

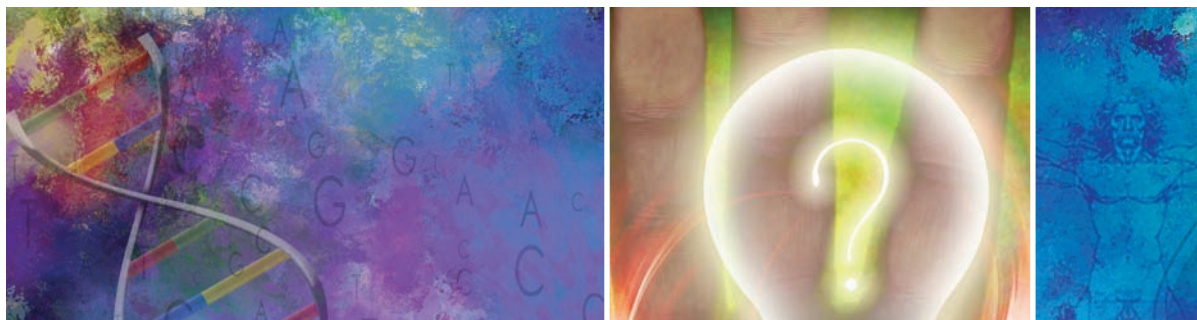


Stimulating Innovation in the Biologics Industry: A Balanced Approach to Marketing Exclusivity

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September 2008



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Executive Summary

New and improved medications are critical to Americans' health and welfare. Today, the most significant, but also most expensive, advances in medications come in *biologics*. Biologics are protein-based, rather than chemical-based, medicines. The new drugs can be of tremendous help in alleviating, if not curing, a wide range of heartbreaking diseases. At the same time, their prices are remarkably high, leaving millions of uninsured and underinsured Americans unable to access their use.

As policymakers in Congress debate legislation to create an approval pathway for affordable biologic medicines, a strong case has been made regarding the potential savings and increased access that will result. These savings could run in the tens of billions of dollars annually and have a significant impact on access for patients. They would also dramatically lower costs to health care purchases, be they payors from private industry or the government — the single largest purchaser of prescription medications.

The key issue in providing affordable access to biologic wonder drugs is doing so without limiting their development. This paper focuses on how best to encourage continued innovation in this sector by providing the appropriate degree of monopoly protection. Four bills pending in Congress propose to do for biologic medications what the 1984 landmark Hatch-Waxman bill did for chemical medications, namely, promote a competitive marketplace that would dramatically lower prices while also ensuring strong incentives to innovate. Yet three of the four bills contain *exclusivity* provisions that run the danger of overextending monopoly protection. Doing so would, paradoxically, undermine innovation and the bills' own objectives.

Bestowing lengthy monopolies by statute on brand biologic companies not only greatly delays entry by competitors with low-cost alternatives, but also excludes other innovators from building — in a timely manner — on the stock of prior knowledge — much of which was accumulated at public expense.

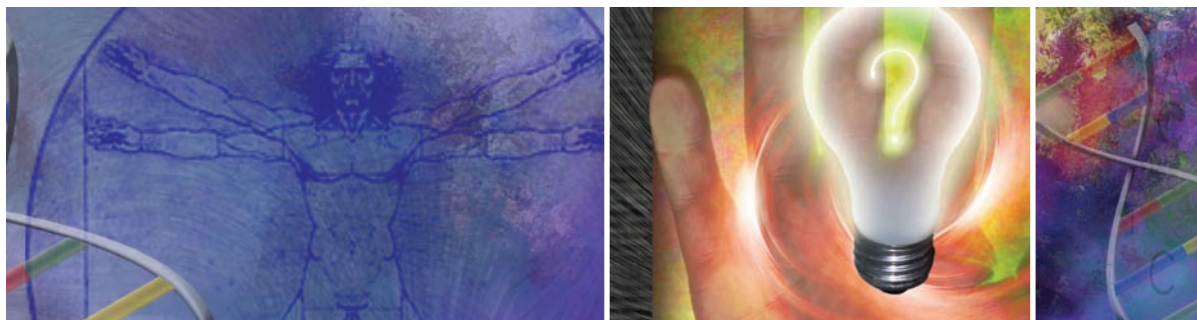
New medications that alleviate or cure terrible disease are such remarkable gifts that we all want to do everything possible to continue their discovery. But the new drugs of today are not those of tomorrow. The reason is clear. Today's inventors have strong incentives to protect their discoveries, not to make new ones whose arrival on the market would undermine their existing profits.

Numerous papers in the economics literature on invention and monopoly protection stress that competition, not protection, is the true source of innovation and that overextending monopoly protection can be counterproductive. It may do little or nothing to incentivize new discovery, and may simply delay when the next discovery comes on board. Thus, rights to exclusive marketing periods can lead to less, not more, innovation over time. This is particularly true given the potential to use exclusivity periods to “evergreen” one's products — to secure additional long periods of monopoly based on minor product modifications.

Hatch-Waxman has proved remarkably successful in balancing incentives to innovate with the need for access to new medicines. Given this success and the absence of any material differences between the biologics and chemical medical industries arguing for longer monopoly protection, Congress should consider the Hatch-Waxman model for exclusivity rather than proposals that would distort the market and undercut innovation.

¹ I was asked by Teva Pharmaceuticals USA, which provided the funding for this study, to assess the impact of varying lengths of market exclusivity on innovation in the context of the biotechnology sector. The views expressed here are those of mine and not necessarily those of Teva Pharmaceuticals USA.





Introduction

New and improved medications are a vital and growing part of America's \$2 trillion healthcare system.² Today, one of every 10 healthcare dollars is spent on prescription drugs, compared to one of every 20 in 1980.³ The nature of medicines is also changing. The most significant, but also most expensive, advances are coming in *biologics*.

Biologics are protein-based, rather than chemical-based, medicines.⁴ When Americans take pills, capsules, and liquid medications, they are taking chemical compounds. But for many serious illnesses, they increasingly rely on injections and infusions of biologics.

The new drugs can be of tremendous help in relieving pain and suffering. In some cases they represent miracle cures. But their prices are staggering. Biologics cost, on average, 22 times more per daily dose than chemical medications;⁵ the most expensive biologics cost over \$100,000 a year. The public's annual bill for biologics has been growing at a 15 percent rate, with this year's total exceeding \$40 billion.⁶

For those lucky enough to gain access to these new super-expensive but often highly effective medications, there is real hope. Biologics are now fighting arthritis, asthma, Alzheimer's, heart disease, Crohn's disease, several cancers, psoriasis, multiple sclerosis, Lou Gehrig's disease, and AIDS. And *if* innovation continues, new biologics will be developed to battle the full range of cancers as well as a host of other diseases.

The *if* here is a big one. Innovation in biologics is now threatened, ironically, by specific exclusivity provisions in what is otherwise

long-overdue legislation to provide Americans with accessible alternatives to extraordinarily high-priced brand biologic medicines.⁷

The exclusivity provisions come in two forms — *data exclusivity* and *approval exclusivity* (often referred to as market exclusivity). Both extend the duration of monopoly protection afforded brand drug products; i.e., both convey *marketing exclusivity*. And both depart very sharply from longstanding U.S. policies in balancing intellectual property protection and the U.S. economy's lifeblood — competition.

The proposed legislation comprises four bills before Congress. Each bill authorizes the Food and Drug Administration (FDA) to do for biologic medicines what it's been doing under the Hatch-Waxman Act of 1984 for chemical-based medicines, namely expedite approval of generic alternatives to drive down prescription costs.⁸

Biologics cost, on average, 22 times more per daily dose than chemical medications;⁵ the most expensive biologics cost over \$100,000 a year.

The bills are *Access to Life Saving Medicine Act* (S623/HR1038), introduced by Congressman Henry Waxman and Senator Charles Schumer; *The Biologics Price Competition and Innovation Act of 2007* (S1695), introduced by Senator Edward Kennedy; *The Pathway for Biosimilars Act* (HR 5629), introduced by Congresswoman Anna Eshoo and Congressman Joseph Barton; and *The Patient Protection and Innovative Biologic Medicines Act of 2007* (HR1956), introduced by Congressman Jay Inslee.

