrete Structures, Inc. v. New Enterprise Stone and Lime Co., 377 F.3d 1379, 1382 (Fed. Cir. 2004).

[24] 35 U.S.C. § 271(a) (2006).

[25] 35 U.S.C. § 283 (2006). *See* eBay Inc. v. MercExchange L.L.C., 547 U.S. 388 (2006).

[26] 35 U.S.C. § 284 (2006).

[27] 35 U.S.C. §154(a)(2) (2006). Although the patent term is based upon the filing date, the patentee obtains no enforceable legal rights until the USPTO allows the application to issue as a granted patent. A number of Patent Act provisions may modify the basic 20-year term, including examination delays at the USPTO and delays in obtaining marketing approval for the patented invention from other federal agencies.

[28] 28 U.S.C. § 1295(a)(1) (2006).

[29] 28 U.S.C. § 1254(1) (2006).

[30] Janice M. Mueller & Donald S. Chisum, "Enabling Patent Law's Inherent Anticipation Doctrine," 45 *Houston Law Review* (2008), 1101.

intermediates, formulations, mechanisms of action, packaging, delivery profiles, screening methods, and biological targets.[31] Rebecca Eisenberg, a member of the faculty of the University of Michigan Law School, asserts that in recent years innovative firms have made skillful use of current patent law doctrines, becoming "quite creative about strategies to secure 'evergreening' patents in order to defer the date their products go off-patent.... "[32]

A simple example illustrates how different patents may cover the same product. Suppose that a brand-name drug company, Alpha Pharmaceutical Co., discovers that a new chemical compound is useful for treating a particular disease. Alpha files a patent application on that active ingredient on January 1, 2005. The USPTO approves the application, resulting in a patent that will expire twenty years later—on January 1, 2025. On February 1, 2010, Alpha files a second application at the USPTO based upon its invention of an improved method of manufacturing the previously patented active ingredient. That application is also approved, leading to a patent that will expire on February 1, 2030.

Under this example, a generic drug company may begin selling products that employ the active ingredient starting in 2025, when the first patent expires. However, the generic firm may not use the improved manufacturing method at that time. It must instead use another manufacturing technology until 2030, when the second patent expires. [33]

Although the phenomenon of evergreeening may be most visible in the pharmaceutical industry, it is not necessarily limited to that industry. The patent statute allows inventors of any sort of technology to obtain patents upon improvements. Discussion over evergreening may focus upon the pharmaceutical industry for any number of reasons, including the traditionally resource-intensive nature of pharmaceutical research and development, as well as the continuing public debate over the cost of health care.

The term "evergreening" typically refers to the construction of a patent portfolio that covers a single product. However, it has also been used in connection with marketing strategies allegedly employed by brand-name pharmaceutical firms. According to intellectual property attorney Michael Enzo Furrow, these strategies include "launching a patent prescription drug in an over-the-counter (OTC) form prior to expiration of marketing exclusivity to build up an OTC market position against future competition," "launching a generic version of an approved drug upon patent expiration," and "marketing techniques to get consumers to switch to newer formulations ... of drug products from earlier formulations ... for which patent protection has not yet, but is soon to, run out, thus undercutting market demand for generic versions of the older formulation."[34] Each of these approaches is said to allow "innovator firms to maximize their monopoly period."[35] Other observers disagree with this assessment, however, asserting that these strategies promote the ability of private firms to develop and market new medications. A subsequent portion of this report will discuss these competing views.

[31] *See* John R. Thomas, Pharmaceutical Patent Law 38-46 (Bureau of National Affairs 2005).

[32] Rebecca S. Eisenberg, "The Role of the FDA in Innovation Policy," 13 *Michigan Telecommunications and Technology Law Review* (2007), 345.

[33] The generic firm may also opt to challenge the patents through various mechanisms at the USPTO and in the courts.

[34] *See* Furrow, *supra*.

