Improvements and Alternatives to Intellectual Property: A survey

Candidate: Marcelo Yuji Nomoto^{*} Thesis Adviser: Luis H. B. Braido

Getulio Vargas Foundation †

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Abstract

An important share of the economic growth is due to innovations. This thesis reviews the recent literature in intellectual property. This survey discusses the following papers: Kremer (1998), Boldrin and Levine (2001), Kremer (2001), Shavell and Ypersele (2001), Lerner (2002) and DiMasi, Hansen, and Grabowski (2003). These include both empirical and theoretical articles. In the first category, there is one study about the responses in innovation caused by a change in patent's strength and another about the cost of developing new drugs. The theoretical studies propose enhancements and alternatives to the patent system, e.g. optional rewards, patent buyouts, elimination of patents in some sectors and advanced purchase commitments.

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[†]Graduate School of Economics, mnomoto@fgvmail.br

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1 Introduction

Innovation is responsible for a great share of the economic growth. A recent example is the development of the computer industry that spillover to practically every field causing great impacts on economic growth. Pharmaceuticals are another area in which innovations brought great social benefits. These innovations caused people to live longer with more quality.

There are several ways to encourage innovation. Tournaments, fellowships, awards, patents and copyrights are some examples. By far, the most used system of innovation incentives is Intellectual Property which includes mainly patents and copyrights.

However, this system has efficiency problems. First, innovators are awarded with monopoly rights over their invention for a period, which causes deadweight losses. This means that part of the welfare gain from the innovation is neither received by the innovator nor by the consumer which causes underinvestment in innovations. Another problem is that firms have incentive to invent around existing patents to steal profits, which is not optimal. On the other hand, one important advantage of this system is that the innovator's reward is proportional to the innovation's value.

The deadweight loss problem should be enough to motivate research in more appropriate mechanism to generate innovations. But economic researchers do not seen to have given the adequate importance to the theme, despite its role in economic growth. Section 2 discusses rewards and buyouts as alternatives to reduce this problem.

Another important problem is the absence of cooperation among researchers. The first to fill a patent application receives all benefits. Therefore, innovators try to keep their research secret until the filling. One consequence is a slower development process. Another source of inefficiency is research races. In this races, several firms try to develop the same innovation independently. While this may speed up inventions, it is clearly a waste of resources that could be used to research other innovations. None of the papers in this survey addresses successfully these problems.

What to do when patents are not enough incentive to develop a very important product? Section 3 shows that an advance purchase commitment may be the solution.

What would happen if patents cease to exist? Boldrin and Levine (2001) have a theory in which innovations occur without the need of intellectual property. Section 4 discusses this theory.

Theoretically, patents should spur innovation. What is the empirical evidence? Lerner's (2002) empirical study finds evidence that stronger patents may cause less innovation. Section 5 analyses this paper.

Another problem with patents is that some countries, mainly developing ones, break patents of some pharmaceutical products to provide treatment for its population. That causes pharmaceutical firms not to spent on R&D for tropical diseases. Section 6 presents DiMasi, Hansen, and Grabowski (2003) in which the authors estimated the cost of development of a new drug.

Finally, the conclusions are in last section.

The appendix contains summaries of the papers discussed in this survey.

2 How to reduce the deadweight loss problem?

There are several ways to reduce or eliminate deadweight losses. One way is to allow price discrimination. If patent holders were allowed to discriminate prices, they would sell more units and have more profits. This simple solution would reduce deadweight losses and increase incentives to innovate. On another hand, it is not easy to discriminate prices and this solution has not much political support.

To place innovations in public domain may be an alternative. This solution eliminates deadweight losses but it reduces incentives to innovate, unless innovators are compensated in some way.

Kremer (1998) and Shavell and Ypersele (2001) present alternatives that compensate innovators for their inventions and place innovations in public domain. The former presents a mechanism in which the government buys patents from innovators willing to sell while the later proposes a reward system to replace patents, which may be optional.

In Kremer's solution, the government buys patents to place them in public domain. This solves the deadweight loss problem, raises the private incentives closer to the social value of the innovation and avoids the incentives to invent around existing patents to steal profits. But this solution depends on the participation of innovators, since the government does not force them to sell their inventions.

The mechanism is a second-price, sealed bid auction to determine the invention's value. The process begin with a inventor who wants to sell his or her patent to the government, and in order to do so he or she needs to pay the administrative cost of the auction. The government asks for bids, which under a second-price auction should be the expected value of the patent to bidders given their information. To incentive the bidders to reveal their true patent's valuation, the government randomizes after buying the patent if it will go to public domain or if it will be sold to the auction's winner, with probabilities (1 - p) and p respectively.

The government then offers to buy the patent at a markup times the private value extracted from the auction. The inventor decide if he or she wants to sell. If he or she do not sell the invention, he or she retains the patent, only incurring administrative costs of the auction. In case he or she decides to sell, the government randomizes as described before.

To estimate the patent's private value, the government should use all bids received, rather than only the highest one, because there is no reason to ignore information from lower bids.

The markup serves to adjust the value of benefits to innovators since social return to innovation under patents is two and half times the private rate of return.

The main problems in this approach are collusion, informational advantages of inventors, innovators that are low cost producers and dealing with complementary and substitute innovations. Collusion is a great problem because the innovator always receives the bid plus markup while the bidder only pays with probability p. The author proposes several mechanisms to prevent collusion:

- 1. When the government uses the third bid to calculate buyout price, it is very hard to the inventor cheat on the auction because it is necessary that three buyers take part on collusion.
- 2. The government should be able to call the bluff when it suspects that bids are

higher than the invention's value. Suppose the government with information extracted from other bidders conclude that the invention's value is approximately π , but the highest bid is $\pi + x$. The government could, in this situation, pay $\pi + \$1$ to the inventor and charge $\pi + x$ to the auction's winner for the invention. Then the government would make a profit of x-1 from the attempt of fraud.

- 3. The government should have list of suspects of fraud and prohibit them to participate. Should not be hard to elaborate such list, because these participants will have great losses when they buy the patent.
- 4. The government should investigate inventor financial ties with bidders and punish inventors who fail to disclose their ties. This should avoid the use of front companies.
- 5. If there is a fee or if companies had to make a deposit to participate in auctions then it would become unprofitable to inventors create dummy companies to bid in their products. Alternatively, government could focus on drugs, because firms in the industry are already known, making frauds more difficult.
- 6. The government should prohibit inventors to buy back their inventions and to make side payments to bidders. The later is, in the author's opinion, the most difficult aspect to control to avoid collusion.
- 7. A waiting period. The government would let inventions under patents over several years before buyout. This would give more information about patents' value and ceiling price would be a multiple of annual revenues before buyout. A problem is the incentive to inventors try to raise sales artificially. Another ceiling price could be prebuyout price times postbuyout consumption.
- Another option could be capping the buyout price by total sales times the estimated social value per dose of drug. The government should do this estimation.

9. One last suggestion is a mechanism where the price is capped by profits from product. This mechanism is the same as before until randomization. But what happens after randomization is different. Now, inventor receives $(M/p) \min(\text{bid}, \pi)$ for invention only if the invention is sold to the highest bidder. If the invention is placed in public domain, the inventor receives nothing. The expected value of buyout price in this case is $M \min(\text{bid}, \pi)$. The inventor could insure the risk of receiving nothing in this situation without great difficulties.

When the innovator has informational advantage, the problem is the winner's curse. In this situation, bidders will bid low values. The markup reduces this problem since it gives the inventor incentive to reveal as much information as possible. Asymmetric information makes it difficult for small biotech firms to sell patents to large ones, and it even prevents some transactions. But even without any markup trade takes place frequently. So it is possible to affirm that a 100 percent markup will convince many patent proprietaries to sell their patents.

Sometimes the inventor has advantages in producing the good. In this situation, inefficiency may arise if another firm receives monopoly rights. Furthermore, releasing the invention in public domain may not affect the deadweight loss.

Suppose that an inventor can produce the good at cost c_0 while the *i*th lowest cost producer can produce it at cost c_i . Demand for the good is $Q = P^{\alpha}$, $\alpha < -1$. If a producer was the patent holder and had cost c_i , the optimal price would be $c_i \alpha / (\alpha + 1)$ and he or she would profit

$$\pi_i = c_i^{1+\alpha} \left(\frac{\alpha}{\alpha+1}\right)^{\alpha} \left(\frac{-1}{\alpha+1}\right).$$
(2.1)

In a second-price auction this producer would bid π_i . The government receives bids and offers $MZ\pi_j$ for the patent, where Z is a multiplier, e.g. the historical ratio of the *j*th highest to the highest bid, M > 1 is the markup. The patent will only be sold if $\pi_0 < MZ\pi_j + (1-p)\pi_{\text{COMP}}$, where π_0 is the value of a monopoly on the good for the inventor, *p* is the probability that the government sells the patent to the auction's winner, π_{COMP} is the value to the inventor of producing the good in competition with other firms. If the patent is placed in public domain and $c_1/c_0 < \alpha/(\alpha+1)$, the inventor does not have a great cost advantage and will face Bertrand competition. He or she will profit $\pi_{\text{COMP}} = c_1^{\alpha} + (c_1 - c_0)$.

However if $c_1/c_0 > \alpha/(\alpha + 1)$ then the inventor has a great cost advantage. So great that he or she will be able to sell at monopoly price even with the good in public domain. He or she will profit π_0 in this case.

Note that inventors will almost aways sell their patents. If $c_j/c_0 < (MZ)^{-1/(1+\alpha)}$, the cost advantage is not too great relative to markup. Then $MZ\pi_j > \pi_0$ and they will sell. When $c_1/c_0 > \alpha/(\alpha + 1)$, they will sell if p is small enough, because their profit in competition will be the same as under monopoly, $\pi_{\text{COMP}} = \pi_0$.

The author points out that his method is more efficient when the industry has no great cost differences across firms and when the difference between competitive price and monopoly price is large. In this scenario, the cost advantage problem has little or no importance.

The markup does not make innovators always accept the government offer. There will be some cases in which the cost to acquire information about the patent will be to high, or the industry has too few competitors willing to buy the patent and this will cause bids to be too low, making the government offer to be refused. But, because the administrative cost of the auction is paid by the patent seller, the government will not incur a loss. The original patent holder will keep the patent in this situation.

While markup raises incentive to research, expectation that substitutes to patented products will be developed more quickly reduces this incentive.

