DRUG PATENT LENGTH

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The 20-year patent term is meant to offer a uniform period of protection to all inventions. In practice, inventors enjoy varying lengths of effective patent life over their inventions, and the variations depend in large part on the amount of time it takes them to develop their invention. The 20-year patent term runs from the filing date of a patent, which for most inventions occurs early in product development. The longer it takes to get an invention onto the market, the shorter its effective patent life becomes. In the pharmaceutical industry, this dynamic causes severe distortions in R&D investments. The drugs that take the longest to develop generally have the highest R&D costs, and hence require more protection to motivate investment in their development, while the drugs that move quickly onto the market tend to have lower R&D costs, and thus need less protection. Rather than awarding a longer patent term where it is needed, the patent system actually gives a shorter effective patent life to the drugs that take longer to develop and a longer effective patent life to drugs that can be developed quickly. The result is a system that fails to motivate the development of many drugs with long development times, including drugs for early-stage cancer and cancer prevention that might have tremendous social value but would take too long to test in clinical trials.

This paper proceeds in five parts. Part I provides a brief overview of the economics of the patent system. Patents promote innovation by awarding firms a temporary exclusive right to

manufacture, use and sell their inventions. As a result, patents also increase consumer prices for the inventions they cover, thereby reducing the public's access to those inventions and thus generating deadweight loss. Despite the higher prices caused by patent protection, the public can still benefit from patents when the inventions they protect would not have been created or developed absent that protection. Consequently, to the extent that the incentives for creating and developing these inventions would be inadequate without patents because competitors could easily imitate the inventions without incurring the same R&D costs, the patent system serves the public interest. On the other hand, when patents go to inventions that the public would have received anyway, the public is subjected to unnecessary high prices, resulting in deadweight loss. The patent system is designed to screen out such inventions, and therefore avoid inflicting unnecessary deadweight loss upon the public, by applying certain standards of patentability to claimed inventions.

Part II compares the duration of patent protection under current law, a uniform 20-year term that applies to all inventions, with the economic analysis of a uniform optimal patent length and individually tailored terms of protection. Much like the question of whether an invention should be patentable, the appropriate duration of patent protection is the minimum amount needed to act as an incentive for the creation and development of that invention. Anything longer forces the public to pay higher prices for more time than is necessary and thus causes excessive deadweight loss, while a shorter patent term would provide an inadequate incentive for innovation and the public would not receive the invention. Inventions should therefore receive a patent that lasts just long enough to generate enough profits to cover their total development costs (including the costs of capital and risk of failure). Under such a system, inventions with substantial R&D costs relative to the annual net profits they generate would receive a longer

patent term compared to inventions with lower R&D costs relative to their market returns. There are administrative costs to these efforts to tailor the patent term to different inventions, however, and those costs must be weighed against the benefits (and feasibility) of reducing deadweight loss and promoting more innovation with variable patent terms. Congress' choice of a uniform patent term reflects a decision favoring administrative simplicity over accuracy. The 20-year patent term proscribed by law, however, is largely the product of path dependency.

Part III identifies a significant and previously overlooked flaw in the 20-year patent term; although the amount of time it takes to develop an invention is positively correlated with a longer necessary patent length, the effective patent life inventions receive is inversely related to the time they spend in development. The ideal patent length for an invention depends in large part on its R&D costs and development time, the latter being relevant to the developer's total costs of capital. Since the 20-year patent term runs from the patents' filing date instead of when it reaches the market, the time an invention spends in development is often subtracted from its effective patent life. This policy has a perverse effect on the incentives for innovation, providing a shorter effective patent life to the inventions that need more protection to motivate their development, while providing a longer effective patent life to the inventions that need less protection. This suggests that the "uniform" 20-year patent term may generate significantly more unnecessary deadweight loss than previously thought. Moreover, in industries where R&D investments are sensitive to the patent term and new technologies sometimes need to spend years in development before reaching the market, the current 20-year patent term may be insufficient for a sizable portion of socially valuable inventions.

Part IV argues that these adverse effects of the 20-year patent term are especially great in the pharmaceutical industry. Patents play an essential role in promoting drug development

because drug R&D involves tremendous costs and risks for innovators, while generic competitors can enter the market at minimal cost. The drugs that take longer to develop on average require larger R&D investments that are vulnerable to free-riding, and thus require a longer period of protection to recover the investments. Instead of awarding those drugs a longer market-exclusivity period, the patent system does the exact opposite, subtracting from their effective patent life much of the time spent in development. Although current law provides for certain patent-term extensions for drugs that add back onto their patent life a portion of the time they spent in development, these extensions only partially mitigate the distortion caused by the early running of the patent term.[1] As a result, the patent system skews the patent reward in favor of drugs that take less time to develop, even though those drugs are likely in less need of any additional reward.

This distortion is particularly worrisome in its affect on the search for effective cancer treatments, since it discourages drug companies from investing in drugs for early-stage cancer or cancer prevention due to the lengthy clinical trials needed to test them. Cancer trials often require mortality data as their outcome. Although it is possible to conduct such studies on late-stage cancer patients because their life expectancy is relatively short, using early-stage cancer patients as subjects would require a much longer clinical trial, and much of the patent term would be gone before the drug ever reached the market. As a result, private industry largely ignores the market for drugs for early-stage cancer and cancer prevention, even though the social value of such treatments is likely to be substantial.

Part V discusses solutions to the problems caused by the timing of the drug patent term. One possibility is for Congress to provide drug companies a genuinely uniform patent term for

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[1] Indeed, the design of the current patent-term extensions for drugs, not to mention the praise they have received from scholars, reflects how the perverse nature of current patent term has been overlooked.

their products, thereby correcting the current patent term's tendency to shorten the effective patent life of a drug as its need for protection grows. This section focuses on a more aggressive approach, the adoption of a variable patent term for drugs that uses information about the cost and duration of a drug's development period to either lengthen or shorten its patent term in the appropriate direction. Although information about the expenses incurred during R&D are often unobservable to the government, in the pharmaceutical industry the FDA is uniquely well positioned to observe both the duration of a drug's clinical development and, if asked to do so, perhaps even the costs of those clinical trials. Under these circumstances, a flexible patent term that accounts for the expense and time invested in a drug's development could lead to more innovation and less deadweight loss compared to even a genuinely uniform patent term. There are risks to this approach, however. The government might calibrate the variable patent term incorrectly, resulting in less innovation or more deadweight loss compared to possible uniform patent terms. Moreover, pharmaceutical companies might try to game the system by wasting money in R&D to extend their patent terms. In light of these potential implementation problems, it is unclear whether a variable drug patent term would is likely to outperform a reasonable uniform patent length.

I.   THE ECONOMICS OF THE PATENT GRANT

Patents benefit the public by promoting innovation, but they also drive up prices and therefore create deadweight loss. If the government awards a patent on an invention that the public would have enjoyed access to even if patent protection had not been available, consumers are needlessly subjected to artificially high prices. As a general rule, therefore, patents should only be awarded to inventions that otherwise would not have been created or developed absent

that reward. The patentability requirements for inventions help perform this gate-keeping role by denying protection to inventions that are obvious or not new. These sorting mechanisms are far from perfect, but there is little doubt that the patent system must do something to distinguish the inventions that need protection from those that do not.

The primary economic goal of the patent system is to promote the creation, development and commercialization of inventions that the public would not otherwise receive.[2] Although R&D is often expensive and risky, it can yield great benefits to the public in the form of valuable new technologies.[3] Yet without government intervention, private firms will often be unwilling to make those R&D investments when competitors can "free-ride" off of their efforts, copying successful new inventions without making any significant R&D investments themselves. The first mover would be unable to recoup its R&D expenses, and thus would invest its money elsewhere. The patent system attempts to resolve this problem by providing inventors the exclusive rights to make, sell and use their inventions.[4]

Patents may benefit the public by promoting R&D investments, but they also harm consumers by increasing the prices for patented inventions. If a firm has a strong patent position over one of its inventions, it can prevent competitors from selling imitations of that product. This gives the firm market power that usually translates into higher consumer prices. These supra-competitive prices make it harder for consumers to afford patented inventions, and so consumers buy less of those goods than they otherwise would in a competitive market. The

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[2] *See* Kenneth W. Dam, *The Economic Underpinnings of Patent Law*, 23 J. LEGAL STUD. 247, 247-48 (1994).

[3] *See* Charles I. Jones & John C. Williams, *Measuring the Social Return to R&D*, 113 QUARTERLY J. ECON. 1119 (1998).

[4] *See, e.g.*, Peter Menell & Suzanne Scotchmer, *Intellectual Property*, *in* 2 HANDBOOK OF LAW & ECONOMICS 1476 (A. Mitchell Polinsky & Steven Shavell eds. 2007); STEVEN SHAVELL, FOUNDATIONS OF ECONOMIC ANALYSIS OF LAW 138 (2004).

reduction in social welfare caused by this drop in consumption is called deadweight loss, and since the inducement for private investment in R&D under a patent system is profits earned by charging higher prices for patented inventions, deadweight is seen as an inevitable consequence of using patents to promote innovation.[5]

Despite this deadweight-loss problem associated with patent grants, patents still benefit society when they are issued for inventions that otherwise would not reach the public.[6] When R&D costs are significant and vulnerable to free riding, granting a patent may be essential for motivating the timely creation and development of that invention. The public must choose between awarding a patent on such inventions and paying higher prices, or withholding patent protection and foregoing access to those inventions entirely (or perhaps waiting an excessive amount of time before receiving the inventions). Since limited public access to an invention is generally preferable to no access at all, it is usually better to grant the patent.[7]

The opposite is true for inventions that do not need patent protection to spur their creation and development. When the government grants a patent on an invention that the public will receive anyway, the public is forced to pay higher prices needlessly.[8] The deadweight loss caused by reduced public access to the invention under these circumstances likely outweighs any benefits from granting the patent. As a general rule, therefore, patents should only be awarded when necessary for the public to enjoy the invention.

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[5] *See* 1 SUBCOMM. ON PATENTS, TRADEMARKS & COPYRIGHTS OF THE SENATE COMM. ON THE JUDICIARY, 85TH CONG., AN ECONOMIC REVIEW OF THE PATENT SYSTEM 36-38 (Comm. Print 1958) (prepared by Fritz Machlup).

[6] *See* Dan L. Burk and Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1599 (2003); SHAVELL, *supra* note 4, at 144, 152; Roberts v. Sears, Roebuck & Co., 723 F.2d 1324, 1345-46 (7th Cir. 1983) (*en banc*) (Posner, J., concurring in part and dissenting in part).

[7] For possible exceptions, see infra text accompanying notes _-_.

[8] *See* F.M. SCHERER, INDUSTRIAL MARKET STRUCTURE AND ECONOMIC PERFORMANCE 440-41 (2d ed., F.M. Scherer ed. 1980).

This general rule is subject to a number of potential exceptions, although those exceptions are likely small. A patent could be worthwhile even when unnecessary for promoting the creation and development of an invention if the information contained in the patent grant is of great social value, such as when it spurs other innovation and would not otherwise be revealed in a timely fashion.[9] There remains some doubt as to the importance of patent disclosures in promoting other innovations,[10] however, and many scholars argue that excessive patenting can actually deter future innovation by making it necessary to enter into complex licensing arrangements or creating the risk of stumbling into a patent-infringement suit.[11] Another potential cost of the patent grant is provoking an R&D race, wherein competing firms engage in wasteful and duplicative R&D in a race to be the first to create and patent an invention.[12] Not all competition in R&D is wasteful, however, and many scholars believe that competitive pressure during R&D often benefits the public, both by speeding up the development of inventions and by increasing the chances that at least one of the competing R&D projects is successful.[13] Although

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[9] Patents are said to benefit the public by promoting the disclosure of valuable technical information, and it is possible that the spillover benefits from technical information disclosed in a patent application exceed the deadweight loss from patent pricing. *Cf.* Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470 (1974) (explaining that the disclosures in patent applications increase the "general store of knowledge" and are "assumed [to] stimulate ideas and the eventual development of further significant advances in the art"); Wesley M. Cohen et al., *R&D Spillovers, Patents and the Incentives to Innovate in Japan and the United States*, 31 RES. POLICY 1349 (2002).

[10] For a more skeptical view of the potential social value of patent disclosures, *see* Robert Mazzoleni & Richard R. Nelson, *Economic Theories about the Benefits and Costs of Patents*, 32 J. ECON. ISSUES 1031 (1998); Note, *Disclosure Function of the Patent System (or Lack Thereof)*, 118 HARV. L. REV. 2007 (2005).

[11] *See* Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCI. 698 (1998); JAMES BESSEN & MICHAEL J. MEURER, PATENT FAILURE: HOW JUDGES, BUREAUCRATS, AND LAWYERS PUT INNOVATION AT RISK (2008);

[12] *See* WILLIAM M. LANDES & RICHARD A. POSNER, THE ECONOMIC STRUCTURE OF INTELLECTUAL PROPERTY LAW 315-16 (2003). In theory these patent races could eat up much of the social surplus created by the patented invention, leaving the public little better off than if the invention were never created.

[13] *See, e.g.*, Mark A. Lemley, *Ex Ante Verses Ex Post Justifications for Intellectual Property*, 71 U. CHI. L. REV. 129 (2004); Robert P. Merges & Richard R. Nelson, *On the Complex Economics of Patent Scope*, 90 COLUM. L. REV. 839, 842-44, 908-16 (1990); Arti Kaur Rai, *Regulating Scientific Research: Intellectual Property Rights and the Norms of Science*, 94 NW. U.L. REV. 77, 120-135 (1999). To the extent that patent races pose a serious problem, the

these secondary economic effects of the patent grant are potentially significant, they are still largely secondary to the question of whether the public would receive the invention without offering a patent.[14]

The standards of patentability are consistent with this basic rule that patents should only be granted when necessary for the public to receive the invention, as the patent system seeks to exclude inventions that are not novel or are obvious.[15] The novelty requirement denies protection to inventions that were previously disclosed to the public, reflecting a policy judgment that the public has no need for patents to enjoy the inventions that already exist.[16] The nonobviousness requirement denies patent protection for inventions that are not sufficiently innovative, presuming that those inventions involved little risk and would have occurred to others around the same time.[17] Admittedly, the novelty and nonobviousness standards are imperfect screening tools[18] and they impose significant administrative costs on the patent

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patent system can mitigate this threat by awarding broad patents on inventions early in their development. *See* Edmund Kitch, *The Nature and Function of the Patent System*, 20 J.L. & ECON. 265, 276-77 (1977). When the public benefits from competition during R&D, however, early and broad patents might be detrimental.

[14] *See, e.g.*, ADAM B. JAFFE & JOSH LERNER, INNOVATION AND ITS DISCONTENTS: HOW OUR BROKEN PATENT SYSTEM IS ENDANGERING INNOVATION AND PROGRESS, AND WHAT TO DO ABOUT IT (2004).

[15] *See* Rebecca S. Eisenberg, *Analyze This: A Law and Economics Agenda for the Patent System*, 53 VAND. L. REV. 2081 (2000); SHAVELL, *supra* note 4, at 144, 152; Roberts v. Sears, Roebuck & Co., 723 F.2d 1324, 1345-46 (7th Cir. 1983) (*en banc*) (Posner, J., concurring in part and dissenting in part).

[16] *See* F. Scott Kieff, *The Case for Registering Patents and the Law and Economics of Present Patent-Obtaining Rules*, 45 B.C.L. REV. 55, 81-96 (2003); Robert P. Merges, *Uncertainty and the Standard of Patentability*, 7 HIGH TECH. L.J. 1, 12 (1992).

[17] *See* Rebecca S. Eisenberg, *Obvious To Whom? Evaluating Inventions from the Perspective of PHOSITA*, 19 BERKELEY TECH. L.J. 885, 886 (2004); *See* ROBERT PATRICK MERGES & JOHN FITZGERALD DUFFY, PATENT LAW AND POLICY: CASES AND MATERIALS 646 (3d ed. 2002).

[18] It is not uncommon for the PTO to grant patents on inventions that have no need for protection, some of which are upheld by the courts. *See* John H. Barton, *Non-Obviousness* 43 IDEA 475, 487-88, 96 (2003); Eisenberg, supra note 17, at 886; ADAM B. JAFFE & JOSH LERNER, INNOVATION AND ITS DISCONTENTS: HOW OUR BROKEN PATENT SYSTEM IS ENDANGERING INNOVATION AND PROGRESS, AND WHAT TO DO ABOUT IT (2004) (arguing that the PTO grants unnecessary patents due to the lax application of the patentability requirements). Combined with high litigation costs and unpredictable outcomes, these bad patents can result in significant social losses. *See* JAMES BESSEN & MICHAEL J. MEURER, PATENT FAILURE: HOW JUDGES, BUREAUCRATS, AND LAWYERS PUT INNOVATION

system.[19]   Yet it is widely accepted that their existence benefits the public by reducing deadweight loss from unnecessary patent grants.[20]

In sum, the patent system can provide great social value to the public by promoting innovation, but its grants normally should be restricted to inventions that the public would not otherwise enjoy or would receive only after a lengthy delay.   Imprudent patent grants to inventions that do not need that protection impose unnecessary deadweight loss on the public. Policy levers such as the novelty and nonobviousness requirements are costly and imperfect, but nonetheless play a critical role in lessening the deadweight loss caused by the patent system, thereby benefiting the public.