[35] *Id.*

Continuation Application Practice

Some observers believe that the practice of patent evergreening is promoted by the availability of "continuation applications."[36] Stated generally, a continuation application is one that has been "re-filed" at the USPTO. Among other benefits, continuation patent applications allow inventors to extend the period of examination at the USPTO in order to amend existing claims or submit new ones.[37]

The use of continuation applications may be illustrated by a straightforward example. Suppose that an inventor files a patent application on July 1, 2002. After the USPTO examiner subsequently issues a "final rejection" of that application, the inventor files a continuation application on August 1, 2004. The continuation application includes the same information as the 2002 application. By filing it, the inventor may continue to assert to the USPTO that a patent should issue on that invention. If the USPTO approves the continuation application, it will issue as a patent that expires on July 1, 2022—twenty years from the date of filing of the original or "parent" application.

It should be appreciated that an applicant may file a continuation application even though the "parent" application has resulted in an issued patent itself. Even in circumstances where the USPTO examiner has allowed all of the claims of a patent application to issue, the inventor may nonetheless file a continuation application. He may do so in order to obtain broader claims, to obtain claims that more closely track his competitor's products, or for any other reason.

Continuation practice has proven controversial, in part because of its potential role in patent evergreening. Christopher Holman, a member of the law faculty of the University of Missouri-Kansas City, explains that "pharmaceutical companies have traditionally employed continuation practice to evergreen their proprietary position.... "[38] On the other hand, continuation applications may allow innovative firms to procure patent claims that relate to the products that they will ultimately market. For example, a pharmaceutical firm may file a patent application incorporating claims directed towards a broad category of compounds. At the time of the initial filing, however, that firm may not have conducted the extensive testing and research that is often needed to identify the particular member of that category that will be brought to market. Under current law, once that particular compound has been identified, the firm may file a continuation application specifically claiming that compound.[39]

The Hatch-Waxman Act

To the extent discussion over patent evergreening focuses upon the pharmaceutical industry, legislation commonly known as the Hatch-Waxman Act bears mention.[40] The Hatch-Waxman Act

[36] 35 U.S.C. § 120 (2006).

[37] *See* Gary C. Ganzi, "Patent Continuation Practice and Public Notice: Can They Coexist?," 89 *Journal of the Patent and Trademark Office Society* (July 2007), 545.

[38] Chistopher M. Holman, "Biotechnology's Prescription for Patent Reform," 5 *John Marshall Journal of Intellectual Property Law* (2006), 318.

[39] See Letter to the Honorable Jon Dudas, Under Secretary of Commerce and Director of the USPTO, from David E. Korn, Assistant General Counsel, Pharmaceutical Research and Manufacturers of America (May 2, 2006), at 3 (available at http://www.uspto.gov/web/offices/pac/dapp/opla/comments/fpp_continuation/phrma_con.pdf).

[40] Drug Price Competition and Patent Term Restoration Act of 1984, P.L. 84-417, 98 Stat. 1585 (1984).

governs the procedures through which a potential generic drug manufacturer may obtain FDA marketing approval on a drug that has been patented by another. Some observers believe that the Hatch-Waxman Act provided additional incentives to evergreen.[41] Legislative amendments introduced in 2003 may have mitigated this effect, however.[42]

The Hatch-Waxman Act requires brand-name drug companies to identify certain patents that pertain to their pharmaceutical products.[43] The FDA provides this information to the public in a publication commonly known as the "Orange Book."[44] A generic firm that wishes to sell its own version of a brand-name pharmaceutical must account for any patents that are listed in the Orange Book when it files its Abbreviated New Drug Application, or ANDA. If a patent is listed, and the generic firm does not wish to wait until it has expired to market its product, the generic firm must state its position as to why that patent is invalid or not infringed by the generic product.[45] Under the statute, such a "paragraph IV certification" is considered an act of patent infringement.[46] The brand-name drug company may then commence litigation against the generic firm.

If the brand-name drug company chooses to litigate, then the Hatch-Waxman Act prevents the FDA from granting marketing approval to the generic firm for 30 months.[47] This "30-month stay" is intended to provide a period of time for the parties to resolve their intellectual property dispute before the generic drug enters the market.[48] The 30-month period may be modified in certain situations. For example, if the generic firm prevails in the litigation before the expiration of 30 months, the statutory stay will be lifted.[49]

Prior to 2003 amendments to the Hatch-Waxman Act, brand-name firms were at times able to obtain multiple 30-month stays. They could do so by obtaining additional patents prior to FDA approval of the generic firm's marketing application. Once the patent was published in the Orange Book, the generic firm was then required to provide a new certification—potentially resulting in a new 30-month stay.[50] Shashank Upadhye, Vice President of Apotex, Inc., a generic drug company, explained that this system:

> resulted in "evergreening" patents that cause new and repetitive 30-month stays. [In one litigation] Apotex was subject to five different 30-month stays. The second stay kicked in some 17 months into the first one and in the end, the total time of the stays was about 65 months. Under the old regime, a well-planned evergreen would allow a newly issued patent to list in the Orange Book right around Month 30 of the first stay so that a new lawsuit would generate a new 30-month stay.[51]

[41] *See* Alison R. McCabe, "A Precarious Balancing Act—The Role of the FDA as Protector of Public Health and Industry Wealth," 36 *Suffolk Law Review* (2003), 787.

[42] *See* Derzko, *supra*.

[43] 21 U.S.C. § 355(b)(1) (2006).

[44] 21 C.F.R. § 314.53(e) (2009).

[45] 21 U.S.C. § 355(j)(2)(A)(vii) (2006).

[46] 35 U.S.C. § 271(e)(2) (2006).

[47] 21 U.S.C. § 355(j)(5)(B)(iii) (2006).

[48] *See* Shashank Upadhye, *Generic Pharmaceutical Patent and FDA Law* (2008) §11:4.

[49] 21 U.S.C. § 355(j)(5)(B)(iii)(I) (2006).

[50] *See* Matthew Avery, "Continuing Abuse of the Hatch-Waxman Act by Pharmaceutical Patent Holders and the Failure of the 2003 Amendments," 60 *Hastings Law Journal* (2008), 171.

[51] Updadhye, *supra*, at §11:17.

Out of recognition of this issue, 2003 amendments to the Hatch-Waxman Act stipulate that patent owners may obtain only a single 30-month stay.[52] Although patents that issue after litigation has commenced may be listed in the Orange Book, and are then subject to a certification by the generic firm, they no longer effectively prolong the statutory stay period. As explained by Stephanie Greene, a member of the faculty of Boston College:

> This change in the law ends the problem of successive thirty-month stays that may occur when innovators list patents after an ANDA is filed. The new law allows a thirty-month stay only for infringement suits filed regarding patents listed in the Orange Book at the time the ANDA was filed.[53]

Of course, even though follow-on patents no longer serve as the basis for additional 30-month stays, they remain enforceable proprietary rights against generic firms. As a result, the 2003 legislative amendments may not have eliminated incentives to evergreen.

Debate Over Evergreening

Assertions that innovative firms, and particularly brand-name pharmaceutical companies, have engaged in evergreening practices have inspired a lively policy discussion. As explained by Robin Feldman, a member of the faculty of the University of California at Hastings College of the Law, "[s]cholars have expressed concern over patent holders' attempts to refresh their patents by patenting updated versions, alternative delivery methods, or other variations of the original product."[54] Other experts believe that the patent system appropriately allows for patents to issue on improvement technologies. This report next reviews this debate.

Critics assert that evergreening effectively extends the term of exclusivity that the patent holder obtains.[55] Congress has established a term of patent protection that ordinarily extends for a maximum of 20 years from the date of filing.[56] However, obtaining multiple patents that effectively cover the same marketed product may effectively extend the aggregate period of patent protection that applies to that product. According to some critics, evergreening is an abusive practice that conflicts with congressional judgment concerning the appropriate duration of patent rights.[57]

Critics further argue that evergreening impedes the introduction of generic medications and has a negative effect upon public health in the United States.[58] Aaron Kesselheim, instructor in

[52] Medicare Modernization Act, § 1102(a)(2)(A) (codified as amended at 21 U.S.C. § 355(j)(5)(B)(iii) (2006)); *see also* Barry J. Marenberg, Changes to the Hatch-Waxman Act Following the "Medicare Prescription Drug, Improvement and Modernization Act of 2003," 23 *Biotechnology Law Reporter* (2004), 277.

[53] Stephanie Greene, "A Prescription for Change: How the Medicare Act Revises Hatch-Waxman to Speed Market Entry of Generic Drugs," 30 *Journal of Corporation Law* (2005), 309.

[54] Robin Feldman, "Rethinking Rights in Biospace," 79 *Southern California Law Review* (2005), 1.