The stated goal of each bill is to foster a robust generic biologics industry. But provisions in the Kennedy bill conveying four years

² Centers for Medicare and Medicaid Website. http://www.cms.hhs.gov/NationalHealthExpendData/02_NationalHealthAccountsHistorical.asp, accessed on 27 June 2008.

³ Ibid.

⁴ Epogen, which treats anemia, is an example. It's produced by extracting proteins from animal cells and replicating them in vitro. Nexium, which targets heartburn and acid reflux, is produced by combining chemical compounds with no reliance on animal tissue.

⁵ Ibid., p. 7.

⁶ <http://www.cbo.gov/ftpdocs/94xx/doc9496/s1695.pdf> This expenditure is being made primarily via third-party insurers or the government.

⁷ The European Union created a new regulatory pathway for follow-on biologics in 2005. By 2010, when a number of brand biologics go off patent in the EU, we should see significant biologic generic entry.

⁸ The European Union passed such legislation in 2005. As a result, Europeans can now access low-cost generic versions of a number of leading biologics, including Epogen.

of data exclusivity followed by eight years of approval exclusivity, provisions in the Eshoo-Barton bill conveying 12 years of data exclusivity followed by two years of approval exclusivity, and provisions in the Inslee bill also conveying 12 years of data exclusivity followed by two years of approval exclusivity could delay by years the advent of low-cost generic alternatives.

Ongoing evergreening of biologics can extend their monopoly protection far into the future. Such “innovation” blocks true discoveries that would materially improve the public’s health, and undermine existing product sales.

Most importantly, the exclusivity provisions could stifle the discovery of new biologic treatments for the terrible afflictions just mentioned. This is particularly true in light of the industry’s ability to *evergreen* its drugs — to spend the time afforded by initial monopoly protection to make minor modifications to the biologic’s formulation and, thereby, garner extra periods of statutory exclusivity. Ongoing evergreening of biologics can extend their monopoly protection far into the future. Such “innovation” blocks true discoveries that would materially improve the public’s health, and undermine existing product sales.

Given the medical and economic stakes involved, it’s important for Congress to consider carefully the potential for exclusivity provisions to significantly retard innovation in biologics by undermining the ability of competitors to offer low-cost, competing products in a meaningful time frame.

This paper pursues this objective. It begins by briefly questioning two presumptions when it comes to monopoly protection policy and the drug industry. The first is that longer periods of monopoly protection necessarily promote innovation. The second is that extending the duration of monopoly protection, while it may have winners and losers, causes no overall economic loss, i.e., no economic inefficiency.

These questions provide the context for the next task — assessing the exclusivity provisions specially designed for the brand biologic companies and explaining how exclusivity provisions in three of four biogenerics bills would dramatically extend monopoly protection afforded to brand biologics.

But my main focus will be to amplify the point raised immediately below, namely, that extended periods of exclusivity pose a

threat to sustaining a rapid rate of innovation. This analysis forms the basis for my recommendation that when it comes to promoting biologic competition Congress should stick with what works, namely Hatch-Waxman, with its very limited exclusivity.

Economic theory speaks clearly here. So does the evidence. There are, quite simply, no compelling differences between the chemical-based and protein-based medication industries to justify deviating from a policy that has succeeded for over a quarter of a century in both dramatically reducing drug prices and stimulating innovation.

Indeed, to the extent there are differences, they generally favor less exclusivity. A key example here is the likelihood that obtaining FDA approval of generic biologics will take considerably longer than obtaining FDA approval of a chemical entity.⁹ If this proves true, it will automatically provide brand companies with an extended period of effective exclusivity even absent any legislated exclusivity.

Can Extended Periods of Exclusivity Threaten Innovation?

Raising this question may sound surprising given that some period of exclusive marketing rights is required to incentivize discovery. But starting a train is not the same as keeping it moving, let alone getting it to run at the proper speed. When it comes to innovation, each “discovery” builds on prior knowledge, with progress measured by the next innovation, not the last, and by how fast the next innovation gets to market.¹⁰

Policies that lengthen the time between innovations may do little to stimulate more innovation; instead, they may simply reduce the pace of innovation (the number of discoveries per unit of time) on which the economy’s growth so critically depends.

The key problem with providing excessive monopoly protection is that once an invention has been made, the inventor faces different incentives. The main goal becomes marketing and protecting one’s intellectual property, not developing a dramatically different and better version of the product. Doing so would diminish, if not vitiate, the value of the initial invention, which may have been undertaken at considerable cost. Hence, at least within a given product line, yesterday’s inventors are much less likely to be either today’s innovators or tomorrow’s.

This point comes across clearly in the economics literature starting with the seminal 1959 paper on intellectual property by Nobel

⁹ Shapiro, Robert, op. cit., p.4.

¹⁰ Isaac Newton paid deference to this process in his famous statement: “If I have seen further it is by standing on ye shoulders of Giants.”

laureate Kenneth Arrow.¹¹ In the years since Arrow showed that “the incentive to invent is less under monopolistic than under competitive conditions,” numerous economists have developed alternative models of the innovation process, but they invariably reach the same conclusion — *monopolists don’t innovate*. The reason is simple: bringing new products to the market undercuts a monopolist’s revenues on his existing products.

Distorting the Economy via Excessive Monopoly Protection

Prolonged monopoly protection raises additional concerns. It distorts consumer choice by maintaining artificially high prices of those final goods and services that are being protected. The same point applies to all the monopoly-protected inputs purchased by businesses. If their prices remain too high for too long, too few of the inputs will be used in production. The result will be a production distortion.

Distortion arising from excessively long monopoly protection is called *rent seeking*. In the context of inventing, the rent seekers are the inventors and the rent they seek is the monopoly profits from their discoveries. For those winning the race to discovery, the rewards are great. But all those losing the race have expended resources, potentially very large amounts of resources, for naught. To be clear, some losers and losses are inevitable. The issue is how many would-be inventors, with what size losses, monopoly-protection policy will create.

Another distortion, which arises in the context of biologics, involves access. Because biologics are so expensive and because America has so many uninsured and underinsured people with limited access to these medications, those with access to these medicines may not have the most need for them. There is clearly an equity issue here. But there is also a separate issue of efficiency. Markets in which some people face one set of prices for goods and services and other people face another set are inefficient for a simple reason — there are beneficial economic trades between the two sets of people that are not occurring.

These economic and other distortions discussed in this paper are important. Economists reference them as *excess burdens*, *dead-weight losses*, or *economic inefficiencies*. But no matter what they are called, these distortions entail real economic costs to society. Concern about these efficiency costs explains why we restrict monopolies, why we have patent limits, why we have free domestic trade, and why we form free trade agreements.

Data Exclusivity, Approval Exclusivity, and Marketing Exclusivity

As introduced in part of Hatch-Waxman, *data exclusivity* refers to a period of time during which a potential generic supplier of a brand drug is prohibited from filing for an ANDA (Abbreviated New Drug Application).¹² This prohibition is a type of gag order. It is effectively conveyed by preventing potential generic suppliers from using publicly available clinical trial and related data to substantiate the safety of their medically equivalent/similar medicines.

Approval exclusivity, sometimes referred to as *market exclusivity*, is a period of time during which a generic drug supplier can file for FDA approval, but cannot receive approval. In other words, FDA approval is exclusively limited to brand companies during this period even if all prerequisites for FDA approval of generic alternatives have been established.

Since data exclusivity prevents even seeking FDA approval and approval exclusivity prevents receiving FDA approval, even if one has sought it by substantiating medical equivalence/similarity, both data exclusivity and approval exclusivity constitute *marketing exclusivity* — periods during which brand companies are exclusively permitted to market the medication in question.

Prolonged monopoly protection raises additional concerns. It distorts consumer choice by maintaining artificially high prices of those final goods and services that have been patented.

