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Briefing Paper

Promoting Good Ideas on Drugs: Are Patents the Best Way?

The Relative Efficiency of Patent and Public Support for Bio-Medical Research

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EXECUTIVE SUMMARY

A widely publicized analysis of pharmaceutical research (DiMasi, 2002), found that the cost of developing new drugs is rising far more rapidly than the rate of inflation. Its findings indicated that research costs had risen at the rate of more than 10.0 percent annually between 1987 and 2000, with research and development costs estimated at $802 million per drug in 2000. As research costs rise, it becomes more important to the economy that research be carried through in the most efficient possible manner.

Although nearly half of biomedical research spending in the United States is supported by either the government or non-profit sector, the bulk of the research involved in actually carrying drugs through the clinical testing process needed to gain FDA approval is carried on by the pharmaceutical industry and financed through patent protection. While patent protection may have once been the most efficient way to support this research, this does not mean it necessarily will continue to be the most efficient means to support research as costs continue to increase. It is possible that alternative methods—for example, direct contracting to develop drugs or vaccines (as some firms advocated in response to the Anthrax scare) may prove more efficient, given current and future economic considerations. In such an alternative system, research findings would be placed in the public domain, and firms would be able to compete in the same way as generic producers do at present. This paper examines this possibility.

Basic economic theory indicates that as research costs rise, they will eventually reach a point where public/ non-profit funding will be more efficient than patent supported research. The reason for this is that patents effectively allow private firms to charge an excise tax—the mark-up allowed by the patent monopoly—on prescription drugs. The economic distortions associated with such a tax are proportional to the square of the mark-up. Therefore, if drug companies have to charge twice as high a mark-up in order to cover their research costs, then the size of the economic distortions will be multiplied fourfold. This means that even if patent supported research is somewhat more efficient than public/ non-profit supported research on a dollar for dollar basis, at some point the distortions created by the patent mark-up must eventually offset this greater efficiency.

Economic theory also predicts that patent protection will lead to wasteful rent seeking behavior by firms, as they attempt to maximize their patent rents. The paper notes six important ways in which patent rents in the pharmaceutical industry lead to wasteful or harmful behavior:

1) the research and development of copycat drugs—in a world with patent protection, copycat drugs can reduce prices by providing competition. However, in the absence of patent protection, most of this research would serve little purpose, since there would be little benefit from developing second and third drugs, when a first one has already been shown to be effective. According to a recent study commissioned by the Pharmaceutical Manufacturers and

Researchers of America (PhRMA), the drug industry association, copycat drugs may account for more than 70 percent of all research spending.

2) advertising and sales promotion—patent rents provide firms with a large incentive to try to persuade doctors and patients to use their drugs. These sales efforts can even go as far as outright bribes to doctors to prescribe drugs, as happened recently in Germany. According to PhRMA, the industry employs nearly twice as many people in sales and marketing as in research and development.

3) restricting the dissemination of research findings and/or falsifying research results—the industry has strong financial incentives to prevent the disclosure of its research findings until it has filed for all the patents that could prove profitable. This slows scientific progress. There is also evidence that the industry has on occasion attempted to keep secret research findings that suggest its products are ineffective or possibly harmful.

4) legal costs associated with filing and protecting patents—the industry employs large numbers of lawyers to secure and enforce its patents. These costs can also include side payments to generic producers to keep competition out of the market.

5) political lobbying for the protection and extension of patent monopolies—the pharmaceutical industry typically ranks near the top in campaign contributions. It has also begun financing "grassroots" lobbying efforts by people afflicted with specific diseases and their friends and relatives.

6) the production of gray market drugs, which may not meet safety standards—the existence of large patent mark-ups provides a strong incentive for the production of unauthorized versions of drugs (sometimes abroad), just as is the case with illegal drugs like marijuana or cocaine.

Economic theory predicts that the waste associated with each of these forms of rent-seeking will increase at a rate that is proportionate to the square of the increase in the patent mark-up.

The paper then produces a set of estimates of the amount of additional public money (net of current spending and tax credits) that would be needed to replace the patent supported research currently being conducted by the pharmaceutical industry. Depending on the portion of current research wasted on copycat drugs, and the relative efficiency of public/non-profit supported research and patent supported research, it was estimated that it would have taken additional expenditures of between 4.0 billion and $27.6 billion in 2000 to replace the $25.8 billion that the industry claims to have spent on research.

The paper then estimates the savings that the government and consumers would have experienced in 2000, if drugs had not been subject to patent protection. It estimates that the gross savings would have been between $72.8 and $89.6 billion. The savings net of the additional research spending needed to replace the industry's spending would have been between $39.2 and $85.0 billion.

Finally, the paper uses forecasts of prescription drug spending from the Health Care Financing Administration to project the future savings and economic gains that would result from switching to a system of public/non-profit supported research. These projections show that most, if not all, of the additional funding for research could be taken directly from the government's savings due to lower prescription drug costs for Medicaid, Medicare, and other government supported purchases. This means that there would be little, if any, need for new tax revenue to support publicly funded drug research. The gains to the private sector from lower drug prices would be substantial. By 2024, when the full impact of the switch to publicly supported research will be felt, the private sector will be saving between $560 and $670 billion a year due to lower prescription drug prices, an amount equal to 1.7 to 2.0 percent of GDP.

This decline in drug prices would also be expected to have substantial secondary impacts on the economy. In effect, it leads to a substantial increase in the real wage, which would create a large number of new jobs. It should lead to an increase in annual GDP of approximately 2.6 to 3.0 percent. This would be associated with an increase of between 3.8 and 4.5 million jobs. There are few possible economic policy changes that could potentially have an impact of a comparably magnitude.

INTRODUCTION

It is widely recognized that the cost of researching new drugs is rising rapidly, both in absolute terms and as a share of GDP.[2] As these costs grow, it becomes more important that research expenditures are carried through in the most efficient possible manner. In policy circles it is generally assumed that the current mix of public and private support is optimal. Under this system, basic research is primarily supported by governments, universities, and private foundations and charities. The process of actually developing drugs and carrying them through the stages of clinical testing needed for regulatory approval is primarily left to private corporations, which recoup these costs through patent protection.

In fact, there is little, if any, theoretical or empirical basis for assuming that the current mix of responsibilities between the public, non-profit, and corporate sector is optimal. Even if this mix may have maximized efficiency at some previous point in time, there is no guarantee that it is still optimal at present, or that it will continue to be in the future, as research costs increase through time.

This paper examines the theoretical argument for the current system of mixed public and private patent supported research, compared with a system that relies on an expanded role for the public and non-profit sectors in the development of new drugs. It then examines evidence on the size of the distortions created by the current patent system, and estimates the potential gains from eliminating these distortions by expanding public sector support for biomedical research.

THE THEORETICAL CASE FOR PATENT SUPPORTED BIO-MEDICAL RESEARCH

The basic argument for funding research through the patent system stems from the belief that the private sector can carry through research more efficiently than the public sector. In other words, the implicit assumption in this view is that it takes more than one dollar of publicly supported research to produce results of the same value as a dollar of privately supported research (e.g. Kremer 2000). For example, if all the research and tests associated with the development of a new drug in the private sector would cost $100 million, then it might cost $125 million or even $150 million if the government were to try to carry through the research itself, or

[2] A recent study (DiMasi et al, 2002) estimated the cost of researching a new drug in 2000 at $802 million. An earlier study, using the same methodology (DiMasi et al, 1991), put the cost of developing a new drug in 1987 at $231 million. Inflation would have raised the cost in 2000 dollars to $320 million. By this methodology, the real cost of developing new drugs increased by approximately 150 percent over this 13 year period, a 7.3 percent real annual rate. It is worth noting that there have been numerous questions raised about the methodology used in these studies (e.g. Public Citizen 2001; and Office of Technology Assessment, 1993).

contract out with private firms. Research costs are therefore minimized by allowing the private sector to carry through the process of research and development of new drugs, after the basic research phase (which is supported by the government or non-profit institutions), with their expenses being recouped through a limited period of monopoly provided by patent protection.

All economists recognize the static inefficiency associated with patent protection. The government's enforcement of a private monopoly allows corporations to sell drugs at prices that are far above their cost of production. From the standpoint of consumers, the granting of a patent monopoly produces the same sort of distortions as imposing a tax on drugs—in other words the distortions could be modeled in the same way as a tax—with the difference being that the tax is imposed by a private corporation. If patents are the best way to support research and development of new drugs, then the distortions attributable to the patent monopoly must be less than the efficiency gains from having the private sector rather than the public sector carry through the research. In other words, if the country saves $50 million by leaving the development of a new drug to the private sector, then it will only on net benefits from this system if the distortions resulting from patent protection are less than $50 million. If the distortions are more than $50 million, the public would be better served by having the government carry through the development of the drug, even though it is less efficient than the private sector in doing research.

