

8. An Economic Analysis of Patents and the Health Impact Fund

Patents are an effective mechanism to stimulate innovation, but lead to a number of economic inefficiencies – most importantly, “deadweight losses” caused by high prices, and sub-optimal innovation investment decisions. The HIF can rectify some of these inefficiencies for registered drugs, while offering increased opportunities for pharmaceutical innovators. The HIF’s reward mechanism ensures that the rewards are not excessive, and the new funding required is likely to be very modest.

INTRODUCTION

The patent system is a mechanism for incentivizing innovation: essentially, it allows firms to exclude others from the use of an innovation so that the patentee can capture more of the benefits created. It is a robust, but imperfect, system which has served society well. This chapter discusses both the merits and failings of this system, particularly with respect to pharmaceuticals. It shows how the Health Impact Fund addresses many of the failings, not by eliminating patents, but by building on them, and offering innovators a new way of using patent exclusivity to earn profits.

PATENTS

Description of the Patent System

A patent is a special privilege conferred by a government. It entitles the patent owner to use the legal system to stop unauthorized use of an innovation disclosed in the patent, typically for a period of 20 years. The patent system is designed to provide a reward for inventions that are made public, and it does so by temporarily preventing any competition relying on the patented innovation. In pharmaceuticals, patents are particularly important, since competition with generic products tends to be fierce and the cost of product research and development (R&D) very large relative to the cost of production.¹ In a free market system without patents (and other rewards for innovation), pharmaceutical firms would be unable to

earn enough from their inventions to recover their R&D outlays and would therefore be unwilling to invest in the development of new medicines.

The existing pharmaceutical Patent System is defined primarily by the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement, signed at the end of the Uruguay Round of WTO negotiations in 1995. This agreement governs nearly all aspects of intellectual property in international trade. TRIPS requires all WTO member states to adhere to strict patent protection laws for patented pharmaceuticals; at least 20 years of market exclusivity are guaranteed. The patent system, while still defined in domestic law and enforced in each country by its government, has now become effectively internationalized through the TRIPS agreement. Prior to TRIPS, different countries had different patent laws, which often reflected their level of development and the social goals that patent laws were thought necessary to achieve. Developed countries typically had the broadest and most restrictive patent laws, providing strong protection for monopoly manufacturing and sale of a wide range of patented products.

Poor countries’ access to cheap generic versions of patented medicines ended in 2005, when the 10-year compliance window for TRIPS came to a close in all but the so-called least developed countries. WTO members were required to bring their domestic patent laws up to the standards of TRIPS, effectively universalizing the strong patent protection favored in developed countries. The provisions of this treaty have been supplemented, as part of bilateral trade

84 THE HEALTH IMPACT FUND

agreements, by bilateral “TRIPS-plus” measures that further strengthen the protection of pharmaceutical patents, sometimes extending monopolies beyond 20 years through “data protection”.²

Until quite recently, patent laws were much less generous to innovators in most developed countries. Despite this, even very poor developing countries have signed on to TRIPS at the same level of patent protection as is granted in the most developed countries. It is clear that relatively poor small countries have little to gain directly from this. They could have continued to free ride on the innovation incentives created in the rest of the world, which are not meaningfully strengthened by the addition of their own domestic patents, and would thereby have spared their populations the high prices domestic patents enable. So it was presumably the promise of greater access to Western markets that motivated these countries to accept intellectual property protections that are substantially higher than those the most industrialized countries had just a few decades ago.

Strengths of the Patent System

The patent system – as a means of inducing innovation – has a number of very attractive properties. First, all the risk of R&D is left with the firm that tries to develop an innovation. Thus, if a firm makes a poor choice of how to invest its money – in a drug which is ineffective or unsafe or for some other reason unprofitable – it does so at no cost to the public. Second, the party that typically has the most information about the prospects for successfully developing a product or process is the one that makes the investment decision. This allocation of responsibility for investment decisions decreases the likelihood that resources will be squandered on projects that are unlikely to come to fruition or are unimportant to consumers. Scotchmer (2004, p.38) notes that the decentralization of investment decisions is key to the patent system because ideas for innovations are widely distributed among firms and inventors, and no central authority can know about all these different ideas. Third, under the patent system rewards for successful development of innovations are positively correlated with consumers’ valuations of the innova-

tion, since the larger the aggregate demand for the product, the greater the valuation of the product embodying the innovation and the larger the innovator’s profits. Thus, firms have stronger incentives to invest into research (a) the less it costs, (b) the more likely it is to lead to a patentable innovation, and (c) the more highly the public is likely to value this innovation. Finally, the patent is limited in duration and thus the invention disclosed in the patent will eventually become freely available for use by the public.

