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"NAPSTERIZING" PHARMACEUTICALS: ACCESS, INNOVATION, AND CONSUMER WELFARE

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ABSTRACT

We analyze the effects on consumers of an extreme policy experiment -- "Napsterizing" pharmaceuticals -- whereby all patent rights on branded prescription drugs are eliminated for both existing and future prescription drugs without compensation to the patent holders. The question of whether this policy maximizes consumer welfare cannot be resolved on an *a priori* basis due to an obvious tradeoff: While accelerating generic entry will yield substantial gains in consumer surplus associated with greater access to the current stock of pharmaceuticals, future consumers will be harmed by reducing the flow of new pharmaceuticals to the market.

Our estimates of the consumer surpluses at stake are based on the stylized facts concerning how generic entry has affected prices, outputs, and market shares. We find that providing greater access to the current stock of prescription drugs yields large benefits to existing consumers. However, realizing those benefits has a substantially greater cost in terms of lost consumer benefits from reductions in the flow of new drugs. Specifically, the model yields the result that for every dollar in consumer benefit realized from providing greater access to the current stock, future consumers would be harmed at a rate of three dollars in present value terms from reduced future innovation. We obtain this result even accounting for the stylized fact that after generic entry branded drugs continue to earn significant price premia over generic products and hence recognizing that Napsterizing does not completely eliminate the incentives to innovate.

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1. Introduction

A significant ongoing public policy debate focuses on consumer access to prescription drugs and, more particularly, on how long branded drugs should be protected from generic competition. Since 1984 competition between branded drugs and generics in the U.S. has been framed by legislation known as the Hatch-Waxman Act, which both reduced the regulatory burden on generic drugs seeking to enter the market after patents expire and established mechanisms to extend the effective patent life of new drugs.[1] The experience since implementation of the law indicates that the manufacturers of generic drugs set prices significantly lower than the prices charged by the manufacturers of brand name drugs while under patent.

In a context where it is manifestly clear to all concerned that the price of patented drugs is high relative to marginal cost, it is not surprising that the policy debate features the conflict between consumer welfare and manufacturer profits. In this study, however, we evaluate the issues solely from the point of view of *consumer welfare*. Relative to the standard welfare analysis, this narrower focus underscores the fundamental nature of the tradeoff involving consumer interests. More specifically, we analyze the effects on consumers of an extreme policy experiment -- "Napsterizing" pharmaceuticals[2] -- whereby all patent rights on branded prescription drugs are eliminated for both existing and future prescription drugs without compensation to the patent holders. We integrate into our framework important insights from prior research into the nature of the competition between branded drugs and their generic counterparts, as well as the process by which new chemical entities (NCEs) are developed.

The question of what policies maximize consumer interests cannot be resolved on

an *a priori* basis due to an obvious tradeoff: While accelerating generic entry will yield substantial gains in consumer surplus associated with greater access to the current stock of pharmaceuticals, future consumers will be harmed by reducing the flow of new pharmaceuticals to the market.[3] To gain insight into the debate, it is necessary to quantify the static welfare benefits, i.e., the increase in consumer surplus from providing greater access to prescription drugs now available, and the dynamic welfare benefits, i.e., the consumer surplus from the prospective flow of new prescription drugs. Underlying the policy question are fundamental issues such as the optimal degree of intellectual property protections and the extent to which markets offer incentives to innovate.

In Section 2 of the paper we review various findings and stylized facts from prior research that we use to specify elements in our structural analysis. These elements include (a) the effects of generic entry on prices, market shares, and profits, (b) the economics of the research and development process, (c) effects of prescription drugs in improving health, and (d) the estimated values consumers realize from improved health. In Section 3 we present a simple model of the pharmaceutical market that illuminates the nature of the basic tradeoff. For example, we identify the specific components of the gains in consumer surplus realized when generics enter.

In the balance of the paper we develop two complementary structural models to measure the tradeoff in consumer welfare associated with eliminating patents on pharmaceuticals. In Section 4 we specify in detail the static benefits from lower prices on existing drugs and the dynamic losses from reductions in future innovation caused by accelerating generic entry. Our estimates of the consumer surpluses at stake are based on the stylized facts concerning how generic entry has affected prices, outputs, and market

shares. We find that providing greater access to the current stock of prescription drugs would yield large benefits to existing consumers in absolute terms. However, realizing those benefits has a substantially greater cost in terms of lost consumer benefits from reductions in the flow of new drugs. Specifically, the model yields the result that for every dollar in consumer benefit realized from providing greater access to the current stock, future consumers would be harmed at a rate of three dollars in present value terms from reduced future innovation. We obtain this result even accounting for the stylized fact that after generic entry branded drugs continue to earn significant price premia over generic products and hence recognizing that Napsterizing does not completely eliminate the incentives to innovate. Nevertheless, the absence of an extended period of market exclusivity reduces incentives to innovate and ultimately denies future consumers benefits that far exceed the gains to current consumers from lower prices on the stock of drugs already on the market.

These results obtained in Section 4 presume the linkages between the underlying demand for health and the derived consumer demand for drugs. In contrast, in Section 5 we gauge the consumer surpluses involved using a health production function model that makes explicit the relationships among pharmaceutical innovations, improved health, and consumer demand.[4] While this analysis yields higher absolute values for the gains in consumer surplus from lower prices and the losses from reductions in the flow of future NCEs, the results corroborate that accelerating generic entry harms consumers on net.

One implication of our 3:1 tradeoff is that that current policy offers sub-optimal patent protection. This implication in turn is consistent with a significant literature that establishes that public policies tend to be fashioned in light of the interests of groups that

are identified and well-organized.[5] There is an obvious risk that actual and potential consumers of currently available prescription drugs will have a greater voice than unidentified potential consumers of prescription drugs not yet on the market. While we will refrain from speculation about related policy issues in the software and entertainment industries, a similar framework could be applied to analyze the effects of "Napsterizing" these other markets.

2. Stylized Facts concerning Generic Competition, the Innovation Process, and Consumer Benefits

a. *Generic Competition*

Prior to the passage of the Hatch-Waxman Act in 1984, generic producers had to independently establish the safety and efficacy of their products by conducting costly clinical trials.[6] The legislation streamlined this process by substituting a requirement that generic entrants establish only bioequivalence with the existing drug. With the regulatory protection for brand name manufacturers significantly reduced, patent protection became the principal means by which incumbents maintained their market exclusivity.[7] The Hatch-Waxman Act also established complex rules governing the resolution of patent disputes as well as defining the effective patent life during which time a branded drug enjoys market exclusivity.[8]

For our purposes it is important to identify the effects of the legislation on effective patent life and to understand the effects of generic competition. Regarding the former, the static welfare gains from earlier generic entry will be greater the longer the effective patent life. Conversely, shorter patent periods will increase the total gains from an innovative drug because generic competition for that drug will occur earlier. We have

reviewed all NCEs coming to market in recent years and report the results concerning effective patent life in Table 1. The data show (a) that newly approved NCEs have come on to the market with about eight to ten years of effective patent life or market exclusivity, and (b) that since 1997 the average exclusivity periods for newly approved NCEs have declined. Average durations range from 6.5 to 9.1 years for NCEs approved during 2001, for example, compared to a range of 10.8 to 13.4 years for NCEs approved in 1997. One factor contributing to the change during this period is that clinical tests have taken longer in recent years due to the focus on more complex chronic diseases.[9]

Table 1
Average Patent and Exclusivity Periods for
NCEs Approved During 1997-2001

Year	Shortest Duration*	Longest Duration**
1997	10.8	13.4
1998	13.0	15.0
1999	8.6	10.2
2000	8.3	11.9
2001	6.5	9.1
Average, 1997-2001	9.8	12.3

*Average number of years between the NDA approval and the earliest possible patent (or exclusivity) expiration.

**Average number of years between the NDA approval and the latest possible patent (or exclusivity) expiration.

Sources: U.S. Food and Drug Administration, Drug Approvals; List, 1997-2001. U.S. Food and Drug Administration, Electronic Orange Book.

Once patents do expire, all major branded drugs attract generic competition.[10] As of 2001 generic drugs accounted for 42 percent of total prescriptions.[11] There is uncertainty about how total prescription drug revenues are divided between patented and

unpatented—generic plus off-patent branded—drugs. We estimate that of the approximately $208 billion dollars in prescription drug sales for 2001,[12] the share of branded drugs under patent probably accounts for 75 to 80 percent of the total revenues with the balance accounted for by generics and branded drugs without patent protection.