II.   THE ECONOMICS OF PATENT LENGTH

A. The Standard Economic Account of Patent Length

The appropriate duration of patent protection is the minimum amount needed to call forth an invention.   More precisely, it is the length of protection a firm needs for its invention to generate profits covering the total cost and risk of its R&D project.   Under this standard, the ideal patent length is likely to vary significantly among inventions. In applying a uniform patent term to all inventions, the patent system offers too much protection to some of them, which creates unnecessary deadweight loss, while offering too little protection to others, which prevents them from reaching the public.   Although a uniform patent term can be set optimally to

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AT RISK (2008). At the same time, other inventions are deemed obvious or not new by the PTO and courts even though they will not reach the public without patent protection. *See* Benjamin N. Roin, *Unpatentable Drugs and the Standards of Patentability*, 117 TEX. L. REV. 503 (2009).

[19] *See* BESSEN & MEURER, *supra* note 18; JAFFE & LERNER, *supra* note 18; Mark A. Lemley, *Rational Ignorance at the Patent Office*, 95 NW. U.L. REV. 1495 (2001).

[20] *See, e.g.*, JAFFE & LERNER, *supra* note 18; Kieff, *supra* note 16, at 81-96.

maximize social welfare within the constraints of single patent term, it is always a second-best solution.

Much like the question of whether an invention should be patentable, the ideal patent length for an invention is one that is long enough to motivate its creation, development and commercialization, but no longer.[21] If a 20-year patent term is the minimum needed for private industry to bring a particular invention to the public, offering anything less is no different from offering no patent protection at all; private industry is unlikely to develop the invention and the public will not receive its benefits. Anything longer than 20 years would also be detrimental because it would force the public to pay higher prices for the invention – and thus suffer additional deadweight loss – without the offsetting benefit of promoting innovation. To the extent that the patent system seeks to promote innovation while avoiding unnecessary deadweight loss from patent pricing, therefore, the ideal patent term for an invention is the precise amount of time needed for it to be brought to the public.[22]

In a perfect world, therefore, the patent term would be the period of market exclusivity necessary for an invention's developer to recover its total investment in R&D accounting for the risk that the R&D project would fail.[23] In calculating the ideal patent length for an invention, therefore, it is first necessary to determine the total R&D costs of bringing that invention to the public, including the developer's out-of-pocket R&D expenses, the duration of the R&D project, its costs of capital, and the risk of technological or commercial failure in that R&D.[24] Once the

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[21] *See* SHAVELL, *supra* note 4, at 145-46.

[22] *See* Louis Kaplow, *The Patent-Antitrust Intersection: A Reappraisal*, 97 HARV. L. REV. 1813 (1984).

[23] The ideal patent length also might be affected by the other forces that delay the marketing of imitation products.

[24] To prevent wasteful patent races caused by the promise of earning excessive rents from a patented invention, the government would need to estimate the risk of failure appropriately. The ideal patent length must account for the risk for the basic technological and commercial uncertainty of the R&D that produced the invention, but it should

total R&D investment is known, it would then be necessary to predict the future sales volume of the invention and the firm's profit per sale while it is under patent protection, thereby providing an estimate of the future stream of profits from the invention. If the invention would be sold under monopolistic competition even without patent protection, it would also be necessary to estimate the profit flow from the invention in the absence of a patent. Assuming a competitive market, however, the ideal patent length for an invention is the amount of time needed for the firm's profits from selling the invention under patent protection to equal that firm's total investment in R&D.

Given the diverse technological and economic pressures facing different industries, the ideal patent length likely varies significantly across inventions.[25] While some R&D projects take more than a decade to complete and require hundreds of millions of dollars in investment,[26] others are finished quickly at relatively little cost.[27] Similarly, an R&D project's likelihood of success can range from a sure thing to a long shot. The greatest point of variation for inventions is likely the profits they generate, since some earn their manufacturers billions of dollars annually while others barely cover their manufacturing costs.[28] As a result of this heterogeneity, some inventions might require as much as 30 years of market exclusivity to motivate their

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not account for the risk that a competing firm would develop the technology first and capture some (or all) of the profits. *See infra* note _.

[25] *See* Burk & Lemley, *supra* note 6, at 1581-83.

[26] *See* Edmund W. Kitch, *The Nature and Function of the Patent System*, 20 J.L. & ECON. 265, 271, 272 tbl. 1 (1977); *infra* text accompanying note 94.

[27] *See* FEDERAL TRADE COMMISSION, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY, ch. 3, 45-46 (2003) (noting that "innovation in the software and Internet industries generally requires considerably less capital than innovation in other high-tech industries," and that "entire product life cycles sometimes pass before patents can be issued").

[28] *See infra* notes 215-217.

development,[29] while others need only 6 months of exclusivity to reach the public, and some need no protection at all.[30]

Since the appropriate patent term is different for different inventions, a patent system that offers the same fixed term of protection to all inventions will generate unnecessary deadweight loss and fail to motivate the development of at least some inventions. Assuming that the duration of patent protection is both positive and finite, a uniform term will be too long for some inventions and to short for others. Whenever it is possible to shorten some inventions' patent terms without deterring their development, the patent system is subjecting the public to an excessive period of monopoly pricing and spurring wasteful patent races.[31] When there are inventions that would be developed if the patent term were longer, the public is losing out on welfare-enhancing innovation. Although the inventions that need lengthy periods of protection will often be of less social value than the ones where a shorter patent term is adequate,[32] those

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[29] There should be few inventions that require 30 years of market exclusivity to motivate their development because the anticipation of profits 30 years in the future would be subject to a steep discount for computing present value. *See* GEORGE STIGLER, THE ORGANIZATION OF INDUSTRY _ (1983).

[30] In a perfect patent system, inventions with an ideal patent length of zero would be denied a patent, perhaps under the novelty or nonobviousness requirement.

[31] When the patent on an invention promises to generate profits in excess of the total investment in R&D (accounting for the risk of failure) needed to produce that invention, there is a danger that multiple firms will race to capture those profits in a competition to be the first to patent the invention. *See* WILLIAM M. LANDES & RICHARD A. POSNER, THE ECONOMIC STRUCTURE OF INTELLECTUAL PROPERTY LAW 300-301 (2003). Competition in R&D can be beneficial, but when firms are racing to capture profits that some other firm would otherwise receive, their R&D spending can be wasteful and duplicative. *See* Menell & Scotchmer, *supra* note 4, at _. These patent races are only possible if the expected profits from an invention are sufficient to make up for the risk of losing the race. Perfectly tailored patent lengths would allow for profits to cover the costs and uncertainty of the R&D, but not the uncertainty created by the type of "business stealing" competition that drives patent races. If patent terms were set appropriately, therefore, the reward for innovation would be too small to lure additional firms into a wasteful R&D race over a fixed pool of profits.

[32] The reasons why an invention would need a longer period of patent protection are that its R&D costs are higher, its R&D involved a greater risk of failure, or that the annual profits it generates are lower. *See* text accompanying note 23. Higher R&D costs, greater uncertainty and lower market-based profits all lessen the social value of the R&D project.

inventions would still be beneficial,[33] and perhaps greatly so.[34] If the ideal patent term varies across inventions, a uniform patent term cannot achieve a first-best outcome.

An optimal uniform patent length is one that strikes the best possible balance between deadweight loss and promoting innovation within the constraints of a single patent term. At any given patent term, lengthening its duration will spur more innovation, but will also increase the deadweight loss from patent pricing for all of those inventions the public was already receiving under the old patent term. Shortening the patent term reduces the amount of innovation, but also lowers the deadweight loss for all of the inventions that the public still receives under the shorter term. An optimal patent term is one that maximizes overall social value by balancing these two effects, such that the marginal social cost of either lengthening or shortening patent life is equal to the marginal social benefit of the change.[35]

Nonetheless, even an optimal uniform patent term would still generate unnecessary deadweight loss and fail to motivate the development of some socially valuable inventions. Moreover, it is unclear how a government might identify this optimal uniform patent length,[36]

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[33] In theory, any invention that generates a profit – *i.e.*, net profits exceeded the total risk-adjusted investment in R&D – under the patent system always has positive social value because the consumers who purchased the invention (presumably) received greater benefits from the invention than what they paid. *See* SUZANNE SCOTCHMER, INNOVATION AND INCENTIVES _ (2004).

[34] *See* F.M. Scherer, *Nordhaus' Theory of Optimal Patent Life: A Geometric Reinterpretation*, 62 AM. ECON. REV. 422, 427 (1972) ("[I]t is at least conceivable that certain inventions with very high 'best guess' benefit-cost ratios require unusually bold, farsighted, time-consuming departures from orthodox technology, with extraordinary attendant uncertainties and risks. In these cases, strong patent protection offering the prospect of exceptional rewards … may be necessary to induce investment.").

[35] W. NORDHAUS, INVENTION, GROWTH AND WELFARE 70-90 (1969); Kaplow, *supra* note _, at 1825.

[36] The government would need to know the social value of the inventions that will be gained or lost from a change in the patent term, a difficult task when speculating about future innovation. It would also need to know the change in deadweight loss from a shift in patent length, which requires estimates of demand elasticity and other hard-to-get information about inventions.

although it is probably possible to make a rough estimate based on aggregate economic figures.[37] Given the limits of a uniform patent term, however, several different scholars have suggested that a variable term of protection would be preferable.[38]

B. *The Duration and Timing of the Current Patent Term*

Under current law, all patented inventions receive a 20-year term of protection than runs from the filing date of their patent application.[39] The 20-year duration of the current patent term is largely a product of historical precedent. On the other hand, the timing of the patent term, which runs from the patent's filing date, was a deliberate policy choice, but it was not meant to be a major legislative change.

Congress has shown little interest in tailoring patent length to the needs of particular inventions, industries or technologies, instead offering a uniform patent term.[40] When Congress first created the patent system in 1790, the range of technological fields was relatively small,[41] which provided fewer reasons for distinguishing among inventions when awarding patent

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[37] *See, e.g.*, Nordhaus, *supra* note _. *Cf.* David S. Abrams, *Did TRIPS Spur Innovation? An Analysis of Patent Duration and Incentives to Innovate*, 157 U. PENN. L. REV. __ (2009) (calculating the increase in patenting caused by a modest increase in the patent term during the transition from 17 to 20-year patents).

[38] F.M. Scherer, *Nordhaus' Theory of Optimal Patent Life: A Geometric Reinterpretation*, 62 AM. ECON. REV. 422, 426-27 (1972); SHAVELL, *supra* note 4, at 154 & n.38; *see also* Eric E. Johnson, *Calibrating Patent Lifetimes*, 22 SANTA CLARA COMPUTER AND HIGH TECH. L.J. 269 (2006); Frank Partnoy, *Finance and Patent Length* (2001) 12-17, U. San Diego Law & Econ. Research Paper No. 19, *available at* http//ssrn.com/abstract=285144. *But see* Duffy, *supra* note 197; *cf.* William D. Nordhaus, *The Optimal Life of a Patent: Reply*, 62 AM. ECON. REV. 428, 430 (1972) ("[A] fixed patent life is not optimal in theory, although it may be unavoidable in practice.").

[39] 35 U.S.C. § 154(a)(2).

[40] *See* C. Michael White, *Why a Seventeen Year Patent?*, 38 J. PAT. OFF. SOC'Y 839 (1956). The patent reform proposals that have been circulating Congress contain nothing about variable patent lengths or changes to the patent term. *See* http://www.patentsmatter.com/index.php.

[41] *Cf.* Dan L. Burk & Mark A. Lemley, *Is Patent Law Technology-Specific?*, 17 BERKELEY TECH. L.J. 1155, 1155-56 (2002) (noting that the because the patent system was "[d]esigned more than 100 years ago to meet the simpler needs of an industrial era, it is an undifferentiated, one-size-fits-all system").

lengths. Over the past 200 odd years, however, scientific progress has produced a wide range of distinctive technologies and industries with differing needs for patent protection.[42] Nonetheless, Congress has retained a uniform term of protection to be awarded to all patented inventions, perhaps reflecting the judgment that the administrative costs and complexity of a variable patent term (along with the danger posed by the opportunity for rent-seeking) would be greater than the benefits from a more tailored patent length.

Under current law, once an invention clears the patentability standards, the patent system grants it a uniform 20-year term of protection. This 20-year term runs from the filing date of the patent application,[43] and (leaving aside certain extensions sometimes available for inventions subject to pre-market regulatory review, such as drugs[44]) it establishes the duration of patent protection for all inventions, regardless of their development costs or the profits they generate. The same rule applies throughout much of the world; indeed, 20 years is the minimum patent term for inventions allowed under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), to which most countries are signatories.[45]

The origins of this 20-year term have more to do with historical precedent than any sort of economic inquiry into the optimal patent term.[46] When the United States created its patent system in 1790, it followed England's lead in offering a fixed 14-year term to all patented

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[42] *See* Burk & Lemley, *supra* note 6, at 1581-95.

[43] 35 U.S.C. § 154(a)(2).

[44] *See* 35 U.S.C. §§ 155 & 155A. *See infra* text accompanying notes _-_.

[45] Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), Apr. 15, 1994, art. 33, 33 I.L.M. 81, 93-94. The TRIPS Agreement also contains an antidiscrimination provision that bars signatory nations from adopting industry-specific patent rules. *Id.*, art. 27(1). Depending upon its design, a variable patent term might violate this provision of TRIPS, although it is unclear whether any other country would bother challenging those laws in WTO, which is the enforcement mechanism for TRIPS violations. *See* Roin, *supra* note 18, at 558 n.292.

[46] *See* Machlup, *supra* note 5, at 9; C. Michael White, *Why a Seventeen Year Patent?*, 38 J. PAT. OFF. SOC'Y 839 (1956).

inventions.[47] The English Parliament is said to have chosen that 14-year term because it believed developing inventions would take two apprenticeship periods, which lasted seven years.[48] In 1836, Congress amended the patent laws to allow patentees to petition to have their patent term extended by seven years if proper need were shown.[49] When the petition process proved burdensome, Congress tried to eliminate the 7-year extension, but legislators were divided over whether to go back to the old 14-year term or make the 7-year extension part of the standard patent term. Legislators reached a compromise in 1861, roughly splitting the difference between the original 14-year term and the 14-year term with a 7-year extension by adopting a fixed 17-year patent term.[50] That 17-year term remained unchanged for over 130 years.[51]

Congress adopted the current 20-year patent term in 1994 when it implemented the TRIPS Agreement, although the change to the duration of patent protection was meant to be more procedural than substantive.[52] Prior to entering into TRIPS, the United States was one of the few countries where the patent term started running from the date it issued as opposed to the filing date. TRIPS required the United States to amend its patent laws such that the patent term would instead run from the filing date.[53] Since patents cannot be enforced until they issue, this new rule shortens the effective patent life of inventions by whatever the amount of time the PTO

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[47] Patent Act of 1790, ch. 7, 1 Stat. 109-112 (Apr. 10, 1790).

[48] *See* White, *supra* note 46, at 841-42; Frank Partnoy, *Finance and Patent Length* (2001) 8-9, U. San Diego Law & Econ. Research Paper No. 19, *available at* http//ssrn.com/abstract=285144.

[49] *See* Patent Act of 1836, ch. 18 (1836); White, *supra* note 46.

[50] *See* Guarantee Ins. v. Sellers, 123 U.S. 276 (1887); 12 Stat. 246, 249, 16 (1861).

[51] *See* Machlup, *supra* note 5, at 9; White, *supra* note 48.

[52] Kenneth J. Burchfiel, *U.S. GATT Legislation Changes Patent Term*, 77 J. PAT. & TRADEMARK OFF. SOC'Y 222 (1995); Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), Apr. 15, 1994, art. 33, 33 I.L.M. 81, 93-94.

[53] *See id.*

takes to review and grant the application. Estimating that the PTO takes three years on average to issue a patent, Congress lengthened the 17-year patent term to the current 20-year period, thereby preserving the effect of the old 17-year term established back in 1861.[54]

While the 20-year patent term was designed to provide 17 years of actual patent protection awarded on average, Congress knew that by starting the clock on the patent term on the application filing date, an invention's effective patent life would depend on the time it took to prosecute the patent.[55] Scholars mostly approved of this change in the operation of the patent term because the old method of starting the patent term on the date the patent issued was vulnerable to abuse by patent applicants.[56] While the new patent term promised to stop these abuses, it also threatened to penalize firms for delays caused by the PTO in the issuance of their patents.[57] To protect firms losing patent life due to regulatory delays, Congress added provisions to the law that provide patent term extensions to compensate for patents that take longer than three years to prosecute due to delay by the PTO,[58] thereby preserving for them the 17-year term.

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[54] Mark A. Lemley, *An Empirical Study of the Twenty-Year Patent Term*, 22 AIPLA QUARTERLY J. 369, 374-76 (1994).