Being able to file for FDA approval, even during periods when the FDA is precluded from granting approval, is important. Generic drug suppliers may not be able to contest the patents of a brand provider *unless* the generic supplier has filed with the FDA. Consequently, data exclusivity represents absolute monopoly protection for brand suppliers — monopolies that are granted even if a brand’s patents are found to be invalid following judicial review.

Using data exclusivity periods to prevent the courts from adjudicating patent challenges goes well beyond standard patent protection policy provided under GATT. Indeed, providing data exclusivity is tantamount to the government simply doing away with patents altogether and conveying exclusive product marketing rights to favored companies by fiat. Such a policy is at considerable odds with the principles of free markets.

¹¹ Arrow, Kenneth J., “Economic Welfare and the Allocation of Resources for Invention,” Rand Corporation working paper P-1856-RC, December 15, 1959.

¹² To be precise, the FDA is prohibited during the period from using the brand company’s safety and effectiveness findings (data) as a basis for approving medically equivalent generic alternatives.

As indicated, approval exclusivity comes into play after data exclusivity expires. Although approval exclusivity permits competing drug companies to file their product applications with the FDA and, in the process, potentially contest the validity of patents of drugs already on the market, it tells competitors that no matter whether they win their patent fights or not, they will not get to market until this extra protection period has run its course.

Given Hatch-Waxman's significant patent restoration provision, its exclusivity will rarely extend the total length of monopoly protection.¹⁴

The clock on the total period of data plus approval exclusivity starts with FDA approval of the brand drug. The reason is that the exclusion is determined with respect to the filing and approval of ANDAs. But an ANDA presupposes an NDA (a New Drug Application); the government's exclusivity clock doesn't start until the government approves the new brand drug and allows it to go on the market.

The upshot here is that if the total period of exclusivity exceeds the amount of patent protection left at the time of FDA NDA approval, monopoly protection will be expanded by the number of years that exclusivity exceeds remaining patent life.

Take, for example, a new biologic that receives FDA approval 12 years after initial patent filing. Under GATT, the biologic should receive eight more years of patent protection (20 years total less the 12 years already elapsed). But were the Eshoo-Barton or Inslee bills passed, the biologic would qualify for 14 years of exclusivity beyond the date of FDA approval. Since 14 exceeds eight, the biologic would receive 14 years of protection post-FDA approval rather than eight. And since 14 plus 12 equals 26, the biologic ends up with 26 years, rather than 20 years, of monopoly protection. This represents a 30 percent increase in monopoly protection relative to the GATT norm — the standard protection being provided to inventions of all other goods and services apart from drugs!

Exclusivity, Patent Restoration, and Marketing Stays under Hatch-Waxman

The Hatch-Waxman Act does provide for data and approval exclusivity for chemical entities, but on a much more limited basis than that proposed in the Kennedy, Eshoo-Barton, and Inslee generic biologics bills. Instead of the combined data plus approval exclusivity periods of 12 years (four data plus eight

approval) years proposed in the Kennedy bill and 14 years (12 data and two approval) proposed in both the Eshoo-Barton and Inslee biogenerics bills, Hatch-Waxman offers five years of exclusivity generally, with four years of data exclusivity followed by one year of approval exclusivity if an applicant files a patent challenge in the fourth year. The Waxman biogenerics bill does not address data or approval exclusivity whatsoever.

The Hatch-Waxman Act also provides for *patent restoration*; the Act restores to a new chemical entity's patent life half of the time spent in clinical testing and all of the time spent securing FDA approval, up to a maximum of five years. The amount of patent restoration is also subject to a ceiling; total patent life beyond FDA approval cannot exceed 14 years. Thus, a new chemical drug that receives FDA approval after 12 years from initial patent application, having spent four years in clinical trials and two years undergoing FDA review, has three years of patent restoration time tacked onto the standard 20-year patent term provided under GATT. This provides the drug with 24 years of patent life, of which 12 is post-FDA approval.

In contrast, if FDA approval had occurred eight years from patent application, six of which again had been spent in trials and FDA review, the patent would be extended by only two years — to 22 years total — because any longer extension would mean more than 14 years of patent life beyond the date of FDA approval.¹³

Given Hatch-Waxman's significant patent restoration provision, its exclusivity will rarely extend the total length of monopoly protection.¹⁴ But it does delay by at least four years the ability of competitors to contest the patents of brand companies. Another feature of Hatch-Waxman that delays competitors in overturning invalid patents and quickly getting to market is the ability of brand companies to have the courts automatically stay FDA approval of an ANDA for two and a half years if the brand company sues the competitor for patent infringement.

Hatch-Waxman's Applicability to Biogenerics

It's important to realize that one portion of Hatch-Waxman, namely patent-term restoration, applies to biologic medications as well as chemical medications, even though there is currently no pathway for generic biologics to receive FDA approval and reach market. And since none of the biologics bills abrogate Hatch-Waxman's provisions, brand biologics, under all of the bills, will still retain patent restoration. Hence, under all but the Waxman biogenerics bills, brand biologics will enjoy four legislated types of monopoly protection — GATT, data exclusivity, approval exclusivity,

¹³ As these two illustrations indicate, drugs brought to market early are being penalized by these provisions relative to those brought to market late. Providing incentives to delay the introduction of new medications seems a significant deficiency in the Hatch-Waxman Act.

¹⁴ Grabowski, Henry G., and John M. Vernon. "Effective Patent Life in Pharmaceuticals," *International Journal of Technology Management*, Vol. 19, 2000, p. 116, states that "The effects of Waxman-Hatch and GATT on EPL (effective patent life) have been modest to date."

Table 1: Years of Monopoly Protection from Date of Patent Application

Years between Patent Application and FDA Approval of Brand Drug	GATT – Non-Drugs	Hatch-Waxman Chemical Drugs	Waxman Biologics Bill	Kennedy Biologics Bill	Eshoo-Barton Bill	Inslee Biologics Bill
6	20	20	20	20	23	23
8	20	22	22	22	25	25
12	20	23	23	24	29	29
16	20	23	23	28	33	33
20	20	25	25	32	37	37

Table assumes no evergreening, incorporates exclusivities, and assumes five years for testing and approval of biosimilars (see Shapiro, 2008) commencing at ANDA filing and a three-year patent restoration period.

and patent restoration. Each of these protections can impact the total length of monopoly protection depending on the particular circumstances involved. Under the Waxman bill, brand biologics would enjoy GATT and patent restoration protections.

The Proposed Expansion of Monopoly Protection for Biologics

Table 1 examines the duration of monopoly protection that each of the biogenerics bills would extend to brand biologics companies under different assumptions about the amount of time brand companies spend between submitting a patent and achieving FDA approval of their product.

The table takes into account GATT's 20-year patent duration rule, exclusivity provisions, patent restoration, and the time required for biologic generic companies to receive FDA approval of their medically similar alternatives. I assume that, starting from the end of the period of data exclusivity, it would take biologic generic companies five years to develop a generic biologic, file for FDA approval, and receive FDA approval.¹⁵

For purposes of comparison, the table shows the duration of monopoly protection under pure GATT treatment (the treatment of non-drug products) and under Hatch-Waxman Act treatment (the treatment for new chemical entities). In calculating the length

of protection under Hatch-Waxman, I assume a three-year patent restoration extension — the average such extension calculated by the Congressional Budget Office.¹⁶ Finally, I ignore the potential of brand companies to receive FDA-approval stays and to evergreen their products.¹⁷

In considering table 1's findings, it's important to bear in mind that innovations build on one another. Hence, permanently lengthening monopoly protection from 20 to, say, 25 years represents a 25 percent permanent delay in the advent of the next (the second) innovation. In this case, the second innovation arrives five years late, the third 10 years late, the fourth 15 years late, etc. Over the course of a century, the country experiences not five innovations, but four. And successive generations end up being harmed to an ever-increasing degree.