The competition between branded and generic drugs has been the subject of much research. Grabowski and Vernon (1992) examine the effects of generic entry on prices and market shares using a sample of 18 drug products during the period 1984-1988. Grabowski and Vernon (1996) update their earlier study, bringing the sample period forward to 1993. These and other studies confirm that once multiple generic manufacturers enter, they typically price their drugs at discounts of 70 to 90 percent below the incumbent's price prior to entry. This observation implies that the ratio of price to marginal cost for branded drugs with patent protection is about 6:1, and also implies that the elasticity of demand prior to generic entry is about –1.2.[13]

A noteworthy finding from the studies by Grabowski and Vernon is that the brand name producers did not typically cut their prices in response to generic entry and indeed that incumbents raise their real prices post entry. This finding in turn reveals that consumers are not homogeneous and, more specifically, that they differ in their willingness to pay a premium for the branded product. Thus, incumbents decide to cede the bulk of the market to generics and retain the relatively small brand loyal segment. In their later study, Grabowski and Vernon found more rapid decreases in brand name market share following generic entry.[14] Within a year of generic entry, market shares of the incumbents typically fall to about twenty percent.[15]

Grabowski and Vernon found that erosion of the branded manufacturer's market

share accelerated over the course of their 1992 and 1996 studies. Generics introduced in the period 1984-85 garnered 45 percent of the market after two years, while those introduced in the period 1989-91 gained on average 59 percent of the market.[16] This trend towards faster generic penetration has continued, with market shares of incumbent manufacturers now falling to 20 percent or less within a year of generic entry.

The facts that the branded drugs continue to capture a non-trivial market share and command price premia in the face of generic competition indicate that the prospective returns to innovators would not be completely eliminated even if patent rights were voided. In addition, a new branded drug, even without patent protection, would likely enjoy a period of *de facto* market exclusivity, perhaps in the range of a year, due to the time required to establish that the generic product is bio-equivalent to the pioneer substance. Our subsequent analysis incorporates these insights regarding price-cost margins, demand elasticity, and the extent of market exclusivity.

b. The Innovative Process and the Role of Patents

The effects of generic competition on the innovative process are not transparent in part due to the complicated underlying scientific and approval processes and the uncertainty about the value of potential outputs relative to the research and development (R&D) costs. Before submitting a New Drug Application (NDA) to the Federal Drug Administration (FDA), the manufacturer must have completed Phase 1 and Phase 2 clinical trials. The NDA is typically submitted as the large scale Phase 3 clinical trials are well underway.[17] The FDA may place a clinical hold on these trials at any time if it believes the study is either unsafe or deficient in design. The average drug takes twelve years to develop and test, with up to an additional two years for FDA approval.[18]

Although there is considerable debate about the average cost of developing a new drug, recent studies estimate that the cost of bringing an NCE to market can range from $600 million to $800 million.[19] The screening process for new drugs is such that, according to this same study, out of every 5,000 chemicals tested in animals, only five ever go on to human clinical testing, and of this five only one ever goes onto the market.

The time needed to complete clinical trials has lengthened in recent years. One study attributes this lengthening to the increasingly complex diseases being treated. Chronic and degenerative diseases pose particularly difficult problems, as less is known about the operation of such afflictions.[20] However, the time needed for FDA review has shortened as the median length of FDA review has fallen from 32 months in 1986 to under twelve months in 1999.[21]

Grabowski and Vernon (1992) explored the inhibiting effects of generic competition on innovation with a simulation analysis. They evaluated the effects of generic penetration on two types of research and development: "pioneering" research efforts with high risks and high returns and "imitative" efforts to develop compounds similar to commercially successful products. They find that an increase in the equilibrium generic penetration rate from 10 percent to 50 percent significantly reduces the returns to research and development and so reduces investments in these efforts.[22] Grabowski and Vernon's simulation results suggest as well that these adverse effects of generic penetration may be offset with relatively modest increases in effective patent life for new drugs. Effective patent life can be increased either directly by extending the number of years of patent protection, or indirectly by reducing the time to regulatory approval. Reductions in regulatory approval times are somewhat more effective in

increasing cash flow as these reductions add years to the less heavily discounted beginning of the product lifecycle, rather than the end.[23]

Jensen (1987) examined the relationship between research and development expenditures and drug discoveries. Using a sample of 28 pharmaceutical firms during the period 1969 through 1979, she finds a positive correlation between research expenditures and the probability of discovering a new drug and estimates the elasticity of the arrival rate of new drugs with respect to research expenditures for various firms. Jensen found that firm size had no particular impact on the marginal productivity of research expenditure. Larger firms spend more on research and development, but once this is controlled, a research program is no more likely to be successful in a large firm as opposed to a smaller firm. Another finding is that increasing regulatory delay in approving new drugs decreases the number of new chemical entities discovered per year. Finally, Jensen found that the probability of discovering a new drug decreased over the sample period. Continuation of this trend in subsequent years could explain the large increase in recent years in the cost of discovering and introducing new drugs. While these results predate both the Hatch-Waxman Act and the substantial consolidation of research pharmaceutical companies during the 1980s and 1990s, her results at a minimum establish a direct relationship between research and development efforts and the number of NCEs.

Henderson and Cockburn (1996) also examine the relationship between firm size and research productivity using overall firm level data and investments in particular research programs. The structure of their data allows them to test for the presence of both economies of scale and economies of scope. They, like Jensen, do not find evidence

of returns to scale. The elasticity of significant patentable discoveries is roughly the same across different sized firms. The authors also evaluate the effectiveness of individual research programs within the firms and again find no evidence of economies of scale in the individual research program. Size of the research program is, if anything, negatively correlated with research productivity. However, the research program level data reveals evidence of both economies of scale and scope at the firm level. That is, the size of the firm in which the program is located will affect research productivity, with more productive research programs located in larger firms. They also find substantial economies of scope, such that moving a research program from an average firm to one with an additional active research program will raise its productivity by around 15 percent.[24]

Henderson and Cockburn also develop the argument that the greater research productivity of large firms is due at least as much to economies of scope and the resulting spillovers of knowledge from program to program as it is to economies of scale. Larger firms appear to be better able to develop and exploit these knowledge spillovers. The authors emphasize, however, that idiosyncratic effects (the firm's identity, the specific program, and the specific therapeutic class) are more influential than economies of scale and scope.

c. *Innovation and Health*

Life expectancy in the U.S. rose in the last century by more than any period in history.[25] A relevant issue for our analysis is, of course, the extent to which pharmaceutical innovations contributed to the gains and how much future innovations

can further add to longevity. Lichtenberg (2002) examined these questions, focusing on the rise in U.S. life expectancy from 69.7 to 76.5 years over the period 1960 to 1997, and modeled longevity as the dependent variable in a health production function that includes medical technology, medical innovations, and expenditures.[26] In principle, all medical innovations contribute to improvements in health status, but Lichtenberg includes only pharmaceuticals as it is the only category for which there are reliable data.[27] He finds that both health expenditure and medical innovation contributed significantly to the observed increase in longevity. Public medical expenditure yielded additional life expectancy, presumably by targeting poorer populations where it was especially effective. However, the results indicate that while approximately $11,000 in medical expenditures is required to gain one life-year, $1345 in pharmaceutical research and development is needed to yield the same benefit.

Regarding the value of continued innovation, Lichtenberg (2001) explores the efficacy of newer branded drugs relative to drugs off patent in treating particular conditions. Using the 1996 Medical Expenditure Panel Survey (MEPS), which contains information on patients and their medical conditions, the results indicate that the substitution of new drugs for older drugs led to significant reductions in patient mortality and morbidity, as well as in total medical expenditure. While the results indicate reductions in all types of non-drug medical expenditures, the largest benefit came from inpatient expenditure. Lichtenberg's estimates show that the total reduction in non-drug health expenditure exceeds the increase in drug expenditure by a factor of four, leading to large savings in the cost of treating a particular illness. He finds significant benefits to introducing new drugs and concludes that restricting access to newer, branded drugs in

favor of older, generic drugs would be misguided. Not only would total treatment costs increase, but medical outcomes would also worsen.

d. *Consumer Benefits*

The extent of consumer benefits from increased longevity and improved quality of life depend on consumer valuation of these benefits, and also on their cost. Murphy and Topel (1999) evaluate consumers' willingness to pay for improvements in medical knowledge using an expected present value of lifetime utility framework. Given that measures focusing only on earned income will undervalue improvements in longevity gained by the non-working elderly, their framework includes willingness-to-pay measures for market and non-market time. Total valuations increase proportionately with both wealth and population. Age is a factor as well. Advances in Alzheimer's disease research are more valuable to the elderly, whose need for such advances may be more imminent, than to younger individuals who would discount the future gains more heavily. Medical progress against specific diseases is also complementary. The greater is life expectancy, the greater is the lifetime probability of contracting other ailments. The higher the survival rate at any particular age, the more individuals who can benefit from increases in longevity. In contrast, when remaining life expectancy is low, consumers will not place much value on increases in survival rates.

Murphy and Topel, using value of a statistical life of $5,000,000,[28] estimated the dollar value the U.S. population realized from the dramatic reductions in death rates between 1970 and 1990 and the associated gains in longevity. The estimated annual value of $2.8 trillion each year is nearly one-half of GDP. Over half of this value,

approximately $1.5 trillion, comes from the reduction in death rates from heart disease alone.

