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"Pharmaceuticals, Prescription Plans, and Promoting Progress"

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PHARMACEUTICALS, PRESCRIPTION PLANS, AND PROMOTING PROGRESS

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Abstract

Monopoly response to buyers who pay fraction c of the product cost is to raise the buyer price for the initial quantity q_0 from p_0 to $\frac{1}{c}p_0$, and adjust to a different price and quantity only if profits are thereby raised further. A 25% prescription drug plan co-payment provision, for example, magnifies the pharmaceutical patent holder's profits more than a fourfold increase in price at the original output would do. This is detrimental to the adoption and use of prescription drug plans. In addition to the appearance of abusing a prescription drug program, the inducement to patentable pharmaceutical research and development (R&D) cannot be optimal both before and after such a plan's institution. Possibly it is optimal in neither. This paper describes an efficient incentive plan for R&D that does not depend on monopoly and thus is not an impediment to co-pay provisions that might be part of a prescription drug plan.

JEL Classification Numbers:

Key Words: Research and Development, Prescription Drug, Co-payment, Patent Protection, Intervention Principle

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PHARMACEUTICALS, PRESCRIPTION PLANS, AND PROMOTING PROGRESS

I Introduction

Intellectual property policy and the pharmaceutical industry have placed Americans on the horns of a dilemma. On one hand, the special position conferred by patent protection on pharmaceutical companies distorts drug prices, limits the treatment options for individuals without prescription drug coverage, and causes US consumers—many who are sick and not working—to pay too much for their drug medications. Price differences for branded drugs sold abroad have risen to the status of evening news. Images of busloads of senior citizens traveling to Canada to buy cheaper drugs highlight the passion felt by many that the US consumer pays too much. Many argue for a large public response to high drug prices, calling for the federal government to use its market position through Medicare and Medicaid to force drug producers to lower their prices. Others argue that US citizens should be permitted to import lower-priced drugs from online pharmacies. Some go so far as to suggest that the ban on drug importation from Canada has little to do with safety, but is, in fact, part of a conspiracy between the industry and the Food and Drug Administration to discredit the Canadian agency responsible for drug oversight with the objective of preserving the high prices charged by US manufacturers (Barlett and Steele, 2004).

On the other hand, creating a prescription drug insurance plan with a co-payment provision invites the monopolist's response which is to raise the drug price in proportion to the inverse of the co-pay. A 25% co-pay, for example, would imply that the monopolist raises its price to four times the initial level and adjusts the resulting price-quantity point on the effective demand curve by moving from the initial quantity only if profits are thereby raised further. This is significant because co-payments for prescription drugs are declining. The percentage of prescription drug expenditures paid out-of-pocket by US consumers has fallen from 60% in 1990 to 30% today. Absent other market changes[1] this fact would predict an approximate increase in drug prices of 100%. From 1990 to 2002 the pharmaceutical component of the Medical CPI actually increased 75%. Consumer advocates express concern that the prices of drugs, especially those consumed by the elderly, have surged since the Medicare drug program was first introduced in mid-2001 (Martinez, 2004). However, the industry's actions should elicit little surprise. They are the natural result of an inefficient and outmoded means of encouraging research and development.

Large sunk costs, high fixed costs, low variable costs, segmentable markets, and strong patent protection for drug discoveries characterize the pharmaceutical industry. Market power restricts competition and guarantees to patent holders a monopoly position for the effective life of the patent, currently approximately 8-10 years after introduction of the drug on the market. Pharmaceutical companies maintain

that they must be allowed to charge high prices to support continued innovation and an uninterrupted flow of new products. Even so, because the estimated cost of developing a drug is over $800 million (DiMasi et al., 2003), patent protection does not guarantee that a drug will be economically successful. It is reported that the likelihood of recovering research expenditures on a marketable drug is less than one in three (Grabowski, Vernon, and DiMasi, 2002).

Prescription drug insurance and patented drug pricing bring three issues to the fore. The first is relevant to the observed price increases for prescription drugs: the exercise of market power. The second is suggested by the first: identifying the best way to reward useful innovators while spreading the benefits of their inventions as quickly and widely as possible. The third is suggested by the second: calculating accurately the optimal amount of the reward to be paid to the innovator.

Those who believe that these problems have been solved are probably mistaken in their confidence. Take, for example, the question of calculating a reward. In principle, as much of the benefits of a new invention should accrue to the inventor as are needed to cause the greatest possible future invention making.[2] In a static setting, this involves, among other things, knowing the consumer surplus associated with an invention. Consumer surplus information is not provided by the monopoly profits of the seller, if patent rights are granted, or other immediate price and quantity observations if they are not. Most inventions provide benefits for more than one period. In that event, benefits depend on the stream of changing consumer surpluses into the indefinite future, and these depend on the timing of the invention and introduction of substitute and competing products that may become available at unknown future points in time. Innovations in sailing ship design provide less value when propulsion systems have moved on to internal combustion engines and nuclear power, for example. A fixed choice of patent life profits is an arbitrary account of future surpluses.

Nothing can be done to eliminate the need to approximate the net social value created by an invention. Whether patents are used or not, prediction is difficult "especially when it involves the future." On points one and two (market power price response and identifying the best way to reward innovators), however, the intervention principle—the rule that a market intervention directed most closely to the margin to be influenced is efficient—is applicable. In the pharmaceutical context the principle implies a policy that presents no adverse interactions with co-payment provisions of prescription drug plans, is incentive-based, and is implementationally uncomplicated. Short of full Ramsey pricing across the entire economy, it moves further in the direction of first best efficiency and marginal cost pricing than other alternatives. This approach is the subject of the present paper.

In what follows we show that a program where new drugs that are patented, immediately freely placed into the public domain, and inventors are rewarded on the basis of an intertemporal bounty that is tied to future market sales is superior to traditional patents and bears many desirable qualities relative to patent alternatives that require auctions or other devices to estimate future surplus values.

Our goal is to add to the small but exciting and growing literature that has begun to search out socially preferable alternatives to the patent system. Section II begins with a discussion of the dimensions and importance of the problem, followed in section III with a review of the literature on policies toward research and development where the emphasis is placed on the static and dynamic incentive issues. Section IV provides a proof of the first-best intervention principle as a reference point for the discussion of alternatives to the patent system in section V. Section VI is devoted to discussing practical application issues and objections to the intertemporal bounty which is implied by the intervention principle. In this section, we also discuss a similar system applied to the music industry. Section VIIconcludes.