Compare, to begin, the standard 20-year GATT monopoly protection period with the 29-year period provided under the Eshoo-Barton and Inslee biologics bills, assuming the brand biologic company expends 12 years achieving FDA approval. The difference between 29 years and 20 years is 45 percent. This is a very substantial deviation from GATT and has the potential to substantially reduce the pace of innovation.

Under the Kennedy bill, the duration of monopoly protection for this case is five years shorter, i.e., 24 years. The difference reflects the two-year shorter length of total exclusivity under the

¹⁵ See Shapiro (2008), op. cit.

¹⁶ Congressional Budget Office, "How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry," July 1998, table 8, p. 40.

¹⁷ These stays appear to have the potential to add another half year of monopoly protection under the Eshoo-Barton and Inslee bills for all cases considered in table 1.

Table 2: Years of Marketing Exclusivity from Date of Patent Application

Years between Patent Application and FDA Approval of Brand Drug	GATT – Non-Drugs	Hatch-Waxman Chemical Drugs	Waxman Biologics Bill	Kennedy Biologics Bill	Eshoo-Barton Bill	Inslee Biologics Bill
6	14	14	14	14	17	17
8	12	14	14	14	17	17
12	8	11	11	12	17	17
16	4	7	7	12	17	17
20	0	5	5	12	17	17

Table assumes no evergreening, incorporates exclusivities, assumes five years for testing and approval of biosimilars commencing at ANDA filing, and assumes a three-year patent restoration period.

Kennedy bill compared to the Eshoo-Barton and Inslee bills and the fact that the Kennedy bill allows filing for ANDA after four years as opposed to after 12 years in the Eshoo-Barton and Inslee bills. Under the Kennedy bill, generic biologic firms would, I assume, spend the eight years after filing, but before being able to receive final FDA approval, in doing the testing under FDA supervision needed to obtain final approval once the eight years of approval exclusivity had run its course.¹⁸

Compared with the Eshoo-Barton and Inslee bills, the Kennedy bill entails shorter monopoly protection. But monopoly protection under the Kennedy bill is still much longer than under Hatch-Waxman in the case the brand company takes more than 12 years to get to market. Remarkably, the Kennedy, Eshoo-Barton, and Inslee bills reward delay in getting to market with longer monopoly protection, with each year of delay beyond 12 leading to roughly one more year of protection. One wonders why legislators would want to encourage delay in the pace at which innovative drugs are brought to market and lower the speed at which today's innovations are incorporated in tomorrow's discoveries.

Table 2 puts this point in higher relief. It shows the duration of marketing exclusivity available to the biologic brand company for different periods of time the brand takes to get to market. Note that Hatch-Waxman and the Waxman biologics bill penalize delays

in reaching the market by reducing monopoly protection by roughly one year for each year of delay.

Can table 2's huge differences in marketing exclusivity periods for a) chemical medications subject to Hatch-Waxman and b) biological medications under either the Kennedy, Eshoo-Barton, or Inslee bills be justified by much longer startup times for new biological entities compared with new chemical entities? The answer is no. As Henry Grabowski has shown, the average development time for new biological entities is only 7.4 months longer than that for new chemical entities.¹⁹ In comparison, relative to Hatch-Waxman, the Eshoo-Barton and Inslee bills call for between 12 months and 120 months of extra monopoly protection depending on when the biologic is brought to market.

What about costs and risk? Do either of these factors justify longer monopoly protection for biologics than chemical entities?

The answer is no. Consider first the issue of cost. There is no question that bringing a new biologic medication to market is exceptionally expensive — an estimated \$1.24 billion.²⁰ But cost per se is not economically relevant. What matters is cost relative to reward. Invention X may cost \$1 million to bring to market and invention Y \$1 billion, but the projected revenues for Y may exceed those for X by far more than a factor of 1,000. In this case, less

¹⁸ Note that patent restoration does not extend the length of monopoly protection in this case, since it adds, by assumption, three years to the GATT's 20, which equals 23, which is less than 24.

¹⁹ Grabowski, Henry. "Follow-On Biologics: Data Exclusivity and the Balance Between Innovation and Competition." *Nature Reviews Drug Discovery*, Volume 7, June 2008.

²⁰ See DiMasi, Joseph A. Ronald W. Hansen, and Henry G. Grabowski, "The Price of Innovation: New Estimates of Drug Development Costs," *The Journal of Health Economics*, Volume 22, Issue 2, March 2003, pp. 151-185 and Grabowski, Henry, "Follow-On Biologics: Data Exclusivity and the Balance Between Innovation and Competition," *Nature Reviews Drug Discovery*, Volume 7, June 2008. \$802 million is, by the way, the estimated cost of bringing a new chemical medication to market.

monopoly protection is needed to promote invention of Y than of X.

Compared with pharmaceuticals, biologics are more costly to produce. But their reward is also considerably higher. Indeed, compared to chemical medications, biologic medications appear to have a lower ratio of invention cost to invention reward.²¹ Moreover, there is no presumption in the economics literature on optimal monopoly protection that products entailing higher cost relative to reward should be provided longer periods of protection.

Next, consider risk. Only one in five of all drugs tested clinically makes it to market,²² with the success rate possibly lower in biologics. But modern finance teaches us that collections of individual investments, each of which is highly risky, can, thanks to the law of averages (law of large numbers), be quite safe. If only one in 20 experimental drugs makes it to market, but you experiment with 1,000 such drugs, you can be pretty sure that close to 50 will be successful. Stated differently, the risk that most advocates of longer monopoly protection cite as supportive of such a policy is *diversifiable risk* – risk that is diversified away in the financial marketplace and that doesn't raise the cost of capital confronting biotech companies.²³

When it comes to *non-diversifiable risk*, the biotech industry is riskier than most, but not by much. Consequently, the cost of equity capital in biotech is only 18 percent higher than the average across all other industries. Moreover, a quarter of U.S. industries are riskier than biotech, but none of these garner longer monopoly protection. The appendix lists the 25 industries with higher costs of equity capital than biotech. The semiconductor industry is the most risky, with a cost of capital 89 percent above the average. The pharmaceuticals industry, interestingly enough, is much riskier than biotech. Its cost of capital is 35 percent above average.²⁴

Evergreening

Evergreening will multiply the economic costs of expanding monopoly protection via exclusivity arrangements. Brand companies can, and routinely do, make relatively minor changes to their existing products in order to restart their monopoly-protection clocks. These changes include changing the medication strength of pills (e.g., changing the pills from .10 mg to .15 mg), changing the form of medication (e.g., switching from pill to capsule),

modifying the method of delivery (e.g., from injection to inhalation), expanding indications (applying the medicine to additional conditions), pegylation (which has the effect of reducing doses per time period via time-release mechanisms), and glycosylation (adding sugar molecules to the medication).

To understand the risk evergreening poses to true innovation and competition in the industry, suppose either the Eshoo-Barton or Inslee bill is passed and a brand biologic company called BioBrand, Inc., spends 12 years getting its biologic drug produced, tested, and FDA-approved. According to table 1, 17 years later (29 years after the patent is initially filed) generic competitors will finally be able to bring a competing medication to market.

Or will they? Given evergreening, BioBrand can readily come up with a small change along one of the aforementioned product characteristic dimensions, clinically tested, obtained FDA approval of the “new” product, receive another 14 years of data and approval exclusivity, promote it aggressively with doctors and patients (referred to as *converting the market*),²⁵ and effectively extend the monopoly protection on the original product from 29 to 43 years!²⁶ And then BioBrand could tack on another 14 years if it introduced another minor, approved modification in year 43. In the drug world, brand companies have, in such situations, substantially diminished the market for the previous-generation products when they launch a new generation. They do so by converting prescriptions to the new product. Hence, upon approval, the previous-generation generic product has little or no market potential.

Brand companies can, and routinely do, make relatively minor changes to their existing products in order to restart their monopoly-protection clocks.