To keep a socially optimal research level, the markup has to be larger than current ratio from social value of inventions to their private value. To show this, Kremer (1998) uses a model of creative destruction. In this model, research at time t can be written as $x_t = \phi(M_t, x_{t+1})$, where M_t is the subsidy to research at $t, \phi_1 > 0$ and $\phi_2 < 0$. Define x^s as the research level that would be chosen by a social planner and $x^s > x^p$. The optimal markup solves $x^s = \phi(M^s, x^s)$. M^s is greater than the markup needed to induce x^s given expectations that future patents will not be bought, M^p , because M^p solves $x^s = \phi(M^p, x^p)$.

The author recommends joint randomization to solve problems with complemen-

tary and substitute inventions. The later problem arises when a seller is offering the government a patent that is a substitute to another one. If the offered patent is placed in public domain, it would become a formidable competitor for the one patented before. This would discourage investments in research.

Joint randomization works in the following way: Every time a new patent, that is substitute to another patent not in public domain, is offered to the government, the owner of the original patent may ask to sell his or her own. The government then asks for bids for each invention separately, but makes just one randomization. With probability p both inventions go to the respective auction winners and with probability (1 - p) both are placed in public domain. With the joint randomization the inventions are valued on the contingency that both inventions and future substitutes will stay in private domain.

Notice that no bureaucracy is necessary to implement the system. Every claim that an invention is substitute to another one would be accepted, because it causes no harm and has the benefit that another invention may be placed in public domain.

Another use for joint randomization is when complementary patents are sold to the government. The patent value is higher when a complement to a patent is or will be in public domain. Under these circumstances, separate auctions may cause the government to pay more than the social value of inventions. This may incentive inventors to break their inventions in various complementary patents before selling them to the government.

To prevent this, the government should not buy complementary inventions separately. If they belong to a single owner, the government should offer to buy all complements. If the owner refuses the government should offer to buy a single invention randomly chosen, but the inventor cannot offer to sell the other inventions to the government later. And this inventor will have a waiting period before he or she can sell future developed compliments of his or her invention to the government.

If inventions belong to different owners the government should ask for bids to each owner patents separately and for the whole set of complimentary patents. If owners fail to joint sell, the government should buy the patent of only one randomly chosen seller, with probability proportional to the expected value of the seller's patents. In both situations, sellers will be better off than under the current patent system.

Two last comments end this paper analysis. First, firms do not need a licence to improve products in public domain. As long as the improvement is patentable, there will be incentive to invent it. And there is much more incentive to invent complementary products, because the quantity sold of the original product will be larger when the product is in public domain, favoring complements.

On another hand, one important problem in this approach is that selectively putting inventions in public domain may cause the adoption of an inferior technology, since these inventions are sold at competitive prices. This makes them formidable competitors, even to superior innovations.

Shavell and Ypersele (2001) proposes an optional reward system to avoid deadweight losses. In this system innovators may choose to receive a reward instead of a patent for their inventions. If this happens, the innovation is placed in public domain. Otherwise, the innovator receives a patent for his or her invention.

They build a model to show that this system is superior to patents. In the model a risk neutral potential innovator chooses investment in research k. The probability of an innovation is p(k), and it increases on k; p'(k) > 0; p''(k) < 0. If an innovation is discovered, it generates a product that can be produced at cost c. The inverse demand curve for the product is d(q;t) where q is the quantity of product and t is a parameter in $[t_a, t_b]$. The probability density of t is g(t) > 0 on $[t_a, t_b]$. As usual $d_q(q;t) < 0$. The authors assume that at t_a there is positive monopoly profits, deadweight losses and social surplus, and they are increasing in t. Social welfare is the expected value of utility obtained from the product by individuals, minus production costs, and minus research investment. With the exception of t, every function and variable described above is common knowledge. Only the innovator knows the value of t.

Under patent regime, when an innovation occurs, the innovator holds exclusive rights over the product. Assuming profit maximization, he or she sells the monopoly quantity $q_m(t)$ and earn monopoly profits $\pi(t)$. The innovator will choose k to maximize

$$p(k)\pi(t) - k. \tag{2.2}$$

As $\pi(t)$ is the payoff from an innovation, he or she will choose $k(\pi(t))$.

Under the optional reward regime the innovator chooses if he or she wants to patent his or her invention or if he or she prefers to receive a reward for it. He will pick the one with highest expected value. Thus he or she will choose patent if and only if $r < \pi(t)$. This is illustrated in figure 1.

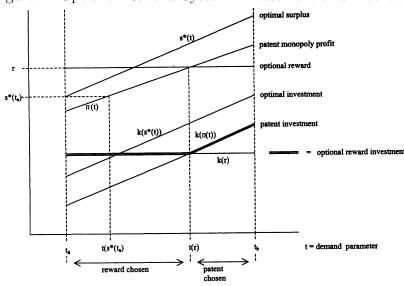


Figure 1: Optional Reward System: Investment and Incentives

Source: Shavell and Ypersele (2001)

If $r < \pi(t_a)$, then the optional reward system is equivalent to the patent system because the innovator will always choose patents. Hence to determine the optimal reward the authors made a restriction: $r \ge \pi(t_a)$. Let $l(r) \equiv \pi^{-1}(r)$ for r in $\pi(t_a), \pi(t_b)$, and let $t(r) = t_b$ for $r > \pi(t_b)$. Social welfare becomes:

$$W_O(r) = \int_{t_a}^{t(r)} [p(k(r))s^*(t) - k(r)]g(t)dt + \int_{t(r)}^{t_b} [p(k(\pi(t)))(s^*(t) - l(t))k(\pi(t))]g(t)dt.$$
(2.3)

The derivative of (2.3) is

$$W'_{O}(r) = k'(r)[p'(k(r))E(s^{*}|t \le t(r)) - 1]G(t(r)) + t'(r)p(k(r))l(t(r))g(t(r)), \quad (2.4)$$

where G is the cumulative distribution function of g and $E(s^*|t \leq t(r))$ is the expected value of $s^*(t)$ conditional on $t \leq t(r)$. First term in (2.4) is the inframarginal effect, representing the increase in research investment when the innovator chooses

reward. Second term is the marginal effect, i.e. the effect from innovators deciding to accept reward instead of to patent their products. This effect does not change investment because the reward is equal to monopoly profits when this change happens, it only eliminates deadweight loss.

First term of (2.4) is nonnegative and second term is positive when $r < E(s^*|t \le t(r))$ is positive (thus $[p'(k(r))E(s^*|t \le t(r))-1]$ is positive). Since $s^*(t_a) < E(s^*|t \le t(r))$ the optimal reward r^{**} is always greater than $s^*(t_a)$. If the optimal reward is greater than $\pi(t_b)$ the system is equivalent to a mandatory reward r^{**} .

Suppose an optional reward system with $r = \pi(t_a)$. In this case the innovator would choose to patent his or her invention (except on a set of measure zero, when $t = t_a$). But in this point $W'_O(r) > 0$, hence to increase the reward raises welfare. This result shows that an optional reward system is superior to a patent system.

If government can observe quantity sold q and use this information to choose reward, the results are better. In this case, reward is now r(q) and the innovator chooses k(r(q(t))). Assuming that he or she can not influence q(t), welfare in this scenario is

$$W_{r}(r(q)) = \int_{t_{a}}^{t_{b}} [p(k(r(q(t)))s^{*}(t) - k(r(q(t)))]g(t)dt$$

=
$$\int_{q_{a}}^{q_{b}} [p(k(r(q)))E(s^{*}|q) - k(r(q))]f(q)dq,$$
 (2.5)

where $E(s^*|q)$ is the mean of $s^*(t)$ given that q(t) = q, f(q) is the density of q derived from g(t) and $q_i = q(t_i)$. From (2.5) it is easy to see that optimal r(q) is $E(s^*|q)$. Conditional optimal is usually different from unconditional optimal and therefore, it is superior. This means that an optional conditional reward is more superior to a patent system than an unconditional one.

One great problem is how to determine the reward. The authors defend that the government should use sales data and, when possible, frequency of use of music, computer software and television production to define the reward. Using this system the government does not need to fear the existence of incentives to ask for rewards if the invention is not relevant. But as Kremer (1998) points: "General Motors could stick a useless piece of metal onto a Chevrolet, and as long as the automobile sold due to other attractive features, GM could argue it deserved the reward." The authors claim that the government could supplement rewards on an annual basis.

Another point is the difference between government and innovators information. They claim that ex-ante innovators' information is substantially imperfect and government's information will be reasonably good ex-post. So, as long as rewards are based on ex-post information, and the government's ex-post information is as good as the innovator's ex-ante information, not only optional rewards, but also mandatory rewards are superior to intellectual property rights.

Shavell and Ypersele (2001) argue that optional reward has many advantages over the patent system, including practical ones. The industry should not object it because it could only raise profits. And since the system is optional, the government would not try to pay too little as rewards. They suggest that this system would have more advantages in areas where social losses caused by intellectual property rights are high, e.g. pharmaceuticals, computer software, and recorded music and visual products.

Both alternatives discussed in this section reduce the problem of deadweight losses. Kremer (1998) has a better mechanism to solve this problem, since the markup increases incentives to invest and to sell patents to the government simultaneously. A great problem that both papers fail to mention is which country pays to place patents in public domain. When one country places the invention in public domain, firms will sell this good at competitive price. These firms have incentive to export the good, and since they are selling at competitive price, other countries have incentive to import the invention without place the innovation in public domain. Innovators will expect this situation and will only sell for a higher price. The creation of a international fund to buy patents may solve this problem.

3 What to do when patents are not enough incentive?

Sometimes patents are not enough to incentive socially optimal innovations. Deadweight losses may be sufficiently large to discourage some research. Solutions to this problem are discussed in section 2.

Some countries do not have laws of patent. In these countries firms may copy patented innovations. People can buy cheaper innovations in these places. Other countries break patents in some areas like pharmaceuticals. The result is cheaper medications.

On another hand, there are less incentive to innovate in these places. This is a large problem when some disease affects only countries without patent protection. Since there is no incentive, firms will not research medications or vaccines to these diseases.

There are other options to incentive research. One of them is direct government support, in which government pays for research in some fields. But it is hard to choice the research to fund and the results are not predictable.

Another alternative is research tournaments. The problem in this approach is that even if no researcher finds a vaccine or medication, the sponsor has to pay the prize.

Kremer (2001) presents a mechanism to incentive development of vaccines. He argues that an advance commitment to buy a large quantity of these vaccines could incentive their development.

Benefits from a 80 percent effective malaria vaccine could be cost-effective even at a price of \$41 per immunized person on a total of 42.1 million people immunized every year. The revenues to the producer would be more than \$1.7 billion annually.