Weaknesses of the Patent System

Lack of Access

The most obvious objection to the patent system is that the high prices it enables inhibit access for some consumers who are able and willing to pay for the product at prices higher than the average cost of production, yet are unable or unwilling to pay the higher price enabled by the patent. The patent system thus creates economic inefficiencies, known as deadweight losses. In pharmaceutical markets, deadweight losses are likely to be enormous, particularly in countries where drug insurance is not widely available.³ This inefficiency means that many patients go untreated and the patentee fails to benefit from potentially profitable sales. This enormous waste comes primarily through limiting sales to the poor in developing countries, who are not able to purchase essential medicines.⁴

One response to the problem of high prices, which limit access for poor consumers especially in less developed countries, is a strategy of differential pricing. Thus some firms, such as Glaxo, have a policy of charging high prices in the wealthiest countries, lower prices in medium income countries, and at-cost prices in the poorest countries. However, such price discrimination is not universally used, for a variety of reasons. First, there are substantial higher-income markets in many poor countries, and the profit-maximizing pricing strategy within the country itself may be to charge high prices (Flynn *et al*, 2008). Second, charging different prices in different countries can lead to parallel imports between countries – the importation of inexpensive drugs from

poor countries into rich countries – which results in some loss to the patentee of sales at high prices in the richer countries. Finally, there is a web of price-referencing schemes between countries, many of which refer to foreign prices in setting domestic reimbursement levels. Thus while a differential pricing strategy seems at first glance to benefit both innovators and consumers, the fact that innovators have not universally set prices in different countries at levels which reflect incomes indicates that firms do not typically consider this strategy to be beneficial to them.⁵

High prices also lead to deadweight losses in wealthy countries, as consumers without complete insurance choose not to purchase prescribed medicines, or as insurers decide not to reimburse certain medicines. For example, in the United States, many insurance plans require co-payments of between 20% and 33% on “Tier 4” drugs. When drugs are priced in the thousands of dollars, this can impose severe financial hardship on patients, resulting in their not following the prescribed therapy. In countries with government-sponsored drug insurance programs, some expensive drugs are simply not being listed on the formulary as eligible for reimbursement. Such deadweight losses are inevitable given substantially different willingness to pay across payers, because the patentee maximizes profits by setting a price which excludes some potential buyers.

Counterfeiting

A second problem that results in part from the high prices of patented pharmaceuticals is the profitability of counterfeiting. According to a recent World Health Organization study, “counterfeits are deliberately and fraudulently mislabeled with respect to identity or source. Counterfeiting occurs both with branded and generic products and counterfeit medicines may include products with the correct ingredients but fake packaging, with the wrong ingredients, without active ingredients or with insufficient active ingredients.”⁶ The proportion of drugs which are counterfeit is unknown, though estimates range from approximately 1% in developed countries to well over 10% in developing countries.⁷ (Sometimes infringing generics which are correctly labeled but

infringing are described as counterfeits, and in fact the incentives to infringe are similar to the incentives to counterfeit.)

Counterfeit drugs that are fraudulently mislabeled as to their source, but that are faithful copies of the original, cost the innovator lost revenues. In this case, counterfeits are essentially a form of theft from the innovator, and reduce the incentive to innovate. More troublingly, many counterfeit drugs simply do not contain the listed ingredients in the listed amount, and some do not contain these ingredients at all. This not only harms the innovator by taking away market share; it also damages the reputation of the branded product that is being counterfeited. Counterfeit medicines also harm patients when they do not contain the listed ingredients, contain them in the wrong concentration, or contain other toxic substances.

When counterfeits contain less than the correct amount of the active ingredient they may also increase drug resistance. For example, a recent study of malaria drugs sold in the most severely affected parts of Africa showed that over a third of all drugs tested did not contain the advertised amounts of the ingredients (Bate et al. 2008). 42% of tested products claiming to be artemisinin monotherapies were found to not meet “international standards” for active pharmaceutical ingredient content. The use of artemisinin monotherapies – especially in partial doses – is likely to lead to parasitic resistance to the extremely effective artemisinin combination therapies which are now recommended by WHO.

Innovation

Perhaps the greatest weakness of the patent system is that it fails to induce the most efficient set of innovations. We consider two aspects of efficiency: “internal” efficiency refers to how well resources are allocated over all possible R&D projects; and “external” efficiency refers to how well resources are allocated between R&D and other activities. Given any amount to be invested into innovative activities, internal efficiency is attained when the benefit to society of investing another dollar into any given innovation project is equalized across all projects with

positive funding, and when the benefit from projects that receive no funding is below that of projects that do receive funding. External efficiency is achieved when the marginal benefit to society from increasing R&D spending is equal to the marginal benefit from investing in other activities.

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An important point in the definitions of efficiency above is that the social benefit should be equal to the social cost at the margin. However, under the patent system, innovative companies generally consider only their private benefit when making investment decisions. Therefore, the patent system gives firms research incentives that are distorted from what would be socially optimal. In particular, these incentives are too weak for most areas of research and biased in specific ways described below.

Patent duration. There are limits on the duration of the patent. The limitation on duration reduces the incentives to invest in innovations that will have substantial impact more than twenty years into the future. In the pharmaceutical industry, this means that the patent system does little to incentivize basic research, and creates sub-optimal incentives for other research as well. Thus in general the incentives for R&D are reduced below what would be optimal and are skewed particularly towards innovations with benefits that can be realized within twenty years.