[55] *See id*. at 379; Kenneth J. Burchfiel, *U.S. GATT Legislation Changes Patent Term*, 77 J. PAT. & TRADEMARK OFF. SOC'Y 222, 222 (1995).

[56] *See, e.g.*, Lemley, *supra* note _, at 422. By drawing out the prosecution of their patent applications before the PTO, firms could delay the start of their 17-year term. *Id*. at 377. Under the law at that time, patents were not published until they issued, and so other firms would not know of the pending patent application until the PTO granted it. *See* 35 U.S.C. § 22 (1994). A small number of firms took advantage of these two rules to engage in a practice known as "submarine patenting." They would delay the issuance of their patents for years (or decades) while waiting for the technology to be widely adopted by firms thinking it was in the public domain, and then spring their patent on the unsuspecting public. *See* Lemley, *supra* note _, at 376-81. Stopping this practice was believed to be one of the primary advantages of changing to a 20-year patent term that runs from the filing date. *See id*. at 379.

[57] Firms in the biotechnology industry were particularly concerned about this change, *see* Lemley, *supra* note , at 376 & n.30, probably because their patents take longer than most to issue. *See* John R. Allison & Mark A. Lemley, *Who's Patenting What? An Empirical Exploration of Patent Prosecution*, 53 VAND. L. REV. 2099, 2102 (2000).

[58] 35 U.S.C. § 154(b); *see* John G. Byrne, *Changes on the Frontier of Intellectual Property Law: An Overview of the Changes Required by GATT*, 34 DUQ. L. REV. 121, 130 (1995).

After more than 200 years of technological and economic changes, it is remarkable how little the patent term has changed since Congress first adopted a uniform 14-year patent length. Despite tremendous scientific progress that has led to increasingly divergent technologies, Congress has retained a system of uniform patent lengths that predates the industrial revolution. Little has changed in the duration of that uniform patent term as well. Indeed, aside from the 1836 experiment in which Congress created the discretionary seven-year term extension, Congressional action on patent length appears to have been aimed at preserving the status quo. Even the 1994 amendments, which changed the timing of the patent term to run from a patent's issue date to its filing date, were accompanied by a three-year increase in the patent term to compensate for the average amount of time need to prosecute a patent, and by certain patent term extensions that would preserve the 17-year term when the PTO takes longer than three years to approve a patent. For whatever reason, both the duration of the patent term and its uniform character appear highly resistant to change.

III. THE TIMING OF THE 20-YEAR PATENT TERM: PENALIZING DEVELOPMENT EFFORTS INSTEAD OF REWARDING THEM

The 20-year patent term is often described as a uniform patent length, but in fact the effective patent life received by inventions can vary dramatically. Most firms file their patent application early in product development, and the 20-year term starts running on the filing date of the application. The longer it takes for firms to develop their inventions, therefore, the less time they have on the market before their patent expires. This policy of subtracting the amount of time it takes to develop an invention from its effective patent life is the very opposite of what the patent system should be doing. Longer development times generally correspond to greater total R&D costs, both because of the costs of capital and the correlation between development

time and out-of-pocket costs. Assuming that the investment of time and money in developing an invention are vulnerable to free-riding by competitors, a longer development time corresponds to the need for a longer patent term. Since the patent system does the exact opposite, it discourages investment in inventions with longer development times while providing excessive rewards to inventions that move quickly through development. These distortions will not be felt in every industry, but they might be extreme in technologies where development times are often lengthy and the incentives for investing in R&D are sensitive to the patent term.

The patent system permits firms to file patent applications on their inventions well before they are on the market. Patent law's utility standard establishes the minimum requirements for when an invention can be patented, and it sets a fairly low bar.[59] Patent applications merely need to describe the idea of the invention, disclose a way to make and use it, and, for certain types of inventions, provide some minimal evidence that the invention will work.[60] Under these modest requirements, firms can usually file a patent application claiming their invention before they even construct a prototype of it.[61] At this early stage in the R&D process, most inventions still require further development before they can be marketed,[62] such as product testing and subsequent design modifications.[63] Oftentimes firms also need to establish an infrastructure to produce the invention, such as manufacturing facilities, and an internal operation to manage its

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[59] *See* STEPHEN A. BECKER, PATENT APPLICATIONS HANDBOOK § 6:31 (2006).

[60] *See* Christopher A. Cotropia, *The Folly of Early Filing in Patent Law*, 61 Hastings L.J. __, __ (2009).

[61] *See* ROBERT PATRICK MERGES & JOHN FITZGERALD DUFFY, PATENT LAW AND POLICY: CASES AND MATERIALS - ___ (4th ed. 2007).

[62] *See* Edmund W. Kitch, *The Nature and Function of the Patent System*, 20 J.L. & ECON. 265, 276-77 (1977).

[63] *Cf.* OFFICE OF TECHNOLOGY ASSESSMENT, INNOVATION AND COMMERCIALIZATION OF EMERGING TECHNOLOGIES 21 (1995) (describing some of the complexity of the "product development phase").

commercialization.[64]   Completing these development efforts can take months, years, or even decades.[65]   In many cases, therefore, inventions are ready to be patented fairly early in their R&D, long before they reach the public.

Once an invention is ready to be patented, firms generally file their application as quickly as possible because any delay can jeopardize their patent rights.[66]   The law prohibits firms from taking an "unreasonably long" amount of time in getting to the patent office.[67]   It is possible to postpone filing an application for a short while. In theory, firms could hold back on filing their patent applications until their inventions were closer to commercialization.   Any such delay creates a risk of losing one's patent rights, however, since another firm might file a patent claiming the invention[68] or publish something that puts it in the public domain.[69]   Likewise, related technological developments might begin to make the invention appear obvious, and thus prevent the firm from later patenting it.[70]   In practice, therefore, firms usually try to file their patents as soon as they are able to do so, lest they forfeit their rights to the invention.[71]

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[64] *See id*. at 23.

[65] *See* Edmund W. Kitch, *The Nature and Function of the Patent System*, 20 J.L. & ECON. 265, 276-77 (1977).

[66] *See* Christopher A. Cotropia, *The Folly of Early Filing in Patent Law*, 61 Hastings L.J. __, __ (2009).

[67] Peeler v. Miller, 535 F.2d 647 (C.C.P.A. 1976).

[68] Although the United States still maintains a first-to-invent rule of priority, the first-to-file typically wins any subsequent priority fight. *See* Charles R.B. Macedo, *First-to-File: Is American Adoption of the International Standard in Patent Law Worth the Price?*, 1988 COLUM. BUS. L. REV. 543. Moreover, the other developed nations all follow a first-to-file system of priority. See *id*. Even if the first-to-invent manages to win a priority fight in the U.S., therefore, it will be unable to claim its patent rights abroad.

[69] *See* Gideon Parchomovsky, *Publish or Perish*, 98 MICH. L. REV. 926 (2000).

[70] *See* Harold C. Wegner & Stephen Maebius, *The Global Biotech Patent Application*, *in* BIOTECHNOLOGY LAW: BIOTECHNOLOGY PATENTS & BUSINESS STRATEGIES IN THE NEW MILLENNIUM, at 129-30 (PLI Pats., Copyrights, Trademarks, and Literary Prop. Course, Handbook Series No. G0-00R6, 2001).

[71] *See, e.g.*, Robert Greene Sterne et al., *The 2005 U.S. Patent Landscape for Electronic Companies*, PRACTICING LAW INSTITUTE PATENTS, COPYRIGHTS, TRADEMARKS, AND LITERARY PROPERTY COURSE HANDBOOK SERIES NO. 5994, 295, 337 (2005).

Since the patent term starts running when firms file their patent application, the longer it takes to develop an invention for commercialization, the less time the firm has to take advantage of its patent to earn a profit.[72] The 20-year patent term runs from the patent's filing date, not when the invention reaches the market.[73] To generate any profits, however, the invention must be developed and put on the market. Time spent developing an invention for commercial use – *i.e.*, the time from patent filing to commercialization – therefore reduces the time available for the firm to earn a profit selling the invention under patent protection. An invention's effective patent life thus depends on how long it takes to develop it for commercialization.

When an invention cannot reach the public without a significant investment in its development, the necessity of such development effort often increases the need for patent protection. The cost of developing an invention can be substantial. Indeed, it frequently costs more to develop an invention than the cost of the initial research that led to its creation.[74] To the extent that those development costs are subject to free-riding by competitors, such that the innovative firm incurs costs (or faces uncertainty) in developing the invention that competitors avoid by imitating the innovator's efforts, the development costs likely increase the length of market exclusivity needed for the firm to recoup its R&D investment. In other words, the minimum patent term needed to incentivize the creation and development of an invention increases along with the development costs that are vulnerable to free-riding.[75]

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[72] *See* Michael Abramowicz, *The Danger of Underdeveloped Patent Prospects*, 92 CORNELL L. REV. 1065, __ (2007).

[73] 35 U.S.C. § 154(a)(2).

[74] *See* WILLIAM J. BAUMOL, THE FREE-MARKET INNOVATION MACHINE: ANALYZING THE GROWTH MIRACLE OF CAPITALISM 10 (2002). [fix]

[75] *See supra* text accompanying notes __-__.

Likewise, the amount of time it takes to develop an invention is positively correlated with its appropriate patent length, all else equal. When an invention spends more time in development relative to others, it often reflects a comparatively larger investment that is vulnerable to free-riding. The more time it takes to get an invention onto the market, the greater the opportunity costs of capital spent, which increases the costs of development.[76] A longer development time also generally reflects larger out-of-pocket costs for the project itself. When the costs and time needed for competitors to imitate an invention are largely unrelated to the time and expense of developing that invention in the first place, as is often the case for inventions that are easy to reverse engineer,[77] a longer development time is correlated with a longer optimal patent term. Likewise, shorter development times indicate the need for a smaller period of protection.

By starting the clock on an invention's patent life on its filing date, the patent term works in the opposite direction that one would expect. Inventions that can be developed quickly receive a longer effective patent life even though their abbreviated development time suggests that a shorter patent life would be adequate. Longer development times correspond to the need for a longer patent term, but the time an invention spends in development actually subtracts from its effective patent life. The sliding scale of protection offered by the 20-year patent term is therefore inversely related to an invention's likely need for protection given its development time.

One might hope that this system would perhaps have the benefit of speeding up the pace of innovation. The timing of the patent term certainly provides an incentive for firms to hurry

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[76] *See* Partnoy, *supra* note 48, at 22-27.

[77] *See* Pamela Samuelson & Suzanne Scotchmer, *The Law and Economics of Reverse Engineering*, 111 YALE L.J. 1575, 1586-87 (2001).

their R&D projects, and under certain conditions this added incentive might correct for flaws in the patent system that could otherwise cause firms to develop their inventions too slowly. Most inventions eventually lose their market share to other, superior inventions, and therefore have a finite period during which they create social value. If that period of market value is unrelated to the date when the invention reaches the market,[78] then when a firm takes an additional year to develop an invention, the public loses one year's worth of that invention's value. Since the patent term runs from the filing date, a one-year delay costs the firm one-year's worth of monopoly profits, which roughly aligns the interests of the firm with those of the public.

This benefit from the early running of the patent term may be illusive, however, because the added incentive to rush through development may be redundant or be penalizing firms for time constraints that are outside their control; and when the patent term does cause firms to speed up their development efforts, it is unclear whether the public would benefit or be harmed as a result. To the extent that the pace of a firm's R&D is controlled by external forces, such as technological hurdles and regulatory requirements, the incentive to hurry through development to preserve patent life would have little effect, since the firm is simply unable to move any faster. The forced alignment of public and private interests regarding the pace of R&D also might be redundant in a competitive R&D environment, since firms with similar products will be racing against one another to get their invention onto the market first and capture the resulting competitive advantages.[79] Moreover, the policy of running the patent term from the filing date can pressure firms to take socially-excessive risks in their efforts to accelerate an R&D project,

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[78] It is unclear how often this will be true. Many of the inventions that replace older ones on the market may have been based in part on what was learned from having the older product on the market, observing its pros and cons to see how it could be improved.

[79] *See* F.M. Scherer, *Markets and Uncertainty in Pharmaceutical Development* (2007), *available at* ___. R&D appears to be fairly competitive in most industries, including pharmaceuticals. *Id*.

potentially causing them to cut corners that jeopardize the projects' chances of success.[80] From a theoretical perspective, therefore, it is unclear whether a patent term that runs from the filing date instead of market entry provides better or worse incentives for firms to optimize the pace and conduct of their R&D.

Although these concerns about the patent term's effect on the speed and outcome of R&D are legitimate, the core issues remain unchanged: deadweight loss and the incentives for innovation. A patent system that awards too much patent protection to inventions with short development times and too little protection to inventions with long development times can be expected to generate excessive deadweight loss while failing to promote some socially valuable innovation. Patent policy usually involves a tradeoff between those two consequences. Rules that strengthen patent protection over inventions increase both the incentives for innovation and the deadweight loss from patent pricing, while policies that weaken patent protection have the opposite effect.[81] The early running of the patent term actually worsens the system's performance along both dimensions. Inventions that move through development quickly are receiving longer effective patent lives than needed for the public to benefit from them, creating unnecessary deadweight loss[82] and perhaps wasteful R&D spending due to patent races. At the

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[80] Under a finite patent term, the profits from innovation are less than the social value created. When an R&D project fails that could have succeeded, the social loss from that failure is greater than loss suffered by the innovating firm. As a result, firms do not fully internalize the cost of the risks they might take when trying to accelerate an R&D project in ways that might lead to its unnecessary failure. Running the patent term from the filing date pressures firms to speed up development, thereby exacerbating the problem.

[81] *See* Kaplow, *supra* note _, at __. [fix]

[82] *But see* John F. Duffy, *A Minimum Optimal Patent Term* (2003), available at http://ssrn.com/abstract=354282; John F. Duffy, *Rethinking the Prospect Theory of Patents*, 71 U. CHI. L. REV. 502 (2004). Duffy argues that a seemingly excessive patent term might not lead to an excessive period of market exclusivity for an invention, and thus no additional deadweight loss, because the excessive reward will cause firms to file their patents earlier, leading to the earlier expiration of their patent rights. *Id*. at 475-480 (arguing that an excessive patent term operates much like a "Demsetzian auction," where firms "bid" with earlier patent filing dates that result in shorter effective patent lives or fewer profits because of the earlier market entry). In other words, when the patent term for an invention is more than needed to motivate its development, competing firms will race to secure the profits from the patent by

same time, because the effective patent life of an invention diminishes as the time (and thus the cost) of developing it goes up, the patent term likely discourages firms from investing in innovation that requires lengthy development periods.

Previous scholarship on the patent term overlooks this perverse relationship between an invention's effective patent life and its need for protection. A few scholars noticed that because the patent term starts running on the filing date, inventions with long development times might not have enough patent life remaining when they reach the market for private industry to invest in their R&D.[83] Michael Abramowicz labeled this phenomenon a "patent underdevelopment problem," describing the potential danger of lost innovation that might result as the incentive to develop an invention disappears when its patent life runs down.[84] This observation is accurate, of course, but it also overlooks the problem identified in this article. It is not just that firms may ignore inventions with usually long development times. The real problem is that the existing patent term actively penalizes firms for the time they spend developing their inventions, even

trying to be the first to file their application, and that competition will a filing date so early that the expected profits become zero due to the earlier patent expiration date. These patent races have their costs, however, leading firms to engage in wasteful research spending in an effort to be the first to the patent office. *See supra* note __. Moreover, it is unclear whether firms are often in a position to file their patent applications early enough to offset the excessive reward offered by a longer-than-needed patent term. Firms already rush to file their patent applications to prevent others from beating them to the PTO or disclosing something that will put the invention in the public domain. *See supra* text accompanying notes _-_. To file their patent applications on an even earlier date, firms would likely need to accelerate their research programs to push forward the moment of invention. It sounds plausible that firms could sometimes speed up their research by several months or even a year or two, but if the patent term is too long by five or even ten years, it is unclear that firms could normally accelerate their research to match. Their research might be based on an idea that simply didn't occur to anyone until recently, or it might have been inspired or made possible by outside technological developments. *See* SUZANNE SCOTCHMER, INNOVATION AND INCENTIVES 54-55 (2006). When the moment of invention is primarily determined by such an exogenous event, firms are unlikely to file their patents early enough to avoid the deadweight loss from an excessive patent term.

[83] *See, e.g.*, White, *supra* note _, at 853 (noting that inventions with an "unduly long development period" might exhaust most or all of their patent life before reaching the market, perhaps undermining the incentive to make them).

[84] Michael Abramowicz, *The Danger of Underdeveloped Patent Prospects*, 92 CORNELL L. REV. 1065, 1094-98 (2007) ("[O]ne danger of granting patents in gene sequences is that, by the time researchers see a therapeutic use on the horizon, the patent term might have expired or too little patent term will remain to make the research financially worthwhile."); *cf.* Rebecca S. Eisenberg, *The Problem of New Uses*, 5 YALE J. HEALTH POL'Y. L. & ETHICS 717 (2005) (explaining that pharmaceutical companies often fail to invest in establishing new therapeutic uses for their existing drugs because there is not enough time remaining on their patent to recover the necessary investment).

though those development efforts usually justify awarding a longer relative term of protection.[85] The effective patent life of an invention is inversely related to its need for protection as reflected by the time invested in its development.