This value shows that the research towards a malaria vaccine could recover the costs of development and generate a large profit, increasing social welfare. But a private company is not able to recover its costs because even vaccines that cost a dollar or two per dose do not reach most children. Private benefits are much lower than social ones and this causes under investment on malaria vaccine research.

If pharmaceutical companies could charge the amount each nation is willing to pay and intellectual property rights were respected globally, then the market could achieve efficient size to incentive the production of these vaccines.

The author suggests that the advanced purchase commitment is a good incentive in the end of development process. In the other steps, different mechanisms may be more efficient.

On initial stages of a new vaccine development, programs that funds research through public investment, tax credits for R&D, grants, etc. may be a better option. The main advantage of these programs is that researchers share their knowledge by publishing their work. This accelerates the development of products.

Another advantage is that the risk of failure is transferred from researching firms to society at large, which is beneficial when the shareholders of these firms cannot diversify this risk in stock markets.

On later stages of development, advanced purchase commitments are better incentives for vaccine development. The rise of biotech industry and existence of venture capital favor these programs. The main advantage of such program is that the government pays only for a vaccine that is actually developed.

In these stages, there may be several projects of new vaccines. It is hard to select the best research projects. Researchers are over optimistic about their own line of research and it is difficult to answer if the investment would improve social welfare.

Advance purchase commitments avoid investment that is not welfare improving. Since the payment is made only when a vaccine is ready, it avoids waste of public resources. The program rewards only successful projects. In this case, the amount of payments measures how much a country values the vaccine.

Furthermore, biotech and venture capital companies are encouraged to select promising projects and target a marketable vaccine.

Other types of incentives have problems in the final stages of development. Public-sector equity investments have a selection problem because only firms less confident in their research would seek public investments. Firms highly confident will refuse public investment since this would reduce their share on profits.

Public directed research has problems in selection of research projects and in the process of shutting down disappointing projects. It is easier for private companies to shut down projects that are shown not to be worth pursuing anymore.

Subsidizing private research through tax credits has problems too because even firms that research subjects with little relation to the diseases that can be used to ask for credits will claim eligibility. On the other hand, credits linked to vaccine sales are a better mechanism to obtain a private developed vaccine because it avoids this type of problem.

To illustrate problems in push programs the author cites the work of Desowitz

(1991) that relates the history of the push program of the U.S. Agency for International Development (USAID) on 1980s that tried to develop a malaria vaccine.

Three teams of researchers were funded by that program and only one of them developed a candidate vaccine. This candidate vaccine was tested in 9 volunteers and only 2 were protected against malaria while the test pointed side effects. These results caused a claim by USAID in 1984 that a vaccine against malaria should be ready in five years. Despite this claim, until today there is no such vaccine. The other teams had worse results on preliminary work but they continued to receive funding. The principal investigators of both teams transferred grant funds to their personal accounts and were later indicted for theft.

USAID spent over \$60 million funding malaria research with little results. The project director of USAID's malaria vaccine, James Erickson, pleaded guilty on some charges after the discovery of a contract to acquire monkeys from an associate who paid Erickson a kickback.

Erickson was oversight by the American Institute of Biological science, but he and the project manager responsible for the oversight were lovers.

This is an extreme case of failure in funding projects. But it illustrates how a researcher may deviate resources away from what they were given for. Another point is that the three groups of researchers were over optimistic about the possible results of their research.

The combination of direct support and advanced purchase commitments may be more effective because the work on less intellectual rewarding levels of research would have monetary reward. This would incentive a faster development of vaccines.

The author concludes that the social value of new vaccines may be much higher than private incentives. This causes potential vaccine developers to pass up socially desirable research on vaccines.

Even if these vaccines were developed, they would not be widely available because they would be sold at monopoly prices.

Commitments to purchase future developed vaccines to distribution on developing countries provides incentives to vaccine research and guarantees that they will reach people who needs them. And taxpayers only would pay when a vaccine is developed.

One problem with Kremer's approach is that pharmaceutical firms do not trust the countries that need do to an advanced purchase commitment. These countries do not have patent laws, break specific pharmaceutical patents or use their power to purchase vaccines at lower prices. Once a vaccine is ready for use, it would be no surprise if a country withdraws the purchase commitment and breaks the patent of this vaccine. Therefore, some international organization need to guarantee this advanced purchase commitment or it probably will not work.

4 What would happen if patents cease to exist?

Innovations have been occurring even before the existence of patents. Therefore, while patents may incentive innovation, they are not necessary for innovation to exist.

One current example is development of open source software. Thousands of people build better programs everyday, and the source code is available to anyone. If patents cease to exist, it would be easier to develop open source software, since programmers will be allowed to use patented code.

On another hand, there would be less innovation in several industries. The development cost of a new product may be very expensive. If anyone could copy others inventions, nobody would spend money in R&D.

Boldrin and Levine (2001) elaborated a model in which innovation occurs under perfect competition. Their motivation is that historically there was no intellectual property, but yet innovation took place.

One fundamental hypothesis of their model is that ideas do not spillover. Ideas only have value embodied in goods or people. This implies that for someone to learn the idea, he or she needs access to people or goods that embody the idea. The authors argument that ideas are rival because people or goods embodying it are rival.

Boldrin and Levine (2001) define innovation as the first time a good is actually produced or an activity is employed. Then they suppose that one innovation was produced and there is k > 0 units of product. This product is such that every copy of it is a perfect substitute of the original. The copying process of the product demands only time. Then $0 < c \leq k$ units are consumed and k - c are used to make copies. These k - c units result in $\beta(k - c)$ units in next period, where $\beta > 1$. Since the good may be durable, there are another ζc units on next period. $\zeta \leq 1$ because of depreciation and $\zeta \leq \beta$ because it is not easier to copy the product while using it. u(c) is the representative consumer's utility function, u is strictly increasing, concave, and bounded below. The representative consumer lives forever and discounts the future at rate $0 \leq \delta < 1$. The authors assume that technology and preferences are such that feasible utility is bounded above.

The solution of this problem is a concave value function v(k), the unique solution of

$$v(k) = \max_{0 \le c \le k} \{ u(c) + \delta v(\beta k - (\beta - \zeta)c) \}.$$

In equilibrium $p_t = u'(c_t)$. From the resource constraint

$$c_t = \frac{\beta k_t - k_{t+1}}{\beta - \zeta}.$$

If ζ is large enough relative to β it may be optimal not to invest.

The price q_t of the durable good k_t is

$$q_t = v'(k_t) = p_t \frac{\beta}{\beta - \zeta}$$

Since $p_t > 0$, $q_t > 0$ for all t. The zero profit condition implies that q_t decreases at a rate $1/\beta$ per period of time.

When an innovator creates something he or she has $k_0 = 1$ units of the new product. In a competitive market this unit sells for q_0 . Assuming a cost C > 0 to create the first unit of the good, innovation will occur if $c \leq q_0$.

The difference between this model and those in which innovations are non rival is that $\beta < \infty$, meaning that the number of copies made in a period is limited. But there is no limit on the number of units that can be produced and there is no cost to produce these units. The authors believe that non rivalry is only an approximation to the fact that reproduction costs are very small.

When the reproduction costs diminish and there is no intellectual property, innovations cease to exist in traditional models. That happens because the inventor will not be able to receive for his or her invention more than the production cost. But under Boldrin and Levine's model this is not necessarily true. In the first period the inventor has the only copy of his or her invention and its price is $q_0 \ge u'(c_0)$, which is bounded below by u'(1). Therefore the first copy price will never fall to zero if consumers are impatient. And under this framework a reduction in reproduction costs may even raise the price of the first unit.

Notice that $\partial q_0 / \partial p_0 > 0$ and

$$rac{dq_0}{deta} = u^{''}(c_0)rac{dc_0}{deta} - u^{'}(c_0)rac{\zeta}{(eta-\zeta)^2}$$

When β is sufficiently large relative to ζ the first term dominates. In this case the result depends on whether consumption is substitute or complement across time periods. If it is substitute, then a raise in β diminishes consumption and consequently raises the first unit price. If it is complementary, then the opposite happens and rents fall.

The authors provide an example where the utility function has the CES form $u(c) = -(1/\theta)(c)^{-\theta}, \ \theta > -1$. If demand is inelastic then $\theta > 0$ and there is little substitutability across periods. As $\beta \to \infty$ the initial consumption $c_0 \to \bar{c} < 1$. Thus in this case the rents fall, but not toward zero and innovation will happen under a competitive framework if $\bar{p} = u'(\bar{c}) > C$.

If demand is elastic, $\theta \in (-1, 0]$ then there is a high intertemporal substitution in consumption. In this situation utility becomes unbounded as $\beta \to \delta^{1/\theta}$. As β approaches this limit, $c_0 \to 0$ and the invention price becomes infinite. Hence if β is large enough in this case, every social desirable invention will occur.

One case not discussed yet is $\zeta = \beta$. In this situation, capital grows at rate β and the initial rent is

$$q_t = \sum_{i=0}^{\infty} (\beta \rho)^i p_{t+i} = \sum_{i=0}^{\infty} (\beta \delta)^i u'(\beta^i k_t).$$

Again, price is bounded below by marginal utility of the first unit and the initial rent becomes infinite as β increases.

The authors question if the reproduction rate is becoming larger. They do not believe that this is happening for patentable ideas because the knowledge necessary to understand and reproduce these ideas is increasing, since ideas are becoming more complex. But for copyrightable creations, they believe that electronic reproduction over the Internet makes β to increase. Computers also reduce indivisibility C. One example is that a music studio is much cheaper today than a decade ago.

Boldrin and Levine (2001) also models innovations that occur in sequence. Now there are many qualities of capital beginning with quantity zero. Capital of type *i* is k_i and each unit of k_i allocated to production of consumption results in $(\gamma)^i$ units of output, where $\gamma > 1$. That means that higher quality capital is more efficient. Every capital used to produce consumption is depreciated at rate $(1 - \zeta)$. If c_i is produced using type *i* capital then there is $k_i - c_i/\gamma^i$ units available to produce capital. As before each unit of type *i* capital may be used to produce $\beta > 1$ units of the same type of capital. But now there is an option to produce type i+1 capital and h_i is the investment on it. Each unit invested results in ρh_i units of i+1 capital. It is assumed that $\rho < \beta$ and there is a minimum of $\underline{h} > 0$ that needs to be invested on the ρ technology before getting any output. This represents indivisibility in innovation, which was the role of *C* in the previous model. Therefore there will be investment in higher quality capital only if the rents of introducing k_{i+1} are large enough to compensate the investment of at least \underline{h}/ρ units of k_i . To make sure that sustained growth is possible it is assumed $\delta(\beta - \zeta) > 1$.