[55] *See* Sarah Beth Myers, "A Healthy Solution for Patients and Patents: How India's Legal Victory Against A Pharmaceutical Giant Reconciles Human Rights with Intellectual Property Rights," 10 *Vanderbilt Journal of Entertainment and Technology Law* (2008), 763.

[56] 35 U.S.C. § 154(a)(2) (2006).

[57] *See* Jerome H. Reichman, "Rethinking the Role of Clinical Trial Data in International Intellectual Property Law: The Case for a Public Goods Approach," 13 *Marquette Intellectual Property Law Review* (2009), 1.

[58] See Christine S. Paine, Comment, "Brand-Name Drug Manufacturers Risk Antitrust Violations by Slowing Generic Production Through Patent Layering," 33 *Seton Hall Law Review* (2003), 479.

medicine at Harvard Medical School, asserts that "[l]oose interpretation of patent laws has permitted patent evergreening, where overly broad or otherwise inappropriate patents have been granted on peripheral aspects of pharmaceutical products, leading to extensions in market exclusivity."[59]

Other observers further state or imply that evergreening leads to patents that relate to trivial advances or simple variations of known technologies. As explained by patent lawyer Janet Gongola, "generics allege that innovators 'game' the system by filing patent applications for peripheral aspects of inventions such as a drug's color, label, or indication."[60] Such patents are said to be of low quality and doubtful validity. Yet they may "increase the infringement minefield that generics must navigate when bringing a product to market."[61]

Although the practice of evergreening has attracted considerable criticism, many observers believe these critiques are misplaced. Indeed, some consider the term "evergreening" to be inappropriate, and even derogatory in nature.[62] They explain that the patent laws promote both original and improvement inventions, that most technological advance occurs incrementally, that improvements may be developed by competitors of the original innovator, that many improvement patents cover advances that are of considerable medical significance, and that patents on improvements may not impede the ability of competitors to market products that were covered by expired patents on original technologies. This report reviews these assertions in turn.

First, these observers note that the patent system allows patents to be obtained on both original and improvement technologies. As a result, the patent law encourages the development of both kinds of inventions. They also explain that under the Patent Act, each invention must fulfill a number of requirements in order to be subject to patent protection. Among these criteria are that the invention must be novel,[63] nonobvious,[64] and fully disclosed in an application submitted to the USPTO.[65] These statutory standards are applied neutrally to each kind of invention, whether it may be characterized as an "original" (such as a medication that has never been previously approved by the FDA) or an "improvement" (such as a new formulation of a known medication).

Patent law experts believe that these legal standards appropriately recognize that most technological progress occurs on an incremental basis. Attorney Ivar Kaardal explains that "most patents ... are granted for incremental, or even insignificant, technological advances."[66] Some observers believe that, on an individual or collective basis, patents on more marginal improvements may provide the public with valuable sources of technological information. As Jeanne C. Fromer, a member of the Fordham Law School faculty, states:

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[59] Aaron S. Kesselheim, "Think Globally, Prescribe Locally: How Rational Pharmaceutical Policy in the U.S. Can Improve Global Access to Essential Medicines," 34 *American Journal of Law and Medicine* (2008), 125.

[60] Janet A. Gongola, "Prescriptions for Change: The Hatch-Waxman Act and the New Legislation to Increase the Availability of Generic Drugs to Consumers," 36 *Indiana Law Journal* (2003), 787.

[61] Furrow, *supra.*

[62] *See* Evergreening Briefing, *supra*.

[63] 35 U.S.C. § 102 (2006).

[64] 35 U.S.C. § 103 (2006).

[65] 35 U.S.C. § 112 (2006).

[66] Ivar M. Kaardal, "The American Inventors Protection Act, the Independent Inventor's Interest & Consumer Choice in the Market," 84 *Journal of the Patent and Trademark Office Society* (2002), 503.