The value to the U.S. population from improvements in life expectancy dwarfs the increase in health expenditures over the same period, and so indicates that the consumer surpluses realized are significant. Indeed, if all medical expenditures are directed towards increasing longevity, then current annual expenditures of approximately $1.2 trillion are a bargain, returning over 100 percent annually in increased longevity. The annual value of gains in longevity is expected to grow in real terms in the future, as the U.S. population ages, (making progress against specific diseases more valuable), as life expectancy grows, (making complementary disease reductions more valuable), and as the U.S population grows and becomes wealthier (spreading the gains over more and wealthier individuals).

In contrast to the overall consumer surpluses from medical innovations, the extent of consumer gains from new drugs (given their additional costs) is more difficult to estimate. Lichtenberg (2001) examines the benefits and costs associated with substituting newer, usually patented, drugs for older, generic drugs. Adoption of newer drugs is shown to be the largest single contributor to increasing drug expenditure. Industry sources estimate that of the 14.7 percent increase in drug expenditures in 2000, only 3.9 percent was due to price increases on existing products and the remainder is due to substitution of newer drugs as well as increased overall utilization.[29] What is unclear is how much of the price increase due to the substitution of newer, more effective drugs represents increases in quality. A study by Berndt, Cockburn and Grilliches (1996) examined the quality component of prices for the prescription antidepressant market.

Depending on time period studied, the authors found that substantial portions of the raw price changes in the antidepressant markets could be accounted for by improvements in the quality and effectiveness of the drugs.

3. "Napsterizing" Pharmaceuticals: An example

From the review in the previous section, we take as stylized facts that generic entry reduces returns to pharmaceutical R&D, which in turn will lead to fewer pharmaceutical innovations. Also, the evidence reviewed above indicates that such innovations have contributed to historic increases in life expectancy and that consumer valuations of those increases are substantial. This raises the question of whether facilitating generic entry will retard further increases in longevity, and in other health improvements in the quality of life, that depend on future innovation.

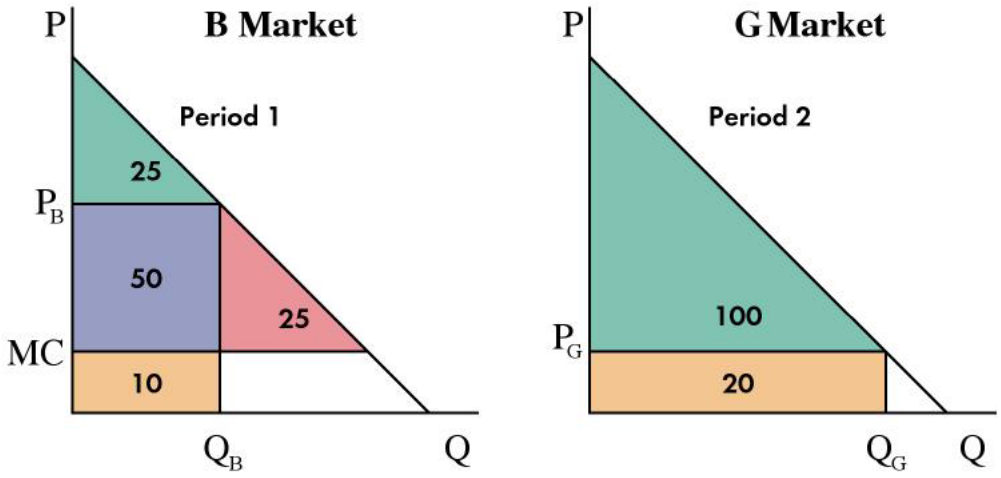
We now begin the analysis of the tradeoff between the benefits of providing consumers with greater access to the existing stock of available drugs and the consumer gains from future innovations. In this section we illustrate the effects of eliminating all patent protection on prescription drugs using an abbreviated example with the following characteristics. First, in the regime with patent protection, one new branded drug is patented in period one, goes off patent in period two, and then has no further value. Second, with patent protection, innovative firms develop one new drug that replaces the obsolete drug in each period, so as to maintain a steady state whereby the number of drugs on patent is constant. Third, we assume the social discount rate is zero. Fourth, in contrast to the analysis in the next section, there is no "brand loyal" consumer segment once a branded drug goes off patent. Finally, we assume that if patent protection is eliminated, the generics are able to enter immediately.[30]

Therefore, the example features two markets. The branded drugs under patent are sold in segment B and drugs lacking patent protection (generic and off-patent brand name drugs) are sold in segment G. The life cycle for a new drug is two periods, such that a drug invented and sold under patent in period 1 loses that protection in period 2. Thereafter, the drug has no market.

Using the stylized facts concerning the ratio of price to marginal costs, the manufacturer of the branded product under patent will set a price in period 1 of P_B that is six times the marginal cost. The elasticity of demand at the selected price is -1.2. Assuming that the demand curves in both markets are linear, identical, and constant over time, Figure 1 illustrates the life cycle of a new drug. Revenues in the brand name, protected segment ("B Market") equal 60. Average and marginal costs (i.e., excluding the research and development required to bring the product to market) are one-sixth of revenues, or 10, so that the contribution (i.e., the difference between revenues and variable costs) is 50. This contribution, by assumption, creates a sufficiently strong incentive to sustain the steady-state flow of new drugs.

Figure 1

Drug Life-Cycle: Two Period Case



The sales of the branded drug in period 1 generate consumer surplus of 25, defined according to standard methodology as the difference between the total consumer valuation of Q_B, which equals 85, and the expenditures by consumers of 60. The gap between price and marginal cost generates the monopoly welfare loss of 25. These losses are associated with the consumers who value the branded drug in excess of marginal costs, but less than P_B; if these additional sales were to take place at prices less than P_B, consumers would realize gains from trade.

In period 2, when the branded drug loses its patent protection and generics are introduced ("G Market"), price falls to marginal cost and output rises to Q_G. With the linear demand curve and constant marginal cost, output Q_G is twice that of Q_B, and the total variable costs associated with the higher output will equal 20. With the price decrease from generic competition, consumer surplus increases to 100. The gain in consumer surplus comes from the transfer of contribution (producer surplus) to consumers and the elimination of the deadweight loss. With the zero discount rate the

total consumer surplus generated by the innovative drug over its useful life is 125.[31]

Figure 2 illustrates the dynamics over four periods. We see that the total consumer surplus generated over four periods equals 400, three-fourths of which is generated in the "G", or generic market. Periods 2 through 4 present the steady state results. In each of these periods, annual consumer surplus is 125, and the total over the three periods is 375. This result provides a baseline for evaluating the effects of eliminating patents. If the social discount rate were equal to 2% and the steady state lasted forever, the present value consumer surplus of the status quo in our example would be 6250.