There are some specific problems relating to patent duration for pharmaceuticals. For many pharmaceutical products, the effective period of protection granted by the patent system is much closer to ten years, since the clinical trials and the regulatory approval process may take many years. This means that the incentives created by the patent system are particularly strong for those drugs whose clinical trials are likely to be relatively short, since for them the period of effective protection will be relatively long. This structure also gives firms strong incentives to try to speed through clinical trials.⁸

In addition, there are important classes of products – such as anti-infectives – where it makes sense to reserve new drugs to treat only those bacterial or viral infections that do not respond to the older therapies. Such an approach is sensible since it reduces the probability of resistance to the newer drugs. However, it means that the newest drugs may obtain very small sales volumes during the period of patent protection.

Patent scope. Limits on the scope of the patent often allow other firms to invent around the patent. (Inventing around is a strategy of mimicking the patented discovery without actually infringing any of the claims in the patent.) For example, once one company shows that some molecule is useful in addressing some particular health problem, other companies will begin to search for related molecules that work in a similar way. When they succeed, the firm that did the pioneering research will find its profits much reduced (DiMasi and Paquette 2004). This loss to the pioneering innovator is aggravated by the aggressive marketing that pharmaceutical firms undertake in order to persuade doctors to prescribe one medicine rather than another.⁹ Reducing what the patentee can earn from its monopoly, limits on patent scope discourage socially valuable innovations and bias research investment away from products that, if invented, would be easier to imitate.

Inability to perfectly price discriminate. Incentives to invest in R&D are further distorted by the fact that patentees cannot charge different prices to different customers – they cannot find out what each potential buyer is maximally willing to pay and also cannot prevent secondary trading among consumers. Charging one uniform price, the patentee does not appropriate the full social value of its innovation. Much of this social value is captured by the customers who are willing to pay more than the uniform price. And some potential social value is lost entirely as the patentee cannot realize mutually beneficial exchanges with customers who are willing and able to pay more than marginal cost but less than the uniform price. Economists measure this loss in currency units: if a patient cannot afford to pay the uniform price but could have paid \$15 while the patentee's marginal cost is \$10, then there is a \$5 loss in social value from

the unrealized exchange. This calculation leaves out the human cost: the misery and perhaps premature death this exchange would have averted.

The inability to charge different prices to different customers based on their willingness to pay has two important implications: incentives to invest in R&D are (a) weaker than would be socially optimal and (b) biased towards innovations from which the patentee can, at the profit-maximizing price, capture a larger proportion of the total surplus.

It seems possible that the inability to price discriminate has stronger implications in developing countries where there is no drug insurance. In wealthier countries with near-universal insurance, almost all consumers are served, and insurance performs the role of ensuring that low-income consumers are not priced out of the market. In developing countries without insurance, many patients who are ready to pay more than marginal cost are unable to afford the product. As a result, no sales are made to these patients, and a large part of the innovation's potential value is lost to the world and, of course, to the patentee. As a result of this inability to price discriminate, innovators' incentives are reduced compared to the social optimum; and in respect of pharmaceuticals, the incentives are especially reduced for the development of products that insurance companies may decide not to cover.

Externalities. The patentee may be unable to capture the benefits created by a drug which has significant externalities. Drugs and vaccines for contagious diseases are an important example of this problem, as, in addition to benefiting the user, they also benefit many others by reducing their probability of infection. Thus, the private valuation of the purchaser will be below the social value of the product. This leads to suboptimal incentives to develop products, such as vaccines and anti-infectives, which have positive externalities.

Incomplete enforcement and non-patentability. The patentee may not be able to prevent use by consumers of patented innovations, when there is no mechanism for stopping infringement. For example, a firm which discovers a new use for an existing generically available drug could obtain a patent on the new use, but might be unable to prevent competing manufac-

turers from selling the product, since at the point of sale there is no infringement of the patent. Consumers who used the product in the new use would be infringing, but the patentee might be unable to use the law to prevent this.¹⁰ In such a case, the patent system would be of little value to the innovator because the mechanisms for preventing infringement are limited.

A related problem occurs when the enforcement mechanisms in a country are inadequate to prevent counterfeiting or competition from infringing products. This generally reduces incentives to undertake investment in innovations for which the patent system offers limited or ineffectual protection from infringement. With respect to pharmaceuticals for developing countries, since counterfeit products are so widespread, it can be anticipated that the incentives to develop drugs specifically for neglected diseases are meaningfully reduced by the prospect of competition from counterfeit products.

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Enforcement may be completely unavailable for certain molecules with predictable functioning, since the non-obviousness standard under patent law renders those molecules unpatentable. As Roin (2008) observes, the non-obviousness requirement "denies patent protection to the drugs that appear most likely to succeed at the time they are invented and that have expected beneficial properties; i.e., the drugs that appear most promising in early research." This rule can therefore discourage investment into exactly the pharmaceutical research projects which have the highest probability of success.

Cost of application and enforcement. Protecting the patent is costly. A patent is not a guarantee of no infringement, but rather allows the patentee to sue for infringement, and then, if successful in court, to obtain a court order requiring the cessation of infringement. The costs of applying for the patent and then enforcing the patent may be very substantial, reduc-

ing the reward to innovation. A recent study by Besen and Meurer (2008) shows that the costs related to patent litigation are not only very substantial but for some classes of patents exceed the average value realized by patenting. However, for pharmaceuticals in particular, costs related to enforcement are smaller than the value realized. Nevertheless, the prospect of litigation discourages some socially valuable innovative activities and also biases innovation toward products for which litigation costs are expected to consume a smaller proportion of future earnings.