It is important to recognize that this logic implies that current patent system might be desirable for some levels of spending on drug research, but may not be desirable for higher levels of spending. The reason is simple—the distortions associated with the monopoly provided by patent protection are proportionate to the square of the revenue raised as a result of the patent. This means that if a drug manufacturer has to double the amount of money it raises from each patent, in order to recoup higher research costs, then the distortions attributable to the higher price would be multiplied by a factor of four.[3] Assuming that the relative efficiency of privately and publicly supported research does not change, if research costs continually rise, then at some point the distortions that result from patent protection will more than offset the gain from the greater efficiency of privately supported research.

A simple example can make this point more clear. Suppose that it costs drug companies an average of $100 million to research a new drug, while it would cost the government 50 percent more, or $150 million. The drug company then recoups its $100 million investment through the monopoly price that it can charge as a result of patent protection. Suppose that this higher price—as compared to the competitive price that would be charged in the absence of patent protection— leads to a deadweight loss to consumers of $20 billion. (This is the pure inefficiency attributable to the higher price, it is the cost borne by consumers in addition to the $100 million profit earned by the drug company.) In this case, the public on net gains from the patent system, since the $20 million deadweight loss attributable to paying the patent protected

[3] This is a basic theoretical result in public finance economics. The distortion associated with a tax is equal to the reduction in the quantity demanded that results from the tax, multiplied by the lost benefit to consumer for each item not consumed. A discussion of this issue can be found in any standard public finance textbook (e.g. see Bradway and Wildasin, 1984, pp 225-256).

price, is much less than the $50 million gain from having the private sector conduct research rather than the public sector.[4]

However, the advantages of patent supported research are less evident as the amount of research expenditures that are being recouped increases. This is shown in table 1. In each case, it is assumed that government research is only two-thirds as efficient on a dollar for dollar basis as private sector research. In this highly stylized scenario, private sector research is, on net, more efficient than public sector research as long as the spending per drug is relatively low. However, as the spending per drug increases, the deadweight losses associated with the patent protected

Table 1

The Relative Efficiency of Private and Public Sector Research

Private Sector Research Cost	**Public Sector Research Cost**	**Deadweight loss from patent**	**Net Gain from patent**
$100 million	$150 million	$20 million	$30 million
$200 million	$300 million	$80 million	$20 million
$400 million	$600 million	$320 million	$-120 million
$800 million	$1200 million	$1280 million	$-880 million

price come to be relatively more important. In the case where the private sector research costs are $400 million, the deadweight losses from patent protection exceed the gains from the greater efficiency of patent supported research. In the last case shown in the table, where research costs are $800 million per drug, the deadweight losses exceed the benefit from private sector research by $880 million.

The numbers in the table illustrate an important point. The monopoly pricing that is allowed by patent monopolies creates economic distortions. The size of these distortions grows at a rate that is more than proportionate to the size of patent rents. In the case of drug research, this means that there is inevitably some level of research costs, above which it is more efficient to support research through the public sector, rather than relying on patent rents to support private sector search. It is possible that research costs have long ago reached this level, or it may be the case that drug research costs are still far below the level where public sector research would be more efficient, but it is an inescapable conclusion that there is some level of research expenditures where public sector research would be more efficient than private sector research.

[4] The revenue to pay for government supported research must of course also come from taxes. However, the taxes used to raise this revenue, primary individual and corporate income taxes, are generally viewed as far less distortionary than excise taxes, which is effectively what patents impose. More importantly, the percentage increase in these taxes that would be needed to support additional research into pharmaceuticals would be very small by comparison with the percentage increase in the patent mark-up needed to support more costly drug research. According to the pharmaceutical industry's claims, its current research spending is less than 2.0 percent of the general tax revenue collected by the federal government each year.

PATENTS AND RENT SEEKING BEHAVIOR

There is a second part of this story which must be taken into account in evaluating the relative merits of publicly and privately supported research. The above discussion only referred to the deadweight losses to consumers that result from the fact that the patent protected price is above the competitive market price. In other words, this would be the loss to the economy if patents did not induce any economically wasteful behavior by the drug industry. Economic theory predicts that this will not be the case—patent rents provide incentives for firms to engage in many activities that are wasteful from the standpoint of the economy as a whole. The size of this waste will also increase in proportion to the square of the size of the patent rent—again indicating that the waste from rent seeking behavior must eventually exceed any efficiency gains from relying on patent protection rather than public support for drug research.

There are several wasteful (or even harmful) practices which are a predictable result of the economic incentives provided by patent rents. These include:

1) researching copycat drugs,
2) advertising and sales promotion,
3) restricting the free flow of research (or, in extreme cases, falsifying research results),
4) legal costs associated with filing for and protecting patents,
5) political lobbying (or bribes) for the protection and extension of patent monopolies,
6) the production of unauthorized versions of drugs, which do not meet safety standards.

Each of these practices lead to an additional waste of resources as drug companies carry through expenditures which are designed to increase the amount of patent rents that they are able to receive. In the absence of patent rents, they would not have the incentive to engage in the same sort of behavior. For example, if there were no patents on drugs, there would be no point in carrying through research that was intended to produce a copycat drug, which does not show any promise of being significantly more effective than existing drugs. However, when patent protection allows for large rents for certain drugs, there is very strong incentive for firms to try to capture of a portion of these rents with a comparable drug, even if it is not medically superior to the existing drug.[5]

Taking each of these wasteful activities in turn—the research of copycat drugs is a straightforward form of waste that results from patent rents. Firms have an incentive to develop drugs which will allow them to encroach on their competitors' rents, even when they have little

[5] It is worth noting that in the context of the patent system copycat drugs can be desirable. They lead to competition in situations where it otherwise would not exist, and could lead to significant reductions in the prices of some drugs. It is also worth noting that a drug is not medically useless just because it is considered to be imitative rather than a breakthrough drug . Patients react differently to the same drugs, so drugs that are safe and effective for one group of patients, may produce bad reactions or be less effective for another group. Therefore, the fact that alternative drugs are available is generally beneficial, although the pursuit of such alternatives might not have been considered a high priority in the absence of the incentives created by patent monopolies.

or no reason to expect that their research will lead to a better drug. In the absence of patent rents there would be no incentive for this research. However, patent rents provide almost as much incentive to engage in copycat research as there is for research aimed at developing breakthrough drugs. According to the Food and Drug Administration (FDA), the vast majority of drugs fall in this copycat category. Only 24 percent of drugs are classified as representing significant advances over existing drugs (**U.S. FDA 1999**).

In many cases the industry may not have intended to develop a copycat drug. Since the research and development process often takes many years, a drug company may have initiated its research at a time when developing a drug would have been a qualitative breakthrough, but a competitor may beat them to the market. At that point the company would have the choice of abandoning its research, and recovering none of its expenses, or continuing it with the hope of capturing some of the patent rents. While this rationale may place copycat research in a better light, it is nonetheless a source of waste that is created by the patent system.[6]

The sales promotion efforts attributable to patent rents take a variety of forms, including advertising campaigns targeting consumers, direct contact with physicians by salespeople, and elaborate seminars to educate doctors about particular drugs—some of which take place at resorts or involve payments for showing up (e.g. "Fever Pitch: Getting Doctors To Prescribe Is Big Business," by Abigail Zuger, *New York Times*, January 11, 1999, page A1). In one recent case, it appears that outright bribes were used to persuade doctors to prescribe a company's drugs (e.g. "German Doctors Accused of Taking Bribes," by Geoff Dyer and High Williamson, *London Financial Times*, 3-12-02).Another way in which the industry has sought to promote sales to increase its patent rents has been through paying private charities, such as the American Cancer Society, for the use of their name in connection with their drugs (e.g. " Sales Pitches Tied To Charities Draw States' Scrutiny," by Reed Abelson, *New York Times*, May 3, 1999, page A1). The expenses involved in these sorts of activities are clearly quite large. research.[7] [8] According to the industry's own data, in 2000 it employed almost twice as many people in sales promotion as in research, 87,810 in sales compared to 48,527 in research.[9]

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[6] A system of public/non-profit supported research would benefit from competition, and therefore some duplication, in the research process. However, there would not be the same incentives for secrecy, so research that was less promising could be abandoned in favor of research that was more promising. Also, there would not be the same incentive to continue research in order to recover sunk costs, even after an effective drug was developed. Therefore, while copycat research may continue even without the patent system, the amount of resources wasted on such research is likely to be a small fraction of what it is presently.

[7] One extraordinary measure that drug firms have adopted in order to boost sales has been the invention of new diseases, for which their drugs are the best treatment. In recent years there have been several instances in which drug firms have tried (sometimes very successfully) to promote their drugs as a treatment for diseases, the existence of which is not generally recognized by the medical profession (e.g. "Drug Ads Hyping Anxiety Make Some Uneasy," by Shankar Vedantam, *Washington Post*, July 16, 2001, Page A1).

[8] According to some accounts, drug firms have begun carefully tracking the prescribing patterns of individual physicians to determine where their marketing efforts are likely to prove most effective ("High-Tech Stealth Being Used To Sway Doctor Prescriptions," by Sheryl Gay Stolberg and Jeff Gerth, *New York Times*, November 16, 2000, page A1).