Fortunately, the lost innovation and excessive deadweight loss from the early running of the patent term may not occur in many industries because, in general, their R&D investments are largely insensitive to changes in the patent term. The early running of the 20-year patent term should have little effect on inventions that require little time to develop,[86] or ones that lose their market value after only a few years on the market.[87] For those inventions that do require significant investments in development, the 20-year patent term might still be inconsequential if the development efforts give rise to their own form of protection, such as manufacturing-process patents, trade secrets, lead-time advantages, brand-name recognition (in the case of some commercialization efforts) or other first-mover advantages.[88] Inventions with longer development periods require longer patent terms on average only to the extent that the time spent in development reflects R&D investments that are vulnerable to free-riding, and this is not always the case. As a result, it is likely that much of society's R&D spending is unaffected by the early running of the patent term.

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[85] The primary difference between Abramowicz's description of the "underdevelopment problem" and my own account of perverse nature of the patent term is that Abramowicz (implicitly) treats the ideal patent length for any given invention as an exogenous variable, whereas I treat it as a function of development time.

[86] *See* Abramowicz, *supra* note _, at 1070-71; Kitch, *supra* note _, at 276.

[87] *Cf.* SUZANNE SCOTCHMER, INNOVATION AND INCENTIVES 147 (2004) (explaining that "the *effective* patent life is likely to be much shorter than the statutory life" in industries where technological turnover is rapid).

[88] *See* WESLEY M. COHEN ET AL., PROTECTING THEIR INTELLECTUAL ASSETS: APPROPRIABILITY CONDITIONS AND WHY U.S. MANUFACTURING FIRMS PATENT (OR NOT) (Nat'l Bureau of Econ. Research, Working Paper No. 7552, 2000), *at* http://www.nber.org/papers/w7552; Robert Mazzoleni & Richard R. Nelson, *Economic Theories about the Benefits and Costs of Patents*, 32 J. ECON. ISSUES 1031, 1047-48 (1998); F. M. Scherer, *Pharmaceutical Innovation*, AEI-Brookings Joint Center Working Paper No. 07-19, at 27-28 (Jun. 2007); Suzanne Scotchmer & Stephen M. Maurer, *Innovation Today: A Public-Private Partnership*, *in* INNOVATION AND INCENTIVES 243-44 (2004).

The threat posed by the current patent term may not universal, but in industries where R&D investments are sensitive to the patent term and development efforts are sometimes lengthy and subject to free-riding by competitors, the timing of the 20-year patent term presents a potentially serious danger to the public. Inventions in these industries receive effective patent lives of variable length, and that variation is negatively correlated to their need for protection as reflected by the time it took to develop them. As a result, many inventions that cannot reach the market quickly may never be developed, while the inventions that move through development quickly are frequently over-rewarded by the patent system.

IV. PHARMACEUTICAL INNOVATION AND THE 20-YEAR PATENT TERM

The industry most clearly affected by the perverse timing of the 20-year patent term is pharmaceuticals. Patents play a crucial role in promoting pharmaceutical R&D, largely because the investment of time and resources needed to develop a drug is orders-of-magnitude larger than the costs faced by generic manufacturers in entering the market. The economics of the industry are such that the longer it takes to develop a drug, the more protection it likely needs from generic competition to recoup the R&D costs. Yet the drugs that take longer to develop generally receive a shorter effective patent life, while drugs that can be developed quickly receive longer periods of market exclusivity. Although current law provides for certain patent term extensions for drugs, these extensions only partially mitigate the effect of the early running of the patent term. The social welfare consequences of this policy may be extremely negative. Drugs with shorter development times are being systematically over-rewarded, possibly leading to excessive deadweight loss. At the same time, the penalty for longer development times is likely preventing many drugs from reaching the public. The most worrisome examples of such

drugs may be therapeutics for early-stage cancer and cancer prevention, which could have tremendous social value if developed, but would require lengthy clinical trials that would consume most of their patent life.

A. Pharmaceutical Innovation and Its Sensitivity To Patent Length

Pharmaceutical innovation has generated significant benefits for the public over the years. Patents play a crucial role in spurring the creation and development of new drugs, in large part due to the high R&D costs incurred by pharmaceutical companies but not their generic rivals. Investments in pharmaceutical R&D also appear to be highly sensitive to the duration of patent protection available to them, in part because the profits that drugs produce toward the end of their patent life often represents a significant portion of their expected value to pharmaceutical companies. Given the apparent sensitivity of pharmaceutical innovation to changes in the patent term, it is likely that a longer patent term would result in more drugs reaching the public.[89] At the same time, the high prices of patented drugs impose a significant burden on the public, imposing hardship on people who struggle to afford the medication they need.[90] The resulting debate over the appropriate length for drug patents fits into the predictable pattern of comparing the potential benefits from additional innovation with the deadweight loss from lengthier patent terms.

It is widely believed that pharmaceutical innovation has produced tremendous health benefits for the public over the years. Although it can be difficult to accurately measure the

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[89] *Cf.* Henry Grabowski, *Data Exclusivity for New Biological Entities*, Duke University Department of Economics Working Paper (2007), at _.

[90] *Cf.* Aaron S. Kesselheim et al., *Extensions of Intellectual Property Rights and Delayed Adoption of Generic Drugs: Effects on Medicaid Spending*, 25 HEALTH AFFAIRS 1637 (2006).

social returns from R&D,[91] empirical studies of the social welfare gains from pharmaceutical innovation almost all find significant net benefits from the investment.[92] Given the evidence of substantial social gains from the development of existing drugs, encouraging new drug development is widely seen as an important public policy objective.[93]

Most of the investment in pharmaceutical R&D needed produce new drugs could not be sustained in a perfectly competitive market; indeed, the economics of pharmaceutical R&D are a textbook case of how unrestrained competition could stifle socially valuable innovation. Putting a new drug on the market takes 12 years on average and costs upwards of $800 million.[94] More than half of that time and expense arises because of the FDA's clinical trial requirements.[95] Generic manufacturers incur almost none of those R&D costs. They imitate the compounds that pharmaceutical companies identify as therapeutically valuable, saving themselves from the time and expense of discovering and optimizing new drug compounds for clinical trials.[96] Moreover, because generic drugs are not subject to the FDA's clinical-trial requirements that apply to new

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[91] *See* Paul Grootendorst et al., *The Life Expectancy Gains from Pharmaceutical Drugs: A Critical Appraisal of the Literature*, available at _____ (arguing that the existing studies demonstrating high social returns from pharmaceutical R&D investments are flawed).

[92] *See* Roin, *supra* note 18, at 514 (citing numerous studies finding a positive social return from pharmaceutical R&D investments).

[93] *See* CONGRESSIONAL BUDGET OFFICE, RESEARCH AND DEVELOPMENT IN THE PHARMACEUTICAL INDUSTRY __ (2006).

[94] *See* Joseph A. DiMasi et al., *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. HEALTH ECON. 151, 180-83 (2003); Joseph A. DiMasi & Henry G. Grabowski, *The Cost of Biopharmaceutical R&D: Is Biotech Different?*, 28 MANAGERIAL & DECISION ECON. 469 (2007); Christopher P. Adams & Van V. Brantner, *Estimating the Cost of Drug Development: Is it Really $802 Million?*, 25 HEALTH AFFAIRS 420 (2006). This estimate includes the research and development costs of failed drug candidates as well as the opportunity costs of the investments.

[95] *See* DiMasi et al., *supra* note 94.

[96] *See* MARTIN A. VOET, THE GENERIC CHALLENGE: UNDERSTANDING PATENTS, FDA & PHARMACEUTICAL LIFECYCLE MANAGEMENT _ (2005).

drugs,[97] generic manufacturers speed through the regulatory process at the comparative rapid rate of 16 months on average,[98] and generic firms usually spend only a few million dollars to complete the process.[99] Once generic drugs enter the market, they quickly drive down prices and capture most sales, undercutting the pharmaceutical company's profits from the drug.[100] Without some way to delay market entry by generic competitors, pharmaceutical companies would be unable to recoup their R&D investments, and would likely invest their time and resources elsewhere.

Given the massive investment of time and resources needed to develop a new drug compared to the ease with which generic companies can enter the market, it is widely recognized that patents play an essential role in promoting the discovery and development of new drugs.[101] The pharmaceutical industry is one of the most research-intensive industries in the world, and numerous studies have shown that drug companies rely heavily on the patent system to recoup their R&D investments.[102] In fact, pharmaceutical companies generally refuse to develop drugs that lack strong patent protection, and it is not uncommon for them to discard drugs from their pipeline if they decide the patents on them appear weak.[103] Without drug patents (or some other

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[97] *See* 21 U.S.C. § 355(j)(8)(B) [fix].

[98] *See* Steven K. Galson, *2006 CDER Update* 11, (Jan. 18, 2007), *at* http://www.fda.gov/cder/present/galson/default.htm.

[99] *See Big Generic Pharma*, ECONOMIST, vol. 376, Jul. 30, 2005, at 58.

[100] *See* CONG. BUDGET OFFICE, RESEARCH AND DEVELOPMENT IN THE PHARMACEUTICAL INDUSTRY 16 (2006); Richard G. Frank & Erica Seiguer, *Generic Drug Competition in the U.S.*, *in* BUSINESS BRIEFING: PHARMATECH 56, 56–58 (2003), *available at* http://www.touchbriefings.com/download.cfm?fileID=493.

[101] *See, e.g.*, COMM'N ON INTELLECTUAL PROP. RIGHTS IN THE KNOWLEDGE-BASED ECON., NAT'L RESEARCH COUNCIL, A PATENT SYSTEM FOR THE 21ST CENTURY 41 (Stephen A. Merrill et al. eds., 2004).

[102] *See* F. M. SCHERER, THE POLITICAL ECONOMY OF PATENT POLICY REFORM IN THE UNITED STATES 6-9, 13 (Dynamics of Inst. & Markets in Eur., Intell. Prop. Rts. Working Paper No. 26, Dec. 2006), *available at* http://www.dime-eu.org/node/365 (summarizing the literature).

[103] *See* Roin, *supra* note 18, at 545-547.

tool to motivate or fund drug R&D), therefore, the vast majority of existing drugs likely would not have been developed.[104]

For many of the same reasons, investments in pharmaceutical R&D are very sensitive to the amount of time drug companies are given on the market before generics enter. Numerous studies document the close link between the pharmaceutical industry's profits and its R&D spending.[105] The sales volume of drugs – unlike many other technologies – frequently remain strong for several decades after their introduction.[106] In fact, the bulk of the profits from a drug's sale are often back-loaded at the end of its patent term, when the sales volume tends to be highest.[107] The effective patent life on a drug can therefore have a significant effect on the returns from developing it.[108] Given the high upfront costs of getting a new drug onto the market, it is not surprising that the decisions companies make to develop a drug are heavily influenced by the expected period of market exclusivity over it.[109] Changes in the effective patent life of new drugs would likely have a non-trivial effect on industry R&D spending, and thus on the output of new drugs.

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[104] *See, e.g.*, Uwe Reinhardt, *The Pharmaceutical Sector in Health Care*, *in* PHARMACEUTICAL INNOVATION: INCENTIVES, COMPETITION, AND COST-BENEFIT ANALYSIS IN INTERNATIONAL PERSPECTIVE, Frank A. Sloan & Chee-Ruey Hsieh, eds. (2006).

[105] *See, e.g.*, Carmelo Giaccotto et al., *Drug Prices and Research and Development Investment Behavior in the Pharmaceutical Industry*, 48 J.L. & ECON. 195 (2005); F.M. Scherer, *The Link Between Gross Profitability and Pharmaceutical R&D Spending*, 20 HEALTH AFFAIRS 216 (2001).

[106] *See* IMS Health, National Prescription Audit 2008, at .

[107] *See* Henry G. Grabowski & John Vernon, *The Distribution of Sales Revenues from Pharmaceutical Innovation*, 18 PHARMACOECONOMICS Suppl. 1, 21 (2000).

[108] *See* Henry Grabowski, *Are the Economics of Pharmaceutical Research and Development Changing?: Productivity, Patents and Political Pressures*, 22 PHARMACOECONOMICS 15, 21 (Supp. 2, 2004) .

[109] *See* AstraZeneca, *Gowers Review of Intellectual Property – Call for Evidence*, Apr. 26, 2006, at 4; GlaxoSmithKline ("GSK") *Response to Gowers Review on IP*, Apr. 18, 2006, at 15, 23-24; TAMAS BARTFAI & GRAHAM V. LEES, DRUG DISCOVERY: FROM BEDSIDE TO WALL STREET _ (2006).

Although a longer drug-patent term would probably increase the number of new drugs that reach the public, it would also potentially increase the deadweight loss caused by the patent pricing, including from all of the drugs that were going to be developed even under the shorter patent term. The prices charged for patented drugs are often many times higher than the cost of the drug as a generic,[110] and this pricing differential can result in significant market distortions.[111] Roughly a quarter of Americans said that last year they saved money by not filling prescriptions, skipping doses or cutting their pills in half, and most of those people said that their medical condition got worse as a result.[112] Prescription-drug insurance, including Medicaid and Medicare Part D, help avoid much of the potential deadweight loss from drug patents,[113] but many Americans remain uninsured. As a result, even a moderate lengthening of the patent term for all drugs might produce significant deadweight loss.[114]

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[110] *See* James W. Hughes et al., *"Napsterizing" Pharmaceuticals: Access, Innovation, and Consumer Welfare* 6 (Nat'l Bureau of Econ. Research, Working Paper No. 9229, 2000), *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=334321 (indicating a 6:1 ratio of price to marginal cost for branded drugs).

[111] Estimates of the deadweight loss caused by drug patents in the U.S. range from $5 to $30 billion annually. *See* Aidan Hollis, *An Efficient Reward System for Pharmaceutical Innovation* 7-8 (2005), *at* http://econ.ucalgary.ca/fac-files/ah/drugprizes.pdf. *But see* Frank Lichtenberg & Gautier Duflos, *Does Patent Protection Restrict U.S. Drug Use? The Impact of Patent Expiration on U.S. Drug Prices, Marketing, and Utilization* (2009) (finding that the utilization of drugs does not change after the patent expires, likely because the increased demand stemming from lower prices is offset by lower demand caused by the reduction in marketing activities).

[112] Kaiser Public Opinion, *Economic Problems Facing Families* 3-4 (April 2008) *at* http://kff.org/kaiserpolls/upload/7773.pdf.

[113] *See* Darius Lakdawalla & Neeraj Sood, *The Welfare Effects of Public Drug Insurance* (2007), NBER Working Paper Series No. 13501, *at* http://www.nber.org/papers/w13501. The provision of prescription-drug insurance through government funds reduces (or perhaps nearly eliminates) the deadweight loss caused by patent pricing, but also creates distortions from raising revenue through the tax system. *Id*. The relevance of those distortions to these public policy issues is questionable, however. *See* KAPLOW, *supra* note _. If the potential labor distortions from raising tax revenue to pay for prescription drugs does not create deadweight loss relevant to that policy, then the optimal patent term for drugs might be close to infinite (ignoring the threat of patent races) in a world where the government eliminated the deadweight loss from drug-patent pricing through subsidized or government-provided prescription-drug insurance.

[114] *See* Aaron S. Kesselheim et al., *Extensions of Intellectual Property Rights and Delayed Adoption of Generic Drugs: Effects on Medicaid Spending*, 25 HEALTH AFFAIRS 1637 (2006).

Setting the length of protection for drug patents under a uniform patent term inevitably leads to this tradeoff between access and innovation. It is very likely that the public is losing access to some drugs because the patent term is insufficient to motivate their development, and also that some of the drugs now available would have been developed even under a shorter patent term.

B. The Perverse Timing of the Drug Patent Term

The ongoing debate over what the uniform patent term should be for drugs overlooks a critical problem with the current drug patent term: the effective patent life awarded to drugs is inversely related to their need for protection as reflected by their development time. Drug patents are filed early in R&D, and because the patent term starts running on the filing date, drugs that take longer to develop receive a shorter effective patent life. At the same time, a longer development timeline corresponds with higher out-of-pocket development expenses and, more directly, a greater total R&D costs due to the time value of money. The patent system is diminishing the effective patent life of drugs that likely need additional protection to motivate their development, and granting unusually long effective patent lives to drugs that the public would probably receive in exchange for a shorter term.

In the pharmaceutical industry, as in most others, firms typically file their patent applications at an early stage in the R&D process. Although drug patents must contain some experimental evidence supporting the drug's claimed therapeutic value,[115] the PTO does not require evidence from clinical trials.[116] Results from laboratory or animal experiments

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[115] *See* STEPHEN A. BECKER, PATENT APPLICATIONS HANDBOOK § 6:31 (2006).