Racing and duplicative investment. Another important problem with the present patent regime is that firms engage in excessive, duplicative investment. In some cases, discoveries in basic science create opportunities for commercializable innovations which multiple firms invest in. The firms may then end up duplicating one another's research, which is clearly wasteful. Or they may pursue very similar drugs, which is also wasteful because an additional research effort adds very little to the probability of success and an additional drug very little to the medical arsenal.

A separate, but related, problem is that firms may "race" to be first, incurring waste by trying to accelerate their discovery so as to be able to be the first to submit their innovation to the patent office. While generally it is better if a given innovation is made earlier, rather than later, accelerating an innovation may be wasteful when the amount spent to accelerate the patent is greater than the incremental benefit of having the discovery earlier.

Summary. Like other economic instruments, the patent system brings benefits but is incomplete and imperfect. By itself, the patent system is likely to lead to predictable biases in the allocation of research investment, with some areas receiving too much and others too little. Other instruments may be needed to address these limitations.

Inefficient Production

Patentees may be hesitant to sub-contract production to low-cost generic producers, because of the threat of diversion of some product by the contract producer. This may lead to inefficient production

methods, since the patentee may not have the lowest cost technology and also may lack economies of scope in production.

Essential Medicines and the Valuation of Life

An important problem in the patent mechanism arises specifically with respect to the case of essential medicines. The patent system generally rewards innovators through the profits that can be achieved because of the exclusive exploitation of the patented innovation. Suppose for a moment that all the technical problems discussed above had been resolved, so that the incentive for innovation was exactly proportional to the economic value of the innovation as expressed in the aggregate demand curve. There would still be an important problem in the case of essential medicines. The incentive to invest in R&D related to the diseases of the poor would still be relatively small because the poor are, by virtue of their poverty, unable to pay much even to save their lives.

The standard economic valuation of a good is what a person is willing to pay for it. If person A is willing to pay only \$10 for any good, it follows that the good is not worth more than \$10 for that person. If person B is willing to pay \$20 for exactly the same good, and there is only one unit available, then it appears to be "efficient" to allocate the good to B. If A had the good, then he would generally be willing to sell it to be for a price above \$10, and B would be willing to pay a price below \$20.

Now suppose that the good is a pill which will extend either person's life by a year. A is willing to pay his entire wealth, \$10, for the pill, and B is also willing to pay his entire wealth, \$20. How should the pill be allocated? Here, our usual intuition, derived from expressed willingness to trade, fails us. Neither A nor B may be willing to give up the pill for any amount of money, and their "valuation" of the pill might be infinite. Given their wealth, third-party C who owns the pill will price it at \$20 and sell it to B. However, neither \$20 nor \$10 necessarily reflects the true value of the pill to buyers (i.e. what they would be willing to sell it for) – instead it reflects what the seller can get for it.

It is useful to turn to the economic literature on the value of a statistical life for clarification of this point. Viscusi (1993, p. 1942) argues that “The appropriate measure of the value of life from the standpoint of government policy is society’s willingness to pay for the risk reduction, which is the same benefit formulation in all policy evaluation contexts.” The implication is that richer people have higher “value of life,” since they are willing to pay more. And indeed, Viscusi (2003) based on a study of value-of-life estimates from different countries, suggests that the income elasticity of the value of a statistical life is around 0.5-0.6, so that as one’s income increases, so does the willingness to pay for reductions in risk.

It is important to understand how these studies are framed. Workers accept higher risk of death in certain jobs in order to be paid more. In other circumstances, travelers accept higher risk of death in order to travel at lower cost. Similarly, surveys show worker willingness to accept higher rates of death in order to be paid more. Thus, the trade-offs facing workers in these circumstances relate to willingness to exchange greater probability of early death for more available money for spending today. From the perspective of government, designing programs which reduce the probability of death for citizens, such studies provide the correct measure of how much to spend on such programs, since government need not spend more to save a person’s life than the individual is willing to spend.

Thus, we arrive at the conclusion that, if poor workers are willing to accept a given risk of death for a smaller increase in income, it must be the case either that (a) poor people assign a lower value to their life; (b) the marginal utility of income for a poor person is higher; or (c) both (a) and (b). Both of these, from the perspective of government policy, imply that the government should spend less to reduce risks to poor people, since there are more effective ways of increasing the utility of the poor (such as income transfers).

However, in the case of a person who is sick with a disease which will kill him, if the person does not spend his money on a treatment, he will simply die and the money will be useless to him (aside from as a bequest). The trade-off of getting more money today

in exchange for an earlier death does not occur in this situation. That is, there is no benefit in this case from accepting the earlier death. Therefore the willingness to pay should be infinite, although the ability to pay may not be.