[9] (http://www.pharma.org/publications/publications/profile01/app_a3.phtml)

The third source of waste resulting from rent seeking behavior perhaps provides the greatest basis for concern. Drug firms have a strong incentive to keep their research findings secret until they have had an opportunity to exploit all possible patents based on their research. This means that the findings of drug industry sponsored research will provide less benefit than if the same findings were produced in research supported by the public or non-profit sector. In the latter case, the results would be available to other scientists in a far more timely manner, since there would be no incentive to keep findings secret. In fact, scientists working in the public or non-profit sectors would have the opposite incentive, since their reputations would be enhanced by having their findings disseminated as widely as possible.

However, delaying the publication of research findings is a far less serious issue than either withholding findings that reflect negatively on a firm's drug, or even worse, falsifying research. Patent rents provide large incentives for the industry to engage in such behavior. While the government can use punitive measures to attempt to limit the extent to which research findings are concealed or altered, when the incentives are large, the profit motive is likely to prevail over government action.

In recent years there have been numerous accounts of efforts by the drug manufacturers to conceal research findings (e.g. "Missing Data On Celebrex," by Susan Okie, *Washington Post*, August 5, 2001, Page A11; "How a Drug Firm Paid For University Study, Then Undermined It" by Ralph T. King Jr., *Wall Street Journal*, 4-25-96; A1; Blumenthal et al, 1996). Studies have also found evidence that research conducted by the industry is biased towards finding that their drugs are safe and effective.[10] Even without any deliberate falsification on the part of drug companies, researchers may take it upon themselves to produce findings that are advantageous to the industry, due to the large incentives for such findings (e.g. "A Doctor's Drug Studies Turn Into Fraud," by Kurt Eichenwald and Gina Kolata, *New York Times*, May 17, 1999, page A1).

At the least, these concealed or distorted findings can lead patients to waste money on drugs that may provide little benefit, or little additional benefit over non-patented drugs. For example, in one case, a pharmaceutical manufacturer suppressed a study for six years, which showed that its thyroid medication was no more effective than a generic competitor. As a result, patients spent an additional $800 million over this period on the brand drug (see "Drug Firm, Relenting, Allows Unflattering Study to Appear," by Lawrence K. Altman, *New York Times,* April 16, 1997; page A1). In more serious cases, concealing evidence may cause patients to take drugs that are actually harmful to them. For example, there have been cases where firms have pressured the FDA to approve drugs of questionable safety (e.g. see "For ALS Patients, a Drug With a Clouded Future," by Robert O'Harrow Jr., *Washington Post*, July 10, 2000, page A1).[11]

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[10] There is considerable evidence that the source of funding has influenced research findings in recent years (e.g. Bodenheimer 2000; Friedberg, et al 1999; Stelfox et al, 1998; Cho and Bero, 1996; and Davidson, 1986).

[11] The possibility that industry funding may be affecting published research findings is a widely recognized problem among medical researchers. Several leading medical journals have recently adopted policies whereby they refuse to publish articles unless the researchers are willing to sign a statement asserting that they have complete control over the dissemination of research findings ("A Stand for Scientific Independence," by Susan Okie, *Washington Post*, August 5, 2001, Page A1).

The fourth source of waste associated with patent rents is the legal fees and associated costs that companies incur to register and protect their patents. These can end up being quite large since the issues involved are often quite complex and there is so much money at stake. For example, one estimate put the value of a three year extension of Schering-Plough's patent on Claritin at between $1.6-$3.2 billion (Public Citizen, 2001). Through abusing the patent process, firms may be able to extend the length of their patent protection. Patent law in the United States is very favorable to firms attempting to extend their patents providing ample opportunities to defray generic competition with questionable claims. As a result, drug manufacturers spend significant sums on lawyers to design and carry through effective legal strategies. The rents provided by patent monopolies can also provide a basis for payoffs by patent holders to keep generic competitors out of the market even after a patent has expired. There have been some instances where evidence of such payoffs have come to light (e.g. see "How Companies Stall Generics And Keep Themselves Healthy," by Sheryl Gay Stolberg and Jeff Gerth, *New York Times*, July 23, 2000, Section 1 page 1).

Patent rents also create a powerful incentive to interfere in the Food and Drug Administration's (FDA) approval process. This can take the form of both paying lobbyists to apply political pressure to affect the outcome of the process, or paying experts to advocate on behalf of a firm's drugs. A recent study found that 54 percent of the experts who were asked to advise the FDA on its drug approval process had financial interests in the drugs that they were evaluating ("FDA Advisers Tied to Industry," by Dennis Cauchon, *USA Today*, 9-24-00; A1).

The fifth source of waste is the campaign contributions and lobbying expenses that the industry incurs in order to win political support for strengthening and extending the reach of patent protection. The pharmaceutical industry consistently ranks near the top of the list of campaign contributors, giving more than $26 million to political candidates in the 2000 election cycle (Center for Responsive Politics, 2002). Efforts to gain political influence can go through indirect channels. For example, pharmaceutical firms have helped to support the creation of grass roots organizations around specific diseases, which lobby for measures that will increase the demand for their drugs (e.g. "Grass Roots Seeded by Drugmaker," by Robert O'Harrow Jr., *Washington Post*, September 12, 2000, Page A1). In the absence of patent protection, it is unlikely that the drug industry would be as concerned about politics, since there would be so much less at stake.

The sixth source of waste—the production and sale of unauthorized versions of drugs—is a problem that arises largely because of the nature of pharmaceuticals. Ordinarily, unauthorized versions of products (e.g. compact discs or videocassettes) provide gains to consumers, albeit at the expense of lost profits to manufacturers. In these cases, the existence of unauthorized copies can actually reduce the static losses created by copyright protection or some other interference with the market. However, since drugs must meet stringent production standards to ensure that they are safe and effective, the growth of a black market can be extremely detrimental to the public's health. If there is no way of ensuring the quality of the drugs sold in the black market,

then many patients may end up buying drugs that are ineffective or even harmful. As the size of patent rents increase, it is almost inevitable that the black market for drugs will grow as well. If the profit margins grow sufficiently large, there is no reason to believe that the government will be any more effective in restraining a black market in prescription drugs than it has been in restraining the black market in cocaine, heroine, and other illegal drugs (e.g. see "In Tijuana, a New Kind of Drug Peril," by Tim Weiner, *New York Times*, August 14, 2001, page A9 and " Online Sales Spur Illegal Importing Of Medicine To U.S." by Robert Pear, *New York Times*, January 10, 2000 page A1).

It is not generally possible to determine precisely the amount of waste attributable to rent-seeking activity, both because the industry does not disclose how much money it spends in each area, and because most of these activities will have some useful aspects to them. For example, the advertising and sales promotion efforts help to convey information to doctors and patients. But the existence of patent rents implies that firms will engage in more than an optimal amount of sales promotion, so that resources will be wasted in these efforts. From a social standpoint there is no greater benefit in disseminating information about a drug subject to patent protection than a generic drug, but patent rents ensure that physicians and the general public will learn more about the benefits of patent protected drugs. Unfortunately, there has been very little economic research into the amount of waste attributable to rent seeking behavior in the pharmaceutical industry, so any discussion of the resulting costs must be largely speculative.

It is important to recognize that the economic impact of the additional costs associated with rent-seeking behavior are amplified by the fact that they generally increase the mark-up that firms charge on their patent protected drugs. This increases the size of the deadweight loss attributable to the patent. In other words, the mark-up that firms charge over their cost of production must not only recoup their research costs, plus a normal profit, it also must recoup the advertising and sales promotion costs, as well as legal and lobbying expenses associated with protecting and extending the patent. As noted in the first section, the economic distortions attributable to patent protection are proportionate to the square of the mark-up, so the fact that these additional expenses raise the mark-ups that firms charge, can lead to a large increase in the inefficiency associated with patent protection.

It is possible to work from data that Pharmaceutical Research and Manufacturers of America (PhRMA), the industry trade group, publishes each year on research spending to get a rough assessment of the relative costs of patent supported and publicly supported research. In carrying through this assessment, it is important to recognize that using PhRMA's estimate of research spending as the basis of the calculation is likely to lead to an upward bias in the amount of research spending carried through by the industry, since PhRMA's data relies entirely on self-reporting by the industry.

In 2000, the brand name prescription drug manufacturers spent $25.8 billion on research (PhRMA, 2002).[12] Not all of this research depended on patent protection for pharmaceuticals. According to the industry, approximately 8.3 percent of research spending was used for quality control and improving the production process.[13] This spending would be needed whether or not drugs were subject to patent protection. In other words, a generic competitor would have to make the same expenditures in order to ensure that its drugs met established safety standards. This means that only $23.7 billion of the industry's research spending was dependent on patent protection for drugs.

