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Napsterizing Pharmaceuticals:

Access, Innovation, and Welfare*

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Abstract

We analyze the effects of a hypothetical change from the status quo with patent protection on pharmaceuticals to a world in which all patent rights on both existing and future branded drugs would be eliminated. Our analysis takes into account stylized facts concerning the nature of competition between branded and generic competition, the value of the flow of potential new drugs, the effective patent life under the existing Hatch-Waxman framework, and, most critically, the essential features of prescription benefit coverage whereby consumers pay relatively low marginal prices (copayments) for their prescriptions. Our calibration of a simple model indicates that the costs of Napsterizing pharmaceuticals exceed the benefits by a ratio of about 3 to 1.

1. Introduction

In the U.S., the broad framework of rules determining the extent of patent protection to innovative drugs was established by the 1984 Hatch-Waxman legislation, which strengthened patent rights in some respects, but also eased entry by generic drugs after patents expire by introducing the less onerous requirement that generic manufacturers only show that their drugs are bio-equivalent to the patented compound.[1] The legislation has been successful insofar as the flow of innovative drugs under patent has been substantial and entry by generics is typically swift once patents expire. Success in these respects has not, however, eliminated the political pressures to accelerate consumer access to drugs under patent,[2] possibly reflecting (a) greater awareness of the price differences between branded and generic drugs – differences which make it clear that the marginal costs of production and distribution constitute a small fraction of the prices charged for branded drugs while under patent, and (b) the increasing value of various drug therapies to the health and well-being of consumers.[3]

In this study, we analyze the effects of a hypothetical policy experiment from the status quo with patent protection defined by the Hatch-Waxman framework to a world in which all patent rights on both existing and future branded drugs would be eliminated. We use basic price theory to develop insights into the effects of this action – *Napsterizing* pharmaceuticals – on U.S. consumers and, given certain assumptions, on society at large.[4] We proceed in Section 2 by developing an initial structure that identifies the consumer gains from Napsterizing due to the immediate introduction of generic competition for the stock of drugs now under patent and the losses associated with the reduced flow of innovative drugs. We incorporate the central elements of this structure

into a model which accounts for the effects of prescription benefit coverage whereby consumers pay relatively low marginal prices (copayments) for their prescriptions.

As with all analyses of changes in the degree of intellectual property protection, unqualified implications concerning welfare cannot be drawn on an *ex ante* basis, i.e., without developing an understanding of the nature of the fundamental tradeoff between (a) the gain in welfare from providing consumers earlier access to the stock of pharmaceuticals under patent protection, and (b) the harm to consumers from the reductions in the flow of new products. In Section 3 we use relevant stylized facts concerning the nature of competition between branded and generic competition, the effective patent life under the status quo, and the value of the flow of potential new drugs to U.S. consumers to calibrate the model and estimate the welfare effects of the policy change. By calibrating those gains and losses, we are able to show that U.S. consumers collectively would be clearly worse off from Napsterizing pharmaceuticals. Ignoring the effects of prescription benefit coverage, the elimination of patents would create losses in consumer surplus from the reduced flow of innovative drugs that would overwhelm the short term consumer surplus gains associated with increased access to the stock of branded drugs now under patent by a ratio of almost 2 to 1. The case for Napsterizing pharmaceuticals is yet weaker when we take account of the real world effects of prescription benefit coverage. Given that most plans mimic two-part pricing arrangements whereby copayments are below the prices that would prevail in a one-price regime with patent protection, the extent of static inefficiency associated with the *status quo* is lower than it would be in the absence of such coverage. The tradeoff in consumer welfare from Napsterizing in a case with existing prescription benefit coverage worsens

to about 3 to 1.

Our findings suggest that current concerns about the extent of patent protection are misplaced and they also underscore the importance of the insights developed by Lakdawalla and Sood (2006, 2007). Recognizing that various types of health insurance operate as two-part pricing schemes, they demonstrate that there need not be any tradeoff between utilization and innovation incentives. Indeed, the development of prescription benefit plans with relatively low copayments can be viewed as effective market and institutional responses to the underlying challenge of maintaining incentives to innovate while increasing access to patented drugs whose marginal costs are low. With the widespread implementation of plans featuring two-part pricing, support for weakening patents on pharmaceuticals would appear to be motivated more by rent-seeking by particular groups of consumers than by efficiency concerns.

2. Conceptual Framework

a. *Essential Structure*

We first develop a structure that highlights the fundamental tradeoffs in weakening patent protection. In the status quo, branded drugs are sold with the benefit of patent protection and other drugs are sold in markets subject to generic competition. As illustrated in the left-hand side of Figure 1, manufacturers of branded drugs under patent set prices, P_B, and output is Q_B.

[Insert Figure 1 about here]

Revenues in the branded drug market equal 60. Marginal costs (MC) – which exclude the research and development required to bring the product to market – are 10, and the

difference between revenues and these costs (50) is profit or contribution, the potential for which provides incentives to invest in the future flow of new drugs. With linear demand, the sales of branded drugs 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 expenditures by consumers of 60. The gap between consumer value and marginal cost over the range of output Q_B to the welfare-maximizing output, Q_G, i.e., where MC intersects demand, represents the static inefficiency of 25.