II Dimensions of the Problem

> "The people that can least afford [to pay for prescription drugs] are the people who are more likely to consume. Again, do you want drug companies to be responsible [for access]? ... No, you don't" Evans (2003)

Consider a pharmaceutical patent holder that faces downward sloping demand for its prescription drug, $q = D[p^d]$, where p^d is demand price (the price paid by the buyer) and q is the quantity demanded. If a prescription drug program is put in place that subsidizes fraction $(1 - c)$ of the product's cost to buyers, the demand price becomes $p^d = cp^s$ where p^s is the price received by the seller. The patentee maximizes post-program profits

$$\Pi[p^d, c] = R[p^d, c] - C[q[p^d]] = \frac{1}{c} p^d D[p^d] - C[D[p^d]] \tag{1}$$

by choice of price p^d where $C[q]$ is total cost of supplying q units of product. By the envelope theorem,

$$\frac{d\Pi}{dc} = \frac{\partial \Pi}{\partial c} = \frac{\partial R}{\partial c} = \frac{d(\frac{1}{c})}{dc}\, p^d q. \tag{2}$$

In other words, the effect of the subsidy is to raise expenditures on the good and profits to the patent holder in proportion to the amount that the change in subsidy raises the multiplier $\frac{1}{c}$.

Figure 1 shows the effect on price and quantity for a linear example. Given initial demand curve D, price and quantity are p_0 and q_0 at point a. Introduction of the prescription drug program causes the effective demand curve to shift to D', where the price at point b is $\frac{1}{c}\, p_0$. The monopolist is guaranteed to earn at least the additional profits associated with the multiplied price, but in fact does better because the change affects marginal revenue and the new profit maximizing choice of output occurs at quantity q_1 associated with point c where post-program marginal revenue equals marginal cost. Thus as already noted, using 25% as the assumed co-payment, the pharmaceutical industry gains more than the windfall profits associated with an increase in the price to 4 times the original p_0 at fixed quantity.

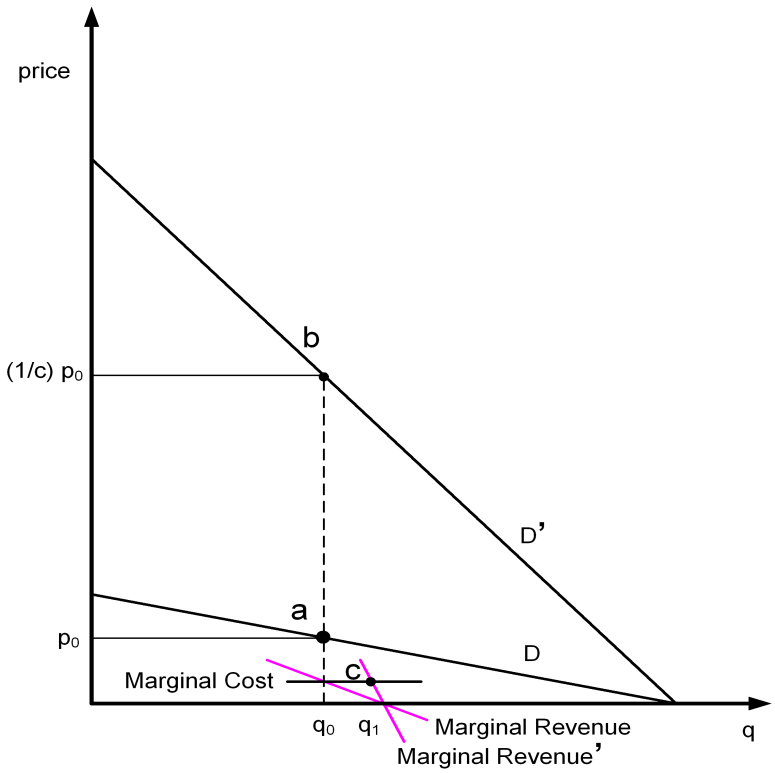

Figure 1: Monopoly Price Response to Buyer Co-Payment

> "With more promising new treatments in the pipeline than ever, I don't believe the billions of people around the world who are suffering from diseases today that may be treatable in the near future can wait." FDA commissioner Mark McClellan (2003)

The importance of access to health care is evident to policymakers as well as to consumers. Access to pharmaceutical drugs depends on availability and affordability. Availability is determined by scientific discovery, while affordability is determined by ability to pay and access to insurance. On average Americans spend a modest one percent of GDP on pharmaceuticals. The problem, therefore, is not so much total spending, but the spending of a relatively few chronically ill individuals who consume most of the drugs. In the words of another observer,

> "How do we share the wonders of this industry so that everyone can partake? And that is a task for Congress, obviously." Reinhardt (2003)

It is clear that the innovator deserves to be rewarded for the research and development effort needed to bring a new drug to the point of market availability, and the consumer deserves access to the drug and has the responsibility to pay for it. If payers in one country negotiate prices that do not cover

fully-allocated costs, including R&D costs, consumers in some other country will have to make up the difference. According to McClellan

> "If we continue on our current path of trying harder and harder to shift the costs of developing new medicines to someone else, rather than paying our fair share, everyone's effort to get a free ride on new drugs will grind the development of new drugs to a halt". McClellan (2003)

For the most affected group of drug users, however, ability to pay means expanded insurance coverage, something that Pauly argued is associated with price escalation as the market power model predicts,

> [Asking consumers to pay] "a significant portion of hospitals' and physicians' receipts helps to keep down the ballooning of costs and charges. There is reason, however, to believe that the spread of insurance of this type has contributed to the upward trend of medical costs." Pauly (1970)

The pharmaceutical access problem therefore is the two-fold problem that the current system for rewarding drug innovation often means high prices, and more generous insurance coverage for affordability leads to greater excercise of market power. Calls for government intervention to control prices creates new threats to the system. While the description of the problem is pretty much agreed upon, the solution is not. In the next section we review the historical policies toward research and development. The subsequent goal will be to offer an option that benefits from what has been learned in the relatively recent past, but at the same time makes drugs immediately available at prices approaching their marginal manufacturing costs.

III Historical Policies Toward Research and Development

Market forces have always required a connection between public and private actions as they relate to research and development.

III.A Government

Encouraging scientific research and new product development has long been an interest of government. Statutes traced back to seventeenth century England rewarded innovation by granting special monopoly rights to an invention. The US patent system emerged as colonists in the New World recognized that rewarding individual innovators would benefit society as a whole. Patent policy was eventually codified in the US Constitution. Article I, Section 8 grants Congress the authority,

> To promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries.