One case analysed is $\underline{h} = 0$. When $\rho\gamma > \beta$, one never uses β technology because ρ technology is dominant. The optimal consumption under competition is obtained when

$$u'(c_t) = \delta(\rho\gamma - \zeta)u'(c_{t+1}).$$
 (4.1)

Since the utility function is strictly concave, u' is strictly decreasing. Thus $c_{t+1} > c_t$ and if -cu''(c)/u'(c) is bounded above as $c \to \infty$ then applying Taylor's theorem, one can show that not only $c_{t+1} > c_t$, but also $(c_{t+1} - c_t)/c_t > \Delta > 0$ and, in this case, c_t grows without bound. So in this model the occurrence of innovations is possible under a competitive scenario.

Another case analysed is if $(\underline{h}) > 0$. When \underline{h} is large enough there will be no investment in innovation and no equilibrium. But if \underline{h} is small enough, it may not be binding at social optimum. In this case, the competitive equilibrium with innovations exists, and the welfare theorems apply.

Based on that fact, one important question is, What happens to investment in the newest technology asymptotically? If it is either constant or increasing, a small enough indivisibility will not be binding, but if it is diminishing any indivisibility will be binding. Assuming that utility has a CES form, $u(c) = -(1/\theta)(c)^{-\theta}, \theta > -1$ the first-order condition (4.1) may be used to find the growth rate of consumption g

$$g = \frac{c_{t+1}}{c_t} = \left(\delta(\rho\gamma - \zeta)\right)^{1/(1+\theta)}$$

There is no difference in which capital type is used to produce consumption and which is used to innovate in the case without indivisibility. This is no longer necessarily true. The optimal plan now may involve using ρ technology in some periods and β in others because of the threshold <u>h</u>. These complications make the full characterization of the equilibrium beyond the scope of the paper. But Boldrin and Levine (2001) provide a sufficient condition for the class of production plans in which old capital is used only to produce consumption.

The necessary and sufficient condition for physical investment to be nondecreasing asymptotically is

$$g - \left(\frac{\rho\gamma - g}{\rho\gamma - \zeta}\right) \left(\frac{g - \zeta}{\rho\gamma - \zeta}\right) \zeta \ge \gamma.$$

Note that $(\rho\gamma - g)/(\rho\gamma - \zeta) + (g - \zeta)/(\rho\gamma - \zeta) = 1$. Thus the restriction is satisfied if $g - \zeta/4 \ge \gamma$. If this condition is satisfied, it is probably satisfied strictly, which is a sufficient condition for asymptotic growth of investment in this class of production plans. Therefore even if in early periods the indivisibility is binding, as time goes by investment grows and the indivisibility will become irrelevant. The authors associate this characteristic to simultaneous discovery in advanced economies. Their view is that even if part of innovations occurs because of patents, another part cannot be explained in the same way, e.g. basic science, where patent law does not apply, open source software, where innovators do not restrict downstream licensing agreements, and fashion industry, where labels are protected but the designs can be reproduced without large costs.

According to this model innovations can thrive in a competitive environment. While conventional theories argue the existence of a fixed cost to produce a nonrivalrous good, this theory argues there exists sunk costs to produce a rivalrous good. In the former situation, since there are increasing returns to scale, competition cannot thrive. In the later one, sunk costs pose no threat to competition, but indivisibility is the great problem.

One competition problem is that rents may not cover the costs to innovate even if the invention is socially desirable. Another one is that the indivisibility may bind and there is no adequate theory of competitive equilibrium with binding indivisibilities. The authors defend the view that competition is a powerful force and it may find its way through indivisibilities.

But even in the case where some socially desirable innovations are not produced under competition, Boldrin and Levine (2001) do not believe that monopoly will have a better output because while a monopolist has incentive to produce one innovation, once that happens he or she has incentive to hold up other innovations.

To show this possibility they elaborate the following example. Commodities and activities are as before and now there is a transferable commodity m. Consumer utility is $m + \sum_{t=0}^{\infty} \delta^t u(c_t)$, where m is a transferable commodity, and the monopolist utility is m. The consumer has an endowment of \bar{m} unities of transferable commodity and the monopolist has an endowment of zero unities of transferable commodity and all initial capital (k_0^0) . The monopolist also has full patent protection over the β , ρ and γ activities. At the beginning of each period, the monopolist chooses a production plan and then price is determined by the consumer's willingness to pay.

Suppose that the period utility function is

$$u(c) = \begin{cases} -(1/\theta_1)c^{-\theta_1} & c \le 1\\ 2 - (1/\theta_2)c^{-\theta_2} & c > 1 \end{cases}$$

where $\theta_1 < 0$ and $\theta_2 > 0$. Thus this is an elastic CES below c = 1 and an inelastic CES above this level of consumption. Suppose for now that there is no indivisibility, no depreciation and the initial capital stock is $k_0^0 = 1$. The asymptotic competitive growth rate in this case is

$$g = (\delta(\rho\gamma - 1))^{1/(1+\theta_2)}$$

and the capital stock will grow over time if

$$g - \left(\frac{\rho\gamma - g}{\rho\gamma - 1}\right) \left(\frac{g - 1}{\rho\gamma - 1}\right) \ge \gamma.$$

Assuming, for example, $\theta_2 = 0.10$, $\rho = 2.20$, $\gamma = 1.05$ and $\delta = 0.98$ this condition holds and the parameters will satisfy the condition for asymptotically non-decreasing investment in innovation. Therefore there will be sustained innovation on competitive equilibrium, even with positive depreciation and a small indivisibility.

A monopolist in this scenario will have maximum revenue (u'(c)c) when he or she produces one unit. As he or she starts with one unit of capital that does not depreciate, he or she can produce one unit of consumption in each period, and this is the best he or she can do in this situation, because if he or she decides to innovate it is necessary to produce a suboptimal quantity in one period to make innovation possible. But this innovation will not result in higher profits on future periods, and then the monopolist will choose not to invest, and as he or she has patent protection, the monopolist will prohibit everyone else to innovate.

So under monopoly the result is a constant output and no innovation at all, while under competition there are successive innovations and the output grows without bound. This result is significantly dependent on the durability of capital, because without indivisibility the optimal method to replace depreciated capital is innovation, even for the monopolist. Although this would not result in output growth under monopoly, at least it would result in successive innovations.

Therefore, when a small amount of depreciation is introduced into the model, the first best is still the competitive equilibrium because the monopoly results in deadweight loss. But now monopoly is as innovative as competition, introducing a new quality of capital every period because of depreciation.

When a small indivisibility is introduced, competition is still the first best while monopoly may cease to innovate. This happens if investment to cover depreciation is less than the amount necessary to create a new quality of capital.

Boldrin and Levine (2001) point that this is an important result because it shows the incentives to innovate in both regimes. Under competition, the industry has incentive to produce innovations beyond the rate of depreciation. As the marginal valuation of the good is sufficient to cover costs of production under competition, the industry will raise output and total stock of capital. This will make it easier to reach the threshold required to innovate. When innovations happen under monopoly, they will be just enough to cover depreciation. The authors suggest that this was the situation before and after the breakup of national monopolies of the telecommunication industry.

If a monopolist receives a patent with k-periods duration, he or she has incentive to suppress invention during this time. In the case where patents are awarded by a patent race, outcome is even worse. The monopolists, except the first, will not invest to cover depreciation of capital stock or will even destroy it, because this raises their revenues. If the monopolist controls β but not ρ technology, consumers would have incentive to become a monopolist buying sufficient k_t^i to use ρ technology. Thus the monopolist would keep the amount of k_t^i available to consumers below \underline{k} , avoiding the introduction of an innovation by consumers. The higher the indivisibility, the easier to prevent consumer innovation.

Boldrin and Levine (2001) argue that competition is a socially beneficial mechanism even in markets for innovations. This casts doubt on the necessity of patents and copyrights to incentive innovation. The analysis of the case with innovation chains is even harsher on patents, because it shows that a monopolist has incentive to hold innovation when he or she detains a patent.

But would it work? The technology to share digital content is already very efficient. One person may watch a movie or hear a song and, at the same time, share this file with thousands of people in peer-to-peer networks. Actually, in these networks even people without the innovation are already producing it. They do not have the entire file, but they are sharing the downloaded pieces as they come. In this scenario, will someone pay a large sum of money for something that will be really cheap in few hours? Is there somebody this impatient?

On the other side of the problem, will a firm invest millions in R&D knowing that in few months a exact copy of its innovation will hit the market? Even if firms discriminate price, in few hours another firm will get a sample of the innovation and start to reverse engineering it. One possible solution is the firm that has an innovation sell first to its competitors. But why would these competitors buy the first copies of an innovation if they can get them much cheaper a little later?

On other hand, there are some examples of innovations developed without in-

tellectual rights protection. One example cited before is the open source software development. But people only need a computer and time to contribute in software development. In other areas, the equipments may be much more expensive. A laboratory to research new drugs costs millions and fewer people have the knowledge to use these equipments.

Therefore, there are several practical issues to be solved before this solution is implemented.

5 Do patents spur innovation? What is the empirical evidence?

Theoretically, patents incentive innovation. Profits from an invention are larger when patents exist. But what does happen when the strength of patent laws changes?

Lerner (2002) analyses impacts of changes in patent policy in sixty nation over 150 years. He is interested in the impact of these changes on quantity of patent applications. He uses two measures of fillings: domestic ones (in the country changing policy) and applications in Great Britain, a country where patent policy was relatively constant.

The author examined a number of guides to patent activity, the World Intellectual Property Office's (WIPO) publications and various national patent offices publications to determine patent policy changes and their impact on number of fillings.

The analysis shows that changes in policy that strengthen patent protection reduce the number of patent applications both in Great Britain and in the country where changes take place. Therefore, such changes did not incentive innovation.

The author also examined some predictions of theoretical literature. He finds that raise patent protection in countries with already strong patents has little impact on innovation. The same happens if its per capita GDP is much lower than other nation's.

A great part of economic literature assumed that stronger patent protection increases innovation rate. The necessary assumption for this conclusion is that patents do not affect incentives to future innovations. When this assumption is dropped, conclusions may change. Research on sequential innovation shows that strong patents may reduce incentives to innovate and they may cause less innovation than no patent protection at all.

The strength of patent protection in a country also affects the impacts of policy changes. When patents are weak and their strength is increased, innovators receive larger rewards for their inventions. But increases in strength when patents are strong may incentive competitors to invent around the original innovation. This reduces the reward to the original inventor, thus reducing incentive to innovate.

Another factor that affects the impact of policy shifts is the nation's stage of development. One possible setting is where modest investment will probably result in substantial innovation but beyond some threshold, discoveries become much more costly. In this setting, an increase in patent protection is likely to have little effect on innovation rate. This is probably the case of developing nations.