Assuming that the consumer demands for branded and generic drugs are identical, then as illustrated in the right-hand side of Figure 1, Q_G is twice as large as Q_B as the prices for generics, P_G, are competed down to MC. The higher level of consumer surplus (100) compared to the branded market is associated with the lack of market power among generic producers and the lack of static inefficiency. [5]

The *short run* effect of Napsterizing subjects the branded market to generic competition. Branded drugs would become available at MC and consumer surplus for those products would rise from 25 to 100 for a gain of 75. This gain to consumers is a combination of transfer from producers (50) and the elimination of the static inefficiency (25). By eliminating the expected gains from patent protection and the corresponding incentives to invest in research and development, the *long run* effect of Napsterizing would be to reduce the flow of new drugs. Consumers lose because the gains in consumer surpluses from branded drugs while still under patent – depicted as 25 in Figure 1 – are not realized in the future. Consumers will also lose the gains from those new branded drugs after the patents expired. Manufacturers would lose the producer surplus – 50 per year in Figure 1 – due to the loss of patent protection.

Given the tradeoffs inherent in weakening patent protection -- greater consumer surplus from improved access to existing drugs in the short run but less investment and reduced flow of new drugs in the long run, one cannot know whether consumers gain or lose in present value terms. Put differently, we know that the static inefficiency from patent protection is eliminated by Napsterizing, but the lack of innovation creates dynamic losses. To derive estimates for the overall effects of Napsterizing pharmaceuticals requires further structure to capture the essential features of the market and factors that govern the nature of the underlying tradeoffs.[6]

b. *Model*

To further analyze the effects of Napsterizing pharmaceuticals on relevant welfare measures, we model the demand for branded drugs as $P = a - bQ$, and assume that marginal costs for all drugs are constant, i.e., $MC = c$. With patent protection, we assume that profits are sufficient to sustain a steady state whereby the innovative investments yield a flow of new patented drugs that leaves the aggregate demand for branded drugs under patent constant. With patent protection, prices as well as output and producer surplus are the same as under monopoly; if patents are eliminated, prices go to MC and output increases to the competitive level:

Monopoly Output: $Q_M = \frac{(a-c)}{2b}$

Producer Surplus: $\pi_M = \frac{(a-c)^2}{4b}$

Monopoly Price: $P_M = \frac{(a+c)}{2}$

Competitive Output: $Q_C = \frac{(a-c)}{b}$

In the balance of this section, we first evaluate Napsterizing in a setting where

there is no prescription benefit coverage. As indicated at the outset, this case is more favorable to the policy change because static inefficiencies are greater when patents are in force and a single-price monopoly equilibrium results. We then evaluate the effects of Napsterizing when individual consumers have prescription benefit coverage whereby individuals pay monthly premia (analogous to entry fees in two-part pricing schemes) and buy their prescription drugs at marginal prices that are closer to, or in the limit equal to, marginal costs.

Napsterizing Pharmaceuticals – No Prescription Benefit Coverage

In the steady state, patent protection generates a flow of new drugs that sustains consumer surplus forever, yielding lifetime consumer welfare of $CS^{-\rho}$, where ρ is the real discount rate and CS is the single-period consumer surplus. If patent protection were eliminated, then the producer surplus would go to zero and it, along with the dissipated static inefficiency, would accrue to consumers for the remaining life of the now-unprotected drugs. The flow of innovative drugs would cease. The resultant lifetime consumer surplus, in present value terms, would equal $[4CS^{-\rho}][1 - e^{-\rho T}]$, where Tdenotes the remaining life of the existing stock.[7] The benefit-cost ratio for maintaining the status quo thus equals $\frac{1}{\left[4[1-e^{-\rho T}]\right]}$, which is independent of the level of consumer surplus, but does depend upon the discount rate and patent life. In our steady-state model, increases in the discount rate and patent length both reduce the relative benefits of maintaining patent protection.

Napsterizing Pharmaceuticals – With Prescription Benefit Coverage

The real world market for prescription drugs deviates from the previous analysis

given that a large and increasing majority of U.S. consumers have prescription benefit coverage.[8] As benefit plans have evolved over the last two decades, individuals typically pay monthly premiums for coverage and per-unit prices for prescriptions. These copayments are often tiered within categories of drug, e.g., generic, preferred branded.[9] It is unambiguous that prescription benefit coverage will reduce static inefficiency provided that utilization increases from the single-price quantity that prevails with patent protection but does not exceed Q_C, the quantity where MC intersects demand.[10]

Napsterizing in the presence of prescription benefit coverage can be evaluated under different assumptions about copayment levels, which we identify as P_α. For any $\alpha \in (0,1)$, the corresponding copayment and the resulting output are given by:[11]

$$P_\alpha = c + (1-\alpha)(a-c).$$

$$Q_\alpha = \alpha Q_C = \alpha \frac{(a-c)}{b}.$$

We develop two particular cases for discussion: (i) α equals 1 and copayments equal marginal costs, which yields the competitive output, Q_C, and (ii) α equals .75 and copayments are set at the midpoint of marginal costs and P_M, which yields an intermediate output level. For a given level of producer surplus, this implies that the per-unit rate, r_C, at which the third-party payors reimburse drug manufacturers, varies between the two cases.

In principle, the contracts between branded manufacturers and the payors can take many forms.[12] In addition, they can yield varying distributional effects. Our analysis proceeds on the assumptions that producer surplus is constant between the single-price equilibrium and the prescription-benefit cases and that the additional gains from trade due

to two-part pricing are realized by consumers, who, it should be noted, cannot be made worse off by prescription benefit coverage due to the participation constraint.[13] These assumptions allow us to focus our efficiency analysis on the consumer surplus tradeoffs, but, as we discuss later, puts the status quo in a favorable light relative to Napsterizing.