> while there are a rising number of patents for incremental technical advances, which individually might not be commercially or informationally valuable, the collectivity of incremental advances provides essential information for further innovation in many areas....[67]

Some commentators also believe the critique that many "evergreen" patents represent trivial variations of earlier technologies is misplaced. They assert that many patented improvements provide significant practical benefits. For example, a new formulation may make a known medication easier to use, leading to greater patient compliance, or cause fewer side effects.[68]

Observers also note that the developer of the "original" product is not always the same entity as the developer of "improvement" technologies. Sometimes competitors of the "original" patent proprietor, including generic drug companies, develop and patent the improvements.[69] The ability of any innovator to obtain a patent is said to encourage competition among different firms, both in innovation and in the marketplace.[70]

Industry experts further observe that patents on improvement inventions may not block competitors from marketing competing products that were covered by patents that have expired. In this respect, it should be appreciated that the scope of protection provided by a particular patent varies in accordance with the degree of technological advance provided by the patented invention.[71] In particular, a patent that claims a new active ingredient for use in a pharmaceutical typically provides more robust proprietary rights than improvement patents.

For example, suppose that a brand-name pharmaceutical firm develops and patents a new medication. Several years later, the same firm develops and patents an extended-release formulation version of the same drug. At such time as the first patent expires, generic drug companies will be able to sell the original formulation of that pharmaceutical.[72] The marketplace will ultimately decide whether the higher costs associated with the extended-release formulation are worthwhile expenditures.

In addition, some experts believe that recent changes to patent law rules may have limited evergreening strategies. One of these changes concerns the calculation of a patent's term. From 1870 to 1995, the maximum term of a U.S. patent was 17 years from the date it issued.[73] U.S. membership in the World Trade Organization (WTO) led to a change in this durational scheme. For patents based upon applications filed on or after June 8, 1995, the maximum term is instead set as 20 years from the date the patent application is filed.[74] Although the life of a patent is now measured from the filing date, an inventor gains no enforceable rights merely by filing a patent application. Those rights accrue only if and when the USPTO allows the patent to issue.[75]

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[67] Jeanne C. Fromer, "Patent Disclosure," 94 *Iowa Law Review* (2009), 539.

[68] *See* Evergreening Briefing, *supra*.

[69] *Id.*

[70] *See* Furrow, *supra*.

[71] *See* Mary Mitchell, "'Genius of Art! What Achievements Are Thine?' The Social Shaping of Inventiveness Requirements in Antebellum Patent Law," 1 *Drexel Law Review* (2009), 143.

[72] *See* Schechter & Thomas, *supra,* at § 8.1.

[73] *Id.* at § 7.4.

[74] 35 U.S.C. § 154(a)(2) (2006).

[75] *See* Schechter & Thomas, *supra*.

Some observers contend that this change in patent term has to some extent discouraged evergreening, at least through the use of continuation practice. The reason is that any patent that issues from a continuation application now expires at the same time as the original application—namely, 20 years from the filing date of the original application. As explained by attorney Natalie M. Derzko, under the previous system of calculating patent term:

> later-filed patent applications relating to earlier filed ones could have been used in certain instances to extend protection over related subject matter beyond the initial 17-year term of a first patent.... Yet the term of all patents now runs 20 years from the first U.S. filing date. Consequently, any such improvement patent arising from a patent application related to an earlier-filed U.S. application would expire on the same date as any original patent issuing from the earlier-filed application. This means that the incentives to "evergreen patents" illegitimately have been significantly curtailed by these developments as to the patent term.[76]

It should be appreciated, however, that patents that result from original filings, rather than continuation applications, continue to enjoy a term of 20 years based upon their own filing date. For example, suppose that a brand-name pharmaceutical firm files a patent application claiming an active ingredient in 2003, resulting in a patent that expires in 2023. In 2008, the same firm files a second, original patent application claiming an extended release formulation of that active ingredient. If that second patent issues, it will not expire until 2028. As a result, strategies that some observers characterize as evergreening remain viable despite statutory changes to the patent term.

Another notable development was the 2007 opinion of the U.S. Supreme Court in *KSR International Co. v. Teleflex Inc*.[77] The *KSR* opinion addresses one of the fundamental requirements for obtaining a patent, the standard of nonobviousness. Under this standard, "[a] patent may not be obtained ... if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious ... to a person having ordinary skill in the art.... "[78] Many observers believe that the *KSR* opinion raised the standard of nonobviousness, making it harder to obtain a patent.[79] If this view is accurate, evergreening may become a less viable tactic because patents to improvement inventions may be more difficult to procure from the USPTO.[80]

Congressional Issues and Options

If Congress decides that patent evergreening does not present a significant issue, then no action need be taken. Should Congress choose to address the issue of evergreening, however, a number of options exist. First, some observers believe that the broad ability to file continuation applications encourages evergreening practices.[81] The USPTO recently promulgated controversial rules that would have limited the availability of continuation applications. A ruling of the Court of

[76] Derzko, *supra*, at 187.