Figure 2

Drug Life Cycle: Four-Period Case

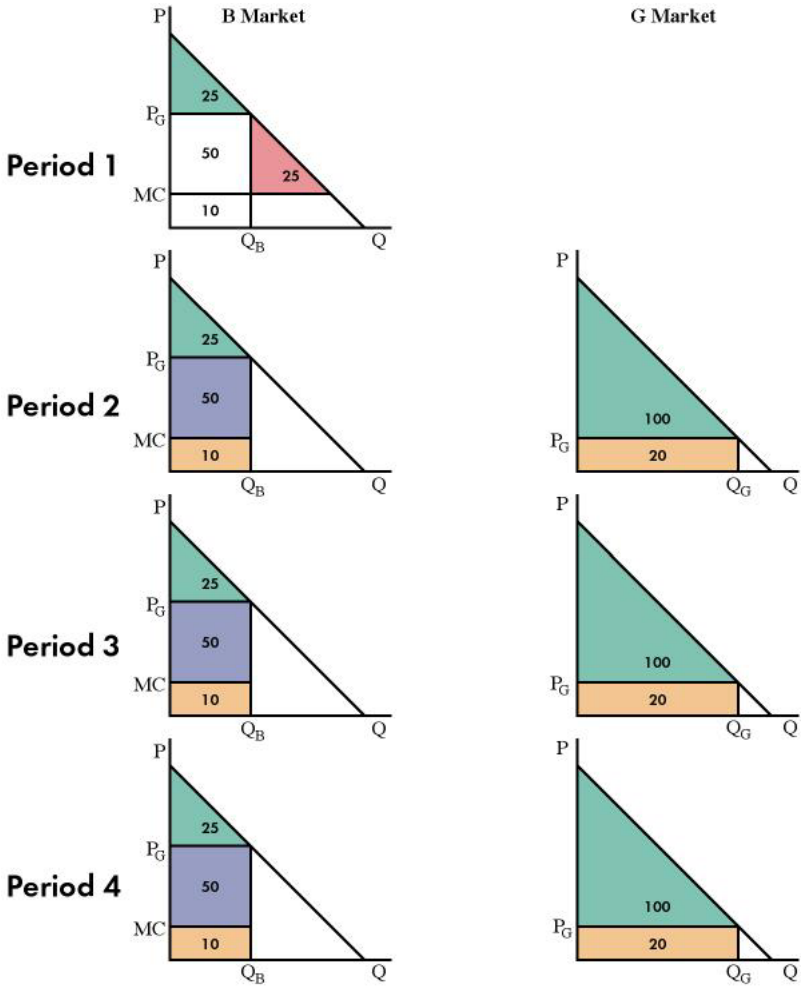
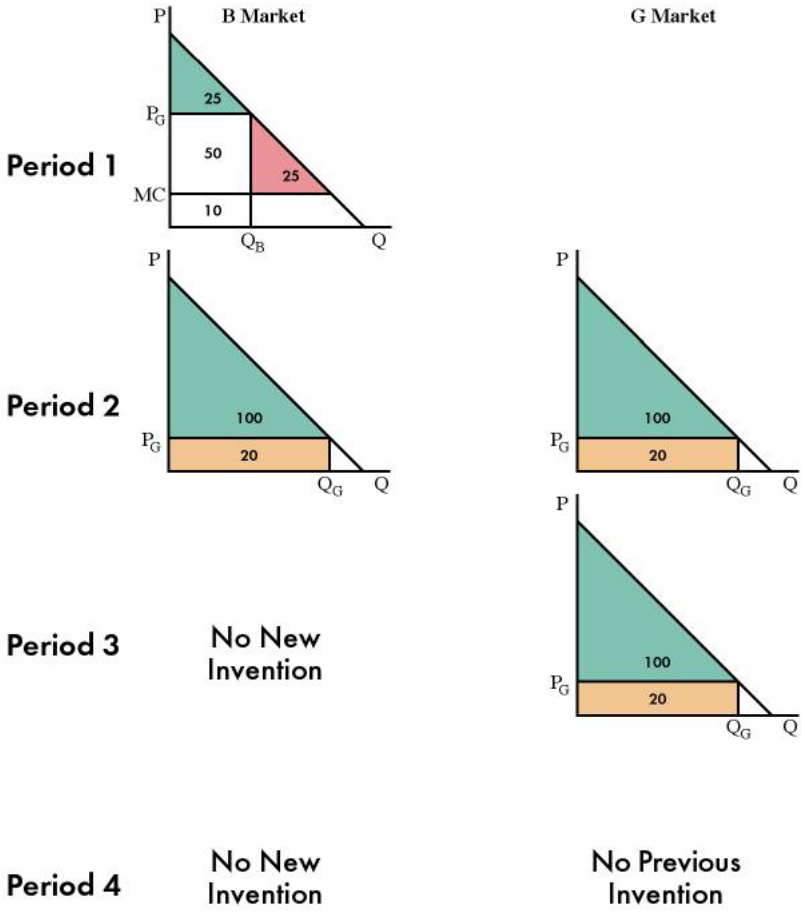


Figure 3 illustrates the situation where patent protection is eliminated at the outset of period 2. In this case, the branded, "B" market becomes identical to the generic, "G" market. By assumption, the period 2 innovative drug is now immediately available at marginal cost and consumer surplus for that product in period 2 rises from 25 to 100 for a gain of 75. Also in period 2, consumers realize surplus of 100 on the period 1 invention that has moved to the generic segment. In period 3 the absence of the incentives from patent protection means that there is no innovation. The drug introduced in period 2 is still available and consumers gain another 100 in surplus. In period 4 no consumer

surplus is realized.

Figure 3
The Effects of Napsterization



In sum, with full access in period 2, the total consumer surplus over periods 2 through 4 falls from the baseline of 375 to 300.[32] Clearly, extending the example to longer time horizons would increase the net loss from the Napsterization policy.

It is useful to consider more generally the assumptions underlying this simple example. The length of market exclusivity for innovative drugs, the life cycle of each drug, and the discount rate are important in the analysis. How would changes in these factors affect the calculations? For example, as the period of patent protection shortens,

the static gains from Napsterizing are reduced. Our analysis in Section 4 is more detailed in such respects and includes sensitivity checks of the major determinants of the tradeoff.

4. Measuring the Tradeoff in Consumer Welfare

Our analysis is based on stylized facts drawn from the research literature and from other public sources. We calculate the changes in consumer surplus from eliminating patents on all branded drugs using the following parameters:

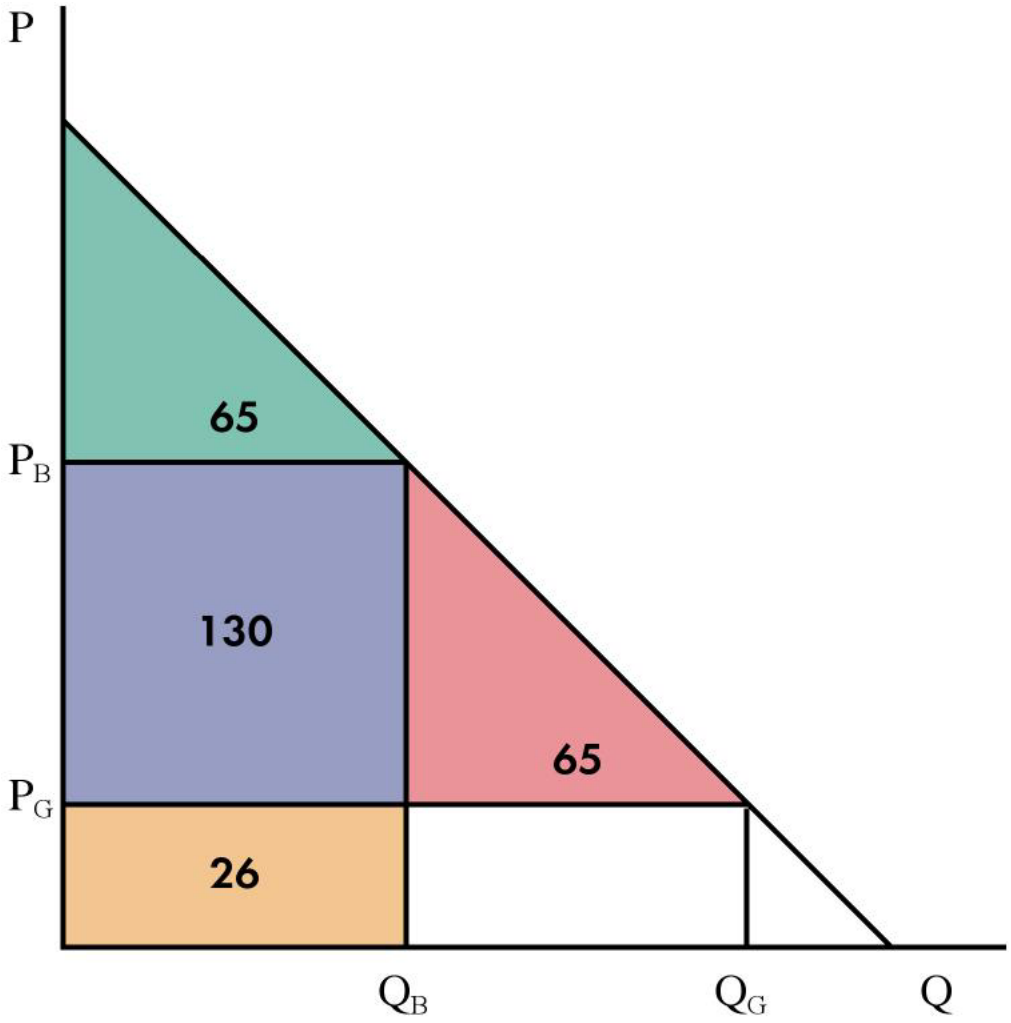
1. Sales of pharmaceutical products in 2001 equaled $208 billion.[33] Approximately 75% of the sales revenue goes to branded drugs that are still on patent.
2. Newly patented new drugs, on average, have market exclusivity for a period of 9 years.[34] The average economic lifetime of new drugs is 25 years.[35]
3. During the period of market exclusivity, the ratio of price to marginal cost is 6:1. With profit-maximizing behavior, the demand elasticity will therefore equal -1.2.
4. Once a drug goes off patent, generic drugs are priced at one-sixth the incumbent's price and gain an eighty percent market quantity share. The non-patented branded drug retains a twenty percent market quantity share and its price does not change in real terms.
5. The real discount rate is 2%.[36] We also assume zero real growth in the size of the market.[37]
6. An innovative firm will invest in research and development efforts at a level that depends on realized contribution on sales of successful drugs.[38]

Contribution is the difference between revenues and variable costs. To parameterize the model we assume that R&D expenditures equal 15% of contribution.[39]

With these parameters, our first step is to measure consumer surplus under the *status quo*, i.e., with patent protection. Consumers derive surplus from two sources: the sale of branded drugs under patent and the sale of drugs off patent. Regarding the former, in the U.S. the annual sales of branded drugs under patent are $156 billion, roughly three-fourths of the annual expenditures on prescription drugs. For the patented drugs, manufacturers gain producer surplus or contribution equal to five-sixths of revenues, or $130 billion.[40] [41] With linear demand and monopoly pricing, consumer surplus equals one-half of the contribution.[42] Thus, with contribution of $130 billion, the annual consumer surplus generated in the patent-protected market equals $65 billion. At this market equilibrium, there is a welfare loss due to the fact that prices exceed marginal cost and this loss, $65 billion, equals the consumer surplus realized. This situation is illustrated in Figure 4.