Case 1: Copayments equal Marginal Costs: The left-hand side of Figure 2 depicts this result. With the copayment equal to marginal costs, output under the status quo (with patent protection) is at the competitive level, $Q_C = \frac{(a-c)}{b}$. With $\pi_\alpha = \pi_M$,[14] the reimbursement rate is given by

$$r_C = c + \tfrac{1}{4}(a - c).$$

[FIGURE 2 ABOUT HERE]

The equilibrium whereby the reimbursement rate - quantity combination is not on the demand curve is consistent with a two-part pricing scheme and allows branded manufacturers to maintain profit levels at the higher output.[15] Consumer copayments are given by the area cQ_C, and revenues to the manufacturer equal $r_C Q_C$, with payments by the third party payor, $(r_C - c)Q_C$, making up the difference. These payments are covered by monthly premiums in the case of private coverage, or by tax revenues in the public case.

Case 2: Copayments between P_M and Marginal Costs: As depicted in the right-hand side of Figure 2 copayments, P_I, are at the midpoint of P_M and marginal costs, yielding the intermediate level of output $Q_I = \frac{3(a-c)}{4b}$. The reimbursement rate that maintains π_M at Q_I is given by:

$$(r_I - c)\frac{3(a-c)}{4b} = \frac{(a-c)^2}{4b},$$

or

$$r_I = c + \tfrac{1}{3}(a - c).^{16}$$

Cases 1 and 2 illustrate that the potential gains from Napsterizing pharmaceuticals depend on the level at which copayments are set in the world with patent protection. In the limiting case where the copayment is set at marginal costs, two-part pricing associated with prescription benefit coverage represents the perfect contracting mechanism for the transfer of products that would otherwise be sold at monopoly prices. As a result, there is no static inefficiency in the status quo and, in terms of overall welfare there are no gains from Napsterizing. In intermediate cases where copayments are above marginal costs, some static inefficiency exists in the status quo and so there is a potential tradeoff between static efficiency gains and dynamic efficiency losses. However, the potential gains dissipate fairly rapidly as we move towards Q_C.[17] With output at the midpoint between Q_M and Q_C, three-fourths of the potential efficiency gains from Napsterizing are realized through two-part pricing.

More generally, the static per-period efficiency gains from Napsterizing in our framework equal:

$$\Delta CS = (1 - \alpha)(a - c) + \frac{1}{2b}(1 - \alpha)^2(a - c)^2,$$

which fall to zero as α approaches 1, i.e., as output approaches the competitive level. Thus, the analysis demonstrates that once prescription benefit coverage and the effects of copayments are considered, the case for Napsterizing pharmaceuticals weakens in terms of overall efficiency.

Regarding the issue of what determines the level of copayments, we note that the

concavity of the isoprofit curve causes the gap between reimbursement rates and copayments to increase over the relevant range of output, i.e., Q_M to Q_C. Referring again to Figure 2, as this gap (and the associated area that represents net costs to third party payors) increases with output, the amount that must be charged in monthly premia must increase. If consumers faced no uncertainty about their demand for prescription drugs and transaction costs were zero, then the high monthly premia would not be a barrier. Indeed, the potential to realize gains from trade would push the contracting parties toward the limiting case of copayments equal to marginal costs. In practice, however, there is uncertainty, and copayments must therefore satisfy two constraints: they must be high enough for third party payors to remain profitable and they must be at a level where consumers want to participate.[18]

3. Calibration of the Gains from Napsterizing Pharmaceuticals

We now turn to calibration of the model taking into account (i) the size of the U.S. market for pharmaceuticals, (ii) the nature of competition between branded and generic drugs, (iii) the effective patent life of new drugs, and (iv) the long run demand for pharmaceuticals. Using a set of stylized facts about the U.S. market, we derive estimates of the effects of Napsterizing pharmaceuticals when there is no prescription benefit coverage and when prescription benefit coverage plans feature copayments above marginal costs.

a. *Stylized Facts*

Size of U.S. market: Of the approximately $300 billion dollars spent on prescription drugs for 2009,[19] about 80 percent is attributable to patented branded drugs,[20] with the remainder going to generic and unpatented branded drugs. Yet, generic drugs

accounted for 75 percent of total prescription volume, up from 57 percent in five years.[21]

Nature of competition between branded and generic drugs: Within the framework established by Hatch-Waxman, patent protection is the most important means by which innovative manufacturers maintain market exclusivity,[22] and as patents expire, all major branded drugs attract generic competition.[23] The subsequent competition between branded and generic drugs has been studied extensively. See by Grabowski and Vernon (1992, 1996), Frank and Salkever (1992, 1997), and Scott-Morton (1999). The most important findings for our purposes are that once multiple generic manufacturers enter, their drugs are priced at discounts of 70 to 90 percent below the branded manufacturer's price prior to patent expiry and generics gain an extremely large and increasing share of sales volumes.[24] The observed price relationships imply that (a) the overall ratio of price for branded drugs with patent protection to marginal cost is about 6:1, (b) the elasticity of demand prior to generic entry is about –1.2,[25] and (c) branded manufacturers make about $250 billion annually in producer surplus on drugs that are patent protected.