[116] *In re Brana*, 51 F.3d 1560, 1567-68 (Fed. Cir. 1995).

supporting the claimed use for the drug are sufficient to file a patent application,[117] and firms usually complete these necessary experiments during early R&D.[118] Once they are ready to patent their drug, any delay in filing the patent applications risks some other firm beating them to the PTO or disclosing something that would invalidate their patent claim.[119] In an industry where firms will not move a product forward in R&D unless its patent protection is secure, pharmaceutical companies take few chances when securing their intellectual property rights, filing their patent applications as early as they can.[120] As a result, pharmaceutical companies typically file their drug patents relatively early in R&D.[121]

Since the 20-year patent term starts running on the patent's filing date, drugs that take longer to develop receive a shorter effective patent life. As noted above, it takes 12 years and costs $800 million on average for a drug to move from discovery to the market.[122] These averages mask significant variation in the time and expense of drug development,[123] however, particularly for the clinical-testing phase, which usually accounts for over half of the duration

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[117] *See* U.S. PATENT & TRADEMARK OFFICE, MANUAL OF PATENT EXAMINING PROCEDURE § 2107.03 (8th ed. 2001).

[118] *See infra* note _.

[119] *See supra* text accompanying note _.

[120] *See* Bruno Galli & Bernard Faller, *Discover A Drug Substance, Formulate and Develop It To A Product*, *in* THE PRACTICE OF MEDICINAL CHEMISTRY 688 (Camille Georges Wermuth ed., 2d. 2003); Stephen T. Schreiner & Patrick A. Doody, *Patent Continuation Applications: How the PTO's Proposed New Rules Undermine an Important Part of the U.S. Patent System with Hundreds of Years of History*, 88 J. PAT. & TRADEMARK OFF. SOC'Y 556, 557 (2006); Harold C. Wegner & Stephen Maebius, *The Global Biotech Patent Application*, *in* BIOTECHNOLOGY LAW: BIOTECHNOLOGY PATENTS & BUSINESS STRATEGIES IN THE NEW MILLENNIUM, at 129-30 (PLI Pats., Copyrights, Trademarks, and Literary Prop. Course, Handbook Series No. G0-00R6, 2001).

[121] *See* Eisenberg, *supra* note _; Gerald J. Mossinghoff, *Overview of the Hatch-Waxman Act and Its Impact on the Drug Development Process*, 54 FOOD & DRUG L.J. 187 (1999).

[122] *See supra* note 94.

[123] *See* BARTFAI & LEES, *supra* note 109; Richard J. Findlay, *Originator Drug Development*, 54 FOOD & DRUG L.J. 227 (1999).

and cost of developing a drug.[124] The out-of-pocket cost of clinical trials can range from $100 million to well over $1 billion depending upon the size of the test groups and nature of the trial.[125] Moreover, while some drugs can speed through clinical trials in just two or three years, others take eight or more years before there is sufficient clinical-trial data to demonstrate their safety and efficacy to the FDA.[126] Drugs patents are usually filed two or more years before the drug enters clinical trials,[127] and so their patent life is running for the duration of the clinical-trial period. Although pharmaceutical companies receive certain extensions on their patent terms for time spent in clinical testing and FDA review (as discussed below in Section IV.C), these extensions compensate for only a portion – usually less than half – of the patent life lost during clinical trials.[128] Even with these extensions, therefore, the time a drug spends in clinical trials reduces its effective patent life.

This relationship between the effective patent life on a drug and the time it spent in clinical trials generally persists even accounting for the various tactics pharmaceutical companies use to extend the patent lives on their drugs. Although pharmaceutical companies can sometimes secure additional patents on a drug during R&D, these patents are usually narrower in scope, and thus afford less protection from generic competitors.[129] In most cases, therefore, pharmaceutical companies must try to block generic entry with a patent filed at least a year – and often far more

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[124] *See supra* note 94.

[125] *See* BARTFAI & LEES, *supra* note 109; *cf.* DiMasi et al., *supra* note _, at 217-18.

[126] John A. DiMasi et al., *R&D Costs and Returns by Therapeutic Category*, 38 DRUG INFO. J. 211 (2004).

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[128] *See* 35 U.S.C. § 156.

[129] *See* Eisenberg, *supra* note _; Roin, *supra* note 18.

– before their drug entered clinical trials.[130] The average effective patent life for a new drug is 10 to 12 years,[131] with drugs that move quickly through pre-clinical and clinical development receiving longer effective patent lives, and drugs that take longer to develop receiving shorter effective patent lives.

At the same time, the amount of time it takes to develop a drug is positively correlated to the minimum period of market exclusivity needed to motivate its creation and development. Pharmaceutical companies investing in the discovery and development of new drugs must earn a sufficient return on their R&D to justify the opportunity costs of the capital they are using; otherwise, investors will direct that money elsewhere. The costs of capital in the pharmaceutical industry have been estimated to be roughly 12%.[132] The longer it takes for an investment in R&D to produce a drug on the market that is generating returns, the greater those returns will need to be to justify the investment.[133] Indeed, estimates of the total R&D costs of developing a new drug indicate that half of the average expenses are due to time costs.[134] Moreover, the duration of the clinical trials a drug must complete is often closely correlated to the out-of-pocket costs of those trials, since the expense of hospitals, physicians, staff, research subjects, and the clinical researchers working on the study will be a function of the time spent on the project.[135] As a result, the length of time a drug spends in development, and particularly the time spent in

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[130] *See* Mossinghoff, *supra* note _. Companies usually file their primary patent on a drug before it enters toxicology screening.

[131] See Henry G. Grabowski & John M. Vernon, *Effective Patent Life in Pharmaceuticals*, 19 INT'L J. TECH. MGMT. 98, 109–17 (2000).

[132] *See* Grabowski, *supra* note _, at 12.

[133] *See* Partnoy, *supra* note 201.

[134] *See* DiMasi et al, *supra* note 94, at 166.

[135] *See* TAMAS BARTFAI & GRAHAM V. LEES, DRUG DISCOVERY: FROM BEDSIDE TO WALL STREET (2006).

clinical development, will have a significant positive relationship on average with the minimum

necessary patent life for motivating investment in the development of that drug.

In essence, therefore, the patent system offers a larger reward to drugs that with lower

total R&D costs on average, and a smaller reward to drugs with higher total R&D costs on

average. In the ongoing debate about the appropriate fixed patent term from drugs, scholars have

overlooked that the current patent term is not uniform, but rather a variable term of protection

that moves in the opposite direction as would an optimally tailored patent term for drugs.

C. The Existing Patent-Term Extensions for Drugs

One response to this critique of the drug-patent term is that current law already provides

patent-term extensions to pharmaceutical companies to make up for some of the time their drugs

spend in clinical trials and regulatory review. Although the existing patent-term extensions

reduce the distortion from the early running of the patent term, they are nowhere close to solving

it – nor were they designed to do so. Congress created them to offset another policy change that

accelerated generic entry into the market, not to correct the penalty imposed on pharmaceutical

companies for the time it takes to develop their drugs. Under current law, firms recover a

portion – no more than half – of the time on their patent lost during clinical trials, and even that

limited recovery is subject to a cap. The patent system therefore continues to penalize

investment in drugs with long development times. Scholarly praise for the patent-term

extensions provided under current law reflects the literature's failure to recognize this problem.

The idea of extending the length of drug patents to make up for FDA-imposed delays is

not new. At least as far back as the 1970s, officials from the pharmaceutical industry were

arguing that the time needed to satisfy the FDA's clinical-trial requirements was unfairly limiting

the effective life of their patents, thereby reducing the incentives for innovation.[136] Industry arguments focused on the effect of the FDA's clinical trial requirements on the average drug, however, not on the penalty for drugs with long development times. In 1981, the House of Representatives considered a bill supported by the pharmaceutical industry that would have added back onto their patent terms the time they lost in clinical trials and FDA review, subject to a seven-year cap on the extensions.[137] Strangely, much of the debate in Congress (and among economists) about the bill was over the question of whether the average effective patent life of new drugs was declining in response to increasingly stringent FDA regulatory requirements,[138] which is essentially irrelevant to the question of how development time should affect patent length. The House voted down the bill, albeit by a close margin.[139]

Three years later, Congress passed a bill that gave pharmaceutical companies a much more limited set of patent-term extensions, and it combined those extensions with provisions designed to speed generic entry onto the market. The Drug Price Competition and Patent Term Restoration ("Hatch-Waxman") Act of 1984[140] allowed pharmaceutical companies to extend the term of their patent by the amount of time the FDA spent reviewing their new drug application

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[136] *See* Peter Barton Hutt, *The Importance of Patent Term Restoration to Pharmaceutical Innovation*, 1 HEALTH AFFAIRS 6 (1982).

[137] *See* Engelberg, *supra* note _, at 397-98 (recounting the pharmaceutical industry's failure to convince the 97th Congress (1980-1982) to provide them with patent term extensions to compensate for lost patent life during pre-market testing and regulatory review). Much of the debate about patent term extensions in Congress and the press was over whether the average effective patent life of new drugs was declining, *see* James J. Wheaton, *Generic Competition and Pharmaceutical Innovation: the Drug Price Competition and Patent Term Restoration Act of 1984*, 35 Catholic U.L. Rev. 433, 448-54 (1986), which is obviously irrelevant to the question of how development time should affect patent length.

[138] *See* James J. Wheaton, *Generic Competition and Pharmaceutical Innovation: the Drug Price Competition and Patent Term Restoration Act of 1984*, 35 Catholic U.L. Rev. 433, 448-54 (1986).

[139] *See* Engelberg, *supra* note , at 397-98.

[140] Drug Price Competition and Patent Term Restoration Act of 1984 ("Hatch-Waxman Act"), Pub. L. No. 98-417, 98 Stat. 1585 (1984).

(roughly 12-16 months on average) and one-half of the time the firm spent testing the drug in clinical trials.[141] The total amount of time added back to the patent life cannot exceed five years, however, and in no case can the extension give the drug an effective patent life of more than 14 years. These provisions were paired with new rules allowing generic manufacturers to test their products before the patent on the original drug expires, thereby streamlining the FDA approval process for generics. Congress reportedly intended the two provisions to cancel each other out and have no net effect on the effective patent life of new drugs.[142]

These patent-term extensions are sometimes lambasted by politicians and public interest groups as needless giveaways to drug companies,[143] but scholars are generally much more positive on the legislation.[144] F.M. Scherer, one of the leading economic scholars on pharmaceutical innovation and on the economics of patent length, describes the bill as "plausibl[y] … an ideal compromise in terms of stimulating pharmaceutical innovation."[145] John Duffy praises the "rough justice" of the compromise in "protect[ing] both patentees and the public from the distortions caused by regulatory delay."[146] And Arti Rai points to the extensions

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[141] *See* 35 U.S.C. § 156.

[142] *See* Engelberg, *supra* note _, at 392; *cf.* Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661, 679 (1990).

[143] *See, e.g.*, Albert Gore, Jr., *Patent Term Extension: An Expensive and Unnecessary Giveaway*, 1 HEALTH AFFAIRS 25 (1982).

[144] Even Michael Abramowicz praised the Act for "help[ing] limit the danger of patent underdevelopment," although he recognized that there is "no guarantee" that the patent term extensions "are long enough to prevent underdevelopment of [all] drugs." *See* Abramowicz, *supra* note _, at 1097.

[145] F.M. Scherer, *The Political Economy of Patent Policy Reform in the United States* 29-30 (Dynamics of Insts. & Mkts. in Eur., Intellectual Prop. Rights Working Paper No. 26, 2006), *available at* http://www.dime-eu.org/files/active/0/IPR-WORKING-PAPER-26_Scherer.pdf.; *cf.* Henry Grabowski & John Vernon, *Longer Patents for Increased Generic Competition: The Waxman-Hatch Act after One Decade*, 10 PHARMACOECONOMICS (Suppl 2) 110 (1996).

[146] Duffy, *supra* note _, at 507 & n.194 (describing the statute as "protect[ing] both patentees and the public from the distortions caused by regulatory delay").

as evidence that "[i]ntellectual property law has been quite sensitive to the research and development hurdles faced by drug manufacturers."[147]

In truth, these extensions only partially mitigate the problem caused by the 20-year term. Pharmaceutical companies can only recover a portion of their patent life lost during clinical development. The time needed to develop new drugs still runs down the clock on their patents, only to a lesser extent than it did before the term extensions were passed. Firms continue to be subject to a fairly continuous penalty for time spent in pre-clinical and clinical development. The problem is most severe for the drugs that take longest to develop because of the five-year cap on patent term extensions. Once that cap is exceeded, any further time spent in development is subtracted directly out of a drug's effective patent life.

D. The Costs of the Timing Problem in the Drug Patent Term: Excessive Deadweight Loss and Lost Drugs

Due to the unfortunately timing of the patent term, the patent system systematically over-rewards drugs with short development times while under-rewarding drugs with longer development times. The resulting harm to the public is likely significant. The drugs that breeze through the FDA or are exempted from clinical-trial requirements are very likely receiving too much patent protection, resulting in excessive deadweight loss. At the same time, the early running of the 20-year patent term likely causes firms not to invest in the many socially valuable drugs that require lengthy development periods. Firms regularly discard promising drug candidates during preclinical development that fail to progress into clinical trials fast enough; firms sometimes abandon drugs in response to unexpected setbacks in clinical trials that would

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[147] Arti K. Rai, *The Information Revolution Reaches Pharmaceuticals: Balancing Innovation Incentives, Cost, and Access in the Post-Genomics Era*, 2001 U. ILL. L. REV. 173, 182-83 (2001).

force them to redo some of their experiments; and they under-invest in drugs that take longer to evaluate in clinical trials, including drugs for cancer and diseases of the central nervous system.

The perverse timing of the 20-year patent term suggests that many drugs with short development times are receiving too much patent protection and thus causing unnecessary deadweight loss. The most likely candidates for drugs that are receiving an excessive reward are the ones that do not require extensive clinical testing by the FDA. After developing and launching a new drug, companies frequently to patent new formulations or dosing regiments of the drug.[148] These new formulations or dosing changes can have significant social value,[149] but they also typically face much less stringent clinical-trial requirements than those imposed upon the drug when it first entered the market, and thus take significantly less time to develop.[150] For example, when the FDA approved Merck's osteoporosis drug Fosamax® in 1995, it was after 13 years of development, giving the drug 12½ years of market exclusivity under its patent.[151] In 2000 the FDA approved a once-weekly dosage of Fosamax® after only 2 years of (much less expensive) development work, giving that patent an expected 18-year effective life.[152] Although it is impossible to state with certainty that an 18-year effective life is excessive for patents on dosing changes such as this, the relatively minor development costs and quick regulatory

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[148] *See* MARTIN A. VOET, THE GENERIC CHALLENGE: UNDERSTANDING PATENTS, FDA & PHARMACEUTICAL LIFE-CYCLE MANAGEMENT 36-38 (2005).

[149] *See* Pedro Cuatrecasas, *Drug Discovery in Jeopardy*, 116 J. CLINICAL INVESTIGATIONS 2837 (2006).

[150] *See* PETER BARTON HUTT ET AL., FOOD AND DRUG LAW: CASES AND MATERIALS 624-734 (3rd 2007).

[151] *See* Approval Letter, Application No. __, Center for Drug Evaluation and Research, at http://www.fda.gov.

[152] U.S. Pat. 5,994,329 (Nov. 30, 1999); FDA Approval, Alendronate: Once Weekly, *available at* http://www.fda.gov. The Federal Circuit invalidated Merck's patent on the once-weekly dosage of Fosamax® based on an earlier newsletter that recommended a once-weekly dosage of the drug. *Merck & Co. v. Teva Pharms. USA, Inc.*, 395 F.3d 1364 (Fed. Cir. 2005).

approval for most such drugs makes it unlikely that 18 years of protection is necessary to motivate their development.[153]

A more serious problem might be the drugs with long development times that never reach the public because their diminishing patent life undermines the incentive to develop them. This phenomenon occurs early in the drug-development process, when the drugs that linger for too long in preclinical research are screened out of development. After filing a patent on a drug, pharmaceutical companies use their scientists to evaluate and improve upon the therapeutic properties of the compound.[154] Any number of things can cause delays in this process, including scientific hurdles related to the drug's toxicity or bioavailability, an initial failure to recognize the drug's potential, or even just bad business decisions.[155] Even at this stage, companies pay close attention to the amount of patent life remaining on their drug candidates,[156] and they frequently drop ones when the time left on their patent is deemed insufficient to recoup the investments needed to develop them.[157]

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[153] It is possible, however, that the ability to get an 18-year effective patent life on the weekly dose of Fosamax constituted part of the incentive for developing the original version of Fosamax.

[154] *See* Camille G. Wermuth, *Medicinal Chemistry: Definition and Objectives, the Three Main Phases of Drug Activity, Drug and Disease Classifications*, *in* THE PRACTICE OF MEDICINAL CHEMISTRY, *supra* note __, at 34.

[155] See Camille Georges Wermuth, THE PRACTICE OF MEDICINAL CHEMISTRY (2d. 2003).

[156] *See* The Association of the British Pharmaceutical Industry, *Response to the Gowers Review of Intellectual Property Call for Evidence*, 2(e), at ___.