Figure 4

Estimated Consumer Surplus and Welfare Loss
Under the Status Quo



The other component of consumer surplus is derived from sales of off-patent branded drugs and their generic counterparts. Total annual expenditures currently equal $52 billion. Approximately 20 percent of the prescription volume represents sales of branded drugs that we assume are priced at the same level as under patent. The balance of 80 percent of the volume is met by generic producers, and is priced at marginal cost. Given the stylized facts listed earlier, revenues in the off-patent market will be split approximately 60-40 between branded and generic manufacturers. In particular, sales of

branded, off-patent drugs will yield $31 billion dollars in revenues, and generic sales $21 billion.[43]

We can derive consumer surplus in the brand loyal section of the off-patent market as was done before for the protected market, which yields contribution in the brand loyal segment of $25 billion (approximately), consumer surplus of $12.5 billion, and deadweight loss of $12.5 billion. Consumer surplus in the price sensitive (generic) segment of the market is calculated by first noting that marginal cost pricing implies zero profits, so that costs equal revenues of $21 billion. Suppose now that this segment of the market was monopolized. With linear demand, costs would equal ½ that amount, or $10.5 billion, sales would equal approximately six times costs, or $63 billion, and contribution $52.5 billion. Consumer surplus and deadweight loss would each equal $26.25 billion. Since this market is not actually monopolized, the entire area under the demand curve, which equals the sum of these three components, will be generated as consumer surplus in the generic segment of the off-patent market. Thus, the total welfare accruing from this segment is $105 billion.

With the patented and off-patent market components of annual consumer surplus, we can calculate the present discounted value of consumer surplus under the status quo. This is our baseline welfare level. Total surplus in the off-patent market is $117.5 billion (105 generic+12.5 branded). Combined with the surplus in the patent-protected market of $65 billion, total annual welfare in the pharmaceutical market under the status quo is $182.5 billion. If we assume this is a steady-state and the social discount rate is 2%, the lifetime consumer surplus associated with the status quo equals $9.1 trillion. Of this total, $3.2 trillion comes from drugs sold while protected, and $5.9 trillion from these

drugs once they go off patent.

We next compute consumer surplus and related measures generated by Napsterization. As indicated in Section 2, a critical issue is the extent to which innovative firms can continue to price above marginal costs and so realize contributions from their prior research and development efforts. While this contribution level certainly will be less than is earned under patent protection, the fact that some brand loyalty exists still provides an incentive to conduct research and development efforts, and we incorporate this fact into our analysis.

Graphically, the maximum potential consumer surplus attainable in one year equals the area under the demand curve and above MC in Figure 4. Since consumer surplus equal to ½ of the area of profit (π_t) already accrues to consumers before Napsterization, the net potential gain in consumer surplus equals $1.5\pi_t$.[44] Post-Napsterization profits of π_t^*, and the associated welfare loss of ½ of these profits, are deducted from this net potential consumer surplus figure to get the annual gains from Napsterization of $1.5(\pi_t - \pi_t^*)$. If we then discount this flow over the remaining life of the drugs now in place in the protected market, $\overline{T}$, beginning in year $\underline{T}$, and discount at $\delta\%$, we arrive at an estimate of the present value of the gains from Napsterization of

$$1.5\int_{\underline{T}}^{\overline{T}} (\pi_t - \pi_t^*)e^{-\delta t}\,dt.$$

Using the stylized data and our assumptions, the static consumer surplus gains from Napsterization are calculated as follows. The total potential annual consumer surplus associated with drugs going off patent is derived from the equilibrium where prices fall to marginal costs. As shown in Figure 4, this potential, including the consumer

surplus realized when the drugs were covered by patents of $65 billion , is $260 billion . Since consumer surplus of $65 was already in place, it is not relevant to the calculation, so the potential gain in consumer surplus is $195 billion. However, not all of that will be realized. Brand-loyal consumers will continue to pay prices above marginal costs and, based on the stylized fact of a 20% market quantity share for the incumbent, the branded manufacturers will earn contribution (producer surplus) of approximately $52 billion. The associated welfare loss of ½ this amount, or $26 billion also reduces the actual consumer surplus realized. The realized gain in consumer surplus per year will thus equal $117 billion. If the average remaining life of the drugs currently under patent is 10 years and the discount rate equal to 2%, the gains from Napsterization are approximately $850 billion. These gains, i.e., the static efficiency gain from Napsterizing pharmaceuticals, result entirely from accelerating generic entry in the market for existing, patent-protected drugs.

We now turn to the prospective losses in consumer surplus from reduced innovation. With the anticipated returns on research and development reduced, funds available for developing new drugs will be limited. This will manifest itself as reduced access to private capital due to higher required rates of return, or to reduced residual contribution available to fund R&D internally. Thus, future flows of consumer surplus will be curtailed by the reduced innovation. This will generate two sources of lost consumer surplus: the gains from new drugs while still on patent, and the gains due to the eventual generic provision of these new drugs in the off-patent market. Regarding the latter, it follows from the structure of the model that the consumer surplus earned in the off-patent market will equal approximately four times the consumer surplus generated by

innovative firms when the drugs were on-patent, less any residual profits and welfare losses[45]

Ironically, increasing generic access now will ultimately stem the future flow of new generic drugs. Fewer new patented drugs are invented now, meaning fewer generic drugs in the future. The ultimate question here is whether the static gains from unlimited immediate access to the yet to be developed existing stock are greater or less than the dynamic gains from invention of, and eventual access to, the future stock, which will be enhanced via some degree of patent protection, as in the status quo.

We compute the dynamic welfare losses by developing a simple model of research and development and innovation that is based on institutional and stylized facts. We utilize the following notation: research and development is a constant fraction (α) of contribution to profits (π), so that R&D expenditures equal $\alpha\pi$. With an annual rate of return to R&D of r%, the profits from new inventions are $\alpha\pi$r. As above, assuming linear demand and constant costs, consumer surplus during the period of patent protection will equal ½ of profits: CS = (½)$\alpha\pi$r. Thus, in the first T_P years of product life (average protected life of new drug) consumer surplus generated will equal:

$$V_{P_t} = .5\alpha r \int_0^{T_P} \pi_s e^{-\delta s} ds,$$

while in the period of useful life governed by generic competition, it will equal (where T_L is the total useful life of the product)

$$V_{G_t} = 2\alpha r \int_{T_P}^{T_L} \pi_s e^{-\delta s} ds.$$

Lifetime surplus from the inventions in each year t will then equal

$$V_t^* = V_{P_t} + V_{G_t}.$$

Using the data developed above and the relevant assumptions, contribution to profits in year t subject to losses from Napsterization are $130 billion. Research expenditures on this contribution would be $20 billion (15% of contribution), and profits from the new research and development approximately $3 billion (15% of R&D). Consumer surplus in each of the 9 protected years is one-half these profits, or $1.5 billion. The present value of this flow, for 9 years, at a real discount rate of 2%, is $13 billion.

Following the lapse of patent protection, the new invention will become generically available. Assuming that these flows begin in year 10, and last until year 25, the consumer surplus generated by generic sales of the new invention equals $3.5 billion per year, with present value over years 10-25 of $37 billion.[46] Thus, the new drugs introduced in any given year will generate $50 billion in consumer surplus over its life cycle. Assuming that the flow repeats itself every year, the present value of all future invention is simply the present value of a flow of $50 billion/year. At a discount rate of 2%, this equals $2.5 trillion. This is the dynamic efficiency loss from Napsterization.

Our earlier calculations showed that the lifetime consumer surplus generated by the status quo equals $9.1 trillion. With Napsterization, the static gains would increase benefits to $10 trillion. However, the lost invention in the future would offset this amount by $2.5 trillion, so that total lifetime surplus under Napsterization would equal $7.5 trillion, for a decline relative to the status quo of almost 20%.

Table 2 summarizes the main results of our analysis. The status quo generates lifetime benefits of over $9 trillion. These would be increased by an additional $ 0.8 trillion if access to protected existing drugs were granted. However, the costs of reduced

future innovation would be on the order of $ 2.5 trillion. Thus, our analysis indicates that, while the static gains in consumer surplus are substantial, they are dwarfed by the dynamic losses in consumer surplus that would result from Napsterizing. Comparing this figure to the static welfare gain of $850 billion, the marginal benefit/marginal cost ratio for maintaining the status quo, conditional on our assumptions, is approximately 3 to 1.