Effective patent life: To establish their patent rights, manufacturers typically file patent applications well before any testing commences. The time that drug manufacturers spend on Phases 1 through 3 testing varies considerably but often exceeds ten years.[26] Once manufacturers reach Phase 3 large-scale clinical trials, they can file a New Drug Application. The total potential patent life for a particular drug can be adjusted based on various Hatch-Waxman provisions. In recent decades the effective patent life of new drugs – the patent life less the time for testing and FDA approval – has been influenced by two potentially offsetting factors: a lengthening in the time required for testing and FDA review of clinical results, which may reflect the difficulties in testing

for chronic and degenerative treatments,[27] and a shortening of time required for FDA overall review.[28] Table 1 reports data on the effective patent life of all New Chemical Entities in recent years. The data show (a) that recently-approved NCEs have come on to the market with about eight to ten years of effective patent life, and (b) that since 1997 the average effective patent life for newly approved NCEs has declined.[29] Based on these data, our calibrations use a 7 year effective patent life.

[TABLE 1 ABOUT HERE]

Long run demand for pharmaceuticals: A critical issue concerns the value consumers will place on future pharmaceutical innovations. Lichtenberg (2002) examines the historical contributions pharmaceuticals have made to increased U.S. life expectancy and finds that pharmaceutical research and development were a comparatively efficient means of generating additional life-years.[30] Lichtenberg (2001) also assesses the value of future medical innovations and finds that substituting new drugs for older drugs leads to significant reductions in patient mortality and morbidity, as well as in total medical expenditures.[31]

Murphy and Topel (2006) value health benefits in terms of the willingness-to-pay framework, which corresponds to the standard concept of consumer surplus used in our analysis. They address how much consumers will value innovations by evaluating how much they value gains in life expectancy and, if those gains are realized, how much they would value further gains in life expectancy.[32] A key insight from Murphy and Topel is that, due to the inherent complementarities among health innovations – new cancer drugs are more valuable if cardiovascular drugs become more effective - the valuations from further medical innovations do not decline. From the point of view of the individual, the

greater is one's life expectancy, the greater is one's probability of contracting a particular disease and so the greater value one would place on an innovation that would counter that disease. For a population, the higher the survival rate at any particular age, the more individuals who can benefit from incremental increases in longevity. From these analyses, our calibrations are premised on the view that a continued flow of innovative drugs would yield significant consumer benefits.

b. Estimation

Consistent with the discussion immediately above, our calibration of the model is based on the following:

1. Total dollar sales of branded pharmaceutical products in 2009 equal $300 billion.[33]

2. Marginal costs are equal one-fifth of the price of branded drugs.

3. Producer surplus for branded manufacturers is $250 billion annually.

4. New Chemical Entities, on average, have market exclusivity for a period of seven years.[34]

5. Once a drug goes off patent or patents are eliminated, generic drugs enter the market immediately and capture the vast majority of sales at prices that approximate marginal costs.

6. The real discount rate is 2%.

7. The overall U.S. pharmaceutical market is in steady state, meaning that annual demand for branded drugs protected by patents is constant and the flow of innovative drugs in the status quo is sufficient to replace those going off patent.

With these stylized facts and assumptions, we summarize the welfare effects of Napsterizing in Table 2. Given that there is no change in the generic drug market, the analysis focuses on the effects in the branded drug market. Napsterizing pharmaceuticals

would confer benefits on current consumers of approximately $3.3 trillion in present value.[35] Consumers would lose, however, the benefits from future innovation. If the status quo is evaluated without prescription benefit coverage, consumers would lose $6.25 trillion in surplus, yielding a benefit-cost ratio for maintaining the status quo of 1.91:1.[36] As explained, the case for Napsterizing weakens when prescription benefit coverage moves status quo output toward the competitive outcome. For the intermediate case analyzed in Section 2, where output $Q_I$is at the midpoint between Q_M and Q_C, consumers would lose $10.94 trillion in surplus, yielding a benefit-cost ratio for maintaining the status quo of 3.34:1.

[TABLE 2 ABOUT HERE]

The overall welfare effects from maintaining patent protection are considerable and much of the differential between the status quo and Napsterizing is accounted for by the gains that consumers realize from the sustained flow of innovative drugs. Producer surplus is reduced to zero when patents are eliminated, which also contributes to the differential in favor of maintaining patent protection. Thus, as reported in Table 2, total welfare with patent protection is roughly six to eight times higher than with Napterizing depending on the effects of prescription benefit coverage. As Figure 3 illustrates, prescription benefit coverage in the intermediate case features an incremental static efficiency gain of $93.75B per year in moving from $Q_M$to Q_I.[37] This difference is reflected in the difference of total welfare amounts in Table 2 for the status quo with prescription benefits and the status quo case without prescription benefits.

[FIGURE 3 ABOUT HERE]

The choice of the 2% real discount rate is important given that consumer gains

from full access to the existing stock of drugs accrue in the near term while the benefits from innovation are realized later. Higher discount rates will lower the benefit-cost ratio of maintaining the status quo by lowering the present value of future gains, and *vice versa*. Holding other parameters constant, our model indicates that the status quo in the intermediate case (with prescription benefit coverage) remains favorable up to a real discount rate of almost 9%. The results are also sensitive to how consumers will value the flow of new drugs. Despite the case for increasing valuations, one could consider alternative scenarios. However, given the 3.31:1 benefit-cost ratio for maintaining patent protection in the intermediate case, the flow of new drugs would have to be of limited value in terms of extending life expectancy or improving quality of life to reverse the finding that Napsterizing pharmaceuticals is welfare-decreasing.