How does this relate to economic value of saving a person’s life? What it suggests is that the willingness of a person to pay for a life-saving drug may not be well reflected by ability to pay. While on average poor people may be willing to take a given risk for a lower compensating payment, this need not indicate that they value their life less than that of a wealthy person; but it may only indicate that the marginal utility of income is higher for them. It does not mean, intrinsically, that the value of a poor person’s life is less than that of a wealthy person. Therefore, when the patent system values an innovation according to the amount that a person is willing to pay, it is using a mechanism which applies generally in cases where willingness to pay is meaningful. When “ability to pay” constrains the willingness to pay, the standard tools for valuing innovation apply poorly.

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Waste

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Aside from the failure of patent system to incentivize the most efficient set of possible innovations, it also induces considerable waste. In particular, it is well known that drug companies invest enormous sums of money in marketing, which is used to increase sales of one drug at the expense of another.

Thus, marketing and administration expenses are by a wide margin the largest single expense in drug company income statements. The outgoing CEO of Glaxo complained about this in a recent article, noting that “In 2006 the top seven pharmaceutical companies spent twice as much on SG&A (about 33% of revenues) as on R&D (about 16% of revenues)” (Garnier 2008, 71). While some marketing is valuable – that is, when it informs physicians and consumers about the benefits of the product – much of it is clearly more about transferring sales than improving the health of patients. The marketing efforts even extend into clinical trials, many of which have more value as marketing instruments than as scientific experiments (Angell 2004, ch. 9).

There is also considerable waste in the set of research projects chosen under the patent system, since firms tend to develop “me-too” drugs which imitate other successful drugs. While having multiple drugs in a therapeutic category can certainly be beneficial, there is reason to think that in some cases there may be too large an incentive to undertake research on products which do little or nothing to increase patient health.

There is also much waste in the patent litigation which inevitably arises out of the patent system. Because extending a monopoly can be enormously profitable, firms engage in all kinds of legal maneuvers, which generic firms must respond to. This results in enormous costs, none of which are beneficial for patients.

Summary

The previous sections have shown that there are a number of problems with the patent system as an incentive mechanism for innovation. Not only are there problems in the patent system which apply in any field, but there are also reasons to think that the incentives to address the disease burden of the poor may fail to fully reflect the value of the health impact achievable.

Synergy for diseases of poverty. One of the striking features of the weaknesses of the patent system is the extent to which these weaknesses seem to apply with particular force to the situation of drugs for

Type II and Type III diseases (those which are largely or almost entirely present only in developing countries). If the value of human life is reflected in the prices which people are willing and able to pay for drugs, then of course drugs which are primarily sold to the poor must be of less commercial interest. But the poor are less appealing commercial targets for other reasons too, as discussed in Chapter 7. The distribution systems in poor countries are often less well developed; and the accompanying health systems required for diagnosis also less extensive, so that there would be less profit to be made from selling to the poor, even if they could pay the same prices for the drugs. Typically, there is relatively weak enforcement of patent rights in poorer countries, which makes it harder for innovators to earn profits in poor countries. In many poor countries, counterfeiting is especially widespread. In addition, in poorer countries, consumers generally lack drug insurance, which makes the inability to price discriminate a more significant problem. Finally, many Type II and Type III diseases are infectious, so that there are significant positive externalities from treatments. This means that the sum of private valuations for drugs for those diseases will be lower than their social value. Collectively, these problems mean that innovating for the diseases of the poor is much less profitable than it is socially valuable, and profits from patent monopolies are likely to present insufficiently large rewards to motivate the kind of investment into innovation which is desirable.

THE HEALTH IMPACT FUND AND ITS RELATIONSHIP TO PATENTS

This chapter has described both strengths and weaknesses of the patent system as mechanism for incentivizing innovation. How does the HIF perform as an incentive system, and how does it fit with the patent system? In considering the HIF, it is important to recall that it is intended to be an optional, supplementary mechanism, and it therefore does not carry the entire weight of responsibility for innovation on its shoulders – what it needs to be is efficient in its own right, and to fill in the gaps in the existing systems.

Similarities to the Patent System

Like the patent system, the HIF puts risks on the innovating firm; it allocates the decision to invest in innovation with the party that has the most information; and it is able to effectively decentralize investment decisions. The HIF mechanism thus shares these strengths of the patent system.

Differences from the Patent System

Improved Access

Unlike the patent system, the HIF is designed to maximize access for all drugs registered with the Fund. With this solution, no mutually beneficial exchanges remain unrealized and deadweight loss is eliminated. Some people will still be too poor to buy medicines even at HIF prices, but this problem is dramatically reduced because the number of patients unable to afford the medicine is much smaller.

Not only will low prices increase access and eliminate deadweight loss, but access will also be enhanced by the efforts of the registrant. As discussed in Chapter 7 there is a “last mile” problem of getting pharmaceuticals to patients, a problem that is particularly acute in developing countries. Given that the payments are based on health impact, however, the HIF registrant will be motivated to invest in marketing and distribution to maximize its profits from sales of the drug, even in situations where the ability of the final consumer to pay for the product is quite small. In this respect, the HIF mechanism is superior to the patent system by itself, given that the weak ability to pay of poor patients may fail to incentivize the requisite investments to turn basic innovations into widely marketed products in poorer countries.