Policy change often outpaces implementation: It was not until 1836 that the US Patent Office was actually authorized to determine if proposed inventions qualified for patent protection.

Regulation of pharmaceutical drugs became the responsibility of the Food and Drug Administration (FDA) in the early twentieth century. Initially, concern focused primarily on drug safety. Then, in 1962 with the passage of the Kefauver-Harris Drug Amendments, the scope of regulation expanded to include not only safety, but also effectiveness. Adopted in the wake of the thalidomide tranquilizer disaster in Europe where over 12,000 babies were born with severe birth defects, the Kefauver amendments required drug makers for the first time to prove the effectiveness of a drug in treating a specific disease or medical condition. In addition, the FDA was given strict control over investigational drug studies, Phase II and Phase III of human trials. DiMasi et al. (2003) estimated that these last two phases of human trials are responsible for approximately three-fourths of the $467 million capitalized clinical costs for a new drug approval. This single aspect of drug regulation is responsible for approximately one-half of the cost of developing a new drug entity.

The most significant change in patent law and its impact on the pharmaceutical industry came in 1984 with the passage of the Drug Price Competition and Patent Term Restoration Act. The so-called Hatch-Waxman Act extended the effective life of a drug patent up to five years and at the same time made it easier for generic drugs to enter the market. The patent life extension was intended to restore part of the patent life that was lost to the expanded regulatory process. It is equal to the sum of the FDA review time for the new drug application and one-half of the time consumed by the clinical trials. Prior to the Hatch-Waxman Act generic drug companies were required to submit their own safety and efficacy evidence to support their new drug application. As a result of the new law, if the generic company can demonstrate bioequivalence to the existing branded drug, it may rely on the original safety and efficacy evidence provided by the branded drug. This Abbreviated New Drug Application (ANDA) is a low-cost option compared to the earlier requirement, cutting at least two years off the application process and saving millions of dollars (Grabowski and Vernon, 1986). Since passage of the Act, the generic share of the unit volume increased from 19 percent to over 50 percent. Within months of patent expiration, the branded drug will see its market share fall substantially.

International property rights were further strengthened as part of the Uruguay Round in the General Agreement on Tariffs and Trade (GATT) negotiations in 1993. Patent infringement by developing countries had become a serious issue in trade negotiations. The Uruguay Round produced an agreement on Trade-Related Aspects of Intellectual Property (TRIPs) that brought about major changes in the patent policies of other countries. For US domestic policy, the most important change was increasing the patent term from 17 years from the date of grant to 20 years from the date of application. Other

important changes provide patent holders the right to prohibit the importation of products that infringe on a valid patent and limit the use of compulsory licensing policies that force patent holders to relinquish property rights on certain essential drugs. When fully implemented by most countries in 2005, TRIPs will serve to strengthen patent protection around the world (Jaffe, 2000; Barton, 2004).

III.B Patents

The goal of the patent system is to insure adequate rewards for research and development consistent with the dissemination of the patented product and information related to it. The economic rationale for patents is based on the understanding that the primary product of R&D, scientific knowledge, has many of the attributes of a public good (Levin, 1986). Though patents create monopoly price distortions, this defect was overshadowed in the early years of the American republic by the advantage that the nation did not need to rely on its tax system for revenues: the inventor or author generated his own reward through selling his invention.

Spence (1984) identified three issues that lead to failure in markets associated with large investments in research and development. First, the value of research and development is determined by what buyers are willing to pay for the product of R&D, and total revenues understate social benefits, both in the aggregate and at the margin. Thus there is no *a priori* reason to think that unaided market outcomes will be optimal in any sense. Second, because R&D is often associated with significant fixed costs (certainly true in the case of pharmaceuticals), imperfect competition and its consequences are likely to characterize the industry. Third, substantial investment in R&D frequently is associated with an appropriability problem, thereby reducing the firm's incentive to conduct R&D. As many have noted, solving the R&D incentive problem by creating a monopoly problem merely trades one inefficiency for another.

With modern economics we can better describe the flaws of the patent system:

- Patents do not transfer to the holder the social surplus that the invention generates. The failure to account for full consumer surplus may mean that the incentive to invent is inefficiently low.
- The well-known experiences of Louis Daguerre (Daguerreotype) and Eli Whitney (cotton gin) whose inventions were quickly "stolen" (effectively expropriated) by the public show that the patent is often little defense against inventions being purloined by others (Kremer, 1998). Pharmaceutical knowledge, once a product is produced, it is frequently easily reverse engineered.
- The patent system fails to account for beneficial externalities that result from the patent. Daguerre's photographic process had a tremendous impact on spurring the widespread development of photography, positive externalities that were never acquired by the inventor. In the case of

new drugs, knowledge spillovers resulting in imperfect appropriability diminish incentives for R&D. The marginal cost of the understanding required to produce a pharmaceutical drug is often close to zero, comprised solely of the cost of transmitting the scientific knowledge.

- Finally, by their nature, patents create monopoly rents. These distort research incentives and encourage inefficient efforts by other firms to create copycat inventions that undercut the patent holder in pursuit of the monopoly rents.

Were newly-invented products immediately to be competitively supplied and the inventor to acquire their social surplus, these problems would vanish.

The point that patents respond in part to the appropriability problem, but provide imperfect protection bears repeating. In its capacity as a barrier to entry, a patent increases the cost of supplying a perfect substitute, but it does not preclude the development of similar drugs designed to treat the same medical condition (Waterson, 1990). In 2000 there were 6 different proton pump inhibitors and 6 histamine H2 receptor antagonists under patent for the treatment of ulcers. There were 7 patented drugs available for the treatment of high cholesterol, 5 antidepressants, and 27 different patented drugs for the treatment of hypertension (MedAdNews, 2000). Taking into consideration the eventuality of within-class competition, the first mover can expect only a temporary advantage until follower drugs in the class are approved. For most classes of drugs, competitors are able to develop imitations or close substitutes in a short period of time. The process of filing for and receiving a patent sometimes discloses enough scientific knowledge to encourage further innovation when combined with the prospect of market rents. Even presuming that markets are monopolistically competitive, patents create allocation problems, provide the innovator with market power and cause pricing distortions.

A natural response is to ask whether we can improve social outcomes by adjusting the patent rules to create a system that provides the optimal balance between the short-run efficiency of marginal cost pricing and the long-run incentives to innovate. Unfortunately, it is unlikely that the patent system, as it is traditionally envisioned, can be fine-tuned to improve social welfare (Scotchmer, 1991). The number of instruments available to policy makers limits the scope of patent law to achieve the desired objectives. In addition to the length of the patent life (20 years for pharmaceuticals), policy is constrained by the breadth of protection, which connects to the likelihood that second-generation technology will infringe on the patent. Whether the patent is awarded to the first to invent (US/Canada priority rule) or to the first to apply (rest of the world), it remains a restricted instrument.