4. Conclusion

Our analysis puts the tradeoffs from eliminating patent protection on pharmaceuticals in a stark light. In our analysis of the case where consumers have prescription benefit coverage and copayments are set at the average of marginal costs and the single-price equilibrium that would result absent coverage, U.S. consumers would lose $6.25T in surplus from the reduced flow of innovative drugs from the policy change, corresponding to a benefit-cost ratio of about 3 to 1 in favor of the status quo.

The two-part pricing arrangements that are now dominant characteristics of benefit plans increase consumer access to branded drugs still under patent and thus reduce the potential benefits from Napterizing pharmaceuticals. The contractual arrangements between third-party payors and pharmaceutical manufacturers allow for the transfer of payments from consumers to manufacturers that maintain or even enhance the

incentives to innovate. The efficiency-enhancing effects of prescription benefit coverage thus represent an effective response to the challenge of maintaining incentives to innovate while allowing access to drugs under patent. In the limit, if prescription benefit coverage yields the competitive output level, there are no static losses associated with patent protection.

Our analysis is premised on the view that the future innovative pharmaceuticals would be highly valuable to U.S. consumers. We acknowledge that our findings can be sensitive to alternative assumptions. If one takes either the view that additional gains to life expectancy would not be highly valued or that the potential for future innovation is limited, then the benefit-cost ratio associated with continuing patent protection would fall. Regarding the former, we see indications that the willingness-to-pay for incremental gains in life expectation or quality of life are not declining, which is consistent with the proposition that the realized gains on these dimensions increase the value of future innovations, due to the inherent complementarities among them. We recognize, however, that one should not, based on our results, generalize about the importance of maintaining or strengthening patent protection in other settings. The effects of Napterizing in other settings will depend on (a) the expected value of future innovations relative to the value of the current stock of intellectual property, and (b) contractual and institutional features that influence the workings of the status quo market.

In light of our results, the intensity of debate concerning access and the direction of many policies concerning pharmaceuticals appear somewhat surprising. They are less so, however, once it is recognized that our results are based on the present value of the policy change. Many of the gains from continuing the status quo are realized over time

and, moreover, it is difficult to imagine how future consumers who would benefit from patent protection would compensate those who would benefit from Napterizing. Regarding the latter, elderly consumers, those who lack prescription benefit coverage, and those with lower incomes may support policies that weaken patents in favor of access despite their adverse effects on overall consumer welfare.

Footnotes

*This paper substantially extends our previous paper of the same title by incorporating the effects of prescription benefit coverage. Comments from Kevin Murphy, Gary Becker, Sam Peltzman, Richard Epstein, and Ernst Berndt are gratefully acknowledged. John Harris provided excellent research assistance.

[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 law attempted to balance the benefits of generic competition and innovation. 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 bio-equivalent to the patented compound and may begin meeting this requirement 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.

[2] Bills that would allow U.S. citizens to import patented pharmaceuticals from abroad were introduced in 2003 and 2007. Neither measure was enacted. See "Senate Likely to Back Drug Reimportation," Washington Post, 5/4/07, pg. A3 and Adams, et al., "How Did the 2003 Prescription Drug Reimportation Bill Pass the House?" unpublished manuscript, 1/7/05. Phillip Elliott, "McCain Calls for Drug Reimportation," Associated Press, November 17, 2007. In 2006, state legislatures adopted or enacted 85 laws or resolutions pertaining to prescription drugs. In addition, more than 600 bills were considered in

these legislatures. In 2008, over 550 bills were introduced in state legislatures, of which 60 became law. Pharmaceutical price legislation was passed or enacted in 31 states. National Council of State Legislatures Web Page, accessed at: http://www.ncsl.org/programs/health/drugbill06.htm, and http://www.ncsl.org/programs/health/drugbill07.htm and http://www.ncsl.org//default.aspx?tabid=14418.

[3] The international pressure for increased access to patented new drugs has also intensified recently. Countries like Brazil and Thailand are adopting liberal interpretations of the "compulsory licensing" provisions of WTO rules and nullifying the patent protection on certain anti-retroviral drugs. These countries then authorize local firms to manufacture generic versions of patented drugs. "A Gathering Storm" *The Economist*, June 6, 2007.

[4] Beginning in 1999, the Internet service Napster allowed consumers to circumvent intellectual property protection on recorded music by facilitating online exchange of recorded music files. Napster was found to have violated the artists' and music distributors' copyright protection (A&M Records, Inc. v. Napster, Inc., 2000).

[5] As illustrated, P_G is six times higher than MC, indicating that the elasticity of demand at P_G is -1.2. This conforms with the results in the literature. See Grabowski and Vernon (1992).

[6] A complete analysis of intellectual property policy changes in one industry would also include potential effects on other industries. We ignore these spillover effects.

[7] With linear demand and constant marginal costs, profits are twice the amount of both consumer surplus and dead weight loss (static inefficiency) with patent protection. Hence, the consumer surplus gains from eliminating patent protection on the stock of drugs are three times the initial consumer surplus in each period.

[8] In 2008, nearly 80 percent of prescription drug purchases were paid for in part by private insurers or government agencies. "Prescription Drug Trends," The Kaiser Family Foundation, May, 2010, Figure 2. Accessed online at http://www.kff.org/rxdrugs/upload/3057-08.pdf.