The author exams the number of patent fillings by residents of 60 countries to evaluate effects of policy changes. The paper evaluates the quantity of patents in the country where the change happens and in Great Britain that had a stable policy during the period studied.

There is no clear mapping between innovative activity and patent applications. There are fillings for very modest innovations and there are also many important discoveries that are not patented. There is little to do about these problems since data about them are not consistently available.

The analysis loses strength because of this fact. And, since the measure is number of patents and not innovation, it is hard to see what the results mean. Sometimes a smaller number of patents and more innovations may happen at the same time.

Lerner (2002) analyzes differences in patent applications associated with policy changes. If the propensity to patent do not vary, this value is a good proxy for changes in innovative activity. But there is nothing that guarantees this stability.

Another way to achieve better results is examining patent fillings not only in one country, but also in Great Britain, a country that kept its patent policy relatively stable. The author uses the overall growth in patent applications as a control for patenting trends. The number of fillings by foreign entities helps the identification of significant policy shifts: a policy change that increases patent protection induces foreign firms to seek patent protection.

The selection of events in the dataset was guided by five principles. First, governments had intention to change policy. This principle eliminated changes within five years of establishment of a nation, its restoration after being part of another nation or a revolution that changed the regime of government. Temporary policy changes during wartime were also excluded.

Second principle was date accuracy. When the author could not determine the year of change, he eliminated it from the sample.

Third principle excluded changes that altered scope of patents because it would be very difficult to interpret the dependent variable. Suppose scope of patents is broadened. Is the reduction on patent fillings caused by a decline on innovation or by the fact that a single patent now covers the equivalent to several fillings before the change?

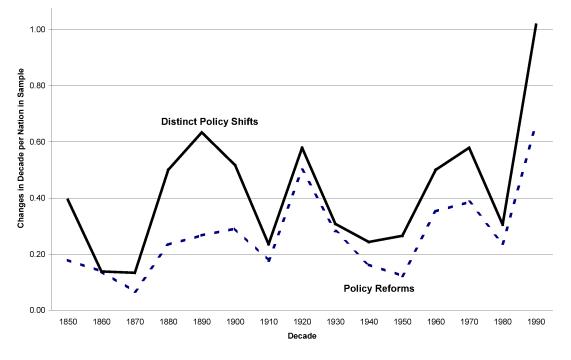
Since the author wanted to compare reactions of domestic and foreign firms to changes, fourth principle eliminated changes that happened at the same time as policy changes that affected only foreign applicants.

Lastly, Lerner (2002) only wanted substantive changes in patent policy. These include the following cases: when a country had no patent protection at all in general or in certain classes of discoveries, modifications on duration of patents to domestic applicants, changes on the cost of patents and modifications on the period of time after which a patent could be revoked or compulsory licensed if it was not worked.

Changes in patent costs are considered only when the raise was higher than 100% or the new cost was lower than 50% of previous one. When several payments were required, net present value was considered.

Figure 2 shows the number of events and policy changes during each decade, normalized by the number of active countries at the beginning of the decade.

The author then measures how many patent applications residents of a country where an event happened filled in Great Britain, in their own country and foreign residents filled in a country where a change happened. Only traditional patents are Figure 2: Number of changes in patent policy over time. The sample consists of the sixty largest countries (by gross domestic product) at the end of 1997, observed from 1850 (or the date of inception as an independent entity) to 1999. The chart presents the number of policy reforms, as well as that of distinct policy shifts, in each decade, normalized by the number of active countries in the sample at the beginning of the decade.



Source: Lerner (2002)

counted, when it is possible to determine their number without other types of prizes.

Lerner (2002) found data on domestic and foreign applications in the country for 145 event windows and British application data for 171 windows. These windows are periods from five years before to five years after policy change.

The author collected information about population of countries, per capita GDP and occurrence of war during more than 3 months within the country affecting more than 10% of its territory, or changes of more than 10% in population or area of the country caused by changes in a country's borders.

Panel A from table 1 shows changes in patent fillings from two years before to two years after a policy change. Missing observations are replaced by data from one or three years before or after to raise the number of observations.

Observations are divided into two groups according to the type of policy change.

Table 1: Impact of a change in patent policy on patenting activity. The sample consists of 177 changes in patent policy between 1852 and 1998 in 60 nations. Panel A displays the change in the number of unadjusted patent applications filed from two years before the event to two years after the event by domestic entities residents of the country undertaking the policy change in Great Britain and in the country undertaking the change, and foreign entities filling in the country undertaking the change. In Panels B and C, these changes are shown net of equal-weighted and value-weighted indexes of patenting in the ten nations with the longest time series of application data. Underneath each adjusted change, the absolute t-statistic of the difference of the change from zero is displayed. In all tests, each observation is weighted by the inverse of its standard deviation of the annual change in patenting from 20 to five years before the policy change.

| Panel A: Unadjusted Changes in Patenting Around Policy Changes | | | | |
|--|--------------------|---------------------|--------------|--|
| U | Residents' | Domestic Entities | Foreign | |
| | Patenting in | Patenting | Patenting | |
| | United Kingdom | in Country | in Country | |
| Positive Patent Policy Changes | -27 | +2424 | +8662 | |
| Ambiguous/Negative Changes | +210 | +529 | +1401 | |
| Positive Changes Involving Coverage | -63 | +2233 | +9739 | |
| Positive Changes Involving Duration | -80 | +2399 | +10957 | |
| Positive Changes Involving Working Periods | -34 | -1081 | +3191 | |
| Panel B: Changes in Patenting Around | Policy Changes, Ad | ljusted by Equal-We | ighted Index | |
| | Residents' | Domestic Entities | Foreign | |
| | Patenting in | Patenting | Patenting | |
| | United Kingdom | in Country | in Country | |
| Positive Patent Policy Changes | -101 | -1617 | +4979 | |
| | ***[4.61] | *[1.86] | **[2.41] | |
| Ambiguous/Negative Changes | -217 | -525 | +390 | |
| | ***[3.19] | [0.34] | [1.28] | |
| Positive Changes Involving Coverage | -98 | +1915 | +7704 | |
| | ***[5.13] | [1.03] | **[2.58] | |
| Positive Changes Involving Duration | -190 | -4714 | +5699 | |
| | ***[4.68] | **[2.22] | *[1.84] | |
| Positive Changes Involving Working Periods | -27 | -1239 | +2772 | |
| | [1.33] | *[1.84] | [1.31] | |
| Panel C: Changes in Patenting Around | | | | |
| | Residents' | Domestic Entities | Foreign | |
| | Patenting in | Patenting | Patenting | |
| | United Kingdom | in Country | in Country | |
| Positive Patent Policy Changes | -100 | -932 | +5617 | |
| | ***[4.52] | *[1.69] | ***[2.85] | |
| Ambiguous/Negative Changes | -137 | -408 | +501 | |
| | **[2.40] | [0.07] | [1.65] | |
| Positive Changes Involving Coverage | -111 | +1781 | +7963 | |
| | ***[5.12] | [0.94] | **[2.57] | |
| Positive Changes Involving Duration | -186 | -3347 | +6690 | |
| | ***[4.63] | **[2.14] | **[2.36] | |
| Positive Changes Involving Working Periods | -27 | -1289 | +2809 | |
| | [1.29] | *[1.89] | [1.27] | |

* = Significant at the 10% confidence level; ** = significant at the 5% level; *** = significant at the 1% level.

Source: Lerner (2002)

Changes that increased patent protection (64%) constitute a group and changes that are either ambiguous (12%) or diminished patent protection (24%) constitute another group.

Domestic and foreign applications increased in countries that enhanced patent protection, while British fillings did not. But these numbers are not controlled by the propensity to patent in the period.

The same data is reported on panels B and C adjusted by two indexes used to capture trends. These indexes use data from the ten nations with the longest time series of patent application data. First one assigns equal weight to every nation, and second weights each observation by patent applications. The adjusted observations are computed by

$$A_{+2} - A_{-2} - \left[\frac{I_{+2} - I_{-2}}{I_{-2}} * A_{-2}\right], \qquad (5.1)$$

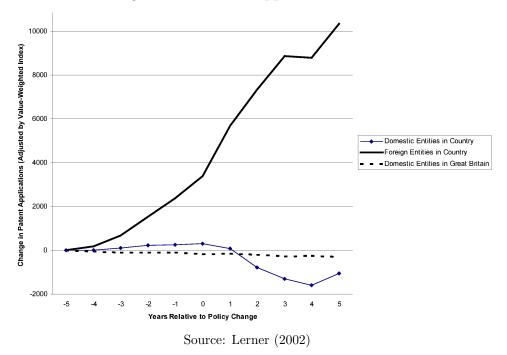
A represents the number of fillings and I represents the level of the index.

After adjustment, a change in policy that strengthened patents caused the decline of patent applications by residents of the country where the change took place both in the country itself and in Great Britain while foreign patent raised. Changes in fillings had much lower magnitude when policy changes were ambiguous or protectionreducing.

Table 1 also shows results for the three most frequent types of changes: enhancements of patent's coverage, length of patents and length of the working period. These changes represent 56%, 50% and 21% respectively of the total of changes.

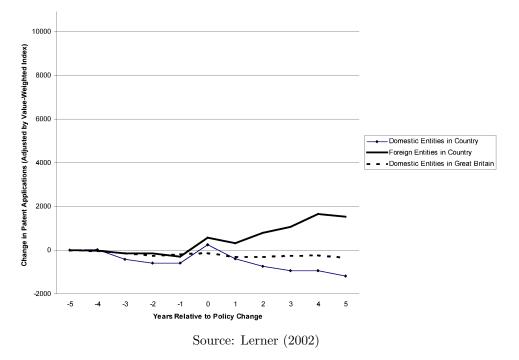
Lerner (2002) also reports the statistical significance of these changes following a method used in finance literature. The author calculates standard deviations of changes in patent applications from 20 years before to 5 years before the policy change and then weighted t-tests and regression analyses by the inverse of standard deviation. This method shows that the fall of patent fillings by residents in response to an increase in patents protection is significant. The increase in patent applications by foreigners is also significant which suggest that the set of changes is significant.

Figure 3 shows average change in patent fillings around changes that increase patent protection and figure 4 shows average for other policy modifications. They confirm what table 1 reports. Figure 3: Patenting changes around the time of patent protection-enhancing policy changes. The sample consists of 177 changes in patent policy between 1852 and 1998 in the sixty largest countries (by gross domestic product) at the end of 1997. The figure displays the change in the number of patent applications filed between five years before the event and five years after the event by domestic entities filing in the country undertaking the change, foreign entities filing in the country undertaking the change are shown net of a value-weighted index of patenting in the ten nations with the longest time series of application data.