IV First Best

Presuming perfect information and full commitment, the efficient remedy for underprovision of a socially valuable activity is a subsidy to the object of interest. We provide a formal demonstration of this technical result first and apply it in what follows to the question of how incentives for pharmaceutical research and development should be structured.

Following standard practice, let $e[p,u]$ be the expenditure function of the representative consumer, where $u = u[x]$ and x is an n-dimensional vector of consumption and $e[p,u] = p \cdot x$ by construction of e. Positive elements of x denote the quantity of goods consumed and negative elements denote the quantity of goods supplied by the consumer, such as labor hours. In a similar manner, define y to be n-dimensional production vector. A positive component of y denotes the quantity of a good supplied to the market and a negative component the quantity of a good used in the production process. Market clearing is insured by the relation

$$x = y + \omega \tag{3}$$

where ω is the economy's vector of endowments. Endowments are goods inherited from nature or the past that are not produced in the current period. To compare one situation to another, let superscript 0 denote the initial situation and superscript 1 the final situation. Often superscript 0 denotes the "pre-program" position and 1 the "post program" position, or vice versa. We allow for the possibility that prices faced by firms may differ from p, $p - \tau = p$ where τ is an n dimensional vector of taxes/subsidies.

Define the change in welfare by $\Delta \overset{o}{W} \equiv e[p^0,u^1] - e[p^0,u^0]$. Because the expenditure function is monotonic in utility for fixed prices, $\Delta \overset{o}{W}$ is positive if and only if $\Delta u = u^1 - u^0 > 0$. We now make use of the observation that if state 0 with the desired level of provision of good 1 has been obtained in the best possible fashion, the move to any other state 1 with the desired provision attained by alternative means must lower utility. By direct computation,

$$\begin{aligned}
\Delta \overset{o}{W} &= -(p^0 \cdot x^1 - e[p^0,u^1]) - p^0 \cdot (x^0 - x^1) \\
&= -(p^0 \cdot x^1 - e[p^0,u^1]) - p^0 \cdot (y^0 - y^1) \\
&= -(p^0 \cdot x^1 - e[p^0,u^1]) \\
&\qquad -p^0 \cdot (y^0 - y^1) \\
&\qquad\qquad -\tau^0 \cdot (y^0 - y^1).
\end{aligned} \tag{4}$$

Presume now that a subsidy to the production of good 1 only has been used to induce production of a targeted level of good 1, ϕ, in the initial equilbrium (i.e. the elements of τ are zero except for the first). Then the first two terms on the right hand side of the last equation in (4) are nonpositive. The first term is nonpositive because of the fact that $e[p^0,u^1]$ is the least cost of attaining utility u^1 and therefore is less than or equal to $p^0 \cdot x^1$ (bundle x^1 also achieves utility $u^1 = u[x^1]$). The second is nonpositive

because of the fact that firms maximize profits at market prices and hence $p^0 \cdot y^0 \geq p^0 \cdot y^1$. The last term becomes $-\tau^0 \cdot (y^0 - y^1) = -\tau_1(\phi - y_1^1)$ where y_1^1 is the output in the economy of good 1 in the final situation. Thus, if the desired level of output of the first good is achieved through the application of a subsidy to production of the first good, any other policy that achieves the same objective lowers welfare when compared to the initial equilibrium because the last term is also nonpositive. In the case of research and development to produce prescription drugs, monopoly will do worse than the subsidy program.

V Alternatives to the Patent System

The need to "promote the progress of science and useful arts" is unchanged from colonial times, but other features of the economic landscape are quite different. For example, modern fiscal tools allow the government to select taxes in more efficient ways. At the same time, we have (and want) broader insurance coverage of prescription drugs which affects the monopoly power exerted by pharmaceutical companies. We also enjoy a better understanding of social efficiency as it relates to the legal and institutional framework governing R&D activity. An efficient tax system almost certainly would not involve creating short-lived monopolies for new inventions. We are therefore able to consider new options.

V.A Government-subsidized research

One alternative to patents that has been suggested is for government to directly subsidize research. This addresses the problem of monopoly, but has the overwhelming disadvantage that the government is paying for *inputs* to the invention process rather than *outputs*. This creates an incentive for research, but not necessarily for socially desirable research.

V.B Prizes

Prizes for inventions have been tried with success in cases where the government or other prize-granting body can specify in advance what it wants. The $10 million Ansari X Prize to design and fly a privately-built aircraft into suborbital space is a good example. In October 2004 SpaceShipOne reached a height of over 100 kilometers for the second time in a one-week period to claim the prize. And setting higher goals, Bigelow Aerospace is offering $50 million to the first private firm that can build a vehicle that can carry a payload equivalent to seven astronauts into orbit. In many cases, however, the government does not know in advance what to support and cannot envision the direction that research should take.

This problem applies to subsidized directed research as well. A system that allows the fecundity of the market to devise and create new products would circumvent this problem.

V.C Patent buyouts and eminent domain

Kremer (1998) suggested patent buyouts via auction as a way to eliminate monopoly patent rents. A related process is buyouts through *eminent domain*, where judges would determine buyout value (Guell and Fishbaum, 1995). An auction has a number of advantages, including the advantage of determining value through a market mechanism. By removing patent rents auctions eliminate a distorting incentive for pharmaceutical firms to prefer to expend effort to finding new uses for under-patent drugs than to developing new uses for out-of-patent drugs. Auctions have the disadvantage that to maintain auction feasibility randomly selected patents would be sold to the highest bidder. In these cases the monopoly inefficiencies remain. Auctions are also potentially vulnerable to collusion, though the degree to which this would be a problem in practice is unclear. Auctions have the potential to create bidding problems if inventors have private information or hold special positions in the market such as being the lowest cost producer and can decide to retain or sell their patents. Ideally, all patents should enter the public domain as soon as this is feasible and the inventor would be in the same position as other users once the product is invented. Only as regards payment for the invention, would the inventor hold a special position.

V.D Application of the intervention principle

Since the most efficient way to accomplish a desired objective is to identify the margin to be influenced and apply a tax or subsidy narrowly to that margin at the minimal level needed to accomplish the objective, patenting prescription drugs violates the principle, as do subsidies to research, and most other proposals. In the case of prescription drugs the social objectives we want firms to accomplish are to:

1. conduct research and development to innovate *useful* new drugs,
2. patent them, and
3. disseminate them as quickly and widely as economically desirable over time until a better product arises.