[9] Third-party payors have moved away from single copayments to tiered copayments (e.g. $15 for a generic prescription, $30 for a "preferred" brand prescription and $45 for a "non-preferred" brand) that provide incentives to use generics and preferred branded products.

[10] Lakdawalla and Sood (2005, 2006, 2007) demonstrate several important results that are consistent with this standard result. Of course, third parties who offer prescription benefit coverage and who negotiate with branded drug manufacturers and retailers incur various transactions costs. While these may limit their ability to achieve first-best outcomes, the ability to implement a two-part pricing scheme is, as discussed, expected to yield gains from trade compared to the alternative outcomes where consumers, at the margin, pay prices that reflect the exercise of market power by branded drug manufacturers.

[11] The lack of full consumer control of purchase decisions may mean that copayments may not fully determine quantity demanded. We do not pursue this issue, however, and in effect assume that physicians and patients are acting jointly. In addition, we assume that the quantity of drugs produced and sold are allocated to consumers who demand them.

[12] Alternative real-world reimbursement schemes with share requirements, exclusivity provisions, lump sum payments, rebates, or quantity discounts could achieve the same results that we illustrate here. We adopt the per-unit reimbursement model for simplicity.

[13] Regarding the distribution of gains from trade, the assumption of constant profits to manufacturers (and zero profits to third-party payors) is relevant to our subsequent findings in that the status quo level of consumer surplus realized is greater under prescription benefit coverage. With this assumption, Napsterizing is less favorable to consumers compared to alternative assumptions, e.g., the assumption that consumer surplus increases only slightly due to prescription benefit coverage with the bulk of the gains going to manufacturers and third-party payors. In general, the gains from trade from two-part pricing can be shared among manufacturers, consumers, and third-party payors subject to participation constraints.

[14] Giving that α indexes output relative to the competitive level, r_C is found by solving the isoprofit constraint with $\alpha = 1$:

$$(r_C - c)\alpha Q_C = \frac{(a-c)^2}{4b}.$$

[15] See the related discussion in Lakdwalla and Sood (2006), pp. 9-10.

[16] In general, if αQ_C is the level of output, where $\alpha \in (0.5, 1.0)$ varies from Q_M to Q_C, the reimbursement rate that returns output of αQ_C while maintaining monopoly profits is $r_\alpha = c + \frac{1}{4}\frac{(a-c)}{\alpha}$.

[17] Lakdwalla and Sood (2006) calculate that at current benefit levels, approximately 82% of the deadweight loss that would occur in pharmaceutical markets with patents is recovered with existing two-part pricing as embodied in health insurance contracts. This is entirely consistent with the results that we report below.

[18] Standard analysis of the viability of the market for prescription benefit coverage would account for the costs of and the demand for third party coverage. Third party payor profitability requires that monthly premia, PR, cover expected costs. Expected costs depend on the risk of illness, s, and costs of treatment, L, and administrative costs, denoted here as the load factor, β. Costs of treatment are simply the rates paid to the branded manufacturer net of copayments, multiplied by the quantity purchased. Third party payors cover their costs on an *ex ante* basis when

$$PR = s(1+\beta)(r_\alpha - P_\alpha)\alpha Q_C.$$

Consumers must balance the benefits of being able to purchase drugs at the copayment prices when sick against the costs of insurance. In the expected utility framework, with wealth Y, expected utilities with and without coverage are

$$V = (1-s)U^H(Y-pr) + sU^S(Y-pr-P_\alpha q_\alpha), \text{ and}$$

$$V = (1-s)U^H(Y) + sU^S(Y-P_M q_M).$$

The superscripts on the state-dependent utility functions denote the "healthy" and "sick" states. In the absence of benefit coverage, the consumer pays the price P_M for branded drugs. For health care consumers to willingly participate in the prescription benefit program, the contract with individual premium, pr, and copayment, P_α, must be structured so that the reduced wealth in the healthy state is more than made up for in expected utility terms when sick. If the individual copayment $pr = \frac{PR}{N}$, where N is the number of members in the plan, is small enough (due to large N), then participation is likely. Of course, if N is small due to an adverse selection problem, the market could collapse because of high premiums. It should be noted as well that coverage is less likely to be profitable, and therefore less likely to be offered by providers, as output approaches the competitive level with the attendant low copayments and higher net costs.

[19] IMSHealth, "IMS Health Reports U.S. Prescription Sales Grew 5.1 Percent in 2009, to $300.3 Billion," web access at http://www.imshealth.com/portal/site/imshealth/.

[20] According to the Kaiser Family Foundation, about 22% of expenditures in 2008 were for generic drugs. Kaiser Family Foundation, "Prescription Drug Trends: Factsheet," May, 2010, accessed online at http://www.kff.org/rxdrugs/upload/3057-08.pdf.

[21] IMSHealth, "IMS Health Reports U.S. Prescription Sales Grew 5.1 Percent in 2009, to $300.3 Billion," web access at http://www.imshealth.com/portal/site/imshealth/.