Table 2
Baseline Results for Status Quo
(in billions of dollars)

	Patent Protected Market	Off-Patent Market	Total Market for Pharmaceuticals
Revenues			
Branded	156	31	187
Generic	0	21	21
Contribution to R&D and Profits			
Branded	130	25	155
Generic	0	0	0
Consumer Surplus			
Branded	65	12.5	77.5
Generic	0	105	105
Annual Consumer Surplus	65	117.5	182.5
Present Value of Lifetime Consumer Surplus (real social discount rate = 2%)	3250	5875	9125
Present Value with no patent protection	750	6725	7475

Sensitivity Analysis

Our focus has been examining the balance between the benefits of the status quo, namely new drug innovation with patent protection and the eventual benefits of full access to currently protected existing drugs when their protection lapses, against its the costs of the status quo, the static consumer welfare losses resulting from patent protection. Our findings indicate that gains in consumer surplus realized from immediate

full access to the existing stock of drugs are outweighed in present value by losses due to foregone innovation by around 3 to 1. In this section, we adjust key parameters of our model to examine the sensitivity of our results to the model assumptions, and also to determine the parameter values at which the costs and benefits of Napsterization roughly balance—meaning that society would be indifferent to Napsterization in terms of consumer surplus.

To initialize the model, we set the key parameters at the following values:

Years of Useful Life	25
Years Exclusivity	9
Years to Enter	1
Real Discount Rate	.02
R&D/Contribution	.15
Rate of Return to R&D	.15
Post-Entry Branded Share	.20

These starting values correspond to the stylized facts described earlier and used in the baseline calculations. The results of the sensitivity analyses are interpreted as holding all of the other parameters at their initial values.

Patent/Exclusivity Period

The length of the patent/exclusivity period accruing to the brand name protected drug is a key determinant of the costs and benefits of Napsterization. As the length of the exclusivity period increases, consumers must wait longer for full access to the existing stock of drugs, and pay more for these drugs in the interim. Thus, as the patent/exclusivity period lengthens, the static consumer gains to Napsterization increase,

as the annual welfare gains from immediate full access are realized for a greater number of years.

At the same time, longer patent/exclusivity periods reduce the dynamic efficiency losses from Napsterization. Longer patent/exclusivity periods lower the consumer surplus realized from innovation, as the prices of new products remain high and the associated efficiency loss is incurred for a longer period. Longer patent/exclusivity periods thus drive the benefit/cost ratio for maintaining the status quo down, as the numerator falls while the denominator rises. Holding all other parameters constant, our model indicates that the benefit/cost ratio falls to unity at an average patent/exclusivity period of 18 to 19 years, as shown in Table 3. Notice that a shorter patent/exclusivity period raises the benefit/cost ratio of the status quo, as the benefits of full access to new innovations are realized earlier.[47] Another way to state this result is to say that, if patent lives were twice as long as they are currently, a Napsterization policy might make more economic sense.

Table 3				
The Effect of Patent/Exclusivity Period on the Benefit/Cost Ratio[1]				
Patent/Exclusivity Period (in years)				
Gains/Losses from Napsterization	**3**	**6**	**9**	**18**
Dynamic Losses of Future Consumer Surplus	3029.7	2757.2	2500.5	1816.8
Static Gains of Current Consumer Surplus	222.7	540.4	839.7	1639.9
Benefit/Cost Ratio	13.6	5.1	3.0	1.1

[1]Note that, by patent/exclusivity period, we refer to the time remaining in any patent or exclusivity period at the time the new drug is first marketed. Because of the substantial time needed to develop, test, and approve new drugs, the remaining patent or exclusivity period is shorter, sometimes much shorter, than the 20–year statutory patent length.

Table 4 examines the sensitivity of the benefit/cost ratio to the length of time required for generics to enter the market-the period of de facto exclusivity due to entry lags described earlier. As seen in the table, the results are not particularly sensitive to variation in this assumption.

Table 4				
The Effect of Time to Generic Entry on the Benefit/Cost Ratio				
Time to Entry (in years)				
Gains/Losses from Napsterization	**0**	**.5**	**1.0**	**1.5**
Dynamic Losses of Future Consumer Surplus	2584.92	2542.3	2500.5	2459.2
Static Gains of Current Consumer Surplus	954.4	896.8	839.7	783.2
Benefit/Cost Ratio	2.7	2.8	3.0	3.1

In Table 5, we examine the effects of longer useful product lives on benefits and costs. This parameter is not binding with respect to the static efficiency gains, since the useful life will always be at least as great as the period of market exclusivity for the existing

stock of drugs. On the other hand, the gains from innovation are affected. Due to discounting the effect is greater in percentage terms the shorter the useful life.

Table 5				
The Effect of Useful Life on the Benefit/Cost Ratio				
	Useful Life (in years)			
Gains/Losses from Napsterization	**20**	**25**	**30**	**35**
Dynamic Losses of Future Consumer Surplus	1946.2	2500.5	3002.2	3456.0
Static Gains of Current Consumer Surplus	839.7	839.7	839.7	839.7
Benefit/Cost Ratio	2.3	3.0	3.6	4.1

Discount Rate

Due to time lags and patent/exclusivity periods, much of the benefits to innovation accrue in the future. The consumer gains to Napsterization accrue in the short term, as these gains are comprised of access to the existing stock of drugs. As our benefit/cost ratio is the balancing of short-term gains against long-term losses, choice of a discount rate will strongly influence the benefit/cost ratio and thus the net benefits of Napsterization. The effect of a higher discount rate will be felt primarily in the dynamic benefits of innovation, as these accrue further into the future than do the static gains.

We use a conservative baseline real discount rate of 2 percent, which approximately equals the real risk-free rate of return (90-day T-Bill rate) for the past 40 years (Economic Report of the President (2002)). As the discount rate rises, the present value of future gains and losses declines. Thus, higher discount rates will lower the benefit/cost ratio by lowering the present value of future gains, and *vice versa*. Holding other parameters constant, our model indicates that the benefit/cost ratio falls to unity at a

discount rate of just under 5 percent. Note also that, if the welfare of future generations is not discounted, as some policy analysts suggest is appropriate, the benefit/cost ratio for the status quo becomes substantially larger.

Table 6				
The Effect of the Discount Rate on the Benefit/Cost Ratio				
Real Discount Rate (percent per year)				
Gains/Losses from Napsterization	**1**	**2**	**3**	**5**
Dynamic Losses of Future Consumer Surplus	5759.7	2500.5	1454.0	673.0
Static Gains of Current Consumer Surplus	882.0	839.7	799.8	726.8
Benefit/Cost Ratio	6.5	3.0	1.8	0.9

Post-Generic Entry Brand Market Share

Brand name drugs retain some market share following generic entry, although that share has generally been shrinking over time. In our model, the retained market share will continue to generate profits for the brand name manufacturer, part of which is used to fund further R&D. As the retained market share rises, the static gains in consumer surplus from Napsterization fall, as consumers gain access to a smaller share of the market. Similarly, consumers gain less from innovation, as larger shares of the market continue to be sold at higher prices. Empirically, the net effect of a lower retained market share is a higher benefit-cost ratio. With a retained market share of zero, the branded good exits from the market, and the benefit/cost ratio for maintaining the status quo equals 3.7. Even with a high retention rate of 40%, the gains from maintaining the status quo are still about 50% greater than the gains from increased access.

Table 7				
The Effect of Retained Market Share on the Benefit/Cost Ratio				
	Retained Market Share (percent)			
Gains/Losses from Napsterization	**0**	**20**	**30**	**40**
Dynamic Losses of Future Consumer Surplus	3115.3	2500.5	1885.8	1271.1
Static Gains of Current Consumer Surplus	839.7	839.7	839.7	839.7
Benefit/Cost Ratio	3.7	3.0	2.2	1.5

R&D effort, measured as a percent of contribution, and the rate of return on R&D enter our model identically in a multiplicative fashion, so the variation in one parameter will yield identical results to variation in the other. Table 8 illustrates the effects of our assumption regarding R&D effort: the higher the fraction of profits allocated to R&D, the greater the benefits of retaining the status quo.[48] Since the fractions enter multiplicatively, they have unitary elasticity, which is an artifact of the model.

Table 8				
The Effect of R&D Effort on the Benefit/Cost Ratio				
	R&D/Sales (percent)			
Gains/Losses from Napsterization	**10**	**15**	**20**	**25**
Dynamic Losses of Future Consumer Surplus	1667.0	2500.5	3334.1	4167.6
Static Gains of Current Consumer Surplus	839.7	839.7	839.7	839.7
Benefit/Cost Ratio	2.0	3.0	4.0	5.0

We also note that our baseline estimate of the benefit/cost ratio of 3.0 is conservative, as it is based on conservative estimates of the model parameters. For

example, retained market shares are likely less than 10 percent. Patent/exclusivity periods are falling. Research and development intensity has been rising in recent years (although there is some evidence that the productivity of this research is declining). New drugs are generally more effective than the older drugs they replace (Lichtenberg, 2001), thus generating higher consumer surplus. In our model, both new and existing drugs generate the same consumer surplus. Finally, we assume no real growth in the demand for pharmaceuticals over time. A growing population, and an aging population means that the future gains in consumer surplus to innovation will in fact be greater than what we estimate here, while the static gains to Napsterization are unchanged. The broad, robust conclusion from these results is that the status quo, based on our analysis, yields greater consumer surplus over time compared to accelerated generic access.