The author also constructs indexes for each class of number of applications, but no significant changes are reported. He also adjusts the index restricting it at all times to nations whose per capita GDP was below 75% of that of the wealthiest nation to avoid distortions caused by developed nations in the index. Again, no significant changes are reported.

Lerner (2002) also analyses cross-sectional differences in the sample. He estimates regressions of adjusted growth in patent applications as dependent variable. The main independent variables are a dummy denoting a change that increases patent protection and a dummy denoting if protection before policy change was strong; a dummy denoting if protection was weak before the change or per capita GDP of the country relative to the wealthiest nation at the time of change. Strong policies have Figure 4: Patenting changes around the time of patent protection-reducing or ambiguous policy changes. The sample consists of 177 changes in patent policy between 1852 and 1998 in the sixty largest countries (by gross domestic product) at the end of 1997. The figure displays the change in the number of patent applications filed between five years before the event and five years after the event by domestic entities filing in the country undertaking the change, foreign entities filing in the country undertaking the change, and residents of the country undertaking the policy change in Great Britain. These changes are shown net of a value-weighted index of patenting in the ten nations with the longest time series of application data.



patent life of eighteen or more years while weak ones have patent life of ten years or less. Interactions between these variables are also included in regression.

The control variables are type of policy change, presence of a war within the country border, number of patent fillings two years before the change, population of nation and change in the country's border.

Results are reported on tables 2 and 3. On table 2, the dependent variable is the number of patent applications in Great Britain by residents of the country where the policy changes. Results confirm part of the theoretical basis. The interaction between the dummy variable denoting strong patent protection before the policy change and the one denoting an increase in patent protection is negative and significant at 5% level in first and second regressions. In fourth regression, the interaction

between relative GDP and the dummy denoting an increase in patent protection is significantly positive. These results suggest that increases in patent protection are less effective in developing countries and when patent protection is strong before the change.

Table 2: Weighted least squares regression analyses of patenting in Great Britain by residents of the countries that underwent patent policy changes around the time of the changes. The sample consists of 177 changes in patent policy between 1852 and 1998 in the sixty largest countries (by gross domestic product) at the end of 1997. The dependent variable is the change in the number of patent applications filed by residents of the country undertaking the policy change in Great Britain from two years prior to the policy change to two years afterwards, net of either of a value-weighted (VW) or equal-weighted (EW) index of patenting in the ten nations with the longest time series of application data. The independent variables are dummy variables denoting whether the policy change entailed an unambiguous increase in protection and the aspects of patent policy that the change covered, variables denoting whether during the period the country began or ended a conflict on its territory or expanded or contracted its territory (with the former instance being coded as +1, the latter as -1, and all others as zero), the number of patent applications by domestic entities in Great Britain two years before the policy change, and the population of the nation at the time of the change. In addition, the various regressions include dummy variables denoting whether the country had a particularly strong or weak patent policy before the change, the nation's per capita gross domestic policy relative to the leading nation at the time, and the interaction of these measures with the dummy variable indicating an increase in patent protection. Each observation is weighted by the inverse of the standard deviation of the annual change in patent applications in Great Britain from twenty to five years before the policy change. Absolute t-statistics in parentheses.

| | Dependent Variable: Change in U.K. Patent Applications Net of | | | |
|-------------------------------------|---|-------------------|--------------------|--------------------|
| | VW Index | EW Index | VW Index | EW Index |
| Positive Patent Policy Change? | 165.94 [0.87] | ***598.53 [3.24] | 19.13 [0.11] | -333.42 [0.88] |
| Strong Protection Prior to Change? | -249.34 [0.96] | 86.93 [0.35] | | |
| Weak Protection Prior to Change? | | | 273.22 [0.32] | |
| GDP as Percent of Leading Nation | | | | ***-1561.76 [2.92] |
| Strong Protection * Positive Change | **-602.57 [1.99] | ***-980.07 [3.34] | | |
| Weak Protection * Positive Change | | | -133.66 [0.14] | |
| Relative GDP * Positive Change | | | | **1292.27 [2.15] |
| Change Involving Coverage? | 50.74 [0.37] | 216.92 [1.65] | 32.63 [0.22] | 61.80 [0.42] |
| Change Involving Duration? | -199.37 [1.41] | -79.30 [0.58] | -171.04 [1.06] | -135.68 [0.91] |
| Change Involving Cost? | ***1014.88 [4.42] | ***1137.36 [5.12] | ***1059.91 [4.24] | ***1252.63 [5.26] |
| Change Involving Working Periods? | *-335.37 [1.78] | -192.88 [1.06] | -249.62 [1.22] | -117.16 [0.61] |
| Inception of Conflict? | -10.97 [0.04] | -332.82 [1.09] | 80.75 [0.24] | -118.82 [0.36] |
| Change in Territory? | ***-1058.54 [3.37] | 130.20 [0.43] | ***-1042.61 [3.03] | -118.22 [0.35] |
| Applications Two Years before Event | ***-0.12 [11.63] | ***-0.13 [13.14] | ***-0.12 [10.13] | ***-0.12 [10.03] |
| Population of Nation | 0.07 [0.07] | 0.27 [0.29] | -0.14 [0.14] | -0.96 [0.94] |
| Constant | 21.18 [0.09] | -523.10 [2.21] | -117.27 [0.50] | 428.65 [1.10] |
| | | | | |
| Number of Observations | 159 | 159 | 159 | 159 |
| F-Statistic | 17.10 | 23.14 | 12.06 | 18.08 |
| p-Value | 0.000 | 0.000 | 0.000 | 0.000 |
| Adjusted R ² | 0.53 | 0.61 | 0.44 | 0.54 |

* = Significant at the 10% confidence level; ** = significant at the 5% level; *** = significant at the 1% level.

Source: Lerner (2002)

The dependent variable in table 3 is patent applications by residents in the country that promoted the policy change. Only two control variables are significant.

Table 3: Weighted least squares regression analyses of domestic patenting by residents of nations undergoing patent policy changes. The sample consists of 177 changes in patent policy between 1852 and 1998 in the sixty largest countries (by gross domestic product) at the end of 1997. The dependent variable is the change in the number of patent applications filed by domestic entities in the country undergoing the policy change from two years prior to the policy change to two years afterwards, net of either a value-weighted (VW) or equal-weighted (EW) index of patenting in the ten nations with the longest time series of application data. The independent variables are dummy variables denoting whether the policy change entailed an unambiguous increase in protection and the aspects of patent policy that the change covered, variables denoting whether during the period the country began or ended a conflict on its territory or expanded or contracted its territory (with the former instance being coded as +1, the latter as -1, and all others as zero), the number of patent applications by domestic entities two years before the policy change, and the population of the nation at the time of the change. In addition, the various regressions include dummy variables denoting whether the country had a particularly strong or weak patent policy before the change, the nation's per capita gross domestic policy relative to the leading nation at the time, and the interaction of these measures with the dummy variable indicating an increase in patent protection. Each observation is weighted by the inverse of the standard deviation of the annual change in domestic patent applications from twenty to five years before the policy change. Absolute t-statistics in parentheses.

| | Dependent Variable: Change in Domestic Patent Applications Net of | | | |
|-------------------------------------|---|------------------|------------------|------------------|
| | VW Index | EW Index | VW Index | EW Index |
| Positive Patent Policy Change? | 1862.87 [0.76] | 2361.31 [0.82] | 2727.11 [1.32] | 2887.20 [0.59] |
| Strong Protection Prior to Change? | -1079.46 [0.30] | -717.08 [0.17] | | |
| Weak Protection Prior to Change? | | | -2018.17 [0.12] | |
| GDP as Percent of Leading Nation | | | | 4630.29 [0.63] |
| Strong Protection * Positive Change | 1657.97 [0.42] | 1230.48 [0.27] | | |
| Weak Protection * Positive Change | | | -611.87 [0.04] | |
| Relative GDP * Positive Change | | | | -615.17 [0.08] |
| Change Involving Coverage? | 1153.91 [0.63] | 1311.54 [0.61] | 1423.43 [0.80] | 1861.75 [0.88] |
| Change Involving Duration? | -373.71 [0.21] | -566.56 [0.27] | -746.30 [0.41] | -387.44 [0.19] |
| Change Involving Cost? | 1979.52 [0.59] | 1872.51 [0.48] | 1580.56 [0.48] | 1226.20 [0.32] |
| Change Involving Working Periods? | 1485.56 [0.53] | 1620.48 [0.50] | 1473.81 [0.53] | 1758.43 [0.54] |
| Inception of Conflict? | -1639.60 [0.41] | -1523.63 [0.33] | -1999.77 [0.51] | -2125.00 [0.46] |
| Change in Territory? | -1231.93 [0.36] | -934.01 [0.23] | -1215.29 [0.35] | 322.75 [0.08] |
| Applications Two Years before Event | ***-0.23 [16.53] | ***-0.31 [18.95] | ***-0.24 [16.65] | ***-0.32 [18.64] |
| Population of Nation | ***25.20 [3.05] | ***26.56 [2.74] | ***26.46 [3.22] | ***30.19 [2.94] |
| Constant | -1449.71 [0.43] | -1500.72 [0.38] | -1756.58 [0.60] | -4797.64 [0.88] |
| Number of Observations | 132 | 132 | 132 | 132 |
| F-Statistic | 27.83 | 36.82 | 28.05 | 37.29 |
| p-Value | 0.000 | 0.000 | 0.000 | 0.000 |
| Adjusted R ² | 0.69 | 0.75 | 0.69 | 0.75 |

* = Significant at the 10% confidence level; ** = significant at the 5% level; *** = significant at the 1% level.

Source: Lerner (2002)

The author also does regressions with different event windows, additional control variables, different definition of patent protection's strength or weakness to check robustness of the results. He also estimates Heckman sample selection regressions and uses an instrumental variable to reduce endogeneity problems. None of these modifications changes significantly results, reported in table 4.

There are some problems in these regressions. Endogeneity is one of them, and the author argues that a dummy for policy changes in ten years following the Paris Convention of 1883 or the preliminary version of the TRIPs agreement of 1993 are instruments for the measure of positive patent policy changes. But if a country accept the agreement and changed its policy, the endogeneity problem persists. Therefore this is not a good instrumental variable.

Another problem is that the author argues that he estimated Heckman sample selection regressions, but results are in supplemental unreported analyses. Procedures and results should be reported, even if results changed only a little.