However, some portion of this research money was used to research copycat drugs, which would serve little purpose in the absence of patent protection. As noted earlier, the FDA's classification system implies that 76 percent of the drugs approved fall into this copycat category, providing no significant therapeutic advantage over existing drugs. While it might be expected that copycat drugs are less costly to research than breakthrough drugs, the industry recently commissioned a study which found that the research required to produce copycat drugs can be as expensive as the research involved in developing a breakthrough drug (Ernst and Young, 2001). This assumption would imply that 76 percent of the industry's research dollars are devoted toward researching copycat drugs, meaning that the vast majority of research dollars are largely wasted on rent seeking activity encouraged by the patent system. However, it is likely that the PhRMA study exaggerates the cost of researching copycat drugs. Also, copycat drugs are not completely worthless, since they provide alternative treatments that prove medically superior for some patients. However, in most cases, the research that developed the drugs that the FDA views as copycats cannot be considered to be as valuable as the research to develop break through drugs.

For purposes of this analysis it is only necessary to produce a range for the amount of research spending that is channeled in wasteful directions as a result of firms seeking patent rents at the expense of their competitors. As one extreme, it can be assumed that copycat drugs cost as much to research as breakthrough drugs, and that there is little social benefit to these drugs, therefore virtually all (e.g. 90 percent) of the money spent in this research can be viewed as waste.[14] This is the "high waste" scenario shown in table 2. The "low waste" scenario assumes that copycat drugs cost only half as much to research as breakthrough drugs, and that the research is on average half as beneficial as the research intended to produce a breakthrough drug.

[12] This figure includes $6.2 billion in research spending abroad by U.S. based pharmaceuticals.
[13] http://www.pharma.org/publications/publications/profile01/app_a1.phtml.
[14] The possibility that some of the copycat drugs may prove less effective than existing drugs, but nonetheless come into widespread use as a result of effective sales promotion, increases the portion of this spending that should be viewed as wasteful.

Table 2

Pharmaceutical Industry Research Spending in 2000

	A Total Research Spending	B Percent Copycat	C Usefulness of Copycat Research	D Wasted Research Spending (A*B)* (1-C)
High Waste	$25.8 billion	76%	10%	$17.6 billion
Low Waste	$25.8 billion	38%	50%	$4.9 billion

While the estimates in table 2 are speculative, they probably encompass the plausible range, both for the percent of research spending devoted to producing copycat drugs, and the relative usefulness of this research. This implies that the amount of wasteful copycat research induced by patent protection was between $4.9 billion and $17.6 billion in 2000.

The next adjustment to the industry's spending is for the amount that is directly reimbursed in tax credits that the industry receives from the government. When firms increase their research expenditures above their prior level, the additional spending is eligible for a 20 percent research expenditure tax credit. In addition, some categories of spending, such as research into drugs intended to treat rare diseases (orphan drugs) are eligible for even larger credits. In total the industry received more than $500 million in research related tax credits in 1998. Adjusting for the industry's reported growth in research spending, it should have received approximately $600 million in research related tax credits in 2000.[15] These tax credits must be deducted to determine how much effective research was supported by the industry.

Table 3 shows the amount of research spending claimed by the industry and the adjustments that must be made to determine the net effective research supported by patent protection. It is worth noting that the number used for total research spending includes the research carried through in other nations by foreign subsidiaries of U.S. corporations. This means that the question being posed is how much money it would take to replace *all* of the research spending of the U.S. pharmaceutical industry, not just its domestic spending. The subsequent discussion implicitly assumes that none of this spending would come from foreign sources. Since some funding for drug research would almost certainly come from foreign sources in any conceivable scenario, the calculations below over-estimate the amount of additional funding that would be needed to replace the industry's research in the absence of patent protection.

[15] This calculation is based on the Internal Revenue Service's estimate that the industry received $514 million in research and development related tax credits in 1998 (http: // www.irs.gov/pub/irs.soi/98co00nr.xls). The figure was adjusted for 2000 by multiplying by the ratio of 2000 domestic research expenditures to 1998 expenditures (1.16 to 1).

Table 3

Net Effective Patent Supported Drug Research in 2000

	High Waste	**Low Waste**
Reported Research Spending	$25.8 billion	$25.8 billion
minus		
production and quality control	$2.1 billion	$2.1 billion
wasteful copycat spending	$17.6 billion	$4.9 billion
tax credits	$0.6 billion	$0.6 billion
Net Effective Patent Supported Research	**$5.5 billion**	**$18.2 billion**

The "low waste" scenario implies that the net effective research supported through patent protection was approximately $18.2 billion in 2000. The "high waste" scenario implies that patent spending supported the equivalent of just $5.5 billion in useful research. These numbers can be viewed as the amount of additional public/non-profit spending that would be needed to replace patent supported research, if this research were exactly as efficient as private sector research (after excluding the portion of private sector research devoted to the unproductive pursuit of copycat drugs). In other words, it would take between $5.5 billion and $18.2 billion dollars from these sources to fully replace the research that is currently supported by patents.

As a practical matter, as noted earlier, it is possible that public/ non-profit supported research will not be as efficient as patent supported research. It is plausible that market incentives will cause research spending, net of that wasted in copycat efforts, to be more efficient when supported by patents than in the public or non-profit sector. But even this cannot be taken as necessarily true. It is possible to envision flexible and efficient research arrangements in the public and/or non-profit sectors which could be at least as efficient as private sector research.

For example, an expanded public sector research system could contract out the process of drug development with private sector firms (with any resulting patents being placed in the public domain).[16] Such contracts could be subject to competitive bids, so that the funds would be directed to the low cost researcher. It could also establish a system of prizes whereby especially important breakthroughs would receive large monetary awards. In principle, it should be possible to establish a system where those actually engaged in the research process have as much incentive as under the current system.

[16] In fact, this was exactly the course that was advocated by the pharmaceutical industry in the wake of the Anthrax scare in the fall of 2001. The industry wanted the government to contract out the development of an Anthrax vaccine, although it was not clear who would hold any patents that might result from the research ("Industry Seeks U.S. Contracts To Develop Antibiotics," by Keith Bradsher, *New York Times*, October 31, 2001, page B10).

In addition, a publicly supported system would also benefit from the more rapid dissemination of research findings. Under such a system, there would be no reason to keep research findings secret, and in fact any contracts could explicitly require that research findings be made available in a timely manner. There would also not be the same sort of incentive to falsify research findings as exists presently.[17] For these reasons, it is reasonable to believe that money spent on research supported by the public or non-profit sectors could actually be more productive than the money spent in patent supported research.

For this exercise it is only necessary to construct a plausible range of estimates of the ratio of the efficiency of public/non-profit sector research to patent supported research. For the "efficient" public/non-profit scenario, it will be assumed that public/non-profit sector is 25 percent more efficient than the private sector, therefore it will only take 80 cents to produce results that are equivalent to one dollar spent on patent supported research. The "equal" efficiency scenario assumes that a dollar spent in either sector produces the same output. The "inefficient" scenario assumes that it takes $1.25 of public/non-profit sector research to produce as much output as $1.00 of patent supported research. The "very inefficient" scenario assumes that it takes $1.50 of public/non-profit sector research to produce as much output as $1.00 of patent supported research.

Table 4 shows the amount of public/non-profit sector research that would be needed in each of these scenarios, assuming alternatively the "high waste" or "low waste" scenarios shown in table 3. The difference between the total spending estimates and the net new spending is attributable to tax credits that the pharmaceutical industry currently receives to cover a portion

Table 4

Public/ Non-Profit Sector Equivalent of Patent Supported Drug Research in 2000

	Efficient	**Equal**	**Inefficient**	**Very Inefficient**
Total Spending (billions)				
High Waste	$4.6	$6.1	$7.6	$9.2
Low Waste	$14.1	$18.8	$23.5	$28.2
Net New Spending				
High Waste	$4.0	$5.5	$7.0	$8.6
Low Waste	$13.5	$18.2	$22.9	$27.6

[17] Researchers may still have incentives in some cases to falsify results—for example, having significant results for a test may be helpful in getting a journal article accepted or in getting a grant renewed—but these incentives are trivial compared to the incentives that drug companies have to protect their profits on popular drugs.

of its research. In the absence of patent supported research, this money could be used to directly fund additional research.

The table shows that in the extreme case, where a large portion of patent supported research is assumed to be wasted developing copycat drugs of little benefit, and public/non-profit research is assumed to be very efficient, it would take just $4.0 billion in additional spending to fully replace the useful research that is currently being supported by patent protection. This rises to $8.6 billion, if it is assumed that public/non-profit supported research is very inefficient. In the case where relatively little patent supported research is assumed to be wasted in the development of copycat drugs, but public sector non-profit research is assumed to be relatively efficient, it would take $13.5 billion in additional revenue to replace the useful research currently supported by patent protection. This rises to $27.6 billion in the case where this research is assumed to be very inefficient.