Reduced Counterfeiting

Because HIF-registered drugs will be cheaper, there will be less incentive to counterfeit them. Under the current system, either the drug is patented, with high prices, or not patented, with low prices. When patented, the incentives for counterfeiting are high, although the amount of counterfeiting may be lim-

ited by the efforts of the patentee to stop counterfeits. Once the product has been made available for generic production, the incentive to counterfeit becomes weaker, but no firm has a significant interest in patrolling the market to prevent counterfeits. While a drug is registered with the HIF, however, the incentives to counterfeit it will be weak, and the interest of the registrant in preventing counterfeits is strong.¹¹

Consistent Duration

In the HIF mechanism, the reward period starts at the time of commercial marketing of the product, rather than long before, as with the patent system. This reduces the incentive to rush clinical trials. At the same time, it evens out the reward across products: those with shorter clinical trials, and hence longer periods of exclusivity under the patent system, are not advantaged.

Reduced Imitation Despite Limited Patent Scope

As discussed above, an important problem in the patent system is the limited nature of patent scope: a patent can prevent only those imitations that fall within the specific claims of the patent. This limits the ability of the innovator to capture the benefits created by the innovation and may lead to a pace of innovation that is substantially slower than would be socially desirable. The HIF does not prevent imitation either, but the profits to be earned from imitating under the HIF are extremely small. In particular, for an imitative product which only replaces sales by the first firm, but does not increase health impact, the HIF offers no reward at all. In this respect, the HIF provides superior incentives.¹²

Compensating the Registrant for Innovation and Production Separately

Recall that a significant problem for patentees is that they are unable to appropriate the full value of their innovation when potential customers differ in the price each is maximally ready to pay. Such differences may arise either because of different preferences and incomes, or because the health impact differs predict-

ably across individuals. Given any price above marginal cost, the monopolist is sacrificing some profits because of lost sales, and sacrificing other profits from failing to charge a higher price to those consumers who buy at prices lower than they would be willing to pay. The HIF resolves this problem by establishing a low price approximately equal to marginal cost, and then rewarding patentees based on the health impact their innovations create. If this health impact differs among individuals, reward payments will reflect the average, rather than the marginal impact. In the jargon of economics, the HIF uses a two-part tariff to reward the innovator: marginal cost pricing is used to allocate the good efficiently, and direct payments from the HIF to pay for the innovation. Because the reward payments are not tied to the price per unit, the reward can be proportional to the social benefit of the innovation.

Externalities

The HIF rewards innovators not on the basis of the assumed benefit to the user of the innovation, but on the basis of the actual global health benefit. In this way, population benefits, such as reduced risk from infection, are incorporated into the reward calculations and therefore also into the research strategies of innovator companies. The current reward system is irrational in this regard, biasing pharmaceutical firms to discount the global threat posed by local infectious diseases that are not treated. Following the explosive international growth of SARS, of the spread of avian flu, and even of HIV/AIDS, there is an increasing appreciation that everyone is at risk when infectious diseases in far-away places are not treated and controlled effectively (Gostin 2007). It is in everyone's interest, then, that the incentives to pharmaceutical innovators be designed so that the impact of medicines on non-users is taken into consideration. The incentives created by the HIF meet this condition. The incentives created by the current patent system do not.

The underfunding of disease control remains one of the greatest acts of moral irresponsibility and political shortsightedness in the world today.

Jeffrey Sachs

Incomplete Enforcement

As discussed above, the institutional enforcement of the patent system is problematic in many countries. For example, in some countries infringement by generic firms is not preventable through the court system in a timely manner. This problem currently reduces the profits and distorts the incentives of pharmaceutical innovators. But it would have no such effect on HIF registered innovators. The very low prices of their products would deter generic competition. And even if an infringing generic were sold in competition with the registrant's patented product, the registrant would suffer no serious loss because it would still be entitled to health impact payments on the competitor's product.

Similarly, in cases where the innovator has an invention, but the patent system is incapable of preventing infringement, as could occur when the innovation is the development of a new use for an existing generically available drug, the HIF can offer payments based on the innovation. Since the payment mechanism is not based on exclusivity but on health impact, the HIF's ability to reward such innovations is more robust. The patent system normally requires the firm to be able to exclude others from the use of an innovation for the patentee to benefit from it; under the HIF, however, exclusion is not required. In cases where exclusion is not feasible or its enforcement overly costly the HIF is a particularly attractive supplement to the patent system.

Reduced Racing and Duplicative Investment

Because the HIF relies on the patent system to establish ownership rights to the stream of payments, the HIF is also subject to the problem of racing. However, unlike the patent system the HIF does not so strongly encourage duplicative investment into close imitations, because – absent incremental therapeutic benefit – it would not reward such innovations except when they increase access. (There is an exception to this, as discussed in Chapter 3, since the baseline for determining the incremental health impact of a new drug is set two years before the approval of that drug. In those cases, the HIF does not discourage duplica-

tive investment any more than would the patent system on its own.)

Waste

Because of the reduction in imitative competition, with its excessive marketing, and in duplicative investment, the HIF is likely to lead to much less waste than the patent system.