The newness of the developed drug (step 1) is demonstrated by the second step. The usefulness of the drug is demonstrated by the third step which requires marginal cost pricing or, if there are increasing returns to scale in production, as large a scale as possible until those returns are exhausted. The application of the intervention principle to reach these objectives suggests by parallel reasoning the

following program: The government announces a reward that will be paid as a specified subsidy per dollar sold over time of

1. newly invented drugs
2. that are patented, and
3. freely (competitively) licensed.

The reward would apply to all sales, whether by the innovating firm or by others. Free access to the patent and free entry in production of the drug would imply marginal cost pricing. The objectives of innovation and distribution once innovation occurs are met. Notice that the market creates the desired incentives.

Margins at which the reward could be adjusted include the specified rate and the number of years (which could be indefinite) for which the payment applies. Because payment is intertemporal, there is no need to foresee at one moment the full future history and its present discounted value as there might be if an eminent domain action, patent buyout, or subsidy to research were to be employed. No monopoly rights are issued, so static inefficiency is absent. Ideally, the transfers to innovators of this intertemporal bounty would reflect full social benefits, a matter which we take up in the discussion of implementation.

VI The Intertemporal Bounty

The intervention principle identifies the intertemporal bounty with the features just described to meet the threefold objectives of innovation, patenting, and sales. Its practical implementation requires that we address three issues: (1) which new drug innovations will be eligible, (2) what will be the size of the bounty, and (3) how will the bounty be paid?

VI.A Eligibility

The pharmaceutical lobby is a powerful force in policy-making circles. Incremental change is probably necessary as well as preferred. Implementing a major change in the way prescription drugs are treated might best be tested through the prior use of a demonstration project.

Implementation might work as follows. The appropriate government administrative agency would initially solicit pharmaceutical companies to volunteer for the opportunity to participate in a demonstration which would take place over a number of years. Working together, representatives of the agency and the pharmaceutical companies would evaluate relevant market information bearing on the social value (consumer surplus, monopoly profits, monopoly deadweight loss, and competitive sales) for patented

drugs. This information would be used to establish the size of the bounty relative to sales. Thereafter, participant innovating companies (new patent holders, but without monopoly rights) would record all sales data for new patents, their own and the sales of licensees, assigns, and other producers. The patentee would have the obligation to verify sales on which bounty payments would then be made. The government agency has an interest in knowing whether the marketing results are those of a competitive market. Market contestability insures competitive sales.

VI.B Size

The goal of the intertemporal bounty is to reward the discovery of valuable products at a level that induces continuing innovation at the socially desired level. In principle, bounty payments should reflect both the timing and the size of the social value created by the invention through time. Fixed prizes, subsidized research, buyouts via *eminent domain* or auction, as well as bounties all suffer from the need to estimate an imperfectly known set of intertemporal magnitudes. Figure 2 displays a standard demand diagram. Areas A, B, and C under curve D are the social value of the drug supplied at quantity q_0 at marginal cost MC. The figure represents a single time period. A similar diagram applies for succeeding time periods into the future. The value of all such areas (A+B+C) is the social value estimated by different means. Granting monopoly rights provides area B to the patent holder for a limited number of years, clearly an understatement of the true value of a new innovation. An auction seeks to induce firms to provide estimates of the present discounted value of area B over a specified number of years when they calculate their bids, also an understatement. The government uses the bids to form its value for area (A+B+C). Note that unless the innovated product has been marketed, all such values are prospective, and estimates of values far distant into the future become more difficult to make because of changing market conditions. Matching the timing of payments to the timing of social benefits, however, removes the intertemporal problem. In the case of an intertemporal bounty, the pair (p_0, q_0) is observed through time. It does not need to be estimated or predicted for future periods.

Short of innovations controlled by infinitely lived perfectly discriminating monopolists, social value is not observed as a market outcome. While the need to estimate social value is unavoidable in any arrangement that is chosen, this difficulty should not be over stated. There are good ways to identify (A+B+C). Using the assumption that willingness to pay is proportional to income, for example, Kremer (1998) used the US CPS household income distribution data to conclude that the social value of new pharmaceuticals is 2.7 times the profits that would be achieved by a monopolist, area B, and the deadweight loss, area C in Figure 2, would be 25 percent of the sum of profits and consumer surplus (area A+B).

Other authors have been able to produce reasonable estimates about Figure 2 from information about the marginal cost of manufacturing and demand. Assuming a 10% cost of capital, for example,

Danzon (1997) estimates that the marginal cost of manufacturing pharmaceuticals is approximately 30% of monopoly price ($p_0 = .3p_1$). Combining this with demand elasticity data or information about willingness to pay as done by Kremer generates information about the areas in Figure 2. A program that is announced as providing $1 in bounty for every dollar in sales, for example, could be evaluated periodically to see if the bounty reflected the average value of social surplus generated by new innovations over time. Adjustments could be made as desired.

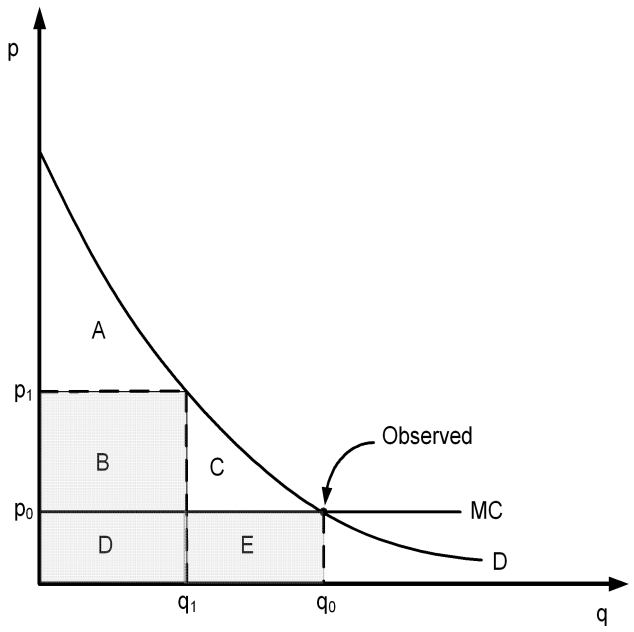

Figure 2: Willingness to Pay Social Value

VI.C How Paid

In the simplest implementation, the bounty would represent an industry average over all prescription drugs, similar to the compulsorily-licensing arrangement in the music industry discussed below in section VI.E. If more product-specific detail is possible based on pre-announced procedures (for example, firms might be allowed to generate test marketing data that demonstrate the shape and elevation of the demand curve) the bounty could be made more product-specific. The more popular the drug among consumers; i.e., the more valuable the drug can be demonstrated to be to society; the more money the innovator would make.