The next issue is how much money would be saved on drug purchases, if patent protection were eliminated. There has been considerable research documenting a wide variation both in the price of brand drugs in different nations, and between the price of brand drugs and generics. In principle, in the absence of patent protection, drug prices in the United States would fall to the level of high quality generic competitors. In some cases this price decline would be quite dramatic. For example, generic versions of many of the drugs used to treat AIDS often sell for less than 10 percent of the price of the brand drugs in the United States.[18]

Another way of assessing this issue is examining the price of drugs in the period after they have lost patent protection. A series of studies found large price declines in drugs after their period of patent protection was removed (Berndt et al, 1996; Griliches and Cockburn, 1994). On average these drugs cost approximately 30-40 percent as much after the patent was removed as they did during the period of patent protection. The actual price decline in a world with no patent protection is almost certain to be somewhat greater. One of the factors which raises costs even after a patent has expired is the legal cost associated with protecting firms from patent disputes. As was noted earlier, patent rents give firms a large incentive to try to protect and extend their patents, even when they may lack a legal basis. Generic producers must incur costs to contest these legal disputes. As a result, the existence of the patent system increases the cost of drugs even in the period after patent protection has expired.

The Australian Productivity Commission recently completed an extensive study of drug prices across nations.[19] It consistently found that prices in the United States were by far the highest in the industrialized world. A calculation that used its lower end estimates of drug prices in the United States, put them at 262 percent of Australian drug prices (page XXIII). Even drugs purchased at the discount prices in the federal supply schedule (used for Medicaid and other government purchases) were estimated to cost 84 percent more than in Australia. The high-end estimates put U.S. drug prices at 350 percent of Australian drug prices, with the high-end estimate for the Federal Supply Schedule (FSS) being 250 percent of Australian drug prices.

[18] For example, a year prescription of some AIDS cocktails cost approximately $10,000 in the United States. Generic producers in India, meeting international standards, can produce the same drugs for $300 to $400 a year.
[19] http://www.pc.gov.au/research/commres/pbsprices/finalreport/pbsprices.pdf

These comparisons set ranges for the same drug in both nations, they do not directly compare generics to brand drugs, which is the appropriate measure for this exercise.

The Canadian Drug Manufacturers Association recently did a comparison of the prices of brand and generic drugs for the 25 top selling drugs in Canada that are subject to generic competition.[20] This study found that the generic drug prices were on average 61.3 percent as high as the brand drugs. This finding can be used to provide a rough estimate of the impact on U.S. drug prices of eliminating patent protection, since the Australian Productivity Commission also estimated Canadian drug prices. While Canadian prices were on average considerably higher than Australian prices, they were still well below the prices charged in the United States. The Canadian prices were approximately 20 percent less than the low estimate of FSS prices and 43 percent less than the low estimate of private sector prices.

Combining the difference between generic and brand prices calculated by the Canadian Drug Manufacturers Association with the Australian Productivity Commission's estimate of the difference between average drug prices in the United States and Canada, provides a basis for estimating the relationship between Canadian generic drug prices and brand drugs in the United States, as shown in table 5.

Table 5

Drug Price Comparisons

Average Drug Prices as a Percent of Australian Drug Prices
Canada—150 percent
United States—262 percent (low estimate)
United States (FSS)—184 percent (low estimate)
United States—350 percent (high estimate)
United States (FSS)—250 percent (high estimate)

U.S. Drug Prices as a Percent of Canadian Drug Prices
Low Estimate—175 percent
Low Estimate (FSS)—123 percent
High Estimate—233 percent
High Estimate (FSS)—167 percent

U.S. Brand Drug Prices as a Percent of Canadian Generic Drug Prices
Low Estimate—285 percent
Low Estimate (FSS)—201 percent
High Estimate—380 percent
High Estimate (FSS)—272 percent

(Source: Australian Productivity Commission, 2001; Canadian Drug Manufacturers Association; and author's calculations).

[20] http://www.cdma-acfpp.org/resourcecentre/odb-99.html

Using the low estimate of U.S. drug prices, Canadian generics sell for approximately 35 percent as much as brand drugs in the United States on average. Using the low estimate for drug prices on the FSS, Canadian generics sell for just less than 50 percent as much as the federal government's payments for brand drugs. These figures will be used as a high price estimate for the cost of prescription drugs in the United States in the absence of patent protection. In other words, the assumption is that in the absence of patent protection, drug prices in the United States would fall to the same price as Canadians currently pay for equivalent generic drugs.

It is important to recognize that this estimate is almost certainly a large understatement of the drop in U.S. drug prices in a post-patent world. The brand/generic comparisons calculated by the Canadian Drug Manufacturers are based on drugs for which generic competition exists. The price of the brand version of these drugs will generally be much lower in the period after the patent had expired than in the period in which the brand drug had a monopoly. In other words, the price reduction moving from a brand drug that is still subject to patent protection to a generic drug, will be far larger than the difference between the price of the brand and generic drug in the period after patent protection has expired. For this reason, this high price estimate—that prescription drugs in a patent free world would cost 35 percent as much as they currently do in the private sector and 50 percent as much under the FSS—is almost certainly a significant overstatement of drug prices in the absence of patent protection.

The low price scenario is derived loosely from the Australian Competitiveness Commission's high estimates of U.S. drug prices. It assumes that drug prices in the absence of patent protection would average 20 percent of their patent protected level, while drugs purchased under the FSS would sell for 33 percent of their current price.

Table 6 shows the static savings in a world where patent protection for drugs were eliminated instantly. For simplicity, it is assumed that all drugs are currently sold at the private sector prices. (The dynamic scenarios in the next section assess the impact of producing drugs without patent protection, given the actual distribution of spending between the private sector and state and federal governments.) The first row in table 6 presents the gross savings from the elimination of patent protection for prescription drugs, since it does not take into account the additional tax revenue that would be needed to pay for expanded public/non-profit sector research. The second row shows net savings assuming that the amount of research spending that would need to be replaced is relatively large—the “low waste, very inefficient” scenario which appears in the last row and column of table 4. The fourth row shows net savings in a scenario in which the amount of additional research required would be very low, the “high waste, very efficient” scenario shown in the third row and first column of table 4. The third row shows the net saving in an intermediate case, which averages these two.

Table 6

Savings From Competition in the Prescription Drug Market

	2000 spending (billions)	patent free spending (high cost)	patent free spending (low cost)	Saving (high cost)	Saving (low cost)
Gross	$112	$39.2	$22.4	$72.8	$89.6
Net (high research)	$112	$39.2	$22.4	$45.2	$62.0
Net (mid research)	$112	$39.2	$22.4	$56.7	$73.5
Net (low research)	$112	$39.2	$22.4	$68.2	$85.0

All the combinations in the table show large savings from switching from the current system of patent supported research to a system that relies on public/non-profit sector research. The lowest figure projection of net savings is $45.2 billion a year, which assumes relatively high prescription drug prices in the absence of patent protection coupled with assumptions that imply that it will require a large amount of new spending to replace the research that is currently being supported through patent protection. The highest projection of net savings, which combines optimistic assumptions on both of these issues, is $85.0 billion, approximately one percent of GDP. The middle set of assumption shows savings ranging from $56.7 to $73.5 billion a year.

These estimates of the economic impact of eliminating drug patents are incomplete, since they do not include the welfare gains that result from having lower drug prices. In effect, the numbers in table 6 are estimates of the reduction in payments from drug consumers to drug producers. However, a measure of the full economic gain would also have to add in the additional benefits that consumers would enjoy as a result of being able to buy drugs at lower prices, in other words, the additional consumer surplus that results from this drop in prices. To calculate the consumer surplus, it would be necessary to know the elasticity of drug consumption with respect to changes in prices.

For purposes of this exercise, it is only necessary to construct a plausible range of elasticities. Drug consumption is generally assumed to be relatively inelastic, since most people will try to purchase the drugs they view as necessary, if they are able to afford them. For purposes of this calculation it is assumed in the low elasticity scenario that the elasticity is 0.15, which means that a 10 percent drop in drug prices would lead to a 1.5 percent increase in drug purchases. The high elasticity scenario assumes an elasticity of 0.3, which implies that a 10 percent fall in drug prices would lead on average to a 3.0 percent increase in drug purchases.[21] To complete the picture, it is also necessary to subtract the additional deadweight loss that would be associated with higher taxes needed to fund more public sector/non-profit research. Most estimates put the deadweight loss associated with the income tax at between 15-20 percent of the

[21] The low and high elasticity assumptions can be reconciled with a Cobb-Douglas utility function with exponents on the drug component of 0.15 and 0.3, respectively.

revenue raised.[22] For simplicity, the calculations in the table all assume the higher 20 percent deadweight loss.