Increased Market Orientation

When compared to the patent system the HIF may seem to be more bureaucratic and less market-oriented, since the payment to the registrant is dependent on a determination by the Assessment Branch of the health impact of the product. But this is a false impression. In fact, outside the HIF, in most health systems, the decision concerning the reward to the innovator is made by the bureaucracy inside the insurance system, which decides whether or not to admit a given product to its formulary, based on the price. This implies that the insurer – in many countries a government agency – must make some administrative determination as to how much it is willing to pay for a given drug. This process is intrinsically more bureaucratic in nature than the competitive mechanism employed by the HIF.

The HIF is less bureaucratic, and more market-oriented, in its determination of the reward for an innovation, than the free market, which is dominated by the administrative determinations of insurers.

It is true that HIF must engage in a great deal more monitoring of sales and performance of registered drugs than do ordinary insurers, since the rewards may change from year to year, based on the known characteristics of the product and its sales volumes. But this is a strength, rather than a drawback: consistent and impartial monitoring of the impact various drugs actually have on human health provides information that is extremely valuable as a guide in future prescribing decisions.

The Relationship Between HIF Payments and Monopoly Rewards

A critical feature of the HIF is that it is supplementary to the patent system and optional. This means that patentees will only register their product with the HIF when they anticipate that they will profit more through the HIF than they would through charging unconstrained prices. For some types of innovations, the HIF will be a natural choice. For example, for patented new uses of older generics there may be no alternative. Similarly, innovators seeking to develop drugs for treating serious diseases that primarily affect the very poor will likely find the HIF to be much more attractive than the patent system. Thus, because it is optional, the HIF expands the opportunities for pharmaceutical innovators to earn profits.

A second important implication of the fact that the HIF is an optional supplement to the patent system is that it ensures that funding partners obtain value for money. It is easy to show why this is so. All products registered with the HIF receive the same payment per QALY. Products which are sold at monopoly prices produce fewer QALYs than if they were sold at marginal cost. Thus, any products outside the HIF must expect to earn a significantly higher net profit per QALY, since otherwise they would be registered with the HIF (where they would earn a lower rate per QALY on a higher number of QALYs). Thus, products registered with the HIF will provide greater value (in terms of QALYs generated per dollar paid) than non-registered products. A mathematical proof of this point is provided in the Technical Appendix to this chapter.

The Allocation of the Cost of Innovation

Given that the HIF is paying innovators directly, it needs to be financed somehow. It may seem obvious that the citizens of the partner countries will have to foot this bill. But in fact, the incremental expense to them is likely to be rather small.

To see why, consider how drug innovation is currently funded: buyers pay high prices for drugs under patent. Of course, in most developed countries, the buyers don't personally pay the entire price. In fact,

in most OECD countries, the government's share of drug expenditures is over 60% (OECD, 2007).¹³ The remainder is paid for mostly through employer-financed health insurance plans, and to a lesser extent, through co-payments by patients. In the United States, the share of pharmaceutical expenditures paid for by patients out-of-pocket is approximately 20% (CMS, 2007, Table 11), with government paying for 35%, and private insurance (mostly employment-based) paying for 45%. Employment-based insurance is essentially a tax on workers, as employers must offer lower wages because each worker adds additional insurance expenses. As economists have pointed out, when employers finance health insurance, the effect is similar to a regressive "payroll tax" which falls indiscriminately on low- and high-income employees (Summers, 1989). The net effect is that in most countries, patients pay for almost all drug costs through actual taxes or through reductions in wages equivalent to payroll taxes.

Thus, to the extent that the HIF pays for drugs which would have been developed in any case and consumed in wealthy as well as poorer countries, the net cost to citizens of wealthy countries is likely to be about the same, and the way that it is financed is also very similar – in both cases, the cost of the medicine is being financed through taxes and tax-like instruments. What is different is that high prices are not the mechanism used to transfer money from the government/insurer; instead there is a direct payment from the government. The national shares of drug costs are also likely to be similar, as at present more affluent countries are paying an overwhelming share of drug costs, as shown in Appendix B. However, with approximately the same amount of funding from approximately the same sources, the HIF enables much more widespread access to such drugs.

To the extent that the HIF pays for drugs or new uses which would not have been developed without the HIF, there is an additional cost to taxpayers. But this additional cost brings into existence additional high-impact medicines cheaply available wherever needed, plus the associated medical knowledge and know-how. Citizens pay for reduced mortality and morbidity worldwide and for reduced risk from diseases that, without the HIF, would have remained

unresearched. As shown in the previous section, the HIF mechanism also ensures that the rate of payment for these new medicines is lower than the payment per unit of health impact for medicines not registered with the HIF. Last but not least, the taxpayers funding the HIF also benefit from the positive externalities that better health worldwide brings for global economic performance.

SUMMARY

The patent system has an impressive record of supporting successful research and development. As a stand-alone mechanism, however, it has some very serious limitations that clearly demonstrate the need for complementary mechanisms. The Health Impact Fund holds great promise as just such a mechanism. The next chapter further examines the HIF in comparison to alternative complements that have been proposed toward better supporting pharmaceutical R&D than the patent system can on its own.