[77] 550 U.S. 398 (2007).

[78] 35 U.S.C. § 103(a) (2006).

[79] *See* Rebecca S. Eisenberg, "Pharma's Nonobvious Problem," 12 *Lewis & Clark Law Review* (2008), 375.

[80] *See* Christopher M. Jackson, "The War on Drugs: How *KSR v. Teleflex* and *Merck v. Integra* Continue the Erosion of Pharmaceutical Patent Protection," 36 *Capital University Law Review* (2008), 1029.

[81] *See* Holman, *supra*.

Appeals held that those rules were invalid because they exceeded the USPTO's authority to regulate, however. Although litigation concerning the USPTO continuation rules remains ongoing at the time this report issued,[82] Congress may wish to consider whether current statutory provisions concerning continuation practice are appropriate.[83]

Second, no provision of the U.S. Patent Act is specifically directed towards evergreening issues.[84] In this respect, legislative developments in other nations might also be of interest. Recent amendments to the Patent Law of India were introduced arguably in order to address concerns over evergreening. Section 3(d) of that statute provides:

> The following are not inventions within the meaning of this Act:
>
> [T]he mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant. Explanation—For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be same substance, unless they differ significantly in properties with regard to efficacy.[85]

As explained by Janice M. Mueller, a member of the law faculty of the University of Pittsburgh, "[t]his express and detailed statutory presumption against patentability of derivatives, unique among the world's patent regimes, reflects a strong resentment towards ever-greening of pharmaceutical patents."[86] However, some commentators have expressed concern that the Indian patent statute may violate obligations established by the World Trade Organization (WTO)—in particular, its requirement that "patents shall be available and patent rights enjoyable without discrimination as ... the field of technology.... "[87]

More generalized reform of the patent system presents a third possibility for dealing with concerns over evergreening. Persistent concerns have been voiced that certain patents upon improvement technologies are of poor quality and doubtful validity.[88] Effective rules that would allow the USPTO to issue high quality patents, as well as procedural and substantive rules that would efficiently resolve disputes with respect to granted patents, may allay some of these concerns. Current bills before the 111th Congress would potentially introduce a broad range of reforms in an effort to improve the patent system, and would perhaps respond to criticisms of evergreening practices.[89]

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[82] *See supra* notes—and accompanying text.

[83] 35 U.S.C. § 120 (2006).

[84] *See* Janice M. Mueller, "The Tiger Awakens: The Tumultuous Transformation of India's Patent System and the Rise of Indian Pharmaceutical Innovation," 68 *University of Pittsburgh Law Review* (2007), 491.

[85] The Patents (Amendment) Act, 2005, No. 15, Acts of Parliament, 2005, §3(d).

[86] Mueller, *supra*.

[87] *Id.*; *see generally* Radhika Bhattacharya, "Are Developing Countries Going Too Far on TRIPS? A Closer Look at the New Laws in India," 34 *American Journal of Law and Medicine* (2008), 395.

[88] *See* Kesselheim, *supra.*

[89] *See* CRS Report R40481, *Patent Reform in the 111th Congress: Innovation Issues*, by Wendy H. Schacht and John R. Thomas.

Concluding Observations

Janice Mueller, a member of the faculty of the University of Pittsburgh School of Law, and Donald Chisum, a retired member of the Santa Clara University Law School faculty, assert that "[d]rawing the line between improper attempts at evergreening and legitimate incremental innovation is a broad and difficult problem in patent law.... "[90] The difficulty of this discussion is suggested by the fact that numerous knowledgeable observers have reached strongly contrasting views concerning the propriety of improvement patenting, the extent of any possible negative social impact of this practice, and even the term "evergreening" itself. Further consideration of possible evergreening practices may nonetheless assist in the identification of policy concerns, aiding in the current legislative debate of reforms to the patent system.

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[90] Mueller and Chisum, *supra.*