An effective statutory anti-evergreening provision in biologics would award full monopoly protection only for the discovery and marketing of a new protein. Minor modifications of new proteins should receive either no monopoly protection or very limited protection. Unfortunately, none of the proposed generic biologics bills incorporates any restrictions on evergreening. Instead, they contain vague language about restricting exclusivity provisions to the “previous licensed reference product,” without ensuring that what's defined to be the previous licensed reference product is, in fact, the underlying amino acid sequence of the new protein and nothing more.

21 It's easy for even excellent economists to fail to scale costs by revenues. In his June 2007 Duke University Department of Economics working paper titled “Data Exclusivity for New Biologics Entities,” Henry Grabowski incorrectly states, “From the standpoint of economic theory, industries where the R&D process is costly and risky need longer exclusivity periods to realize innovation benefits, compared to those industries where innovation is easier and less costly.”

22 Henry Grabowski & John Vernon, *Effective Patent Life in Pharmaceuticals*, 19 Int'l J. Tech. Mgmt. 98 (2000).

23 It's also easy even for excellent economists to confuse diversifiable with aggregate risk. See note 11.

24 The publishing industry doesn't appear in the table because its cost of capital, which is only 7 percent above the average, is below that of biotech. Publishing is another example of an industry in which the chances of success of any given book or other product are very low, yet its overall risk is moderate.

25 Using advertising to transform the old purple-colored Prilosec into the “New Purple Pill” Nexium is viewed as the classic example of *converting the market*.

26 Note that patents and exclusivity are different routes to monopoly protection. Minor modifications in medicines need not result in any new patents, yet may still be approved by the FDA as a new product and, therefore, qualify for data as well as approval exclusivity.

The Hatch-Waxman Act — A Balanced Template for Success

The Hatch-Waxman Act provides an excellent guide to establishing a balanced policy with respect to generic biologics. The Act gave the brand and generic companies less than they wanted, but more than they might have expected. The brand companies were forced to confront intense generic competition once their monopoly was finally terminated. In exchange, they received longer monopoly protection. The generics were forced to wait longer to compete, but benefited from an accelerated FDA approval process.

As indicated, the extension of monopoly protection was accomplished via the Act's patent restoration, data exclusivity, approval exclusivity, and ANDA stay provisions. According to the Congressional Budget Office, these and other features of the Act increased the average length of marketing exclusivity by 2.5 years — roughly a 25 percent increase, on average, in the prevailing duration of marketing exclusivity.²⁷ Duke University economists Henry Grabowski and Margaret Kyle report that marketing exclusivity in pharmaceuticals now generally ranges from 12 to 15 years.²⁸

The Hatch-Waxman Act provides an excellent guide to establishing a balanced policy with respect to generic biologics. The Act gave the brand and generic companies less than they wanted, but more than they might have expected.

Gaining access to a market from which they had formerly been excluded (albeit 2.5 years later than they would have preferred) has been a major incentive for generic pharmaceutical companies. Generics, including generics produced by brand companies, now account for two-thirds of the nearly 4 billion U.S. prescriptions being filled each year. This is remarkable given that the generics' prescription share was only 19 percent in 1984 when Hatch-Waxman was passed.²⁹

Generics have achieved this market penetration by offering medically equivalent products at dramatically lower cost. This competition has spurred further innovation. This brings us to Hatch-Waxman's real winner — the American public, which is now able to purchase large numbers of medications at close to their marginal production costs while also benefiting from newly innovated products. In 2007, the sales-weighted discount off

the brand price of the top 100 (ranked by number of prescriptions) generic drugs was 29.0 percent. This is just the average discount. A total of 22 percent of generics are now offering discounts of 40–60 percent, and 20 percent are offering discounts above 60 percent.³⁰

Hatch-Waxman provides four years of data exclusivity, but these four years do not generally preclude generics from reaching market on time. To see this, consider a new chemical medication that receives FDA approval 12 years after initial patent application. Its data exclusivity clock will run out 16 years after initial patent application (i.e., four years after FDA approval). According to table 1, this is still seven years before a generic is able to come to market. Hence, the generic company has seven years to file for and receive FDA ANDA approval.

This example illustrates an important point. Hatch-Waxman's exclusivity provisions, because they are of an appropriate duration, do not lengthen monopoly protection except in extreme cases that FDA approval comes very late — 19 or 20 years — after initial patent application. The real source of Hatch-Waxman's expansion of monopoly protection is patent restoration.³¹

Competition Stimulates Invention

Hatch-Waxman's success did not come at the price of innovation. On the contrary, the legislation appears to have accelerated innovation. Figure 1 shows that research and development in pharmaceuticals, measured relative to sales, increased dramatically in the years after 1984. R&D is now running between 16 percent and 18 percent of sales, on an annual basis, compared with 8–10 percent of sales prior to Hatch-Waxman.

Figures 2 and 3 provide complementary evidence about the acceleration of invention post Hatch-Waxman. Figure 2 shows that the number of new drug patents issued by the U.S. Patent Office rose dramatically after 1984 and, indeed, has exceeded the pre-1984 levels in each year since the Act was promulgated.

Figure 3 reports the average annual number of FDA approvals of new chemical entities (NCEs) for the periods 1973–1983, 1984–1993, and 1994–2007. The figure shows dramatic increases in NCE approvals subsequent to Hatch-Waxman's 1984 passage. NCE approvals increased by one-third in the decade following the bill's passage. Since 1994, NCEs have been coming at twice the rate observed before Hatch-Waxman.

27 Congressional Budget Office, <http://www.cbo.gov/showdoc.cfm?index=656&sequence=1>

28 Grabowski, Henry G. and Margaret Kyle, "Generic Competition and Market Exclusivity Periods in Pharmaceuticals," *Managerial and Decision Economics*, 28, 491-502, 2007, p. 496.

29 The Congressional Budget Office, "How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry," July 1998, p. ix.

30 Author's calculations; see note 12.

31 Hatch-Waxman's exclusivity provisions are not, however, without teeth. They prevent competitors from challenging patents for four years after FDA approval and from bringing a competitive product to market for five years from FDA approval in the cases that the patent challenge is successful.

Figure 1: Pharmaceutical R&D as a Share of Sales: 1970–2007

Source: PHRMA 2008 Profile.

The fact that Hatch-Waxman did not deter the brand companies from investigating new drugs and bringing them to market is not surprising. The average extra two-and-a-half years of marketing exclusivity provided the brand companies more time to recoup their investments. In addition, the four years of data exclusivity and one year of approval exclusivity afforded brand companies five years during which they could market their FDA-approved products without having to contend with competing products arising from legitimate patent challenges.

These points notwithstanding, if Hatch-Waxman did, on balance, reduce the profitability of developing new drugs, its effects were surely modest and were offset by other factors. Such factors include a shift toward more reliance on medication in treating illness, increasing demand for medications from an aging society, increasing international demand due to rising incomes abroad, etc.

Evidence supporting this view of at most a minor impact of Hatch-Waxman comes from a highly detailed 1998 Congressional Budget Office study, which states: “For all drugs, on average, the increase in generic sales since 1984 has probably not reduced expected returns below the average capitalized costs of R&D. On the margin, however, it is possible that a few drugs that were barely profitable to develop before may no longer be so now.”³² In reaching this conclusion, the CBO pointed out that the distribution of revenues from new drug discoveries is a highly skewed business, with the successful “blockbuster” drugs generating billions of dollars in sales years before any competition from generic companies comes into play.

Brand companies have also been able to recoup some of the losses arising from generic competition by marketing their brand drugs as generics. In fact, one in every six generic prescriptions is currently being filled with a brand generic.³³

³² Congressional Budget Office, op. cit., p. 28.

³³ Author's calculation based on IMS Health data.

Figure 2: Utility Patent Grants for Drug, Bio-Affecting, and Body-Treating Compositions, 1969–2007

Source: http://www.uspto.gov/web/offices/ac/ido/oeip/taf/tecasga/424_tor.htm

*The recent decline in new drug patent grants between 2002 and 2007 may reflect an overburdened PTO. For example, according to Annual Performance and Accountability Reports issued by the PTO between 2002 and 2007, filings of patent applications have increased from 353,000 in 2002 to 467,000 in 2007. Total patents pending have increased from 636,000 (2002) to 1.12 million (2007). Lastly, in the Biotechnology and Organic Chemistry Section (Tech Center 1600), pendency has increased from 27.3 months (2002) to 34.3 months (2007).