VI.D Other Issues

1. Tax Efficiency

The discussion of efficiency of the intervention principle of section IV implicitly presumed that subsidies to accomplish the desired objective were paid from the proceeds of distortionless taxes. Were patent holders to be paid the social value of their inventions from the proceeds of lump sum taxes, the static distortions of monopoly would be eliminated and no new distortions introduced. Barring that, full Ramsey pricing that minimize distortions would require creating an optimal tax plan for the entire economy that takes into account the needs for taxes to finance government, increasing returns industry, and pay for incentives to R&D as discussed here. The real-world issue discussed in this paper involves the need to estimate social value and to replace an imperfect system of patents that creates deadweight loss. The imperfections of monopoly are being replaced by a direct intervention—the intertemporal bounty—that is paid through taxes raised in an imperfect way.[3] Both monopoly and non-lump-sum taxes distort by withholding socially useful product. In a first best world, taxes would cause all prices to deviate from their marginal cost values to minimize economy deadweight loss. Imposing monopoly prices in the pharmaceutical sector, however, is unlikely to result as the implication of such a calculation. It is an empirical question whether the deadweight loss from taxes needed to pay for intertemporal bounties or patent buyouts is less than the deadweight loss of pharmaceutical patent monopolies. We must therefore make the assumption that the tax system is well enough constructed that the deadweight loss generated in paying for the interemporal bounty is less in absolute magnitude than the improvement in social welfare generated by improving the patent system.

This presumption seems to us a reasonable, is implicitly made in the literature, and is not specific to the intertemporal bounty. All discussion of replacing patents, whether it is by auctions, eminent domain buyouts, prizes, direct subsidies to research, or some other mechanism requires that the taxes raised to finance the more efficient mechanism be efficient enough that they do not introduce greater distortions into the system. If this assumption fails, there is little point in searching for an alternative to patents. Moreover, monopoly in the pharmaceutical sector tends to raise severe distributional elements as we have noted: The specter of elderly retired little old widows choosing between food and grotesquely overpriced patented drugs is not pretty. Assuming that the deadweight loss of taxation is smaller than the deadweight loss of patent and that alternatives to patents are evaluated on an equivalent cost to the treasury basis allows them to be compared on their other merits.

2. Objections

Objections to the intertemporal bounty can be considered in terms of its strengths and weaknesses relative to other approaches. Table 1 considers these by comparing the bounty to alternative research

and development incentives.

Patents have the advantage of familiarity. We have many years of experience with them. Their other obvious advantage—that the public treasury is not required to make explicit payments—was an important consideration for selecting patents when they were adopted in the eighteenth century. On the negative side, patents create price distortions that are particularly burdensome when applied to prescription drugs and lead to the monopolist's response to prescription drug plans. Patents also reward inventors with less than the social value of their innovations because monopoly advantages last for a limited number of years only, and because monopoly profits are strictly smaller than social benefits which would include full consumer surplus.

Today there is no longer the need to accept the price distortions caused by patents and the under-incentivization of invention they imply because modern tax vehicles eliminate the need to rule out direct payments to inventors. As noted, monopoly creates price distortions, an incentive for substitute inventions to be researched to acquire the monopoly rents enjoyed by the patentee, and also the incentive for monopoly products to be stolen. Because no monopoly is created and the intertemporal bounty involves compulsory free licensing of patented goods, none of these negatives is present. The intertemporal bounty can be chosen to return to the inventor the full social value of invention in response to the under-incentivization problem. Because payment is made annually, the difficulty of estimating today a stream of future values is obviated.

Another source of objections to an intertemporal bounty might be that subsidized research is superior. As Table 1 indicates, the main problem with subsidized research is that the government is targeting inputs by its subsidy, not output. Because the intertemporal bounty is directed to innovated products that pass a market test it does not suffer from this defect. Subsidies also have the disadvantage that government may not be able to conceive of some inventions in advance and may not know the expected benefits and costs of research. Neither problem is present with the intertemporal bounty.

Prizes directed toward a specific end, in principle, can be both effective and efficient. The existence of the prize must be advertised and made known, and the terms under which the prize is granted be specified, but presuming both, it can be equal or superior to other mechanisms. The issue that a present value must be calculated to determine the right prize has already been discussed with respect to patents and the intertemporal bounty. In many cases, however, the relevant consideration is that prizes do not work well when the government may not know in advance what to support. Thus, for an ongoing program of reward to invention it is not as effective as patent buyouts or intertemporal bounty as a practical matter.

Eminent domain and patent buyouts have a number of features that make them superior to patents, subsidizing research, and prizes. Eminent domain has the disadvantage relative to patent buyouts that judges determine *ex ante* buyout values rather than auctions (see Kremer, 1998) so we will focus our

attention on the comparison of patent buyouts and intertemporal bounties.

The first issues is the need to determine the buyout price. In theory, buyout price should be the present discounted value of the stream of future social values created by the innovation. Convincing patent holders to sell their property rights for a payment determined *ex ante*, is not without negatives. Research indicates that people are both risk averse when faced with low probability losses and risk seeking when it comes to low probability gains (Tversky and Kahneman, 1992). They consistently overestimate the likelihood of low probability events with high potential value. Owners of pharmaceutical patents are no different. They tend to overstate the potential value of their discoveries by overstating the probability of success. No patent owner knows *ex ante* whether a drug discovery will be a market success. If they overstate the probability of success, they overstate the value of the patent and are likely to reject reasonable *ex ante* offers for the rights to the drug. Both patent buyouts and bounties involve coercion in that the property owner is required to sell, place their property up for sale by auction in the former case, or to compulsorily release their product to producing firms in the latter. In both cases, the innovation is freely available to all users.

Both approaches need to determine a market value. The auction uses *ex ante* market information and estimates by bidders of area B in Figure 2 over future periods to estimate area (A+B+C) over future periods. The intertemporal bounty uses market information and estimates of area (D+E) period by period to estimate area (A+B+C) period by period. In the former case there are no market observables, in the latter there are price-quantity pairs at the observed market equilibrium. Both approaches, of course, could make use of surveys, market tests, and other instruments that help to predict the location and shape of relevant demand.