[157] *See* GRAHAM PATRICK, MEDICINAL CHEMIST 178 (2001) ("Since patenting is carried out before the drugs are rigorously tested, several years of the patent are lost while these tests are being carried out. Any unforeseen delay or difficulty during this time may see the project being dropped if it is felt that the remaining patent protection is too short to recover costs."); Maria Souleau, *Legal Aspects of Product Protection – What A Medicinal Chemist Should Know About Patent Protection*, *in* THE PRACTICE OF MEDICINAL CHEMISTRY 721 (Camille Georges Wermuth ed., 2d. 2003) ("In the pharmaceutical industry, many candidate products are not developed because of the short patent term that would remain after development."); GARETH THOMAS, FUNDAMENTALS OF MEDICINAL CHEMISTRY 237 (2003) ("[P]atents normally run for 20 years from the date of application. Consequently, … some compounds are never developed because the patent protected production time available to recoup the cost of development is too short.").

A much more visible problem caused by the drug-patent term arises at the very end of clinical development, when companies respond to delays in clinical trials by abandoning drugs rather than completing their development. Roughly one third of the drugs that enter Phase III clinical trials (the final stage of the FDA's clinical-trial requirements) fail to meet the FDA's safety and efficacy standards and do not reach the market.[158] Many of these drugs are thought to have failed for reasons related to the way they were tested rather than a lack of therapeutic value.[159] Failures in Phase III trials are often attributed to the sponsor having tested the drug at the wrong dose,[160] having a faulty trial design, or failing to identify the appropriate patient subgroups that would best respond to the treatment.[161] Other failures are sometimes due to under-powered clinical trials, where the drug shows efficacy but below the required 95% confidence interval.[162] When a viable drug fails Phase III testing for one of these reasons, the sponsor could complete its development by running a second Phase III trial. Since all of the previous R&D costs are sunk, the only question is whether the costs of another trial will exceed the expected profits from the drug. At this stage of development, however, the time needed to run another phase III trial – two or three years on average[163] – would come directly out of the

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[158] Joseph A. DiMasi & Henry G. Grabowski, *Economics of New Oncology Drug Development*, 25 J. CLINICAL ONCOLOGY 209, 213 (2007).

[159] Ernst R. Berndt et al., *Opportunities for Improving the Drug Development Process: Results from a Survey of Industry and the FDA* 21-22 (2006).

[160] *See id.*

[161] *See* Anup Malani, et al., *Accounting for Difference among Patients in the FDA Approval Process*.

[162] Such mistakes are likely an inevitable consequence by the pressure to run trials that successfully establish the safety and efficacy of a drug while minimizing the cost of clinical trials by keeping their size and duration to a minimum.

[163] *See* DiMasi et al., *supra* note 94.

effective patent life of the drug, eliminating some of its most profitable years on the market, and apparently deterring their development.[164]

The timing of the 20-year patent term also distorts pharmaceutical R&D away from drugs for conditions that require lengthy clinical trials to measure their therapeutic effects. When pharmaceutical companies decide whether to develop a drug, one of the most important factors is the expected length and size of the necessary clinical trials.[165] Some drugs can be tested quickly because the outcome are measurable shortly after patients take the drug, such as with pain relievers and antibiotics.[166] Other drugs require longer clinical trials because their health effects take months or even years to observe, such as anti-depressants and cancer drugs.[167] Many preventative medications fall into this category, like treatments to prevent or slow the progress of Alzheimers,[168] due to the time it takes to measure the necessary outcomes – which involves watching relatively healthy people to see if, or how long it takes them, to get sick. Drugs of this sort almost always require lengthy periods of clinical development, which drives up their R&D costs while simultaneously subtracting from the time they have on the market to recoup that investment. When companies calculate the expected returns from developing a drug, therefore, socially valuable drugs with longer development times can be dropped from the pipeline because the length of patent protection available is too short.[169]

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[164] GlaxoSmithKline, *Response to Gowers Review on IP*, Apr. 18, 2006, at 23-24.

[165] TAMAS BARTFAI & GRAHAM V. LEES, DRUG DISCOVERY: FROM BEDSIDE TO WALL STREET (2006)

[166] John A. DiMasi et al., *R&D Costs and Returns by Therapeutic Category*, 38 DRUG INFO. J. 211 (2004).

[167] *Id*.

[168] *See* Michel Dib, *Issues for Clinical Drug Development in Neurodegenerative Diseases*, 65 DRUGS 2463 (2005).

[169] BARTFAI & LEES, *supra* note 165.

Amidst these serious potential harms from the early running of the patent term, there is a possible benefit from the system in how it might force pharmaceutical companies to move through R&D faster. Unnecessary delays in the public's receipt of a drug can have significant negative social-welfare consequences.[170] To the extent that the early running of the patent term puts some fire under the feet of pharmaceutical companies, forcing them to run their R&D projects at a speed consistent with the socially desirable pace, it could produce great benefits for the public.[171]

In practice, however, there are reasons to doubt that these benefits ever arise. First, the FDA dictates a lot of the content of drug R&D through its clinical-trial requirements, which can mute the effect of incentives placed on innovating firms to accelerate their R&D. Indeed, to the extent that the cost and duration of a drug's R&D is determined by forces outside the control of the company developing it, the early running of the patent term will have no effect on that portion of its development. Second, pharmaceutical companies already have an inventive to rush through R&D because they are usually racing competitors with similar products to be the first to market.[172] Pressure to speed up R&D from the patent term therefore might be redundant of the incentives provided by competition. Third, to the extend that the early running of the patent term accelerates drug R&D, it might cause as much harm as good when pharmaceutical companies use shortcuts that risk the loss of valuable drugs. Efforts to shorten the time spent in clinical development usually involve tradeoffs in accuracy, such as smaller clinical-trial sizes, fewer experiments to find the proper dosing, and the use of questionable predictive markers to halt a

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[170] *See, e.g.*, FRANK R. LICHTENBERG, WHY HAS LONGEVITY INCREASED MORE IN SOME STATES THAN IN OTHERS? THE ROLE OF MEDICAL INNOVATION AND OTHER FACTORS (2007).

[171] *See supra* pg 33.

[172] *See* F.M. Scherer, *Pharmaceutical Innovation*, Working Paper 07-13, June 2007, at _.

drug's development.[173]   These practices all increase the risk that a socially valuable drug will fail to complete the FDA's clinical-trial requirements.   Any benefits from drugs moving faster through R&D therefore could be offset by the loss of some socially valuable drugs.

In the end, the most important consequences of the current patent term are unlikely to be its effect on the pace of drug R&D within firms, but rather its effects on the level of deadweight loss caused by patents and on the output of pharmaceutical innovation.   Given the inverse relationship between the effective patent life awarded to drugs and their probable need for protection based on the length and cost of their R&D, both effects are presumably quite significant.   Drugs that move quickly through R&D probably receive too much patent protection, causing excessive deadweight loss, while private industry leaves drugs on the laboratory shelf when their anticipated development timeline is too long.

E. The Effect of the 20-Year Patent Term on Cancer Drug Development

The distortion caused by the timing of the 20-year patent term is particularly pronounced in pharmacological oncology research. Cancer is one of the leading causes of mortality globally, and there has been only modest progress in fighting the disease over the past thirty years.[174] Although there are many reasons for the stalled "war on cancer," commentators have missed one of the more significant of them: the distortional effect of the patent term on pharmaceutical R&D.   Given the incentive under the patent system to invest in drugs with short development times, private industry looks for cancer treatments meant for the final stages of the disease, which allows them to conduct shorter clinical trials because they can observe more quickly the

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[173] *See* TAMAS & BARTFAI, *supra* note 109 at _; __

[174] *See* Alexander Kamb et al., *Why is Cancer Drug Discovery So Difficult?*, 6 NATURE REVIEWS DRUG DISCOVERY 115 (2007).

drug's effect on patient mortality. Given the advanced nature of their disease, however, the patients in late-stage cancer are incredibly difficult to treat effectively.[175] A more promising approach would likely be to find preventive treatments or drugs for early-stage cancer, when the disease may be more contained and perhaps less aggressive, and when the patients are in better health.[176] Private industry rarely invests in these types of drugs, however, because they would have to wait years to observe the effects of their drugs on mortality rates. For cancer-prevention drugs, the necessary duration of clinical trials – often ten or more years – has driven private investment almost completely out of the field.[177]

Cancer is one of the greatest public health issues now confronting the world. Here in America, roughly one third of people will die from cancer, and many more will suffer through painful cancer treatments.[178] With a few notable exceptions, the only reliable cure for cancer is the surgical removal of tumors, and this treatment usually works only when the cancer is caught early before it spreads. Some cancers can be effectively treated with chemotherapy, immunotherapy and/or radiation, but in many cases these treatments simply slow the progress of the disease. Cancer tends to kill people much earlier than the other leading killer in America, heart disease. And cancer is a much more expensive way to die, generally involving large

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[175] Ronald Lieberman et al., *Executive Summary of the National Cancer Institute Workshop: Highlights and Recommendations*, 57 UROLOGY (Suppl. 4A) 4 (2001).

[176] Ronald B. Herberman et al., *Cancer Chemoprevention and Cancer Preventive Vaccines—A Call to Action: Leaders of Diverse Stakeholder Groups Present Strategies for Overcoming Multiple Barriers to Meet an Urgent Need*, 66 CANCER RES. 11540 (2006).

[177] Herberman et al., *supra* note 176.

[178] AM. CANCER SOC'Y, CANCER FACTS & FIGURES 2007, at 4 (2007).

expenditures on medical treatments that sometimes offer patients only a few extra months of life.[179]

Technological progress in the treatment of cancer has remained stubbornly slow. As it has for many other diseases, private industry has produced a large number of new cancer drugs over the past two decades. In oncology, however, most of these new drugs are chemotherapy treatments for patients with relatively late-stage cancer, and most offer only modest increases in the life expectancy of patients. Compared to the progress seen in the treatment of heart disease, depression, and infectious diseases (especially HIV), pharmaceutical innovation for the treatment of cancer has been a disappointment.[180]

Commentators have explored a number of different reasons for the slow progress in cancer treatment, but have overlooked the role of the patent system in distorting R&D investments in cancer drugs. Establishing the safety and efficacy of a cancer drug in clinical trials is a lengthy process because the standard study end-point, patient mortality, cannot be observed immediately. Researchers must wait for many of the patients in their study to die before they can measure the therapeutic effects of the drug being tested. Since the patent system penalizes investment in drugs with longer development timelines, companies look for cancer drugs that can be tested in clinical trials quickly. Oftentimes the only affordable clinical trials are ones involving patients with late-stage terminal cancer; people expected to live for only another 18 months or so.[181] These patients are probably the hardest to treat, however, since their

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[179] *Id.*; *cf.* David M. Cutler & Mark McClellan, *Is Technological Change in Medicine Worth It?: When Costs and Benefits Are Weighed Together, Advantages Have Proved to Be Worth Far More than Their Costs*, 20 HEALTH AFF. 11, 23 (2001).

[180] Kamb et al., *supra* note 174.

[181] Telephone Interview with Declan Doogan, M.D., President of Research and Dev., Amarin Corp. (Jan. 25, 2007).

cancer is the most advanced and their health the poorest.[182] As a result, most pharmaceutical R&D in oncology is directed toward finding and testing drugs on patients who are the hardest to treat and are unlikely to benefit greatly from the therapy.

Although the public might gain from the development of drugs that prevent cancer or treat the disease in its early stages (when it would be easier to slow the progress of the disease or perhaps even cure it), the patent system discourages this research. Longer clinical-trial periods quickly undermine any possible profits a drug might produce once on the market. For cancer prevention drugs, this problem is so severe that private industry has almost entirely abandoned the field.[183] To demonstrate the safety and efficacy of a cancer prevention drug, a firm would usually have to conduct at least one (and possibly two) clinical trials lasting ten years with approximately ten thousand patients to detect a different cancer rate between the placebo and study group.[184] Drugs that require clinical trials of this size and length would necessitate a lengthy period of market exclusivity to recoup their development expenses. Under current law, however, the required clinical trials for such a drug would run out much of its patent life before it ever reached the market. This phenomenon of private industry failing to invest in drugs that might prevent cancer or treat it at an early stage is the direct result of a poorly designed patent system.

The progress seen in treating and preventing heart disease underscores how lengthy clinical trials can deter the development of important new drugs, and how solving this problem could lead to large social-welfare gains. Although coronary heart disease remains the leading

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[182] Wolfgang W. Huber & Wolfram Parzefall, *Thiols and the Chemoprevention of Cancer*, 7 CURRENT OPINION IN PHARMACOLOGY 404 (2007).

[183] See Herberman et al., *supra* note 176.

[184] James L. Mulshine, *Fostering Chemopreventive Agent Development: How to Proceed?*, 22 J. CELLULAR BIOCHEMISTRY (Suppl.) 254 (1995).

cause of death in America, since 1968 the age-adjusted rate of those deaths has dropped by 50%. The social value of these health gains has been measured at $2 to $3 trillion.[185] Much of these improvements are related to new medical treatments, including drugs that reduce the risk of death from heart disease by lowering blood pressure, reducing hypertension, and lowering bad cholesterol.[186] Unlike cancer drugs, the FDA never required that these drugs for heart disease be proven to reduce mortality in clinical trials. Their manufacturers were allowed on the market with clinical-trial data showing the drugs to be safe and effective in their primary physiological effects, lowering blood pressure, reducing hypertension, and lowering bad cholesterol, respectively – which required much shorter clinical trials.[187] An earlier study – a massive, multi-decade, federally-funded effort known as the Framingham Heart Study – had previously established a correlation between risk of heart disease death and those three conditions. This policy allowed private industry to develop and market drugs for reducing the risk of heart disease death without first demonstrating their actual effect on mortality rates in clinical trials, a regulatory hurdle that would have made it impossible for firms to recoup their investment.

The Framingham Heart Study points to one possible way of spurring the development by private industry of early-stage cancer and chemoprevention drugs: use government funds to run studies that identify and verify "surrogate markers" that can be used to shorten the duration of clinical testing. These studies are perhaps the best solution to this problem, since they generate data that reduces clinical trial costs for multiple drugs in addition to shortening the necessary

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[185] Kevin M. Murphy & Robert H. Topel, *The Value of Health and Longevity*, 114 J. POL. ECON. 871, 899 (2006).

[186] D. STEINBERG, THE CHOLESTEROL WARS (2007).

[187] *Id*.

duration of clinical development. Studies of this nature also help elucidate the biological mechanisms of the disease, and thus aid private industry in identifying new treatments.[188]

There are limits to the value of these studies, however, since their results are not always accurate and for some diseases it is very difficult to find reliable surrogate endpoints for clinical trials. Large-scale studies such as the Framingham Heart Study rely on observational data to identify biomarkers that are correlated with a particular disease outcome, such as high-blood pressure and mortality from heart disease. The correlations identified by these studies are not always representative of a causal relationship, however, it can be hard to tell the difference with an observational study.[189] Moreover, for some conditions the limits of current science make it difficult to identify reliable clinical-trial end points other than mortality or visible disease remission. Many of the most deadly cancers are examples of where scientists have encountered these difficulties.[190]

Given the disappointing progress in cancer research over the past twenty years, one can only speculate as to whether the a more sensible patent system, one that provides a longer effective patent life to drugs with longer development times instead of the other way around, would successfully spur the development of drugs for early-stage cancer or cancer prevention. The answer may depend on scientific opportunities and hurdles that are beyond the control of the patent system. Yet it is hard to justify a policy that effectively blocks pharmaceutical companies

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[188] *See, e.g.*, Steven Gutman and Larry G. Kessler, *The US Food and Drug Administration Perspective on Cancer Biomarker Development*, 6 NATURE REV. CANCER 565 (2006); Gary J. Kelloff & Caroline C. Sigman, *New Science-Based Endpoints to Accelerate Oncology Drug Development*, 41 EUR. J. CANCER 491 (2005).

[189] *See* Russell Katz, *Biomarkers and Surrogate Markers: An FDA Perspective*, 1 NEURORX 189 (2004).

[190] *See* James T. MacGregor, *Biomarkers of Cancer Risk and Therapeutic Benefit: New Technologies, New Opportunities, and Some Challenges*, 32 TOXICOLOGIC PATHOLOGY 99 (Suppl. 1 2004).

from investing in drugs to prevent or treat cancer in its earlier stages, when the opportunity for finding an effective therapeutic is perhaps greatest.

V.   VARIABLE PATENT LENGTHS FOR DRUGS

Under any finite uniform patent term, there will always be inventions for which the patent length offered is insufficient and the inventions are lost to the public. Other inventions will receive too much protection under the uniform patent term, creating excessive deadweight loss. The current patent laws exacerbate these problems by providing more protection to inventions with shorter development times and thus with lower total R&D costs on average, while providing less protection to inventions that take longer to develop and on average have higher total R&D costs. The resulting distortions are probably severe in the drug industry, where R&D can drag on for more than a decade and investments are sensitive to the patent term.