Table 7

Net Efficiency Gain From Competition in the Prescription Drug Market

	Low Elasticity		**High Elasticity**	
Based on 2000 spending	patent free spending (high cost)	patent free spending (low cost)	patent free spending (high cost)	patent free spending (low cost)
	(billions)			
Gross	$5.0	$8.6	$10.4	$18.4
Net (high research)	$-0.6	$3.1	$4.9	$12.9
Net (mid research)	$1.8	$5.4	$7.2	$15.2
Net (low research)	$4.1	$7.7	$9.5	$17.5

The numbers in the table are all positive (except in the case combining all the negative assumptions), which indicates that the efficiency gains associated with lower drugs prices (apart from the gains that result from the elimination of rent seeking activities), are larger than the deadweight losses that would result from higher taxes to support addition public sector/non-profit research, in the scenarios described above. By definition these net efficiency gains become greater, as the elasticity of demand for drugs increases. Also, the gains increase if the percentage reduction in price due to the elimination of patent protection is larger—an outcome that would be expected if the mark-up over costs for prescription drugs increases rapidly as firms attempt to recoup higher research costs. In any case, these figures—coupled with the numbers in table 6—suggest that switching from patent supported drug research to research supported by the public/non-profit sector will produce large gains for the economy.

THE DYNAMIC GAINS FROM PUBLIC SECTOR/NON PROFIT SUPPORTED RESEARCH

The previous discussion presented an outline of how the prescription drug market would be different if the country had in place a system of public sector/ non-profit supported research in 2000. However, as a practical matter, if such a policy were to be adopted, it would be necessary to phase it in through time. In addition, the drug market is expanding quickly, as drug expenditures are growing far more rapidly than the economy as a whole. It is also important to

[22] For example, Fullerton and Henderson (1989) put the deadweight loss from federal income taxes at less than 15 percent of the revenue raised.

take into account the fact that large portion of national spending on drugs is done by the federal and state governments through Medicare, Medicaid and other programs. The savings to these programs from lower drug prices would free up tax revenue which could be used to finance additional spending on research and development for new drugs. The savings in the private sector on drug expenditures translates into a higher real wage, which increases the incentive to work. Determining the distribution of the gains from lower drug prices will provide a better basis for assessing the benefits to the economy from switching to a system of public sector/non-profit supported drug research.

Table 8 shows projections for total spending on prescription drugs through the year 2024, as well as the distribution of the costs among the major payers. (The construction of the table is explained in the appendix.) The projections show that spending on prescription drugs will rise rapidly, both in absolute terms and as a share of GDP. At present, spending on prescription drugs is equal to approximately 1.3 percent of GDP. By the end of this period, spending on prescription drugs is projected to be equal to 3.3 percent of GDP. This indicates that the potential gains from switching to a system of public sector/non-profit supported research will increase significantly through time. The table also shows projections for patent supported research over this period. It is assumed that the share of sales devoted to research spending is 20 percent throughout the period, the peak level hit in 1994.[23]

[23] Thi2008s estimate may overstate the percentage of sales that will go to R&38.5D. The R&D share of sales peaked at 20.4 percent in 1994, and then fell back modestly in the late nineties. In 2001, PHARMA's data indicates that R&D spending was 18.5 percent of sales (PHARMA 2002, table 2).

Table 8
Projected Spending on Prescription Drugs and R&D

(Billions of Current Dollars)

	Total	Share of GDP	Federal	State	Private	R&D Spending
2001	$135.7	1.3%	$16.6	$12.8	$106.3	$27.1
2002	155.0	1.4%	19.1	14.8	121.1	31.0
2003	175.8	1.5%	21.7	17.0	137.1	35.2
2004	197.1	1.6%	24.5	19.4	153.2	39.4
2004	219.9	1.7%	27.7	21.9	170.3	44.0
2006	245.3	1.8%	31.1	24.7	189.5	49.1
2007	272.4	1.9%	34.7	27.7	210.0	54.5
2008	301.5	2.0%	38.5	30.8	232.2	60.3
2009	332.6	2.1%	42.3	34.1	256.2	66.5
2010	366.0	2.2%	46.5	37.6	281.9	73.2
2011	398.9	2.3%	50.7	41.0	307.3	79.8
2012	434.8	2.4%	55.2	44.7	334.9	87.0
2013	474.0	2.4%	60.2	48.7	365.1	94.8
2014	516.6	2.5%	65.6	53.1	397.9	103.3
2015	563.1	2.6%	71.5	57.9	433.7	112.6
2016	608.2	2.7%	77.3	62.5	468.4	121.6
2017	656.8	2.8%	83.5	67.5	505.9	131.4
2018	709.4	2.9%	90.1	72.9	546.4	141.9
2019	766.1	3.0%	97.3	78.7	590.1	153.2
2020	827.4	3.1%	105.1	85.0	637.3	165.5
2021	885.4	3.1%	112.5	91.0	681.9	177.1
2022	947.3	3.2%	120.4	97.3	729.6	189.5
2023	1013.6	3.2%	128.8	104.1	780.7	202.7
2024	1084.6	3.3%	137.8	111.4	835.4	216.9

Source: Health Care Financing Administration and Authors' Calculations

Table 9 shows estimates of the additional government expenditures that would be needed to offset the loss of patent supported research. The first column in table 9 shows the additional spending that would be needed in the efficient public sector/high waste patent supported research scenario shown in table 4. The third column in the table shows the additional spending that would be needed in very inefficient public sector/low waste patent supported research scenario in table 4. The second column presents a middle scenario, which is the average of columns one and three.

Table 9

Additional Public/Non-Profit Expenditures on Drug Research

(Billions of Current Dollars)

	Low	Mid	High
2001	$4.8	$4.8	$16.9
2002	5.5	5.5	19.3
2003	6.3	6.3	21.9
2004	7.0	7.0	24.6
2005	7.8	7.8	27.4
2006	8.7	8.7	30.6
2007	9.7	9.7	34.0
2008	10.7	10.7	37.6
2009	11.8	11.8	41.5
2010	13.0	13.0	45.7
2011	14.2	14.2	49.8
2012	15.5	15.5	54.3
2013	16.9	16.9	59.1
2014	18.4	18.4	64.5
2015	20.0	20.0	70.3
2016	21.7	21.7	75.9
2017	23.4	23.4	82.0
2018	25.3	25.3	88.5
2019	27.3	27.3	95.6
2020	29.5	29.5	103.2
2021	31.5	31.5	110.5
2022	33.7	33.7	118.2
2023	36.1	36.1	126.5
2024	38.6	38.6	135.3

Source: PhRMA 2002 and Authors' Calculations. See Appendix.

It would obviously not be possible to instantaneously replace the current system of patent supported research. To construct a set of projections of the gains from public sector/non-profit supported research, it was assumed that this system would be phased in over a three-year period from 2003-2005. In principle, the level of research spending in 2006 and later years should be large enough to produce research that is comparable in value to the patent supported research that would otherwise be carried through by the pharmaceutical industry.

Table 10a and 10b show the saving that would accrue to each sector under this phase in schedule. The projections in 10a are based on the high cost scenario described in table 6, while table 10b shows projections based on the low cost scenario in table 6. At first the change to public/non-profit supported research would have almost no impact, since there would be a period of time before any drugs developed by this system could work their way through the FDA

approval process. However, by the third year, the projection assumes that there is noticeable difference in drug prices between the baseline and the alternative scenario, as some new drugs appear on the market, without being subject to patent protection. This impact is assumed to increase substantially over the next several years, so that by the tenth year 70 percent of the ultimate price reductions have been realized.[24]

Table 10a

Savings from Public/Non-Profit Drug Research: High Cost
(Billions of Current Dollars)

	Federal	State	Private	Private Savings as a Percent of GDP
2001	$0.0	$0.0	$0.0	0.0%
2002	0.0	0.0	0.0	0.0%
2003	0.0	0.0	0.0	0.0%
2004	0.0	0.0	0.0	0.0%
2005	1.2	1.0	10.0	0.1%
2006	2.7	2.2	22.2	0.2%
2007	4.6	3.6	36.9	0.3%
2008	6.7	5.4	54.5	0.4%
2009	9.3	7.5	75.1	0.5%
2010	12.2	9.9	99.2	0.6%
2011	15.5	12.6	126.1	0.7%
2012	19.3	15.6	157.1	0.8%
2013	22.0	17.8	178.6	0.9%
2014	24.9	20.2	202.6	1.0%
2015	28.3	22.9	229.6	1.1%
2016	31.7	25.6	257.4	1.1%
2017	35.5	28.7	288.1	1.2%
2018	39.7	32.1	322.1	1.3%
2019	44.3	35.8	359.8	1.4%
2020	49.4	40.4	401.4	1.5%
2021	54.6	44.1	443.2	1.6%
2022	60.2	48.7	488.9	1.6%
2023	64.4	52.1	523.1	1.7%
2024	68.9	55.7	559.7	1.7%

Source: Health Care Financing Administration and Authors' Calculations. See Appendix.

[24] This calculation assumes that the percentage of the eventual price reduction from the availability of non-patented drugs increases by 8.75 percentage points beginning in the third year, until the tenth year. After the tenth year, the rate of increase drops to 3 percentage points a year, until 100 percent of the price reduction is realized in the twentieth year.