It's also important to note that although generic drugs now account for the bulk of all prescriptions, they continue to account for only a small minority of all sales. As they did back in 1984, the brand companies garner the lion's share of all pharmaceutical revenue. The brand companies' revenue share is currently 84 percent.³⁴ This revenue, by the way, is now running close to a quarter of a trillion dollars each year.³⁵ Thus, brand drug companies remain hugely profitable, with the average price of a brand drug exceeding that of a generic by a factor of roughly four.³⁶

A final point is that Hatch-Waxman surely lit a fire under the brand companies. It's one thing knowing you have an indefinite monopoly on the development, production, and sale of a medication. It's another thing to know that every year of delay in getting to market means one fewer year during which you are likely to collect monopoly rents on your invention. As table 2's third column documents, Hatch-Waxman sent this message loud and clear to the brand companies.

The Economic Case for Biogenics

This final section briefly discusses the potential cost saving and welfare gains from fostering a biogenics industry. I then review some of the relevant economics literature on monopoly protection, making the points that a) innovation is an ongoing process that can be seriously undermined by excessive protection, b) excessive protection can actually reduce incentives to innovate, and c) excessive protection comes at a considerable price in terms of economic efficiency.

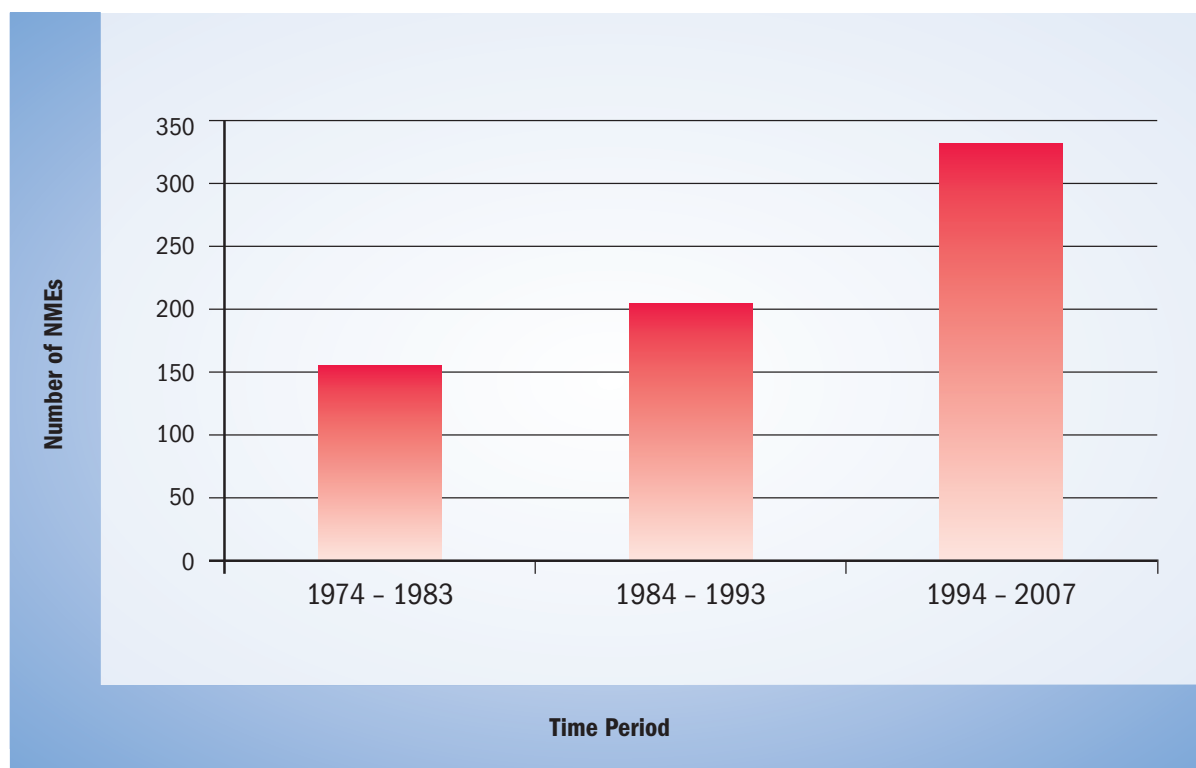
Potential Cost Savings from Biogenics

Recent research suggests such an industry would save the American public at least \$25 billion and as much as \$108 billion over the next decade and greater sums thereafter from biogenics leg-

³⁴ IMS Health, "IMS National Prescription Audit Plus, National Sales Perspectives," December 2007.

³⁵ Generic Pharmaceutical Association, *Statistics: Our Industry*, February 2007

³⁶ *Ibid.*, *FAQs Generics: Lower Cost*, February 2007

Figure 3: FDA Approvals of New Molecular Entities, 1974–2007

Source (for both) <http://www.fda.gov/cder/da/da.htm>

isolation that properly limits the duration of monopoly protection.³⁷

Numbers of this magnitude are hard to translate into their personal welfare impact. So take Remicade, which is used to treat arthritis and Crohn's disease. For those with severe arthritis, Remicade infusions can mean the difference between walking or not; and for those with advanced Crohn's, the infusions can literally mean the difference between life and death. That's the very good news. The bad news is that taking this miracle drug can cost over \$20,000 per year.³⁸ Costs of this magnitude are obviously prohibitive for the roughly 50 million Americans with no health insurance as well as the tens of millions of other Americans who either have no prescription drug coverage or face very high prescription co-pays.³⁹

Reducing the Costs of Biologics Limits Biologics Expenditure Risk

Another economic argument for limiting monopoly protection to biologics involves risk. Even those with excellent prescription drug insurance need to worry about the risk of having to directly pay the high costs of biologics. Why? Because being insured today doesn't guarantee being insured tomorrow. Moreover, as *The New York Times* recently reported, health insurance plans with prescription drug coverage are beginning to charge very high co-pays for biologics — usually 20–33 percent. These charges can cost *insured* patients tens of thousands of dollars a year.⁴⁰ This includes the roughly 33 million elderly Americans on Medicare. A full 86 percent of Medicare Part D prescription drug insurance

37 <http://www.cbo.gov/ftpdocs/94xx/doc9496/s1695.pdf> and Shapiro, Robert J. "The Potential American Market for Generic Biological Treatments and the Associated Cost Savings." www.insmed.com. February 2008. Shapiro's cost savings estimate is much higher than CBO's because he incorporates expanded demand in his analysis. The expansion in demand comes from two sources — more consumption of biologics by those now using biologics and the initiation of use of biologics by those now priced out of the market.

38 Purvis, Leigh and Lee Rucker, AARP Public Policy Institute, May 2007.

http://64.233.169.104/search?q=cache:x2DoGbAwrcJ:www.tennicare.org/actions_alerts/alerts/2007_06_09/biologics_top_20_q_and_a.pdf+annual+cost+of+top+biologic+products&hl=en&ct=clink&cd=3&gl=us Remicade is actually inexpensive compared with some biologics. Herceptin, which treats breast cancer, runs \$124,000 per year. Avastin, which treats colorectal cancer, costs \$60,000 annually, and Avonex, which treats multiple sclerosis, is billed at \$84,000 per year. Twelve of the top 20 biologics now on the market have an average cost per year exceeding \$10,000. Sixteen have an annual average cost exceeding \$5,000. See Purvis and Rucker (2007), *op. cit.*

39 Lowering the costs of biologics directly benefits those using the drugs, but there is also a real benefit to the friends and relatives of those helped by these new medicines. Economists refer to a situation in which person X's welfare depends on his own health and consumption of goods and services as well as on person Y's welfare as one subject to *externalities*. There are clear and obvious externalities when it comes to improving public health because the "public," when not ourselves, is often someone to whom we are very close. Remarkably, the economic value of these externalities is entirely ignored when it comes to weighing the costs of ongoing monopoly protection against the gains. The value could be considerable. Suppose, for example, that each person who is directly helped by having access to a low-cost biologic has 10 close friends or relatives who are indirectly helped. Also suppose that the average value of the external benefit is one-tenth the value to the patient herself. In this case, the savings from low-cost biologics would be double those estimated.