[22] Market exclusivity derives from both effective patent life and statutory exclusivity. Effective patent life is a function of the date of the original patent, reduced by the time needed for FDA approval of the drug, but potentially extended by specific legislative mandates such as the Hatch-Waxman Act (see Note 1, supra.). "Exclusivity" are marketing rights granted by the FDA that may have the effect of extending the market exclusivity (if exclusivity expires after the patent) or not affecting it (if exclusivity expires during the term of the patent). Examples of statutory exclusivity include Orphan Drug Exclusivity (seven years), New Chemical Entity Exclusivity (five years), and Pediatric Exclusivity (six months). See U.S. Food and Drug Administration, "Frequently Asked Patent and Exclusivity Questions."

[23] 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.

[24] According to the Kaiser Family Foundation, between 1999 and 2004 the average generic price as a fraction of the brand price was 94% with one generic competitor, 26% with ten competitors and 13% with 15 competitors. Kaiser Family Foundation, Prescription Drug Trends, May 2007.

[25] This elasticity estimate is derived from the standard economic result that a profit-maximizing firm will set its price-cost margin equal to the inverse of the elasticity of demand.

[26] Phase 1 trials are usually conducted on 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. A New Drug Application (NDA) to the Federal Drug Administration (FDA) follows completion of Phase 1 and Phase 2 trials. Phase 3 clinical trials are large-scale trials with controls and are designed to yield results on safety and effecacy that may be extrapolated to the general population. U.S. Food and Drug Administration, *CDER Handbook.* Viscusi, Vernon, and Harrington (2000, p. 817) reported that Phases 1-3 averaged twelve years in length.

[27] See Accenture (2001) and Kettler (1999).

[28] See U.S. Food and Drug Administration, *FDA Drug Review and Approval Times.* http://www.fda.gov/cder/reports/reviewtimes/default.htm).

[29] For example, average durations range from 6.8 to 9.3 years for NCEs approved during 2005, for example, compared to a range of 10.5 to 14.8 years for NCEs approved in 1997. Another factor affecting patent life is that firms facing patent challenges are entitled, under the Hatch-Waxman, to a 30-month stay of generic introduction to allow time for the patent litigation to be resolved. www.whitehouse.gov/news/releases/2002/10/20021021-4.html]. This new rule reduced the incentive for firms to file multiple new patents for each innovator drug. With fewer patents filed per drug, this rule may have reduced the average patent life of innovator drugs since 2002.

[30] Lichtenberg (2002) focused on the period 1960 to 1997, when life expectancy in the U.S. increased from 69.7 to 76.5 years. He finds that while approximately $11,000 in medical expenditures were required to gain one additional life-year. A much smaller outlay on pharmaceutical research and development ($1345) yielded the same benefit.

[31] Lichtenberg (2001) uses the 1996 Medical Expenditure Panel Survey (MEPS), which contains information on patients and their medical conditions. While his results indicate that new drug therapies reduce types of non-drug medical expenditures, the largest gains are from reduced inpatient expenditures. Overall, he estimates that the total reduction in non-drug health expenditure exceeds the increase in drug expenditure by a factor of four and concludes that restricting access to newer, branded drugs in favor of older, generic drugs would be misguided.

[32] Murphy and Topel use an expected present value of lifetime utility framework that accounts for the value of market and non-market time, age, and other factors. For example, age plays an important role in

diseases such as Alzheimer's given that advances against this disease are more valuable to the elderly than to younger individuals who would discount the future gains more heavily. They estimate the value the U.S. population realized from the dramatic reductions in death rates and the associated gains in longevity between 1970 and 1990. Using a value of a statistical life of $5,000,000, their estimate of the annual value of $3.3 trillion each year in 2009 dollars is nearly one-half of U.S. GDP. (The value of a statistical life is 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, which corresponds to a total value of $5 million ($500*10,000). See Moore and Viscusi (1990).) Over half of Murphy and Topel's estimate, 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 gains are significant. Indeed, if all medical expenditures are directed towards increasing longevity, then annual expenditures of approximately $1.6 trillion are a bargain, returning over 100 percent annually in benefits from increased longevity.

[33] See IMS Health, note 19 supra.

[34] 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). .

[35] Static consumer welfare equals $CS^{-\rho}[1 - e^{-\rho T}]$. $500B of surplus for 7 years yields gains of $3.35T in present value.

[36] As noted above, the present value of lifetime welfare from the status quo here equals CS/ρ. With CS of $125B, and with $\rho = 0.02$, lifetime benefits from the status quo equal $6.25B.

[37] With producers still earning producer surplus of $250 B, the transfer would have to come from healthy insureds, who now pay higher premiums.

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Tables

Table 1
Average Patent and Exclusivity Periods for NCEs Approved During 1997-2005

Year	Shortest Duration*	Longest Duration**
1997	10.5	14.8
1998	11.6	13.8
1999	10.7	14.8
2000	11.0	14.9
2001	11.5	15.0
2002	8.6	12.2
2003	8.7	12.9
2004	6.4	8.7
2005	6.8	9.3
Average, 1997-2005	9.7	12.9

*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, 1997-2006. U.S. Food and Drug Administration, Electronic Orange Book.

Table 2
Welfare Analysis

	(1)	(2)	(3)
	Status Quo without Prescription Benefit Coverage	Status Quo with Prescription Benefit Coverage - Intermediate Case	No Patent Protection - Napsterizing
			*Present Values**
Consumer Surplus	\$6.25T	\$10.94T	\$3.3T
Producer Surplus	\$12.5T	\$12.5T	\$0
Total Welfare	\$18.75T	\$23.44T	\$3.3T
			Benefit-Cost Ratios for Maintaining Status Quo
Consumer Welfare			
Status Quo without Prescription Benefit Coverage versus Napsterizing: (1) versus (3)	1.91		
Status Quo with Prescription Benefit Coverage (Intermediate Case) versus Napsterizing: (2) versus (3)	3.34		
Total Welfare			
Status Quo without Prescription Benefit Coverage versus Napsterizing: (1) versus (3)	5.74		
Status Quo with Prescription Benefit Coverage (Intermediate Case) versus Napsterizing: (2) versus (3)	7.17		

*Discount rate equal to 0.02 for all calculations.