Table 10b
Savings from Public/Non-Profit Drug Research: Low Cost
(Billions of Current Dollars)

	Federal	State	Private	Private Savings as a Percent of GDP
2001	$0.0	$0.0	0.0	0.0
2002	0.0	0.0	0.0	0.0
2003	0.0	0.0	0.0	0.0
2004	0.0	0.0	0.0	0.0
2005	1.6	1.3	11.9	0.1
2006	3.6	2.9	26.5	0.2
2007	6.1	4.8	44.1	0.3
2008	9.0	7.2	65.0	0.4
2009	12.3	9.9	89.7	0.6
2010	16.3	13.2	118.4	0.7
2011	20.7	16.7	150.6	0.9
2012	25.8	20.8	187.6	1.0
2013	29.3	23.7	213.2	1.1
2014	33.3	26.9	241.9	1.2
2015	37.7	30.5	274.1	1.3
2016	42.2	34.2	307.3	1.4
2017	47.3	38.2	344.0	1.5
2018	52.9	42.8	384.7	1.6
2019	59.1	47.8	429.6	1.7
2020	65.9	53.3	479.3	1.8
2021	72.7	58.8	529.2	1.9
2022	80.2	64.9	583.7	2.0
2023	85.9	69.4	624.6	2.0
2024	91.9	74.3	668.3	2.0

Source: Health Care Financing Administration and Authors' Calculations. See Appendix

Since the patent length is twenty years, and some drugs will continue to be patented even after the alternative system is set in place, most of the drugs that would be subject to patent protection in the baseline scenario would still be under patent in this alternative scenario. However, the assumption that 70 percent of the ultimate price reduction would be realized is based on the assumption that competitive drugs will exist in the public domain for many drugs that are still subject to patent protection. In these cases, the price of the patent protected drug will have to fall to a level comparable to the generic drug. The rate of price decline relative to the baseline is assumed to slow, so that by the twentieth year drug prices have fallen to the levels described in the high cost and low cost scenarios in table 6. In reality, there may continue to be some patent protected drugs for long after this point, since firms could still get patents even with the alternative system of support in place, but presumably these drugs would account for only a very small share of drug spending.

Table 11 shows the projected public sector saving in both the high cost and low cost scenarios from tables 10a and 10b alongside the projections for additional public sector research spending from table 9. The public sector savings combine the projections for savings for both the federal and state government. The projections indicate that some additional public spending will be needed to support research in the middle and high research cost scenarios, since the savings on lower drug prices will be fairly limited. However, the additional spending will always be limited, never exceeding 0.3 percent of GDP, even in the high drug cost high research cost scenario. After 10 years, the savings in the high drug cost scenario would be sufficient to fully cover the cost of the additional research spending in the middle price scenario. The savings in the low drug cost scenario would be enough to cover two-third of the additional research spending needed in the high research cost scenario. By 2024, the savings in the high drug cost scenario would be more than enough to cover the additional spending that would be needed in the middle research cost scenario, and sufficient to cover two-thirds of the additional spending needed in the high research cost scenario. The savings in the low drug cost scenario would be sufficient to cover more than 80 percent of the additional research spending in the high research cost scenario.

Table 11

Public Sector Savings on Drug Expenditures and Additional Public-Non-Profit Sector Spending
(Billions of Current Dollars)

	Drug Costs		Research Costs		
	Low	**High**	**Low**	**Mid**	**High**
2001	$0.0	$0.0	$0.0	$0.0	$0.0
2002	0.0	0.0	0.0	0.0	0.0
2003	0.0	0.0	2.1	4.7	7.2
2004	0.0	0.0	4.7	10.5	16.4
2005	2.9	2.2	7.8	17.6	27.4
2006	6.5	4.9	8.7	19.7	30.6
2007	10.9	8.2	9.7	21.8	34.0
2008	16.2	12.1	10.7	24.2	37.6
2009	22.3	16.7	11.8	26.7	41.5
2010	29.4	22.1	13.0	29.3	45.7
2011	37.4	28.1	14.2	32.0	49.8
2012	46.6	35.0	15.5	34.9	54.3
2013	53.0	39.8	16.9	38.0	59.1
2014	60.2	45.1	18.4	41.4	64.5
2015	68.2	51.1	20.0	45.2	70.3
2016	76.4	57.3	21.7	48.8	75.9
2017	85.5	64.1	23.4	52.7	82.0
2018	95.6	71.7	25.3	56.9	88.5
2019	106.8	80.1	27.3	61.4	95.6
2020	119.2	89.4	29.5	66.4	103.2
2021	131.6	98.7	31.5	71.0	110.5
2022	145.1	108.8	33.7	76.0	118.2
2023	155.3	116.5	36.1	81.3	126.5
2024	166.2	124.6	38.6	87.0	135.3

Source: Health Care Financing Administration, PhRMA 2002, and Authors' Calculations. See Appendix.

While there is some degree of uncertainty about the exact balance between the public sector saving on lower drug costs and the amount of additional research spending that will be needed to replace patent supported research, the projections in table 11 suggest that imbalance is not likely to be very large in either direction. It is likely that some net increase in spending on drugs would be needed in the early years after a commitment to increased public support was put in place, since most of the savings would not yet be realized. However, by the end of the period, the savings from lower drug prices should be sufficient to cover the additional research spending needed to replace patent supported research. This means that there would be little if any reason for higher taxes for this purposes, and any tax increase would almost certainly be temporary.

If the additional public sector research costs can be paid for out of savings from lower public sector expenditures on drugs, then the lower prescription drug costs for the private sector can be viewed as a pure gain. Table 12 shows the projected gains measured in current dollars and as shares of GDP in both the high drug cost and low drug cost scenarios. As can be seen, these gains are quite substantial. The savings exceed 1.0 percent of GDP in the 10th year in the low drug cost scenario, and in the 13th year in the high drug cost scenario. The savings continue to increase until they reach 1.7 percent of GDP in the high drug cost scenario (the equivalent of nearly $200 billion in 2002), and 2.0 percent of GDP in the low drug cost scenario (the equivalent of $220 billion in 2002).

Table 12

Private Savings from Public/Non-Profit Sector Research
(Billions of Current Dollars)

	High Cost		**Low Cost**	
	Savings	**Private Savings as a Percent of GDP**	**Savings**	**Private Savings as a Percent of GDP**
2001	$0.0	0.0%	$0.0	0.0%
2002	0.0	0.0%	0.0	0.0%
2003	0.0	0.0%	0.0	0.0%
2004	0.0	0.0%	0.0	0.0%
2005	10.0	0.1%	11.9	0.1%
2006	22.2	0.2%	26.5	0.2%
2007	36.9	0.3%	44.1	0.3%
2008	54.5	0.4%	65.0	0.4%
2009	75.1	0.5%	89.7	0.6%
2010	99.2	0.6%	118.4	0.7%
2011	126.1	0.7%	150.6	0.9%
2012	157.1	0.8%	187.6	1.0%
2013	178.6	0.9%	213.2	1.1%
2014	202.6	1.0%	241.9	1.2%
2015	229.6	1.1%	274.1	1.3%
2016	257.4	1.1%	307.3	1.4%
2017	288.1	1.2%	344.0	1.5%
2018	322.1	1.3%	384.7	1.6%
2019	359.8	1.4%	429.6	1.7%
2020	401.4	1.5%	479.3	1.8%
2021	443.2	1.6%	529.2	1.9%
2022	488.9	1.6%	583.7	2.0%
2023	523.1	1.7%	624.6	2.0%
2024	559.7	1.7%	668.3	2.0%

Savings of this size would have a significant economic impact. Table 13 uses extrapolations from a WEFA forecasting model to derive estimates of the magnitude of the impact of these savings on the economy (WEFA 1990). This model projected that a reduction in oil prices equal to 0.16 percent of GDP would increase GDP by 0.24 percent, while an increase in oil prices equal to 0.25 percent of GDP would lower GDP by 0.48 percent.[25] Table 13 uses the lower scenario of these projections, assuming that the economic impact of savings on prescription drugs is equal to 1.5 times the savings on drugs, measured as a share of GDP. In the low drug cost scenario the gains exceed 1.0 percent of GDP by the eighth year, and 2.0 percent of GDP by the 14th year, and eventually reach 3.0 percent of GDP. The gains in the high cost drug scenario are somewhat smaller but still quite impressive, eventually reaching 2.6 percent of GDP. The table also shows the job impact of these gains, using the assumption that the increase in jobs is proportionate to the increase in GDP. In the high drug cost scenario, the increase in jobs resulting from the switch to publicly supported drug research eventually exceeds 3.8 million. In the low drug cost scenario the job gains exceed 4.5 million by 2024.

[25] These impacts were calculated by taking the difference between oil prices in the high price and low price scenarios compared with the baseline, and assessing the differences in projected real GDP for 2010.