40 Golata, Gina, "Co-Payments Go Way Up for Drugs with High Prices," *The New York Times*, April 14, 2008.

plans are now charging 20–30 percent co-pays for expensive biologics.⁴¹ Another example of the risk of paying for biologics involves diabetes. Hundreds of thousands of Americans with diabetes, many of whom have prescription drug coverage, are now spending upwards of \$1,000 per month to cover the costs of insulin.⁴²

Our exposure to the risk of high-cost biologics is not limited to our own medical needs. If our relatives or friends end up facing huge, uninsured bills for biologics, we'll be asked for financial assistance or feel the need to provide such assistance. All of these factors are playing on the minds of Americans on a daily basis. According to Deloitte's *2008 Survey of Health Care Consumers*, 93 percent of American households say they are unprepared for their future healthcare needs. This uncertainty has a cost that economists are well versed in measuring. They do so by determining how much households would be willing to pay to avoid the risk entirely. Although no one has done such a measurement for healthcare expenditure risk in general, let alone biologics per se, the following speculative measurement suggests the potential magnitude of the biologic cost risk.

In fact, each innovation is part of a chain. Today's innovation cannot proceed if yesterday's is not accessible. And tomorrow's innovation must wait until today's innovation is available for use.

Assume there are 100 million Americans who are uninsured either directly or indirectly (via their uninsured relatives' or friends' exposures) for the costs of biologics and that, on average, insurance against these costs is worth \$100 per person. In this case, eliminating this risk would be worth \$10 billion annually.

Now lowering the cost of biologics is not the same as providing insurance against these costs, but it does provide some perspective on the value to American households of less expensive biologics. This value, to repeat, is not simply in reducing expected outlays, including those coming in the form of higher co-pays and prescription drug insurance premiums. It's also in reducing the risk of unaffordable expenditures on biologic medicines.

Limiting Monopoly Protection to Stimulate Innovation

The importance of successive rounds of innovation — of each innovation building on, but also undermining the monopoly position of the prior round⁴³ — was dubbed *creative destruction* by the father of growth theory, Joseph Schumpeter.⁴⁴ According to Schumpeter, innovation is the engine of growth, and it's not pretty. Entrepreneurs must be able to compete and destroy or they will not create.

In Schumpeter's words, "Economic progress, in capitalist society, means turmoil. [What counts is] competition from the new commodity, the new technology, the new source of supply, the new type of organization ... competition which ... strikes not at the margins of the profits and the outputs of the existing firms, but at their foundations and their very lives."

Paul Romer, today's leading theorist of economic growth, emphasizes the self-propelled nature of growth — that growth feeds upon itself. "We consistently fail to grasp how many ideas remain to be discovered. Possibilities do not add up. They multiply."⁴⁵

Sandwiched between Schumpeter and Romer is the past century's third great student of economic growth, Nobel laureate Robert Solow. Solow developed *growth accounting* and showed that innovation (better technology) is a major source of U.S. economic growth.

In fact, each innovation is part of a chain. Today's innovation cannot proceed if yesterday's is not accessible. And tomorrow's innovation must wait until today's innovation is available for use. Moreover, if the current length of monopoly protection suffices to incentivize today's innovation, extending the length of protection will do nothing to increase current innovation. Instead, it will simply delay future innovation with the economy, over time, falling further and further behind with respect to the level of technology it would otherwise have available.

Economists have modeled this process, conceptualizing innovation in a number of different ways. Andrew Horowitz and Edwin Lia wrote a classic paper in 1996, for example, in which they view innovation as moving up a product quality ladder.⁴⁶ Higher rungs on the ladder entail better technology and higher quality products. The innovator in their model, which need not be the same person or company through time,⁴⁷ can be viewed as holding the top

41 <http://www.drugchannels.net/2008/04/tier-4-co-pays-and-pharmacy-prices.html>.

42 Saul, Stephanie, "Bridling at Insulin's Cost, States Push for Generics," *The New York Times*, January 11, 2007. A biologic version of insulin was extracted in the early 1980s; its most effective form has yet to face competition from generic manufacturers.

43 Jorgenson, Dale, "Accounting for Growth in the Information Age," provides a careful empirical analysis available of technology's contribution to U.S. economic growth.

44 Schumpeter, Joseph, *Capitalism, Socialism, and Democracy*, New York, N.Y.: Harper, 1942.

45 <http://www.econlib.org/library/Enc/EconomicGrowth.html>

46 Horowitz, Andrew W. and Edwin L.C. Lai, "Patent Length and the Rate of Innovation," *International Economic Review*, 37 (4), 1996, pp. 785–901. The ladder model for innovation was originally developed by Gene Grossman and Elhanan Helpman in chapter 4 of their book, *Innovation and Growth in the Global Economy*, Cambridge, Mass.: MIT Press, 1992.

47 The current innovator is indifferent between maintaining his company or selling it (his ladder position) to a competitor who would have the same competition-spurred incentive to innovate.

position on the ladder with generics moving up from below. The closer the generics get, the more competition the current innovator faces. This gives the current innovator an incentive to move to yet a higher position on the ladder. Moving up the ladder is innovation, and the more rungs the innovator (or replacement innovator) climbs over a given period of time, the higher the rate of innovation.

Patent length in the model corresponds to the amount of time the government keeps the generics from using the latest technology — moving up the ladder to where the prior innovators have been. Once the current patent expires, the generic can move up. But when he does, he finds that the top-rung innovator has innovated to an even higher rung, the position of which is temporarily protected by a new patent.

This is not a model of evergreening. Each time the top-rung innovator company innovates, it represents a true improvement in technology — one that comes at a real cost to the company. But it's only the threat of competition that keeps the top-rung innovator (the near monopolist) innovating. And setting the patent length correctly is critical. As the authors point out, "Patent length either too short, or too long, will weaken innovative incentives." In particular, patent length that's too long will lead to more innovation when innovation occurs (the top-rung company will move up more rungs when it realizes it has to innovate to stay ahead because its patent is expiring), but to less frequent innovation. In the extreme, making the patent indefinite kills off innovation entirely; in this case, the top-rung company faces no competitive pressure and would compete only against itself by incurring the cost of inventing a better product.

Another classic paper on patent policy is Nancy Gallini's (1992) *Rand Journal* article.⁴⁸ Gallini's model lets competitors invent around incumbents, but at a cost. If patent length is set too long, competitors realize that they'll not be able to use existing knowledge in a timely manner and that the only way they can compete is to come up with their own invention. Under these circumstances, this makes private sense, but it also makes social nonsense for the same reason that it makes no sense to re-invent the wheel. Knowledge that's been acquired at a cost and that can be conveyed at zero cost is knowledge that should be used.

Gallini's paper, in its own way, gets at the cost of patent races alluded to above. Invention that can be monopolized even for a finite period of time represents a prize worth fighting for. But if only one party can win or, in Gallini's case, if multiple parties can win, but not fully, there can be too much effort put into invention. Again, what's privately optimal can be socially undesirable.