Under a genuinely uniform period of protection, the effective patent life of drugs would be unrelated to the duration of their R&D, correcting the current policy of penalizing firms for the time they spend developing their products. This system would almost certainly be superior to the existing patent term, and Congress could easily implement such a policy. One approach would be for the FDA to provide all drugs with a fixed period of market exclusivity starting from the time they enter the market. New drugs already receive a uniform period of FDA-enforced market exclusivity, but it is only five years long, too short to motivate the development of most drugs.[191] Lengthening that period of exclusivity is perhaps the simplest way of creating a genuinely uniform patent term for drugs. The other route to a uniform patent length is through patent term extensions. Congress could amend the existing extensions for drugs so that firms

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[191] *See* Roin, *supra* note , at 565-567.

recover the full amount of time spend in clinical testing and create new patent term extensions for time spent in preclinical development after the patent filing.

A more aggressive approach to the problem is to create a variable patent term (or variable FDA-exclusivity period) that increases the effective patent life of a drug as the time and costs of its development increase. A uniform patent term is always a second-best option in a world where different inventions require different lengths of market exclusivity to motivate their development. If the drugs that take longer and cost more to develop usually require additional protection, then the system could assign different patent lengths in response to that information. A variable patent term of this sort could reduce deadweight loss and increase innovation compared to an optimal uniform patent term.

Variable patent lengths have their own problems, however, and a poorly designed system could easily backfire on the public. First, the government must be able to observe at least some information about inventions relevant to their ideal patent length without excessive administrative costs. When the administrative burden of gathering that information exceeds the potential benefit of reducing deadweight loss and promoting innovation through more accurate patent lengths, a variable patent term is impractical. Second, because the government's information about each invention will always be incomplete, there is an inevitable risk that a variable patent term will produce worse patent lengths than a uniform term. Moreover, a variable patent term can distort industry behavior by causing firms to try to game the system. Variable patent lengths must be designed in ways that minimize these risks. It is unclear whether the government could create a variable drug patent term that satisfies these criteria.

There are other possible approaches to reducing deadweight loss and spurring innovation in the pharmaceutical industry, including prizes and government subsidies for drug R&D. If the

government were to replace drug patents with cash rewards matching the social value of drugs, it would solve the problems caused by the current patent term. Calculating the social value of a drug is difficult, however, and most of the proposals for drug prizes base the reward either on the value of a drug's patent or on its sales volume over some specified period of time – usually the length of the patent.[192] These systems would reproduce the problems of the current patent term unless a genuinely uniform or appropriate variable patent term is instituted along with the prizes. Another possible solution is for the government to subsidize the development of drugs with long R&D timelines. Government subsidies could be very helpful in spurring the R&D of these drugs, and they would avoid the need to give out longer patent terms. Under a variable patent term, however, any subsidies that reduce the costs of developing new drugs would also shorten the patent lengths assigned to them. Where the government is unable or unwilling to assist in the development of new drugs, the variable patent term will generate private incentives for the investment. If a variable patent term is feasible, it is a complement to a program of government subsidies, not an alternative. This section focuses on whether a variable patent term could reduce deadweight loss and promote innovation in the pharmaceutical industry given the limitations on government information about drugs.

A. A Framework for Evaluating Variable Patent Lengths

In a perfect patent system, the length of protection awarded to inventions would be the minimum amount needed to motivate their creation and development. A variable patent term matching an invention's need for protection would avoid unnecessary deadweight loss and offer

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[192] *See* Michael Kremer, *Patent Buyouts: A Mechanism for Encouraging Innovation*, 113 Q.J. ECON. 1137 (1998); Shavell & van Ypersele, *supra* note _; *See* James Love & Tim Hubbard, *The Big Idea: Prizes to Stimulate R&D for New Medicines*, 82 CHICAGO KENT L. REV. 1519 (2007).

adequate incentives for the development of most socially valuable innovations. Unfortunately, the government lacks the information needed to calculate the ideal patent term for most inventions, and trying to acquire that information would be too costly. A less-ambitious approach would be to sort inventions into different categories based on easily observable characteristics that are correlated with their appropriate patent length. This sorting process would inevitably be flawed without perfect information, but at least it would calibrate the patent term in a way that moves in the right direction, likely reducing deadweight loss and spurring more innovation compared to an optimal uniform patent term. If the variable patent term is poorly designed, however, it could also produce worse outcomes. Industry-specific variable patent terms might make it easier to identify the proper baseline of protection for calibrating patent lengths, increasing the chances that a variable patent term would outperform a uniform term. An industry-specific approach could lead to more rent-seeking, however, which might distort the variable patent term away from the optimum. An additional concern is that under a variable patent term, firms game the system through socially wasteful activity that lengthens their patents. There are several ways for the government to reduce opportunities for abusive strategies, but it might not be able to prevent them entirely.

In a world where different inventions require different patent lengths, a variable patent term could produce significant social welfare gains. With perfect information, the government could determine the exact duration of patent protection necessary for an invention to generate profits covering the costs and uncertainty of its R&D. It could then shorten the patent term on some inventions without jeopardizing the incentive for their development, thus reducing

deadweight loss. It could also give longer patent terms to inventions that need additional protection, thereby increasing the output of socially valuable innovation.[193]

Acquiring the information needed to implement such a system poses a serious challenge. The government would need to know the *total* costs of the R&D projects that produce each invention. Since the ideal patent length is just long enough for a firm to recoup its R&D investment in an invention, the government needs to know the amount spent on the R&D project adjusted to present value, which would require knowing the firm's out-of-pocket R&D expenses, the duration of the R&D project and the firm's cost of capital. The government could ask firms to provide it with this information,[194] but with the length of their patents at stake, firms would have an incentive to inflate their reported R&D costs. The government could run audits to deter these abuses, but those audits would be costly and potentially ineffective.[195] Even if the government knows the R&D costs for an invention, it still needs to estimate the risk of failure in the R&D project that created it – undoubtedly a difficult task. Indeed, one of the justifications for promoting innovation with a patent (or prize) system instead of direct government funding of

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[193] Not all socially valuable inventions can receive a sufficient reward through the patent system because monopoly profits from the sale of an invention are a fraction of the social surplus it creates. *See* Shavell & van Ypersele, *supra* note _, at 532-34. Not even an infinite patent term can correct this shortcoming.

[194] By insisting that firms maintain documentary support of their R&D expenses to permit an audit, the government would be increasing the recordkeeping costs associated with R&D, particularly since firms would now need to keep track of their R&D expenses as they relate to each of the inventions they produce. Anecdotal evidence suggests that there are non-trivial accounting, documentation and legal costs associated with claiming R&D tax credits associated with particular R&D projects. *See* Tom Windram, *How To Realize the Benefits of the R&D Tax Credit*, MANUFACTURING.NET, July 15, 2008, at http://www.manufacturing.net/Articles-How-To-Realize-The-Benefits-Of-The-R-D-Tax-Credit.aspx?menuid=242.

[195] *See* Joel Slemrod & Shlomo Yitzhaki, *Tax Avoidance, Evasion, and Administration*, in 3 HANDBOOK OF PUBLIC ECONOMICS 1423 (2002).

R&D is that private industry is better positioned to evaluate an R&D project's likelihood of success.[196]

An even greater challenge in calculating the appropriate patent length for an invention is predicting the net profits – or the firm's expectation of net profits – from sales of the invention. Assessing the ideal patent length for an invention requires knowing the duration of protection needed for the developer to profit from its R&D investment, which involves estimates of future sales volume for the invention, net profits from each sale, and the firm's cost of capital (for use in discounting future profits to net present value). To predict these figures, the government would need to forecast things such as the demand for the invention, the firm's production costs and capacity, marketing expenses, and its ability to set prices above its marginal cost of production with and without patent protection.[197] Most of these predictions would require significant guesswork, particularly regarding the demand for the invention.[198] The ability to forecast what the public wants is a crucial component of the innovation process, and frequently

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[196] *See* Menell & Scotchmer, *supra* note 4 (the "intellectual property mechanism encourages inventors to weed out their bad ideas."). Nonetheless, the PTO and courts regularly speculate about the technological risks of inventions when they apply the nonobviousness test. *See* Merges, *supra* note 16. The result is perhaps the most vexing area of patent law, with scholars and courts both debating whether courts and PTO are capable of accurately characterizing the ingenuity – *i.e.*, risk and uncertainty – involved in creating an invention. *See* KSR Int'l Co. v. Teleflex Inc., 550 U.S. __ (2007) (discussing the problem of hindsight bias in applying the nonobviousness requirement); John H. Barton, *Non-Obviousness* 43 IDEA 475 (2003); Lee Petherbridge & R. Polk Wagner, *The Federal Circuit and Patentability: An Empirical Assessment of the Law of Obviousness*, 85 TEX. L. REV. 2051 (2007); Stuart Minor Benjamin & Arti K. Rai, *Who's Afraid of the APA? What the Patent System Can Learn from Administrative Law*, 95 GEO. L.J. 269, 278 (2007); Christopher A. Cotropia, *Nonobviousness and the Federal Circuit: An Empirical Analysis of Recent Case Law*, 82 NOTRE DAME L. REV. 911 (2007); Eisenberg, *supra* note __; Samson Vermont, *A New Way to Determine Obviousness: Applying the Pioneer Doctrine to 35 U.S.C. § 103(A)*, 29 AIPLA Q.J. 375 (2001).

[197] *See* John F. Duffy, *A Minimum Optimal Patent Term* 13, *available at* http://ssrn.com/abstract=354282; Kaplow, *supra* note _, at 1823-24, 1842-43; *cf.* William D. Nordhaus, *The Optimal Life of a Patent: Reply*, 62 AM. ECON. REV. 428, 430 (1972) ("[A] fixed patent life is not optimal in theory, although it may be unavoidable in practice").

[198] *See, e.g.*, *infra* text accompanying notes _-_.

involves more uncertainty than the technological challenges of R&D.[199] There is little reason to believe that the government would perform well at this task.[200]

Given the difficulty and administrative costs of determining the optimal patent length of inventions on a case-by-case basis, a better approach to a variable patent term might be to sort inventions based on easily observable characteristics that correlate with their ideal patent length.[201] Although this approach sacrifices some of the variable patent term's accuracy, perfect accuracy is not necessarily the goal, since a variable patent term can outperform a uniform patent length even with an imperfect sorting process. So long as the government can observe some of the variables that define an invention's ideal patent length, it can try to adjust the awarded patent term away from some baseline of protection and closer to the optimum. The existing system, which treats all inventions as equals, could be thought of as a variable patent term that presumes all inventions have the same total R&D costs, faced the same risks in R&D, and will earn the same annual profits. By filling in one or more of these variables with known figures, the government could award patent lengths that at least move in the right direction, unlike a uniform patent term that stays flat regardless of R&D costs, risks and future profits.

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[199] *See* OFFICE OF TECH. ASSESSMENT, INNOVATION AND COMMERCIALIZATION OF EMERGING TECHNOLOGIES 35 (1995).

[200] Perhaps the government could devise a market mechanism, such as an auction, to predict the time needed to recoup R&D expenses, although these systems have their own problems. *Cf.* Michael Abramowicz, *The Danger of Underdeveloped Patent Prospects*, 92 Cornell L. Rev. 1065, 1106-17 (2007) (proposing an auction mechanism for patent term extensions). A more practical alternative would be for the government to monitor the firm's profits instead of trying to predict them ex ante. *See infra* note __.

[201] Several scholars have said that such a system would likely be superior to a uniform patent length. *See* F.M. Scherer, *Nordhaus' Theory of Optimal Patent Life: A Geometric Reinterpretation*, 62 AM. ECON. REV. 422, 426-27 (1972) (suggesting "a flexible system … under which the patent recipient bears the burden of showing why his patent should not expire … three or five years after its issue" by showing "that his invention fell into one or more of the categories in which longer protection is needed."); SHAVELL, *supra* note 4, at 154 & n.38 ("Were the duration of patents decided with regard to the incentive benefits of patents and their social costs, patent length would depend on the class of innovations."). *See also* Eric E. Johnson, *Calibrating Patent Lifetimes*, 22 SANTA CLARA COMPUTER AND HIGH TECH. L.J. 269 (2006); Frank Partnoy, *Finance and Patent Length* (2001) 12-17, U. San Diego Law & Econ. Research Paper No. 19, *available at* http//ssrn.com/abstract=285144.

A variable patent term that relies on incomplete information could significantly improve upon the accuracy of a uniform patent term, but it could also worsen outcomes if it is poorly designed. Suppose the government were to impose a patent term of variable length that depends on the annual profits an invention is expected generate in the future, and that the government can accurately estimate those figures. All else equal, an invention that produces higher annual profits needs a shorter term of protection for the inventor to recoup its R&D investment. In some industries, however, higher annual profits might also correlate with higher R&D costs or greater uncertainty in the R&D project, which would complicate the relationship between the profits an invention generates and its ideal patent length. Assuming that this problem does not arise, the government still does not know the ideal patent length for any given invention. It can only estimate their need for protection relative to one another. As a result, the government would have to pick a baseline length of protection tied to inventions that generate a particular level of profits, and then decide how to scale from that baseline as profits rise or fall. Without perfect information, the government could not identify with certainty the correct baseline or know how to scale from it. Political decisions would be required, and there is plenty of room for error. The wrong baseline could grossly over- or under-reward most inventions compared to many uniform patent term. A variable patent term that moves in the right direction seems more likely to achieve a better result than a uniform patent length, but only on average.

Industry-specific variable patent terms might make it easier for the government to estimate the optimal baseline figures used to calibrate patent lengths. The optimal patent length for any given class of inventions depends on factors such as the marginal returns from additional R&D investments in inventive output, the uncertainty of R&D in the field, the elasticity of

demand for inventions, and the effect of changes in patent length on returns from R&D.[202] The availability of reliable estimates for these variables will generally improve when the relevant class of inventions is a specific industry or technology type.[203] Calculating the optimal patent term for a relatively narrow class of inventions should therefore reduce the amount of guesswork needed. The information available will never be perfect, however, and policymakers will still need to use rough estimates for some variables.

Permitting industry-specific patent lengths might increase the opportunities for industry rent-seeking, perhaps counteracting any benefit from the better estimates of the optimal patent length.[204] Scholars sometimes argue that a system of unitary patent laws makes it harder for powerful industry groups to change the patent laws in their favor, since most such changes would likely affect and be opposed by other industry groups.[205] Inviting industry-specific patent lengths would remove this check on rent-seeking, perhaps resulting in patent lengths that serve the interests of private industry at the expense of the public. On the other hand, it is unclear whether the patent lengths sought by industry would diverge from the social optimum. Outside of the pharmaceutical industry, most firms affected by the patent system are both patent holders and potential defendants in patent infringement suits.[206] Patents are thus a double-edged sword for most firms, and it is not obvious that they would lobby for increased patent lengths.[207] Some

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[202] *See* Nordhaus, *supra* note _; Scherer *supra* note _.

[203] *See* Machlup, supra note 5, at 73; NORDHAUS, *supra* note _, at 81-82.

[204] *See* JAFFE & LERNER, *supra* note 18, at 203-05.

[205] *See* Burk & Lemley, *supra* note 6, at 1637; Neil Munro & Andrew Noyes, *Lobbying and Law: Patent Reform, Pending*, NAT'L J., May 5, 2007.

[206] *Cf.* FED. TRADE COMM'N, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY (2003), *available at* http://www.ftc.gov/os/2003/10/innovationrpt.pdf.

[207] *Cf.* Matt Richtel, *Chairman of Amazon Urges Reduction of Patent Terms*, NEW YORK TIMES, Mar. 11, 2000, C4 (reporting that Jeff Bezos, the founder and CEO of Amazon.com, publicly advocates reducing the patent term for

industries might even lobby for no patent protection at all.[208]   The threat of industry rent-seeking

over patent length is a serious concern, but it is hard to evaluate it without a better sense of how

private industry's interests differ from those of the public on the question of patent length.

The most serious problem with variable patent terms based on incomplete information is

the opportunity it creates for firms to game the system. When the government can only observe

some of an invention's characteristics relevant to its ideal patent length, firms might respond by

manipulating those observable characteristics to lengthen their patent term. If the government

gave shorter patent terms to inventions that generate higher annual profits, then firms might not

invest in socially valuable commercialization activities that would increase sales of their

invention, since any increase in sales volume would subtract from their patent life. Similarly, if

inventions with higher R&D costs receive longer patent terms, firms might find it profitable to

waste money on unnecessary R&D if the resulting patent term extension produces more revenue.

The government could try to avoid these abuses in several ways. One solution is to base

the variable patent term on an invention's predicted R&D costs or annual profits instead of the

observed costs or profits, which would eliminate any incentive to manipulate actual R&D

spending or marketing efforts. In some cases, however, the government is better situated to

observe actual R&D costs or profits than it is to predict them. Under these circumstances, the

government might impose a penalty on firms that are caught abusing the system, although this

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software and business-method patents). The pharmaceutical industry would undoubtedly lobby for longer patent terms, as they now do for longer data exclusivity periods through the Hatch-Waxman Act. *See infra* notes __-__. On the other hand, the generics industry, insurance companies and various other interest groups (such as the AARP) will push for shorter terms of protection for drugs. *See, e.g.*, Alfred B. Engelberg, *Special Patent Provisions for Pharmaceuticals: Have They Outlived Their Usefulness?: A Political, Legislative and Legal History of U.S. Law and Observations for the Future*, 39 IDEA 389, 406 (1999).