Table 13

Economic Impact of Replacing Patent Supported Drug Research With Public/Non-Profit Sector Research

	High Cost (Millions)		**Low Cost** (Millions)	
	Additional Jobs	**Change in GDP**	**Additional Jobs**	**Change in GDP**
2001	0.0	0.0%	0.0	0.0%
2002	0.0	0.0%	0.0	0.0%
2003	0.0	0.0%	0.0	0.0%
2004	0.0	0.0%	0.0	0.0%
2005	0.2	0.2%	0.2	0.2%
2006	0.4	0.3%	0.4	0.3%
2007	0.7	0.5%	0.6	0.5%
2008	0.9	0.6%	0.9	0.6%
2009	1.1	0.8%	1.3	0.9%
2010	1.3	0.9%	1.5	1.1%
2011	1.5	1.1%	2.0	1.4%
2012	1.7	1.2%	2.2	1.5%
2013	2.0	1.4%	2.4	1.7%
2014	2.2	1.5%	2.6	1.8%
2015	2.5	1.7%	2.9	2.0%
2016	2.5	1.7%	3.1	2.1%
2017	2.6	1.8%	3.3	2.3%
2018	2.9	2.0%	3.6	2.4%
2019	3.2	2.1%	3.8	2.6%
2020	3.3	2.3%	4.0	2.7%
2021	3.6	2.4%	4.3	2.9%
2022	3.5	2.4%	4.5	3.0%
2023	3.9	2.6%	4.5	3.0%
2024	3.8	2.6%	4.5	3.0%

GOVERNMENT INTERVENTION: PATENTS OR DIRECT SUPPORT?

It is important to recognize that the choice between patent-supported research and direct funding through the public/non-profit sectors is not a choice between the market and the government, but rather a choice between two different forms of government intervention. Virtually everyone would agree that in the absence of government intervention, there would be a less than optimal amount of research. But, the question being posed is not whether the government should intervene, but rather what is the most efficient form of intervention to address this market failure.

The preceding analysis suggests that patents are a very inefficient form of government intervention, adding tens of billions of dollars to the nation's annual bill for prescription drugs. Furthermore, the pursuit of patent rents leads to further political intervention in the market, which takes a variety of different forms. For example, firms attempt to steer federal research spending at National Institutes of Health into areas that are most likely to lead to breakthroughs from which they can subsequently profit. Second, firms have often attempted to use their political influence to shape patent laws in ways that extend their monopoly. Finally, the decision by the pharmaceutical manufacturers to pursue the development of a particular drug will depend to a large extent on their perception as to whether it will be covered under government programs such as Medicare and Medicaid, and whether it will be possible to exert sufficient political pressure to force private insurers to pay for it. This is likely to be an increasing important problem as drug prices rise in future years.

For these reasons, patents almost certainly involve far more extensive government involvement in the pharmaceutical market than a system of directly supported research, where the production and sale of drugs was entirely left to the market. In this situation, Congress would have to make decisions about the overall appropriations for research spending, as it does now, but the allocation of funds to specific lines of research would be done by health care professionals, independent of political influence, in much the same way as the National Institutes of Health currently parcel out their research funds. In fact, the elimination of patent rents is likely to remove the most obvious source of political interference in the process that presently exists.

Direct funding from the budget is also not the only alternative to patent supported research. At present, approximately 4 percent of research is supported through universities, private foundations, and charities.[26] This funding would presumably continue and grow if patents ceased to be a major source of support. This would be especially true if the government increased incentives for individuals to contribute to such organizations—for example through more generous tax deductions or credits for this purpose. It is also worth noting that the shift in funding sources would have relatively little impact on where research is actually conducted.

[26] http://www.grants.hin.gov/grants/award/trends96/pdfdos/FEDTABLA.PDF

Most of the research funded by the pharmaceutical industry actually takes place at universities or other independent research facilities. Only 9.13 percent of the research funded by the industry is conducted in their own facilities.[27]

There are clearly many innovative methods of alternative funding that could be developed, but the basic point should be clear. These alternatives are likely to reduce, rather than increase, political involvement in research priorities.

It is also important to note the international dimensions of this issue. Enforcing patent protection on pharmaceuticals has been a source of considerable friction between the United States and its trading partners in recent years, especially in the case of patent protection for essential medicines in developing nations. In many cases, requiring that drugs be sold at patent protected prices will be a virtual death sentence to millions of poor people, since this will make the drugs unaffordable.

If the research findings were simply placed in the public domain, it could provide enormous benefits to people in developing nations, in a way that is essentially costless for the United States.[28] (This situation is a step better than simply removing any patent restrictions in developing nations. Since research findings would be fully accessible, much of the reverse engineering that is currently used to copy patented drugs would be unnecessary.) In principle, it would be desirable to have the burden of paying for drug research shared in some manner internationally, so that wealthy nations could not simply free-ride on the research expenditures of others. While there would inevitably be problems in designing an international agreement on this issue, there is no reason to believe that the problems are more difficult than those involved in harmonizing patent rules across international boundaries.

CONCLUSION

Economic theory indicates that drug patents will lead to increasing economic waste as drug research costs rise, and patent rents increase correspondingly. While this should make alternative methods of support for drug development relatively more efficient through time, there has been very little public discussion of alternatives to patent supported research. This paper has produced a range of estimates that provide a basis for comparing the relative efficiency of patent supported and public/non-profit sector supported research.

It shows that, under plausible assumptions, the savings to government programs from having access to drugs not subject to patent protection, should be large enough to fully fund the

[27] http://www.cptech.org/ip/health/econ/usrndbyperformer.html

[28] If a system of public/non-profit supported research is more efficient than the current patent system, then the nation as a whole would benefit, even if research results are freely available to the rest of the world. Of course, if there were a mechanism whereby the U.S. could collect patent type rents internationally, even without imposing patents domestically, then obviously the U.S. as a whole would benefit more than if it just allowed the research to be freely available.

additional research needed to replace patent supported research. This means that the gains to the private sector from lower drug prices would not be offset by any additional taxes. These savings would be quite substantial even with pessimistic assumptions about the impact of the removal of patent protection. When an alternative system of research was fully phased in the savings to the private sector would be between 1.6 and 2.0 percent of GDP. The economic impact of savings of this magnitude would be dramatic, eventually leading to increases of between 2.6-3.0 percent of GDP. This additional output would imply between 3.8 and 4.5 million additional jobs. There are very few policies that could potentially have a comparable impact.

APPENDIX

The projections in table 8 are derived from the Health Care Financing Administration's National Health Care Expenditures Tables (2000-2010), table 11 (http://www.hcfa.gov/stats/NHE-Proj/proj2000/tables/t11.htm). The rate of growth of prescription drug spending is assumed to slow gradually in the years after the end of the projections in 2010. While nominal cost growth averages 11.7 percent in the projection period, it is assumed to slow to 9.0 percent annually in the years 2010-2015, to 8.0 percent in the years from 2015 to 2020, and to 7.0 percent in the years after 2020. If the growth in spending does not slow as much as assumed in these projections, then the gains from switching to a system of public/non-profit sector supported research would be even larger.

Table 9 projects the additional spending (net of tax credits) which would be needed to offset the loss of patent supported research. The "low" scenario is based on "high waste, efficient research" scenario in table 4, which implied that the amount of net new spending would be equal to 17.8 percent of the research spending currently conducted by the pharmaceutical industry. The "high" scenario in table 9 is based on the "low waste, very inefficient research" scenario in table 4, which implies that the amount of public spending needed to replace patent supported research, would be 107 percent of the research expenditures of the pharmaceutical industry.

Table 10a calculates the savings to the private sector and federal and state governments under the assumption that non-patented drugs would cost 50 percent as much as the public sector currently pays, and 35 percent as much as the private sector pays. Table 10b assumes the respective costs as 35 percent for the public sector, and 20 percent for the private sector. The actual savings are assumed to be phased in according to the schedule described in the text. There are no savings in the first 2 years, in years 3 through 10, the amount of savings increases each year by 8.75 percent of the eventual savings (i.e. in year 3, 8.75 percent of the eventual price reduction is realized, in year 4, 17.5 percent of the eventual price reduction is realized, etc.). In years 11 through 20, the amount of savings increases by 3.0 percentage points annually of the eventual price reduction.

Table11 combines the projections of savings to the public sector in tables 10a and 10b with the projections of necessary additional research expenditures in table 9. The "high" cost scenario is from table 10a, while the low cost scenario is from 10b. The research expenditures are assumed to be phased up to the necessary levels over three years beginning in 2003. In 2005, it is assumed that the additional public sector research expenditures will be sufficient to fully replace patent supported research.

Table 12 shows the savings to the private sector from tables 10a and 10b in the high drug cost and low cost drug cost scenarios, respectively. These savings are expressed in current

dollars and as a share of GDP. The GDP projections are taken from the 2001 Medicare Trustees Report, in order to be consistent with the drug expenditure projections.

Table 13 shows the estimated impact of these drug savings on GDP and jobs based on estimates of the sensitivity of GDP to savings on oil expenditures that appeared in the WEFA econometric model (WEFA 1990). This calculation is based on the difference in GDP projected for 2010 in their high oil and mid oil price scenarios. It is assumed that the increase in employment is proportional to the increase in GDP. The base employment growth projections are taken from the 2001 Social Security trustees report.

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