5. Measuring the Tradeoff in Consumer Welfare Using the Health Production Model

An alternative approach to valuing the outcome considered above uses the following structural model of the effects of competition on innovation. The model is based on a health production function model. The model has a recursive framework, and links entry, revenues, research and development, new drugs, health, and consumer surplus in a logical sequence. We parameterize the model using estimates from the published literature, summarized in Section 2 above, on each step, or equation, in the model. The links in the model include the following (we describe the expected links based on the hypothesized entry of a generic competitor):

1. Entry causes revenues to fall: TR=TR(E).
2. Declines in revenues lead to declines in research and development: RD=RD(TR).

3. Declines in research and development lead to declines in the number of new chemical entities: NCE=NCE(RD).
4. Declines in the number of NCEs lead to declines in longevity: LY=LY(NCE).
5. Declines in longevity lead to declines in welfare (consumer surplus): W=W(LY).

Substituting through from (1) to (5) describes the effect of entry on welfare: W=W(E). Balanced against any negative consequences of entry on welfare due to reduced innovation are the gains from increased access. As above, these gains will be due to the shifting of later gains to the present by the average protected life of the existing patented pharmaceuticals.

The relevant literature on equations 1-5 includes the following:[49]

1. TR=TR(E): Grabowski and Vernon (1992)
2. RD=RD(TR): Price Waterhouse Coopers Report and others.
3. NCE=NCE(RD): Jensen (1987),
4. LY=LY(NCE): Lichtenberg (2002).
5. W=W(LY): Topel & Murphy (2002).

The findings in this literature have been summarized earlier in Section 2. In accord with these results, we assume that

1. The long run effect of generic entry on total revenues to branded pharmaceutical companies is a decline in revenues of 65%;
2. A 65% decline in revenues leads to a 65% decline in research and development spending;

3. A 65% decline in research and development spending leads to a 65% decline in NCEs;
4. A 65% decline in NCEs leads to reduced longevity of 1.6 million life years per year;
5. The value of this longevity decline is $240 billion dollars per year.

The present value of the $240 billion per year due to increased longevity that would be eliminated with Napsterization, assuming a 2% discount rate, is $12 trillion. On the other hand, increased access now to the existing stock of drugs, rather than 5 years from now, will lead to a 5% increase in longevity. This translates into incremental benefits from Napsterization of approximately $2 trillion. Thus, the B/C ratio from maintaining the status quo is 6.0 based on this analysis, which is twice as large as the benefit-cost ratio of 3.0 was derived. The dynamic benefits rise to a greater degree than the static, relative to our derived demand model. The fact that the benefit cost ratio is larger, however, confirms our assessment of the earlier ratio as conservative.

6. Conclusion

Our analysis of the extreme policy experiment, whereby full access is granted to the existing stock of pharmaceutical products, presents the tradeoffs involved in a very stark light. Gains to existing consumers from full access would be considerable, on the order of $1 trillion dollars. The intensity of debate surrounding access by this interest group, and its representatives in the generic manufacturing sector, Congress, and elsewhere, is not surprising, given this result. At the same time, the lost opportunities to develop new drugs to address currently untreated illnesses, or to improve upon existing

drugs, carry a considerably larger price tag. The lack of intense lobbying efforts by any consumer groups reflects that fact that many of the beneficiaries of innovation do not at present have a voice in the debate, beyond the extent to which their interests are represented by innovators.

According to our demand analysis, we would lose 3 dollars in benefits of innovation for every dollar we gain due to easier access. This number is conservative, as indicated by our alternative analysis. Its implications for policies concerning periods of market exclusivity, pricing, review times, and other policy variables are the subject of our future research.

Notes

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[1] The Drug Price Competition and Patent Restoration Act of 1984 (P.L. 98-417) is commonly referred to by the names of its two principal sponsors, Senator Orrin Hatch and Representative Henry Waxman. The Title I of the law eases generic entry by allowing generic manufacturers to rely on the clinical testing performed by the brand name manufacturer. A generic manufacturer must show only that its drug is equivalent to the patented compound and may begin this process before the expiration of the patent. The law also encourages challenges of existing patents. A generic manufacturer that successfully challenges a drug patent will not face competition from additional generic competitors for 180 days after market entry.

Title II of the law provides that for every two days spent by innovative firms on the testing and approval process required for Federal Drug Administration approval, patent life is extended one additional day. The total patent life restored cannot exceed five years, nor may these patent extension provisions be used to extend the total effective patent life, i.e., the amount of patent life when the product comes to market, beyond fourteen years (U.S. Congress, (1984)).

The law grants innovating firms exclusive use of their clinical testing data for a period of five years following market introduction. This provision protects the innovating firms

from generic entry using the provisions of Title I during this period. European countries grant innovating firms such data exclusivity for six to ten years, depending on the country. The European Union is attempting to standardize the exclusivity period at 10 years, twice the period granted in the U.S. (Pharmaceutical Research and Manufacturers' Association, Pharmaceutical Industry Profile, 2001, chapter 8).

[2] The Internet service Napster allowed consumers to circumvent intellectual property protection on recorded music by facilitating online exchange of recorded music files without payment to the copyright holders. Napster was found to have violated the artists' and music distributors' copyright protection (A&M Records, Inc. v. Napster, Inc., 2000).

[3] Senator Bradley of New Jersey identified this same tradeoff in the context of a discussion on pharmaceutical price controls:

> "…[W]hat I believe is a major concern…is its (the price ceilings) effect on investment, research, and innovation in this country … . And although it is not easy to predict the reactions in the marketplace to Government intervention, this one is simple: Price controls … will significantly reduce incentives for investment … . Reduction in research will lead to fewer innovations, fewer cures, and fewer hopes for many Americans who are counting on medical breakthroughs to lengthen their lives. Certainly, lower prices will help consumers to be able to afford prescription drugs. But the question is, what are they going to be able to buy?"

Congressional Record-Senate, March 11, 1992, p. S3192. Quoted in Viscusi, Vernon, and Harrington (2000), p. 830.

[4] In other words the two models measure the willingness to pay for health improvement in different ways. The model in Section 4 focuses on the derived demand for drugs while the model in Section 5 uses direct measurements of the demand for changes in longevity.

[5] A complete analysis of political interests would also include both generic and brand name pharmaceutical manufacturers. Of note, Senator Orrin Hatch (R-Utah) characterized the interests of branded and generic pharmaceutical manufacturers as proxies for, respectively, the interests of current and future consumer groups:

> This is a groundbreaking compromise in the public interest. It reconciles the opposing, competitive interests of two segments of the pharmaceutical industry which have often stymied each other's attempts to improve the law. The research-based drug industry obtains an extension of patents for new drug discoveries to compensate them for the time spent off-market in FDA review. The generic drug industry gets to bring generic copies of off-patent drugs to market as soon as the patent expires, without the needless reduplication of studies and tests already in FDA's files. The public receives the best of both worlds-cheaper drugs today and better drugs tomorrow.

Congressional Record-Senate, August 10, 1984, p. 23764. Quoted in Viscusi, Vernon, and Harrington (2000), p. 827.

[6] See Note 1, supra.

[7] We use both the terms market exclusivity and effective patent life to refer to the time

between the introduction of a new drug to the market and when generics can be offered. Various laws including the Hatch-Waxman Act and the Orphan Drug Act specify formal requirements for granting market exclusivity by the Federal Drug Administration. See U.S. Food and Drug Administration, "Frequently Asked Patent and Exclusivity Questions".

[8] Grabowski and Vernon (1996) found that the legislation extended effective patent life to compensate for time lost during the long FDA approval process. They find that the Hatch-Waxman Act added on average 2.3 years to average effective patent life, for a total average patent life of 11.8 years. The period covered by their analysis precedes the data in Table 1 by 10 years.

[9] Longer clinical tests consume patent time, leaving less patent time once the product reaches market. See Kettler (1999).

[10] Scott Morton (1999) investigates entry decisions using a census of all approved Abbreviated New Drug Applications (ANDAs) for the prescription drug market over the period 1984 to 1994 and found that generic competitors differ in their ability to certify, produce, and market specific drugs. Generic entry is modeled as a strategic game where entrants incur fixed costs to enter heterogeneous markets, and firm profitability is a declining function of the number of firms in the industry. As the FDA does not reveal information about applications, potential entrants must decide whether to incur the entry cost without knowing how many other generic competitors have filed ANDAs for a particular drug.

[11] Generic Pharmaceutical Association, "Generic Price and Market Share."

[12] NDC Health, (2002) and "TV Ads Spur a Rise in Prescription Drug Sales," *New York Times*, March 8, 2002.

[13] This elasticity estimate is derived from the standard economic result that a profit-maximizing firm will set its ratio of price to marginal cost equal the inverse of the elasticity of demand. With a price to marginal cost ratio of 6:1, the implied elasticity of demand is –1.2.