One important conclusion is that adjusted changes in patent application numbers by residents are negative when a policy change that increases patent protection is adopted. Another is the confirmation of predictions of economic theorists in crosssectional analysis.

The author points out the advantages of his methodology over other case studies in patents that analyze only a single case, while Lerner (2002) studied 177 policy changes in sixty countries over 150 years.

He also points out limitations of the analysis. One of them is that the study only considers patents. How do trade secrecy, prizes for discoverers, tournament behave at the time of patent policy change? Another important question is how the judicial system interprets new policies: does it actually apply the changes?

Another important limitation is the measure of innovation utilized. The long time frame did not allow to use other measures, e.g. R&D spending, total factor productivity growth and innovations' counts.

There is an important endogeneity problem in the regressions in this paper. The author uses instrumental variables to address the problem, but the instruments are not good, since they are endogenous as well. Table 4: Instrumental variable regression analyses of patenting in Great Britain and domestically by residents of nations undergoing patent policy changes. The sample consists of 177 changes in patent policy between 1852 and 1998 in the sixty largest countries (by gross domestic product) at the end of 1997. The dependent variable is the change in the number of patent applications filed in Great Britain and domestically by residents of the nation undergoing the policy change from two years prior to the policy change to two years afterwards, net of an equal-weighted index of patenting in the ten nations with the longest time series of application data. The independent variables are dummy variables denoting whether the policy change entailed an unambiguous increase in protection and the aspects of patent policy that the change covered, variables denoting whether during the period the country began or ended a conflict on its territory or expanded or contracted its territory (with the former instance being coded as +1, the latter as -1, and all others as zero), the number of patent applications by domestic entities in Great Britain and domestically two years before the policy change, and the population of the nation at the time of the change. In addition, the various regressions include dummy variables denoting whether the country had a particularly strong patent policy before the change, the nation's per capita gross domestic policy relative to the leading nation at the time, and the interaction of these measures with the dummy variable indicating an increase in patent protection. A dummy variable denoting that the policy change took place in the ten years following the signing of the Paris Convention of 1883 and the preliminary version of the TRIPs agreement of 1993 is used as instrument for the measure of positive patent policy changes. Each observation is weighted by the inverse of the standard deviation of the annual change in patent applications in Great Britain and domestically from twenty to five years before the policy change. Absolute t-statistics in parentheses.

| | Den en dens Venie | hler Channel in Deter | 4 A | |
|-------------------------------------|-------------------------------|-----------------------|---|------------------|
| | 1 0 | | Applications, Net of Equal-Weighted Index | |
| | Applications in Great Britain | | Domestic Applications | |
| Positive Patent Policy Change? | ***7737.47 [3.00] | -3342.62 [0.87] | -7243.45 [0.37] | 6075.96 [0.19] |
| Strong Protection Prior to Change? | **4546.50 [2.28] | | -3062.68 [0.16] | |
| GDP as Percent of Leading Nation | | **-9152.71 [2.48] | | 15135.62 [0.57] |
| Strong Protection * Positive Change | **-6671.86 [2.48] | | 1621.90 [0.07] | |
| Relative GDP * Positive Change | | **10667.92 [2.06] | | -18925.80 [0.49] |
| Change Involving Coverage? | **1137.27 [2.15] | -115.15 [0.31] | 202.25 [0.07] | 1569.60 [0.56] |
| Change Involving Duration? | 133.54 [0.29] | -529.23 [1.50] | -1912.28 [0.86] | -926.64 [0.39] |
| Change Involving Cost? | **2655.75 [2.12] | **2128.94 [2.56] | -2480.94 [0.44] | -1792.07 [0.28] |
| Change Involving Working Periods? | **3322.78 [2.26] | 1438.40 [1.57] | -5693.91 [0.58] | -4964.26 [0.77] |
| Inception of Conflict? | *-2221.32 [1.79] | -202.12 [0.23] | -104.44 [0.02] | -627.54 [0.11] |
| Change in Territory? | -1380.91 [1.17] | **-2111.38 [2.14] | 1875.57 [0.29] | 4339.82 [0.66] |
| Applications Two Years before Event | -0.12 [3.52] | ***-0.08 [2.79] | ***-0.24 [9.49] | ***-0.24 [9.84] |
| Population of Nation | 3.45 [1.08] | -4.12 [1.55] | 22.52 [1.41] | 30.62 [1.64] |
| Constant | ***-7283.29 | 2883.99 [1.01] | 8720.00 [0.47] | -3886.16 [0.16] |
| | [2.94] | | | |
| Number of Observations | 159 | 159 | 132 | 132 |
| F-Statistic | 3.08 | 5.34 | 11.29 | 11.34 |
| p-Value | 0.001 | 0.000 | 0.000 | 0.000 |

* = Significant at the 10% confidence level; ** = significant at the 5% level; *** = significant at the 1% level.

Source: Lerner (2002)

Theoretically, stronger patents have no definite effect on innovation. And raise incentives to research may not be socially optimal. Since several firms may research the same problem, resources may be wasted.

Lastly, patent fillings may not be a good approximation for innovative activity. Quality and importance of patents are other important factors to quantify innovation. Therefore it is hard to verify if the theory is accurate based in this paper.

6 What is the cost of a new drug?

How much do firms need to invest to develop a new drug? This value is important since it answers why incentives are needed.

In DiMasi, Hansen, and Grabowski (2003), the authors estimated the average cost of develop a new drug. They found that capitalized average cost is US\$ 802 million (2000 dollars) per new drug.

The estimation is based on micro-level data, obtained from pharmaceutical firms though confidential surveys. These surveys asked about a random sample of drugs developed by the firm. Drugs in the sample were initially tested in human beings during the period 1983-1994. In order to obtain an accurate estimation of the expected cost of development, costs of projects that resulted in failure had to be allocated to the successful ones.

The drug development process goes through several phases: discovery of the compound, preclinical development, clinical testing and application for marketing approval. In this study, it is not possible to separate costs of discovery of the compound from costs of preclinical development.

Clinical testing has three successive phases. In phase I, a few healthy volunteers are tested to obtain information about dosage, absorption, distribution, metabolic effects, excretion and toxicity of the compound.

In phase II, subjects with the disease targeted by the compound are tested to verify its safety and to obtain preliminary data about efficacy. This phase may involve hundreds of subjects. In the last phase, subjects are tested to firmly establish efficacy and uncover infrequent side effects. To gather these information, thousands of subjects may be necessary. Because the development cost is highly dependent on time and on the development phase in which it is abandoned, data are stratified on the length of time of clinical testing and whether or not an application for market approval was filled in the FDA. This application may be a new drug application (NDA) or a biological license application(BLA).

The expected clinical cost is:

$$C = E(c) = p_I \mu_{I|e} + p_{II} \mu_{II|e} + p_{III} \mu_{III|e} + p_A \mu_{A|e},$$

where p_I, p_{II} and p_{III} are the probabilities of a random selected compound enter phases I-III respectively and p_A is the probability of long term animal testing be conducted during the clinical phase. The μ 's are conditional expectations, i.e. the population mean costs for drugs that enter each phase. If one assumes that p's and μ 's are stochastically independent, the expected value C is an unbiased estimate of the population's expected value.

Estimation of parameters p's is done though a two-stage statistical process using drugs in the Tufts Center for the Study of Drug Development (CSDD) database that were first tested in humans between 1983 and 1994.

Preclinical costs are obtained from aggregate data at firm level on spending prior to human testing and on human testing from 1980 to 1999. These data are used to obtain a ratio of R&D expenditures prior to human testing and on human testing using a lag structure because expenditure prior to human testing should occur before the associated human testing cost. This ratio is then multiplied by estimated clinical cost to obtain the estimated pre-human R&D cost.

A cost timeline is established and expenditures are capitalized at an adequate discount rate. In this study the authors use 11% as real cost of capital baseline value. This value is obtained by the difference between nominal cost of capital and inflation rate.

Results of out-of-pocket cost in clinical period are reported in table 5. Mean cost, median cost, standard deviation, N, probability of entering the testing phase and expected cost are presented for each phase.

Table 6 presents the results of mean phase lengths, mean time between successive

| Testing phase | Mean cost | Median cost | Standard deviation | N^{b} | Probability of entering phase (%) | Expected cost |
|------------------|-----------|-------------|--------------------|---------|--------------------------------------|---------------|
| Phase I | 15.2 | 13.9 | 12.8 | 66 | 100.0 | 15.2 |
| Phase II | 23.5 | 17.0 | 22.1 | 53 | 71.0 | 16.7 |
| Phase III | 86.3 | 62.0 | 60.6 | 33 | 31.4 | 27.1 |
| Long-term animal | 5.2 | 3.1 | 4.8 | 20 | 31.4 | 1.6 |
| Total | | | | | | 60.6 |

Table 5: Average out-of-pocket clinical period costs for investigational compounds (in millions of 2000 dollars)^a

^a All costs were deflated using the GDP Implicit Price Deflator. Weighted values were used in calculating means, medians, and standard deviations.

^b N: number of compounds with full cost data for the phase.

Source: DiMasi, Hansen, and Grabowski (2003)

phases, capitalized mean phase cost and capitalized expected phase cost.

Table 6: Average phase times and clinical period costs for investigational compounds (in millions of 2000 dollars)^a

| Testing phase | Mean phase length | Mean time to next phase | Capitalized mean phase cost ^{b, c} | Capitalized expected phase cost ^{b,c} |
|------------------|----------------------|-------------------------|--|--|
| Phase I | 21.6 | 12.3 | 30.5 | 30.5 |
| Phase II | 25.7 | 26.0 | 41.6 | 29.5 |
| Phase III | 30.5 | 33.8 | 119.2 | 37.4 |
| Long-term animal | 36.5 | _ | 9.5 | 3.0 |
| Total | | | | 100.4 |

^a All costs were deflated using the GDP Implicit Price Deflator. Weighted values were used in calculating means, medians, and standard deviations for costs and phase times. Phase times are given in months.

^b The NDA approval phase was estimated to be 18.2 months. Animal testing was estimated to begin 4.2 months after the initiation of phase I.

^c Costs were capitalized at an 11% real discount rate.

Source: DiMasi, Hansen, and Grabowski (2003)

The estimated ratio of preclinical to total R&D expenditure is 30%. This ratio was used to estimate preclinical out-of-pocket and capitalized cost per approved new drug as US\$ 121 and 335 million, respectively.

Therefore full out-of-pocket estimate is US\$ 403 million and the capitalized estimate is US\$ 802 million.

There are several diseases with social costs larger than the values found and yet no effective treatment or vaccine, as patents alone cannot generate the necessary incentives to their development.