Using auctions to estimate value has a number of advantages over other methods, not least of which is that bidders will do their utmost to accurately value the item they are attempting to buy. The main disadvantage of an auction is that if the government uniformly acquires all rights and bidders are never allowed to be successful, the incentive to bid disappears.

If randomly selected patents must be sold to the highest bidder to maintain viability of the auction, the disadvantages of an auction are inescapable. Auctions are potentially susceptible to collusion. Price issues arise for inventors who have private information or lowest cost producers. Resale of patents is another matter. None of these issues is present with a bounty because auctions are not used.

3. International Issues

Supporting pharmaceutical R&D requires incentives that reach beyond the borders of a single country. A global challenge requires a global strategy. The fact that pharmaceutical R&D spending is a global joint cost that benefits consumers around the world creates a cost allocation problem. The cost of R&D is a quasi-fixed cost, no matter how many consumers or how many countries receive access to the drug.

In most countries, drug spending is reimbursed through government-run programs at regulated prices. Regulators tend to focus on country-specific costs in setting prices. But cost structure provides little insight in determining how much of the R&D spending is attributable to any one specific country. The challenge in implementing the bounty program is determining how much each country should contribute to the innovator for use of the patented drug.

The most direct way to cover global joint costs is to allow the patent holder to charge different prices in different countries. Equitable cost sharing across countries should be aimed at estimating the value of the drug to residents of each country. The appropriate bounty paid by each country then would replicate the price differentials implied by Ramsey pricing with each country paying a differential based on its price elasticity of demand. Paying a price equal to the marginal cost of producing the drug, but not contributing the appropriate bounty, results in free riding.

The larger challenge may be to the regulatory culture of many national health systems and getting them to participate in such a radical departure from business as usual. If countries are unwilling to participate in the bounty program or unable to negotiate an appropriate bounty with the innovator company, then the firm would retain the rights to the innovative drug in that country and exercise its monopoly rights to establish a mutually agreed upon price. At the same time, countries agreeing to the bounty program with its marginal cost pricing would agree to restrict parallel trade in the product. At stake is the ability to equitably support pharmaceutical R&D worldwide. Countries that try to acquire the drug through reimportation are merely trying to circumvent their obligation to share in the cost of developing innovative drugs that provide value to their residents.

4. Credibility

Credibility becomes a serious issue if government does not follow through on its pre-commitments to announced bounty schedules. Government can bind its future behavior, however, by prior bonding and having the independent court system enforce dispersal of bonded funds to patent holders. Under the circumstances a bounty based on sales volume reduces the government's ability to unfairly expropriate the value of innovative drugs.

VI.E Music Lessons

John Adams explained that facts are stubborn things: "whatever may be our wishes, our inclinations, or the dictates of our passion," he said, "they cannot alter the state of facts and evidence." The same might be said of efficiency. The patent system is a venerable arrangement that has survived many years. But it was designed for another era with other prime directives. Whatever may be our degree of comfort with it, our inclinations, or the dictates of tradition, they cannot alter the fact that patents, certainly in

the case of pharmaceuticals, are an impediment to the very good that might be achieved through wider and swifter distribution of critical drugs and medications. "When new institutions are proposed, there is a natural tendency to focus on their potential risks and shortcomings. However, it is also important to recognize that existing mechanisms of encouraging innovation have serious flaws." (Kremer, pp. 1162-63.)

In fact, a system similar to the bounty and free licensing system discussed in this paper has been in successful use in the United States for nearly a century. It involves compulsory licensing combined with legislatively set transfers to the originators of intellectual property. These two features: compulsory licensing for widespread distribution of new inventions and a legislatively determined reward when this is done are important features of a bounty system. The sector in question continues to generate vast quantities of new intellectual property and its new inventions are swiftly and widely distributed. The industry is the music industry, and there are lessons that we can learn from it.[4]

In 1909 Congress was concerned about the growing impact of monopoly in the music and music distribution industry. Having been awakened to the effects of monopoly in American in the form of trusts and conglomerates, it passed for the first time legislation to guarantee that music would reach the ears of America unimpeded by the excesses of market power. Today copyright law recognizes distinct rights of reproducing a work, distributing copies of a work, publicly performing a work, and making derivative works. Exceptions to the exclusive rights of the inventor were enacted in the copyright law. At the same time, Congress recognized that new inventions must continue and so provided for payment to the copyright holder.

The use of piano rolls and the advent of the phonograph introduced the ability to mechanically reproduce works of music. The 1909 Copyright Act recognized for the first time the copyright holder's ownership of recording and mechanical reproduction rights in musical works (Krasilovsky and Shemel, p. 153). At the time of passage the Aeolian Company had been gathering up exclusive contracts with most major music publishers to reproduce the works that they owned or controlled (Ibid), threatening to monopolize through its market power the distribution of mechanically reproduced works. Section 1(e) of the act prevented monopoly by requiring that if a copyright owner permitted the use of copyrighted composition for mechanical reproduction, then that material must be licensed to *anyone* else for reproduction.[5] The payment to the copyright owner was legislatively determined at 2 cents "on each such part manufactured" and has been adjusted by Congress over the years. In 2004 the rate was 8.5 cents for songs less than 5 minutes in length, and 1.65 cents per minute for songs longer than 5 minutes.

Compulsory licensing—the obligation to allow anyone who wants to use your composition—has been extended and clarified in subsequent law. Section 115 of the Copyright Act provides that anyone is entitled to a compulsory license for a work that is a non-dramatical musical work, that has been

previously recorded and distributed publicly, and that will be used in a phonorecord (a technical term in the Copyright Act that means audio only recordings). Thus, a copyright holder's monopoly was not allowed for the following uses (Passman, p. 196-7.):

1. Cable television rebroadcasts
2. Public Broadcasting System rebroadcasts
3. Jukeboxes (Interestingly, until 1976 jukeboxes paid nothing for their right to use music.)
4. Digital performance of recordings (Added 1995.)
5. Digital distribution of recordings (Also added in 1995, this covers the internet, phone lines, satellites.)
6. Phonorecords of non-dramatical musical compositions (terms a compulsory mechanical license).