The classic example of such *rent seeking* is referred to as *the Tragedy of the Commons*. In this case, there is a common field that shepherds can use to graze their flocks. But since no one owns the commons or cares about the degree to which the grazing of his sheep limits the grazing of other people's sheep, we end

Once the current patent expires, the generic can move up. But when he does, he finds that the top-rung innovator has innovated to an even higher rung, the position of which is temporarily protected by a new patent.

up with overgrazing. In the extreme, there can be so much overgrazing that no one benefits from the commons — a real tragedy. Similarly, if extending patent length too long makes the prize of coming up with the winning invention so great, far too many would-be inventors will abandon their other pursuits and try to strike it rich. The resulting gold rush can lead to collective (social) costs that entirely wipe out the social benefit from the invention.⁴⁹

Gallini's paper provides yet another deep insight into the problem of excessively long monopoly protection. She points out that extending patent life beyond the socially optimal length may actually be counterproductive in terms of incentivizing innovators to invent. The reason is that an innovator, call her X, will realize that if she wins the patent race, her competitors will know that waiting until her patent expires is waiting too long and that the only way to play is to innovate around her patent. In thinking this through, X will realize that having longer life on a patent that others are going to invent around is like having a very short patent that others will not invent around; i.e., it's like having little incentive to invent in the first place. Gallini summarizes this point by stating "Extending patent life ... may not provide the inventor with increased incentive to research or patent the innovation."

Limiting Monopoly Protection to Increase Economic Efficiency

If less monopoly protection can be more when it comes to stimulating invention, the same holds true when it comes to improving economic efficiency. In his fundamental paper on optimal patent life, William Nordhaus argues that "the optimal life for drastic process inventions seems to be very small, in the order of one-tenth of the actual life of patents. The reason for the very

48 Gallini, Nancy T., "Patent Policy and Costly Imitation," *Rand Journal of Economics*, 23 (1), Spring 1992.

49 Philip Aghion and Peter Howitt in their 1992 *Econometrica* 60, 2, March 1992, pp. 323 – 51 paper titled "A Model of Growth through Creative Destruction" refer to the waste of resources in patent races as "business stealing."

small (optimal) life seems to be that drastic inventions are very important inventions and thus have a great deal of potential deadweight loss if they have long life.”⁵⁰

Drastic inventions refer here to inventions that lead to major reductions in the prices facing consumers once patent protection terminates. But the fact that the true economic cost for consumers of consuming a product is quite low means they should be consuming a lot of it. But with extended monopoly protection this doesn’t happen, or at least doesn’t happen for a very long time. The resulting consumer loss in welfare is called a deadweight loss.

Glenn Loury reaches a similar conclusion to Nordhaus, but in a more realistic setting in which the overall economy’s conditions change when patent policy is modified. Loury states, “Social welfare can be maximized by appropriately limiting entry and firm investments with licensing fees and finite patent life.”⁵¹

Conclusion

Biologic medications hold enormous promise for improving Americans’ health and well-being. Fulfilling that promise requires making sure that all Americans are able to access these medications at affordable prices within a reasonable period of time from their discovery. It also requires ensuring that tomorrow’s biological breakthroughs are able to build on today’s.

Biologic medications hold enormous promise for improving Americans’ health and well being. Fulfilling that promise requires ensuring that all Americans are able to access these medications at affordable prices within a reasonable period of time from their discovery.

Legislation now pending in Congress offers hope to millions of Americans that more affordable versions of biologic medications will soon become available through a competitive marketplace. But exclusivity provisions in three of the four main biogenics bills significantly undermine the legislation’s objectives. These provisions constitute uncontestable grants of monopoly rights by government fiat — something that runs far afield of traditional U.S. patent policy. The provisions would substantially extend the duration of monopoly protection of brand biologic medicines and, thereby, materially delay the arrival of low-cost generic alternatives. These conveyances of exclusive marketing rights not only exclude competing biologic companies from entering the market

with low-cost alternatives for extended periods of time. They also exclude other innovators from building, in a timely manner, on the stock of prior knowledge, much of which was accumulated at public expense. These bills also fail to anticipate and prevent evergreening under which brand companies can obtain repeated periods of exclusivity and monopolize biologic medicines essentially indefinitely.

New medications that alleviate or cure terrible disease are such remarkable gifts to humankind that we must continue to appropriately reward true innovation in this field. But the new drugs of today are not those of tomorrow. And today’s inventors are generally not tomorrow’s. The reason is clear. Today’s inventors have strong incentives to protect their discoveries, not make new ones whose arrival on the market would undermine their existing profits and market share. And, as numerous papers in the economics literature on invention and monopoly protection point out, over-extending monopoly protection can easily boomerang. It may do little or nothing to incentivize new discovery and simply delay when the next discovery comes on board. *In this case, providing greater incentive to innovate leads to less, not more, innovation over time.*

Without question, the American biologics drug industry is a golden goose, which is advancing the healthcare of our citizens. The presumption of many is that feeding this goose more and more will lead it to produce an ever-greater number of eggs at a faster pace. But doing so is very dangerous. After all, why should the goose produce as much when it has less incentive, and why should anyone look for a better goose if the current one cannot be displaced?

Fortunately, we don’t need to guess how much to feed the biologics goose. Its chemical cousin — the pharmaceutical goose — is, from all appearances, essentially identical in its diet and response to incentives. What works for the pharmaceutical goose will surely work for the biologics one. And what works for the pharmaceutical goose in promoting and protecting innovation is the Hatch-Waxman legislation — a bill whose exclusivity provisions are sufficiently balanced as to not over-extend the duration of monopoly protection.

Close to a quarter of a century’s experience speaks clearly. Hatch-Waxman provides its goose with a balanced diet — one that provides brand companies with appropriate incentives to develop and market their products, one that permits competitors to lower pharmaceutical prices to the public in a timely manner, and one that keeps new pharmaceutical discoveries coming at a rapid pace.

50 Nordhaus, William D., “The Optimal Life of a Patent,” Cowles Foundation paper no. 2421, Yale University, November 27, 1967.

51 Loury, Glenn C., “Market Structure and Innovation,” *The Quarterly Journal of Economics*, 93, 3, August 1979, 395–410.

Appendix: Industry Beta and Risk-Adjusted Cost of Equity

Industry Name	Firms in Sample	Beta	Beta/ Mean Beta	Cost of Equity	Cost of Equity/ Mean Cost of Equity
Market	7364	1.24	1.00	10.8%	1.00
Semiconductor	138	2.59	2.09	20.4%	1.89
Semiconductor Equipment	16	2.51	2.02	19.8%	1.83
Wireless Networking	74	2.2	1.77	17.6%	1.63
E-Commerce	56	2.08	1.68	16.8%	1.55
Entertainment Tech.	38	2.06	1.66	16.6%	1.54
Telecom. Equipment	124	1.98	1.60	16.1%	1.49
Internet	266	1.97	1.59	16.0%	1.48
Steel (Integrated)	14	1.97	1.59	16.0%	1.48
Manuf. Housing/RV	18	1.92	1.55	15.6%	1.45
Power	58	1.87	1.51	15.3%	1.41
Computers/Peripherals	144	1.86	1.50	15.2%	1.41
Pharmaceuticals	368	1.78	1.44	14.6%	1.35
Coal	18	1.71	1.38	14.1%	1.31
Steel (General)	26	1.71	1.38	14.1%	1.31
Precision Instrument	103	1.66	1.34	13.8%	1.28
Securities Brokerage	31	1.66	1.34	13.8%	1.28
Homebuilding	36	1.64	1.32	13.6%	1.26
Advertising	40	1.6	1.29	13.4%	1.24
Retail Automotive	16	1.58	1.27	13.2%	1.22
Cable TV	23	1.56	1.26	13.1%	1.21
Computer Software/Svcs.	376	1.56	1.26	13.1%	1.21
Auto & Truck	28	1.54	1.24	12.9%	1.20
Recreation	73	1.54	1.24	12.9%	1.20
Entertainment	93	1.53	1.23	12.9%	1.19
Chemical (Basic)	19	1.52	1.23	12.8%	1.18
Biotechnology	103	1.51	1.22	12.7%	1.18

Source: author's calculations based on betas posted 1/08 by Aswath Damodaran, NYU Professor of Finance at http://pages.stern.nyu.edu/~adamodar/New_Home_Page/datafile/Betas.html. Cost of equity is calculated as $.02 + \text{beta} * (.091 - .02)$, where $.02$ is the risk-free real rate (based on prevailing TIPS yields) and $.091$ is the average annual real return on large-cap equity calculated from Ibbotson data from 1926 to the present.

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