[14] Caves, Whinston and Hurwitz (1991) examine the experience of a panel of thirty drugs that lost patent protection during the period 1976-1987. They found that second and third generic entrants pushed generic prices lower but had little effects on the branded price. During this period generics captured only around 25 percent of the market. However, as noted, these percentages have grown significantly since the authors' sample period, which ended in 1987. Caves et al. also found brand name manufacturers severely reduced promotional outlays in the period leading up to patent expiry. As a result, total quantity of sales actually fell in the period between patent expiry and generic entry. The added sales volume resulting from the lower generic price post entry is, according to the authors, insufficient to compensate for the reduction in the brand manufacturer's reduction in product promotion. Finally, they found no evidence of limit pricing to forestall entry.

[15] We note that the preference for brand names among the "brand loyal" segment may not be as significant as the large price differential between branded and generic drugs at the manufacturer level might suggest. These prices differences are often muted at retail by the pattern of higher retailer markups on generic drugs. Media reports indicate that some

generic drugs had retail markups as high as 1000 percent above cost. *Wall Street Journal,* 12/31/98. In addition, for customers with prescription benefit coverage, the out-of-pocket difference between brand name and generic drugs will depend on the structure of co-payments. More plans now feature higher co-payments when generics are available. Nevertheless, the fact that many prescription plans provide consumers with latitude to choose brand name drugs confirms the point that a subset of consumers has strong preferences in this regard.

[16] See Table II in Grabowski and Vernon (1996).

[17] Phase 1 trials are usually conducted in healthy volunteers, and are designed to determine the pharmacological actions of the drug and its side effects. Results of these trials are used to design valid Phase 2 studies, which are small scale safety and efficacy studies. Phase 3 clinical trials are large scale—hundreds or thousands of patients—controlled trials designed to yield results on safety and effectiveness that may be extrapolated to the general population. U.S. Food and Drug Administration, *CDER Handbook.*

[18] See Viscusi, Vernon, and Harrington (2000), p. 817.

[19] Higher estimates come from Kettler (1999) and Tufts University (2001). However, the lobbying organization Public Citizen estimates the research and development costs to be only $70 million to $150 million for each new drug approval. Public Citizen, (2001).

[20] Accenture, (2001).

[21] U.S. Food and Drug Administration, *FDA Drug Review and Approval Times.*

[22] As indicated above, generic penetration rates are now significantly higher.

[23] According to a 1998 Congressional Budget Office study, an additional year of patent protection would increase the present value of returns to the typical pharmaceutical product by about $12 million, while a one-year acceleration of FDA review would yield an increase of $22 million. Grabowski and Vernon (1992) estimate that the adverse cash flow effects of an increase in generic penetration on incentives to innovate can be offset by a three-year extension in patent life, or by a one-year reduction in regulatory approval process.

[24] Henderson and Cockburn relate these findings to the issue of industry consolidation. Given their finding of significant economies of scale in the research and development efforts, they argue that losses in consumer surplus resulting from the static inefficiency of large pharmaceutical firms might well be offset by the dynamic efficiency gains to greater innovation.

[25] Fogel (2002), Table 1.1.

[26] Life expectancy also depends on the sum of health expenditures or medical innovation in previous periods, net of depreciation, and medical innovation. However, because the causality between health expenditure and longevity can run in both directions (greater expenditures increase longevity, but older individuals spend more on health care), Lichtenberg uses only past health expenditures in his analysis.

[27] Lichtenberg notes that research and development by the pharmaceutical industry accounts for nearly a third of total research and development to improve health and nearly two-thirds of all privately funded medical research.

[28] The value of a statistical life is typically extrapolated from workers' willingness to

accept particular risks. Suppose workers will accept an increase in the risk of death on the job of 1 in 10,000 for an annual wage premium of $500. This risk corresponds to one additional death each year in a population of 10,000, requiring a total risk premium of $5 million ($500*10,000). See Murphy and Topel, p. 19.

[29] Pharmaceutical Research and Manufacturers Association, "The Myth of 'Rising Drug Prices' Exposed."

[30] Note also that we are not focusing on the interbrand competition within therapeutic groups. This competition takes the form of competing to innovate, as well as price and non-price competition among innovators. Our focus is exclusively on competition between brands and generics. For data on interbrand competition, see Pharmaceutical Research and Manufacturers' Association, Pharmaceutical Industry Profile, 2001, chapter 5.

[31] There is also a producer surplus of 50 generated in period 1. Our focus, however, is exclusively on consumer welfare, so we do not include these gains in our analysis. This will understate our estimates of the overall welfare associated with the status quo of patent protection, since it ignores benefits to investors and owners of innovative firms.

[32] The gains from Napsterizing are overstated to the extent that the expropriation of patents reduces incentives in other areas where patents are in place. We note that only two of the top 100 drugs in 1965 remain in the top 100 as of 2001.

[33] NDC Health and *New York Times*, March 8, 2002, note 12 supra.

[34] See Table 1 supra. and the references cited therein.

[35] See Lichtenberg (2002), pg. 11 and Figure 9. Lichtenberg estimates that some 20

percent of drugs approved between 1950 and 1993 are no longer marketed. Lichtenberg (2001) estimates the average age of a brand name drug to be around 23 years while the average age of a generic drug is 38 years (pg. 14). These average ages are conditional upon surviving to date. Our estimate of an economic life of 25 years attempts to capture the concept that most drugs are ultimately rendered obsolete by innovation, even if they continue to be marketed in small quantities. We address the consequences of changing this average economic life estimate in our sensitivity analysis (See Table 4).

[36] This is the average real return on a risk-free investment (a 30 day U.S. Treasury Bill) for the past 40 years. The risk-free rate is used as the social discount rate. Note that this discount rate is appropriate for evaluating future welfare (Arrow and Lind, 1970), and that it differs from the hurdle rates used in corporate project evaluations.

[37] Implicit in this assumption are some more subtle assumptions: 1)that any increases in the real price of pharmaceutical products will represent quality increases; 2) That depreciation of the R&D capital stock is exactly offset by growth in the productivity of R&D.

[38] Profits from successful drugs fund more R&D than that into new products. In particular, profits also fund research into platform technology, general biotechnology research, and academic research on pharmaceutical products. We focus our efforts here on only one aspect of the firms' R&D effort.

[39] With high price/cost margins, the ratio of R&D to sales will be close to the ratio of R&D to contribution. For our baseline estimates, we use an R&D/contribution percentage of 15%. The pharmaceutical industry spends more on R&D as a percentage

of sales than any other industry. The figure has risen from 10 percent in the 1980s to 17.5 percent in 1997. Of firms based in the U.S., R&D as a percentage of sales ranges from 6.2 percent (Baxter International) to 17.6 percent (Pharmacia & Upjohn) in 1996. Price Waterhouse Coopers, (1999), p. 7 and Table 1.

Grabowski and Vernon (1994) estimate the rate of return to pharmaceutical R&D investment to be 11.1 percent. Smith, (1996) pg. 108, estimates the rate of return to be 22 percent per year. Our estimate of 15 percent is in the middle range of existing estimates.

[40] Profits here always refer to profits before research and development expenses. The 5/6 margin is derived from studies of generic entry, which presume that generics eventually price at MC, and where this price equals about 1/6 of the pre-entry price. See, e.g., Grabowski & Vernon, (1993).

[41] Contribution to R&D and profits is a function of past R&D. In keeping with models of R&D capital (Grilliches (1998)), current profits can be viewed as reflecting the cumulative effect of a sequence of R&D investment in previous periods, with the effect of each period's investment diminishing over time due to depreciation of that component of the R&D stock.

[42] The analysis here follows Harberger (1954) and Cowling and Mueller (1978).

[43] If the generic price is 1/6 the branded price, and the generic quantity 4 times the branded quantity, we can derive branded and generic sales using the relationship

$P_B Q_B + P_G Q_G = 52,$ and substituting using $P_G = \frac{1}{6} P_{B,}$ and $Q_G = 4Q_B.$

[44] See Cowling and Mueller note 42 supra.

[45] This reflects the result derived above, where potential gains from Napsterization equal

1.5 times the difference between pre- and post-patent profits. Since consumer surplus on future inventions is not yet earned, it is incorporated in the future gains, so that total future gains are two times the level of future profits. With consumer surplus equal to ½ of profits, it follows that the off-patent surplus will equal four times the on-patent surplus.

[46] The total consumer surplus generated by new products each year once production lapses is partially offset by profits due to competitive reactions of the branded manufacturers, as in the static example.

[47] The rising benefit/cost ratio as the exclusivity period shrinks is an artifact of the fact that neither the rate of R&D spending nor its return are endogenous—influenced by other variables—in our model. Thus, R&D spending continues at the same rate and with the same return even as the period of exclusivity shortens. This obviously decreases the gains to Napsterization—consumers gain full access almost immediately anyway—and increases the value of innovation. In our model, R&D spending does not fall precipitously until Napsterization is complete.

[48] Assuming that the rate of return is exogenous with respect to the rate of R&D effort.

[49] See Section 2 for a detailed summary.

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