[208] Physicians successfully lobbied Congress to prevent the enforcement of surgical method patents. 35 U.S.C. § 287(c). Many tax attorneys seem similarly inclined with regard to patents on tax strategies. *See, e.g.*, Bernard Wolfman, *Patenting Tax Strategies*, 86 TAXES 39 (2008).

policy is only practical if the government can detect wasteful R&D spending or lackluster commercialization efforts. Another approach is to offer relatively modest variations in patent length under the variable term, which would reduce any benefits from wasted R&D spending or reduced investment in commercialization, making it less likely that firms would have an incentive to abuse the system.

In sum, the design of a variable patent term must overcome two critical problems. First, the government must be able to acquire accurate information about individual inventions for purposes of tailoring their patent length without excessive administrative costs. Second, the government must calibrate the variable patent term under conditions of imperfect information. When the government has access to reliable information about an invention's R&D costs, the risk of failure in that R&D project, or the future profits from the invention, a variable patent term can produce less deadweight loss and spur more innovation than an optimal uniform patent term, but only if it is designed correctly.

B. Measuring the Inputs for a System of Variable Drug Patent Lengths

The first question in evaluating the social-welfare consequences of a variable patent term is whether the government can easily observe any characteristics of inventions that are strongly correlated with their ideal patent length. An invention's R&D costs are directly related to the minimum patent length needed to motivate its development. In light of the FDA's regulatory oversight of the pharmaceutical industry, the government has a rare window into the R&D projects that each new drug. Although the government would still have trouble estimating the risk of failure in those R&D project and the profits from future drug sales, it might be able to use

the FDA to reliably estimate the duration and costs of a drug's R&D. The availability of this information could form the backbone of a system of variable drug-patent lengths.

Since the FDA oversees the clinical testing process for drugs, it knows the exact amount of time drugs spend in clinical trials, and probably also the time they spend in late-stage pre-clinical development. Before a pharmaceutical company can start testing one of its new products in humans, the FDA must approve an Investigational New Drug Application for it.[209] This submission marks the beginning of the clinical-trial phase in a drug's development. The application also contains data from the drug's pre-clinical toxicology tests,[210] which might allow the FDA to estimate the duration of late-stage preclinical development as well. Finally, because drug companies cannot sell their drug without filing for FDA approval a New Drug Application that contains, among other things, the raw data from their clinical trials,[211] the FDA knows when clinical testing ends. With the exception of the time spent in early pre-clinical development, therefore, the FDA appears capable of accurately assessing a drug's development time.

Although the government currently does not have access to information about the out-of-pocket clinical-trial costs associated with individual drugs, the FDA might be well-positioned to gather that information if asked. Pharmaceutical companies usually meet with the FDA before and during the clinical-trial phase of drug development to work out the type of testing and data that will be required for regulatory approval.[212] Since the FDA both imposes the testing requirements on drug companies and reviews the data produced through those trials, it is in a

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[209] 21 C.F.R. Part 312.

[210] *Id*.; Peter Barton Hutt, *The Regulation of Drug Products by the United States Food and Drug Administration*, in THE TEXTBOOK OF PHARMACEUTICAL MEDICINE 582 (John P. Griffin & John O'Grady, eds., 5th ed. 2006).

[211] *See* Richard N Spivey et al., *The US FDA in the Drug Development, Evaluation and Approval Process*, in THE TEXTBOOK OF PHARMACEUTICAL MEDICINE 609 (John P. Griffin & John O'Grady, eds., 5th ed. 2006).

[212] *See* Spivey et al., *supra* note _, at 604, 606-607

good position to request (and even audit) cost data from the clinical trials – and perhaps the late-stage preclinical expenses as well.

Evaluating the risk and uncertainty of pharmaceutical R&D is more problematic. Predicting whether a drug will satisfy the FDA's safety and efficacy standards is as much art as it is science.[213] If there were an easy way to evaluate a drug's chances of success, private industry would be using it.

It might be feasible to design a variable patent term based on the profits a drug will generate on the market. The distribution of sales revenue in the pharmaceutical industry is generally quite skewed. The lion's share of industry profits come from the highest selling ("blockbuster") drugs, while perhaps as many as half of all drugs fail to generate enough profits to cover their development costs.[214] For example, the cholesterol-lowering drug Lipitor® had $8.1 billion in U.S. sales in 2007,[215] but sales of the heart-failure drug BiDil® were only $15.3 million,[216] and the first inhaled insulin product Exubera® had only $4 million in sales, so low that Pfizer pulled it from the market.[217] An ideal patent system would theoretically provide a shorter period of protection for those highly profitable drugs while lengthening it for most of the other drugs, where profits come in much slower.

Predicting the price and market demand for a drug is very difficult, however, which makes predicted profits a highly imperfect sorting mechanism for a variable patent term. Even

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[213] See BARTFAI & LEES, *supra* note , at .

[214] *See* Grabowski & Vernon, *supra* note 107, at 28 (2000).

[215] IMS National Sales Perspectives, *Top 15 U.S. Pharmaceutical Products by Sales*, at http://www.imshealth.com.

[216] *See* NitroMed, Inc., Form 10-K (2007) 37-38, *a*t http://library.corporate-ir.net/library/13/130/130535/items/292395/1666858_49501T03_CNB.pdf.; B Séguin et al., *Bidil: Recontextualizing the Race Debate*, THE PHARMACOGENOMICS JOURNAL (2008), 1-5.

[217] *See Pfizer: Last Gasp for Exubera*, PHARMACEUTICAL BUSINESS REVIEW, Oct. 27, 2007.

within private industry, sales forecasts for new drugs are notoriously unreliable.[218] Warner-Lambert never expected Lipitor® to be a big seller, and it almost dropped the drug during development due to low sales predictions.[219] On the other hand, analysts forecasted that BiDil® would generate $500 million to $1 billion in annual sales,[220] and that Exubera® would be a $2 billion per year drug.[221] Estimating the correct price for a drug is just as difficult as predicting market demand,[222] and unless the government itself sets the price of drugs (like in Europe and Japan[223]), those estimates are likely to be just as unreliable. The government could vary drug-patent lengths based on observed sales revenue, which would eliminate the need to predict future demand for the drug. On the other hand, this policy might distort incentives for investing in commercialization efforts, since any investments that result in increased sales volume would also reduce the patent term. Deterring some marketing activities might be beneficial,[224] but this policy might also deter firms from developing new indications for their drugs, which can create significant social value.[225]

    With accurate information about the duration of drug R&D and the potential to acquire information about the costs, a variable patent length for drugs could be built around that

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[218] *See* Patrick Kager & David Williams, *How Do You Solve a Problem Like Manufacturing?*, PHARMACEUTICAL EXECUTIVE, Sept. 1, 2008.

[219] *See* Kager & Williams, *supra* note 218.

[220] *See* Stephanie Saul, *F.D.A. Approves a Heart Drug for African-Americans*, NEW YORK TIMES, Jun. 24, 2005.

[221] *See* Avery Johnson, *Insulin Flop Costs Pfizer $2.8 Billion*, WALL STREET JOURNAL, Oct. 19, 207

[222] *See* Nigel Gregson et al., *Pricing Medicines: Theory and Practice, Challenges and Opportunities*, 4 NATURE REVIEWS DRUG DISCOVERIES 121 (2005).

[223] *See* Garattini et al., *supra* note _. (fix)

[224] *See* JERRY AVORN, POWERFUL MEDICINES: THE BENEFITS, RISKS, AND COSTS OF PRESCRIPTION DRUGS _ (2005).

[225] *See* Eisenberg, *supra* note 84.

information. The patent system could tailor the patent length of drugs according to other factors as well, such as market size or technological risk. These are both promising avenues for further study, but given certain limitations in the government's ability to reliably estimate these factors, this paper restricts its discussion to tailoring drug patent length according to development time and cost.

C. Calibrating a System of Variable Patent Lengths for Drugs

The second inquiry in evaluating the feasibility of a variable patent term is, given the government's limited information about individual inventions, can it still design the variable term to generate less deadweight loss and more innovation than a uniform patent term, and can it prevent private industry from manipulating such a system. The case for imposing a variable patent term would seem to be at its strongest for pharmaceuticals. A more accurate patent term could generate large gains in social welfare by making drugs more affordable and by spurring additional innovation. Moreover, the information needed to tailor patent lengths according to a drug's R&D costs and duration is available to the government at relatively little cost. Calibrating a variable patent term appropriately is tricky, but under the right circumstances it is a manageable task. Opportunities for private industry to game the system are slightly more troubling. If the government cannot adequately police such behavior, the case for a variable patent term becomes weaker.

Instead of a uniform patent term for drugs that runs from the date of FDA approval, Congress could adopt a system where the length of patent protection (or FDA-enforced exclusivity period) is positively correlated with the cost and duration of a drug's R&D. Drugs that take longer and cost more to develop would receive patents of greater duration than drugs

developed quickly and at lesser expense – the exact opposite of the current patent regime. So long as the changes in duration or cost of drug R&D do not correspond to significant countervailing shifts in any of the unobserved variables, such as the risks of R&D or expected profits from the drug, a partial correction based only on the cost and duration of R&D might significantly improve the accuracy of drug-patent lengths.

Assuming that the government is able to observe the cost and duration of drug R&D at modest expense, a variable patent term based on those figures could therefore produce significant social benefit for the public. A critical policy issue for any variable patent term is whether the costs of acquiring information to more accurately calibrate patent terms is worth the resulting benefit of reducing deadweight loss and spurring more innovation. In the market for pharmaceuticals, it is widely thought that drug patents cause non-trivial amounts of deadweight loss by pricing some lower and middle-income consumers out of the market.[226] The record of pharmaceutical innovation and accounts of industry practices also suggest that the pharmaceutical industry leaves many drugs undeveloped and ignores potentially promising lines of research – particularly in preventative medicine – because the current patent term is too short.[227] Given the stakes involved, even a minor improvement in the system for assigning drug-patent lengths could have tremendous social benefits,[228] likely outweighing any administrative costs of observing the duration and cost of a drug's development.

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[226] *See supra* note _.

[227] *See supra* text accompanying notes _-_.

[228] *See, e.g.*, David M. Cutler & Mark McClellan, *Is Technological Change in Medicine Worth It?: When Costs and Benefits Are Weighed Together, Advantages Have Proved to Be Worth Far More than Their Costs*, 20 HEALTH AFF. 11, 23 (2001); Frank R. Lichtenberg, *The Benefits to Society of New Drugs: A Survey of the Econometric Evidence*, *in* ENGAGING THE NEW WORLD: RESPONSES TO THE KNOWLEDGE ECONOMY 204, 205–19 (Bhajan S. Grewal & Margarita Kumnick eds., 2006); Kevin M. Murphy & Robert H. Topel, *The Value of Health and Longevity*, 114 J. POL. ECON. 871, 899 (2006); Hughes et al., *supra* note 31, at 10–14; Tomas J. Philipson & Anupam B. Jena, *Surplus Appropriation from R&D and Health Care Technology Assessment Procedures* 3 (Nat'l Bureau of Econ. Research,

Of course, there is no guarantee that a variable patent term based on the time and costs of R&D would result in more accurate drug patent lengths. Comparing the R&D costs of two drugs predicts which of them is more likely to need a longer term of protection, but it does not reveal the appropriate patent lengths for the two drugs. This calculation requires a judgment call, and the wrong choice could result in a worse outcome than many uniform patent terms. A worst-case scenario would be a variable patent term based on R&D costs that systematically under-rewards drugs at every level of R&D investment, drastically reducing the output of new drugs. Using R&D costs to scale the patent term has the potential to substantially outperform an optimal uniform patent term, but there is also the risk of doing much worse.

If the government took a more conservative approach to calibrating the variable patent term, it might help minimize this risk. The prevalence of prescription-drug insurance greatly reduces the deadweight loss caused by drug patents, and if the government were to expand access those insurance plans,[229] it could error on the side of promoting innovation when it calibrates the patent term.[230] Due to the structure of the existing patent term extensions, the vast majority of drugs receive somewhere between 10 and 14 years of effective patent life.[231] If the government knows the typical R&D costs of the drugs that now receive 14 years of protection, it could use those figures for its baseline, scaling (perhaps conservatively) from a 14-year patent term for drugs with higher or lower R&D costs. This approach would increase the average

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Working Paper No. W12016, 2006), *available at* http://ssrn.com/abstract=881250; Frank A. Sloan & Chee-Ruey Hsieh, Effects of Incentives on Pharmaceutical Innovation 5–9 (July 27, 2006) (unpublished manuscript), *available at* http://www.oberlin.edu/economic/Papers/HealthConf/Sloan.pdf (all indicating that the social benefits of medical–technological innovation far outweighs its social costs).

[229] *See* Lakdawalla & Sood, *supra* note 113.

[230] There remains a risk of patent racing, however, perhaps warranting greater caution in setting long patent terms.

[231] *See supra* text accompanying notes _-_.

effective patent life of most drugs, but if deadweight loss from patent pricing has been minimized by insurance coverage, the gain in innovation would likely outweigh this harm.[232]

The benefits of this system would be threatened, however, if pharmaceutical companies find ways of gaming the variable patent term that increase administrative costs, distort R&D their spending, and reduce the accuracy of patent lengths. In response to a variable patent term based on R&D costs, firms might spend excessively on R&D measures that increase the probability of a drug's success in clinical trials. One problem with lengthening (or shortening) patent durations based on increases (or decreases) in the time and expense of R&D is that those same investments might be decreasing (or increasing) the risk of failure in R&D. Adjusting for one without the other could cause firms to spend additional time and money on R&D efforts that increase a drug's chances of being approved by the FDA – perhaps more than is socially desirable. Under a uniform patent term, however, firms might invest too little in R&D efforts that make their drugs more likely to be approved, since the cost to society of losing a drug is greater than the loss of monopoly profits.[233] As a result, it is unclear whether the variable or uniform patent term would be superior along this dimension.

Another possible problem with variable patent lengths based on R&D costs is that firms might over-invest in R&D that expands the market size of their drugs. A larger market size is correlated with higher profits and a shorter ideal patent length, but if the government looks only at R&D costs when calculating a drug's patent term, R&D investments that increase a drug's sales volume (such as running additional clinical trials to establish multiple uses for a drug) will

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[232] The longer patent terms might produce deadweight loss indirectly if government subsidies are needed for maintaining widespread access to prescription-drug insurance, since those subsidies would require additional taxation. *But see* KAPLOW, *supra* note _ (arguing that there does not need to be any distortionary cost from raising taxes to finance the government provision of public goods – such as pharmaceutical innovation – if the income tax is optimally adjusted).

[233] *See supra* note 80.

boost the firm's profits *and* extend its patent term. Pharmaceutical companies would have an incentive to initially develop their new drugs for multiple indications, whereas the current industry norm is to establish additional uses for the drug only after receiving FDA approval. This effect might be socially wasteful, but given the patent system's tendency to under-reward investments in discovering new uses for existing drugs,[234] it also could be beneficial.

The most serious concern is that firms would simply waste money in R&D for purposes of extending their patent term. Offering only modest variations in the patent term would discourage some of this behavior, but it might also subtract from the benefits of using a variable patent term to spur innovation and reduce deadweight loss. The government could police against these abuses by allowing the FDA to review R&D expenses to exclude wasteful spending, since the FDA knows what clinical trials were required for a drug to be approved, and perhaps has a rough sense of how much those clinical trials should cost. But this system would be far from perfect. An alternative approach is for the government to base the variable patent term on the expected cost and duration of a drug's R&D rather than its observed costs and duration, which would eliminate the incentive to waste money on unnecessary R&D.[235] Selecting the proper patent length ex ante would require a more complicated decision-making process from the government, however, and will prevent the patent system from accounting for unexpected but legitimate R&D expenses when assigning patent lengths. Both approaches add to the administrative costs of the variable patent term.

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[234] *See* Eisenberg, *supra* note __.

[235] Moreover, if there is fear that the variable patent term will cause firms to take too long in R&D, the ex ante term could be set to run from the beginning of clinical trials.

Given the difficulty of calibrating a variable patent term and the costs of preventing drug companies from gaming the system, the case for tailoring drug patent lengths based on the duration and costs of R&D falls short of compelling.

VI. CONCLUSION

The existing patent term is severely flawed. It penalizes inventors who take longer to develop their inventions when, generally speaking, the inventions that take longer to develop require more protection. In the pharmaceutical industry, this policy could be causing significant distortions in R&D investments, perhaps discouraging firms from developing highly valuable – such as most preventative medications – because they require lengthy clinical trials. Creating a genuinely uniform patent term for drugs would correct this problem. A variable patent term that offers longer patent terms to drugs require more costly and time-consuming R&D might be better.