Column 1: Consumer surplus equal to \$125B/year, producer surplus equal to \$250B/year. Flows continue in perpetuity.

Column 2: Consumer surplus equal to $218.75B/year ($125 + 62.5 + 31.25), producer surplus equal to $250B/year. Flows continue in perpetuity.

Column 3: Consumer surplus equal to $500B/year, producer surplus equal to 0. Flows continue for 7 years.

Figure 1
Basic Framework:
Branded and Generic Drug Markets

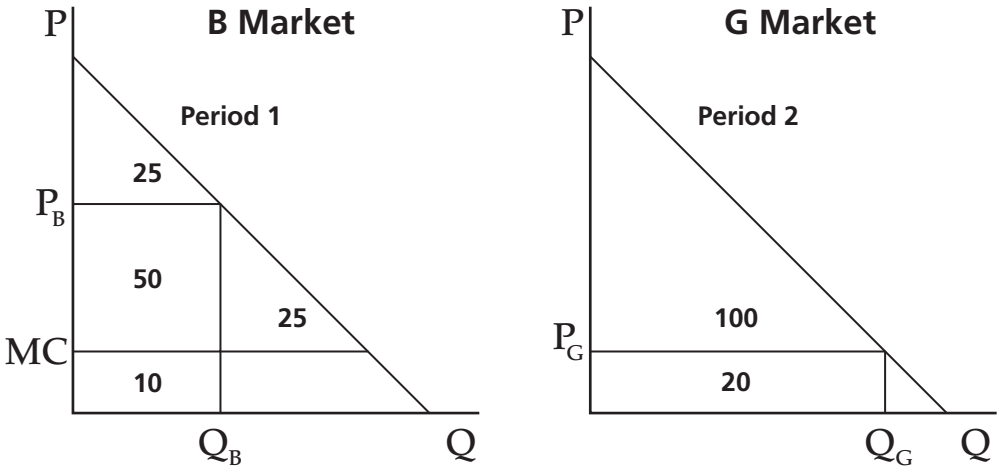
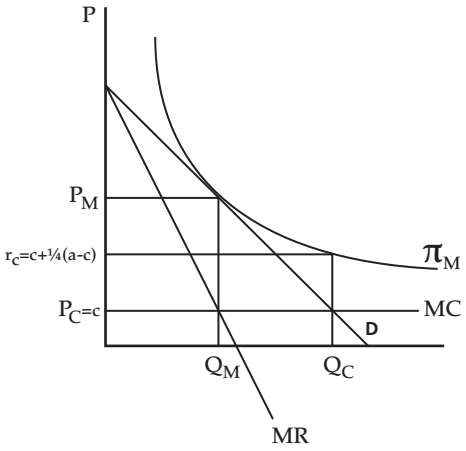

P
B Market
Period 1
25
P_B
50
25
MC
10
Q_B
Q
P
G Market
Period 2
100
P_G
20
Q_G
Q

Figure 2
Napsterizing Scenarios with Prescription Benefit Coverage


P
P_M
$r_c=c+¼(a-c)$
$P_C=c$
π_M
MC
D
Q_M
Q_C
MR

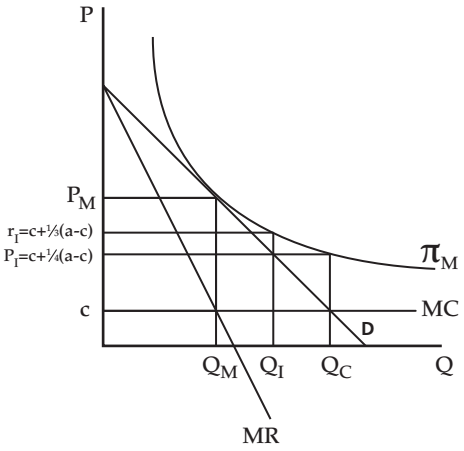
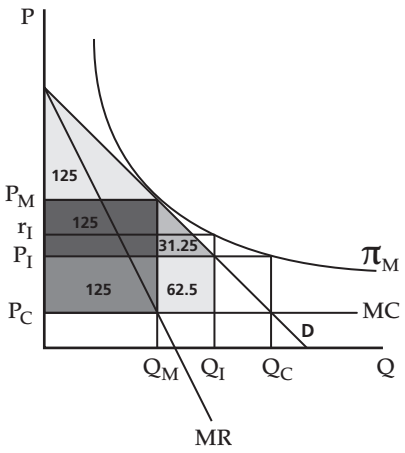

P
P_M
$r_I=c+⅓(a-c)$
$P_I=c+¼(a-c)$
c
π_M
MC
D
Q_M
Q_I
Q_C
Q
MR

Figure 3
Producer and Consumer Surplus in Intermediate Case


P
125
P_M
125
r_I
P_I
31.25
π_M
125
62.5
P_C
MC
D
Q_M
Q_I
Q_C
Q
MR