TECHNICAL APPENDIX

The HIF's mechanism ensures its payment per unit of health impact is lower than the net revenue per unit of health impact paid for medicines which are not registered with the HIF. A simple mathematic proof of this assertion is provided here.

Assume I medicines indexed over i are developed, with a fixed cost of development which is sunk. Each has a specific constant marginal cost c_i .

At the time of market approval, the firm can choose either HIF or monopoly pricing.

Firms outside the HIF set the profit maximizing price p_i for that drug, yielding net revenue $(p_i - c_i)q_i(p_i)$, where $q_i(p_i)$ is the number of units sold at price p_i .

Each unit sold of the drug yields some health impact h_i .

The net revenue earned by the firm per unit of health impact for drug i is therefore the ratio

$$\frac{p_i - c_i}{h_i}$$

All drugs registered in the HIF are sold at a price of $c_i < p_i$, which results in sales volume $q_i(c_i) > q_i(p_i)$.

The patentee receives a payment directly from the HIF, equal to \bar{p} per unit of health impact. Thus its net revenue per unit of health impact is \bar{p} , implying a payment of $\bar{p} h_i$ per unit of the drug. The net revenue of firm i if it registers its product with the HIF is therefore $\bar{p} h_i q_i(c_i)$.

Any firm that could earn more profits outside the HIF would choose to be outside the HIF. This implies $\bar{p} h_i q_i(c_i) < (p_i - c_i) q_i(p_i)$ for all firms outside the HIF. This inequality can be re-written as

$$\bar{p} < \frac{p_i - c_i}{h_i} \frac{q_i(p_i)}{q_i(c_i)}.$$

The left-hand side of this inequality is the net revenue earned by the firm per unit of health impact for a product registered in the HIF. The right-hand side shows the net revenue earned by the firm per unit of health impact for a product not in the HIF, times the ratio

$$\frac{q_i(p_i)}{q_i(c_i)}.$$

This ratio is less than one, implying that the net payment per unit of health impact offered by the HIF is less than the net revenue earned by the firm per unit of health impact for any product outside the HIF. Given that the net revenue per unit of health impact is the same for all products inside the HIF, it follows that the HIF's payment per unit of health impact is lower than the net revenue per unit of health impact for medicines which are (by choice) not registered with the HIF.

NOTES

1. Estimates for the average cost of R&D per new drug approved for sale range between \$200m and \$1.3bn, which includes the cost of essential clinical trials as well as the cost of failed efforts (compounds that are explored but do not come to market). See DiMasi and Grabowski (2007) for high-end estimates.

2. An important part of the process of pharmaceutical innovation is performing clinical trials to demonstrate safety and efficacy of the drug. Generic companies usually rely on the data from these trials as the basis for approval of their bio-equivalent generic drugs. Many countries now grant "data protection" of 5-10 years to the firm which performed the trials, preventing any generic company from obtaining marketing approval for their products on the basis of the trial data during that time. The period of data protection is frequently synchronous with the patent protection, though in some cases it may increase the period of effective protection from generic competition.

3. However, even in countries with drug insurance, the insurer must undertake some rationing to keep prices (and costs to the insurer) down.

4. Compliance may also be affected by high prices. If consumers are unable to afford to purchase the entire prescribed amount, the effect may be an increase in drug-resistant organisms.

5. It is not reasonable to expect for-profit drug companies to systematically lower prices in developing countries on the basis of altruism. While in some cases companies may have lowered prices in poor countries at a cost to their profitability, this would not be consistent with their responsibilities to shareholders if undertaken on a broad scale, and it is not fair to impose such requirements on the pharmaceutical industry (which is developing drugs that will some day be generically available at low prices) when other industries (which do nothing for poor people) have no such expectations placed on them.

6. World Health Organization, "Counterfeit Medicines" Fact Sheet number 275, November 2006. Available at <http://www.who.int/mediacentre/factsheets/fs275/en/print.html>

7. For a discussion of the unreliability of data on

96 THE HEALTH IMPACT FUND

- counterfeit medicines, see Outterson and Smith (2006).
8. While it is good for products to become available earlier, the incentives for pharmaceutical firms to accelerate clinical trials may be too strong. Extending the clinical trial by a month to obtain more data does not merely delay the reward period by a month, it shortens it by a month.
 9. Pharmaceutical firms are well known to invest enormous sums in their marketing. As a recent article by the CEO of Glaxo pointed out, in 2006 the top seven pharmaceutical firms spent twice as much on SG&A (sales, general and administrative expenses) as on research (Garnier 2008).
 10. The difficulty with stopping infringement in such cases is that typically the patentee prevents infringement by stopping the manufacture and sale of the infringing good. However, in the case described above, the patentee would need to observe each consumer using the product, which would make it impossible to police.
 11. Note that the HIF is unlikely to make any payments to the registrant for counterfeit drugs, since those drugs would tend not to be captured in any assessment of how many units had been sold.
 12. Note that in the patent system imitation tends to benefit consumers through increased competition leading to lower prices competition, which may lead to price reductions for consumers. In the HIF system, competition is not required to generate price reductions.
 13. Within the OECD, Mexico has a relatively low share of government expenditure on drugs (compared to total expenditure). However, the government share is likely to rise with incomes.