The law does not apply to first recording and distribution, for which the copyright owner has the authority to negotiate terms and conditions with his publisher. This exception to the compulsory licensing requirement is a market test of sorts, because it means that songs that have no proven marketability are excluded from the system. It is important for the proposed bounty system that no bounty is paid for products that have not passed a market test. Congress mandated rules for notifying the music copyright owner of the intent to invoke a compulsory license to rerecord a work, plus legislated rules about monthly accounting and payments that must be followed. These rules can be avoided if the publisher issues a negotiated license. The compulsory licensing rates became a *de facto* incentive to firms on both sides of the market to reach negotiated license agreements for recordings distributed in the United States. Record companies, in practice, usually provide for mechanical licenses to be issued at three fourths of the per-song statutory rate, regardless of the song's duration. A number of companies, the largest being the Harry Fox Agency founded in 1917, administer "mechanical" rights in the US on a commission basis. A series of institutions have grown up, therefore, around the dissemination of musical works that seems to have worked relatively well.

A large part of the monopoly power that inventors might otherwise have wielded is severely limited by the music provisions of the Copyright Act. Yet the music industry seems to work very well in providing original entertainment works. The features of compulsory licensing for the music industry that are important for our purposes in this paper are three. First, the law requires that any work that is sold to the public *must be licensed* to anyone else. Monopoly rights are curtailed to facilitate wider distribution of works. Second, the terms of distribution are set by statutory rates that are effectively upper bounds on the prices that copyright owners (usually the music publishers) can charge to later users. This represents an intentional legislative reckoning of the value of the distribution benefits of

works on a per song basis. Rates do not vary by song, even though many songs might never rise to the popularity of Billy Joel's *Piano Man*. This gives some encouragement to the notion that intentional valuations may succeed in other contexts. Third, the stream of new musical works seems not to have been harmed by the partial elimination of monopoly rights of the copyright holder. We are reminded that if maximal innovation effort is induced by rewards that fall short of full monopoly rents, it becomes less important that precisely all rents are paid to inventors, nor calculated exactly. Johnny Cash might well have devoted the same effort to the creation of new works if he had received a fractional multiple of what Copyright Law actually provided him.

VII Conclusion

This paper resulted from a sincere desire to remove a roadblock to prescription drug insurance coverage. The desire was to find the best alternative possible. Thus, while we believe the intertemporal bounty is that best alternative, we are more interested in getting to the better alternative than to champion any one plan. We believe that both practical and theoretical considerations introduced here point to the intertemporal bounty. If further debate and research find a better mechanism or refine or improve on the intertemporal bounty, we welcome the improvements.

In summary, what do we know? We know that the rewards of innovation should accrue to the innovator, and a product, once invented, should be competitively supplied. Patents fail on two counts: they provide the innovator less than the stream of future social values generated by the new product and they prevent an innovated product from being competitively supplied. If the social objective is to induce the creation of a new product that is then patented and competitively sold, the efficient intervention is to subsidize the competitive sale of patented products. An intertemporal bounty meets this specification most closely. It also relieves part of the burden of estimating future values because it is applied intertemporally and is tied to measurable future sales. The result is that a newly patented product is available to all producers, the patent holder documents and is paid a bounty as a multiple of future sales and the bounty is set to reflect the social value provided by the product's (competitive) provision each period. Other policies toward research and development including subsidies to research, prizes, and auctions buyouts also have desirable features relative to patents. While no single tool is perfect, we feel that we have made a good case that intertemporal bounties incorporate properties that push them further in the direction of capturing social efficiency.

Notes

[1]Different demand, countervailing market forces, and a different list of drugs under patent come to mind.

[2]It is sometimes asserted that for this to happen all of the future social value of an invention should go to the inventor, but this is not true if full inventive effort is reached short of this amount. That is, Elvis Presley might have devoted all of his efforts to creating new songs for half of what he actually earned for his work.

[3]Baumol and Bradford (1970) provide a discussion of the trade-off.

[4]I would like to thank music attorney Christopher Bradstreet for suggesting to us this connection and references.

[5]Today the term "mechanical" is somewhat of a misnomer, but its use continues to apply to digital and electronic media.

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Table 1: R&D Incentives vs Intertemporal Bounty

(1)	(2)	(3)
Method	Issues	Intertemporal Bounty
Patent	• Creates monopoly price distortions • Inventions rewarded below social value. • Creates distorted incentive that rewards research of substitute inventions to acquire monopoly rents. • Inventions may be expropriated (stolen) by the public (Daguerre, McCormick). • Present value of a future stream of benefits needs to be estimated.	No monopoly is created. Full social value is accounted for. No distortion is present because no monopoly power is granted. There is nothing to steal because inventions are in the public domain. Intertemporal bounty is paid over time so present value is not needed.
Subsidizing Research	• Government is paying for inputs, not the desired output. This creates an incentive for shirking and the wrong kind of research. • Government may not be able to conceive of some inventions in advance. • Government may not know the expected costs and benefits of research.	The bounty is directed precisely toward the desired output: innovated products that pass a market test. Uses the market to conceive of inventions. This is not an issue. Government pays only for market tested outputs. Social value still needs to be estimated and implemented as a multiplier of market sales.
Prizes	• Government may not know in advance what to support. • Present value of a future stream of benefits needs to be estimated.	Uses the market to conceive of inventions. This is not an issue. Intertemporal bounty is paid over time so present value is not needed.
Eminent Domain	• Judges determine *ex ante* buyout value. • A fixed reward creates an incentive for a firm to add useless attachment to a product and claim the reward. • Present value of a future stream of benefits needs to be estimated.	Social value needs to be estimated and implemented, but after the fact as a multiplier of market sales. Payouts go only to ideas that pass the market test. Useless ideas would not pass. Intertemporal bounty is paid over time so present value is not needed.

Table 2: R&D Incentives vs Intertemporal Bounty, Continued

Method	Issues	Intertemporal Bounty
Patent Buy-outs	• There is a need to determine the buy-out price.	Social value needs to be estimated and implemented as a multiplier of market sales.
	• There is a need to determine the present value of future buyout values.	There is no need to determine present value. The bounty is paid out over the future life of the product based on market sales. Superseded inventions lose sales and hence lose bounty.
	• An auction is vulnerable to collusion.	An auction is not used.
	• Randomly selected patents must be sold to the highest bidder to maintain viability of the auction. This leaves some innovations under monopoly patent.	All innovations are freely licensed.
	• Pharmaceutical firms have less incentive to test for new uses for generic drugs than for patented drugs.	Incentives are correct because there is no monopoly reward differential. All drugs are competitively produced and sold.
	• Auction price issues may arise for inventors who are also the lowest cost producers.	An auction is not used.
	• Auction price issues may arise for inventors who have private information.	An auction is not used.
	• In some plans and/or circumstances, inventors could decide to retain or sell patents.	Patents confer no monopoly rights.