This paper quantifies the investment necessary to develop a new drug. Since

this value is lower than the social cost of several diseases, it is necessary to create mechanisms to incentive the development of drugs for these diseases. Kremer (2001) presents a mechanism that may solve this problem in the case of vaccines.

7 Conclusion

This survey presented two empirical papers. The subject of Lerner (2002) is the effect of patent policy changes over innovation and the conclusion is that there is evidence that stronger patents do not incentive innovation. DiMasi, Hansen, and Grabowski (2003)'s subject is new drugs' development costs. This study concluded that capitalized cost, adjusted to the risk of failure, is US\$ 802 million per new drug. This value, as showed in Kremer (2001), is lower than the social cost of malaria but private incentive are not enough to produce a vaccine against it.

The theoretical papers in this study present solutions to some intellectual property's problems. Kremer (2001) suggests an advanced purchase commitment to incentive the development of new vaccines.

Shavell and Ypersele (2001), Kremer (1998) and Boldrin and Levine (2001) propose alternatives to the patent system. The solution proposed in the later one is very controversial because it involves elimination of patents in some sectors. Solutions proposed in first two are far less controversial since they are optional.

This survey suggests that more empirical studies are necessary to gather evidence on the effect of patents over innovation.

Finally, the mechanism proposed by Kremer (1998) should be tested in a small scale practical experiment to verify the theoretical results.

Appendix

7.1 Kremer (1998)

Kremer (1998) proposes a system in which the government buys the patent and places it in public domain. This paper begins with critics to usual incentives to innovation.

First, the patent system has known problems. He discusses how patents create

too little incentive for innovations because investors do not take consumer surplus into account when deciding how much to invest. Patents do not reward inventors for externalities created for other researchers and they distort research because there is too much incentive to create substitutes for patent goods and too little to create complements. Furthermore, social return to innovation under patents are two and half times the private rate of return under the patent system.

Direct government support is also criticized. One problem of this system is that when the government pays for research inputs, there is a moral hazard problem, because it is hard to prevent a researcher from shirking. Paying for output has other problems, e.g. government does not know which inventions are possible and their social benefits. And if the government pays ex-post for an invention, history shows that it tends to expropriate inventors paying too little for their inventions.

7.1.1 Historical Experience

Kremer (1998) gives some historical background on patent buyouts. He cites the case of the Daguerreotype process that was patented and later bought by the French government. After it was placed in public domain, the invention was quickly adopted around the world, and the process was improved.

Another case is the patent of the cotton gin by Eli Whitney. His patent was not respected because it could be easily duplicated by carpenters and blacksmiths, and Southern juries ruled against Whitney in many suits that he filled for patent infringements. He ended up selling the rights to South Carolina, North Carolina and Tennessee, but not before South Carolina had him arrested over a dispute about the patent.

In both cases, the government bought important patents and the inventions' use spread quickly. But in the Daguerreotype case, there was a similar invention, the calotype process invented by William Fox Talbot. Talbot's invention was patented and he charged high fees for the right to use the process. Maybe this and the fact that the Daguerreotype process was free caused the abandonment of the calotype. It is not clear which invention was superior, but this shows that selectively putting inventions in public domain may cause the adoption of an inferior technology.

7.1.2 A Mechanism for Buying out Patents

Kremer's (1998) idea is to use a second-price, sealed bid auction to determine the invention's value. The process begin with an inventor who wants to sell his or her patent to the government, and in order to do so he or she needs to pay the administrative cost of the auction. The government asks for bids, which under a second-price auction should be the expected value of the patent to bidders given their information. To incentive the bidders to reveal their true patent's valuation, the government randomizes after buying the patent if it will go to public domain or if it will be sold to the auction's winner, with probabilities (1-p) and p respectively.

The government then offers to buy the patent at a markup times the private value extracted from the auction. The inventor decide if he or she wants to sell. If he or she do not sell the invention, he or she retains the patent, only incurring administrative costs of the auction. In case he or she decides to sell, the government randomizes as described before.

To estimate the patent's private value, the government should use all bids received, rather than only the highest one, because there is no reason to ignore information from lower bids.

The author summarizes the advantages of this method in a perfectly competitive, collusion-free environment.

- 1. "The markup would raise private incentives for original research closer to the social benefit created by the invention.
- 2. Deadweight losses due to monopoly pricing would be eliminated if patents were put in the public domain
- 3. Since monopoly profits would be eliminated, researchers would not have excessive incentives to invent substitutes for existing drugs to steal profits."

7.1.3 Inventor Informational Advantage

In this case, fearing the winner's curse, the bidders will bid low values. But the markup reduces much of this problem. Kremer gives an example where the inventor knows the patent's value and potential bidders have some information conditional on the FDA drug approval process. Bidders only know that the true value is uniformly distributed in (L, U). If the good is sold for a bid B, bidders know that the true value of the patent is uniformly distributed in $(L, \min(U, MB))$, where M is the markup. In equilibrium, the auction participants will bid the expected value of the patent conditional on winning the auction, that is $(L + \min(U, MB))/2$, which implies

$$B = \min\left(\frac{L+U}{2}, \max\left[0, \frac{L}{2-M}\right]\right)$$
(7.1)

In absence of markup M = 1 and B = L. This means that no patent will ever be sold, since the government will offer B to the inventor. But if M = 2, then B = (L+U)/2 and the government offers L+U for the patent. With this offer, the inventor will always sell the invention.

This result depends greatly on the uniform distribution used in the example and is far less strong if the distribution is skewed, but even in this situation the markup reduces adverse selection problems, but it probably does not eliminate it. The author cites a Grabowski and Vernon's (1990) paper concluding that the unconditional distribution of the realized value of FDA-approved drugs is extremely skewed.

The author believes that the distribution conditional on information available to bidders has much less variance and skewness. This information includes the number of people affected by the disease, efficacy and side effects from the drug found during the FDA approval and if there is any similar drugs on the market.

The inventor has incentive to reveal as much information as possible to reduce adverse selection problems. Asymmetric information makes it difficult for small biotech firms to sell patents to large ones, and it even prevents some transactions. But even without any markup trade takes place frequently. So it is possible to affirm that a 100 percent markup will convince many patent proprietaries to sell their patents.

7.1.4 Inventors Who Are Low-Cost Producers

Sometimes the inventor has advantages in producing the good. In this situation, inefficiency may arise if another firm receives monopoly rights. Furthermore, releasing the invention in public domain may not affect the deadweight loss. Suppose that an inventor can produce the good at cost c_0 while the *i*th lowest cost producer can produce it at cost c_i . Demand for the good is $Q = P^{\alpha}$, $\alpha < -1$. If a producer was the patent holder and had cost c_i , the optimal price would be $c_i \alpha / (\alpha + 1)$ and he or she would profit

$$\pi_i = c_i^{1+\alpha} \left(\frac{\alpha}{\alpha+1}\right)^{\alpha} \left(\frac{-1}{\alpha+1}\right).$$
(7.2)

In a second-price auction this producer would bid π_i . The government receives bids and offers $MZ\pi_j$ for the patent, where Z is a multiplier, e.g. the historical ratio of the *j*th highest to the highest bid, M > 1 is the markup. The patent will only be sold if $\pi_0 < MZ\pi_j + (1-p)\pi_{\text{COMP}}$, where π_0 is the value of a monopoly on the good for the inventor, *p* is the probability that the government sells the patent to the auction's winner, π_{COMP} is the value to the inventor of producing the good in competition with other firms.

If the patent is placed in public domain and $c_1/c_0 < \alpha/(\alpha+1)$, the inventor does not have a great cost advantage and will face Bertrand competition. He will profit $\pi_{\text{COMP}} = c_1^{\alpha} + (c_1 - c_0).$

However if $c_1/c_0 > \alpha/(\alpha + 1)$ then the inventor has a great cost advantage. So great that he or she will be able to sell at monopoly price even with the good in public domain. He will profit π_0 in this case.

Note that inventors will almost aways sell their patents. If $c_j/c_0 < (MZ)^{-1/(1+\alpha)}$, the cost advantage is not too great relative to markup. Then $MZ\pi_j > \pi_0$ and they will sell. When $c_1/c_0 > \alpha/(\alpha + 1)$, they will sell if p is small enough, because their profit in competition will be the same as under monopoly, $\pi_{\text{COMP}} = \pi_0$.

The author points out that this method is more efficient when the industry has no great cost differences across firms and when the difference between competitive price and monopoly price is large.

The markup does not make innovators always accept the government offer. There will be some cases in which the cost to acquire information about the patent will be to high, or the industry has too few competitors willing to buy the patent and this will cause bids to be too low, making the government offer to be refused. But, because the administrative cost of the auction is paid by the patent seller, the government will not incur a loss. The original patent holder will keep the patent in this situation.

7.1.5 Incentives for Product Development

The mechanism creates incentives to develop new products. This happens because the private value of an innovation is $\pi(E)$, where E is the value expend on development and marketing. Without patent buyouts innovators will invest until $\partial \pi/\partial E = 1$. But if they expect to sell with a markup of M they will stop to invest only when $\partial \pi/\partial E = 1/M$.

Besides, if a product is in public domain, firms do not need a licence to improve it. As long as the improvement is patentable, there will be incentive to invent it. And there is much more incentive to invent complementary products, because the quantity sold of the original product will be larger when the product is in public domain, favoring complements.

7.1.6 Patent Buyouts as Research Subsidies

While markup raises incentive to research, expectation that substitutes to patented products will be developed more quickly reduces this incentive.

To keep a socially optimal research level, the markup has to be larger than current ratio from social value of inventions to their private value. To show this, Kremer (1998) uses a model of creative destruction. In this model, research at time t can be written as $x_t = \phi(M_t, x_{t+1})$, where M_t is the subsidy to research at $t, \phi_1 > 0$ and $\phi_2 < 0$. Define x^s as the research level that would be chosen by a social planner and $x^s > x^p$. The optimal markup solves $x^s = \phi(M^s, x^s)$. M^s is greater than the markup needed to induce x^s given expectations that future patents will not be bought, M^p , because M^p solves $x^s = \phi(M^p, x^p)$.

7.1.7 Joint Randomization

The author presents two main reasons to joint randomize patents. One reason apply for substitute patents. When a seller is offering the government a patent that is a substitute to another one, if the offered patent is placed in public domain, it would become a formidable competitor for the one patented before. This would discourage investments in research.

To solve this problem, the author proposes a joint randomization. Every time a new patent, that is substitute to another patent not in public domain, is offered to the government, the owner of the original patent may ask to sell his or her own. The government then asks for bids for each invention separately, but makes just one randomization. With probability p both inventions go to the respective auction winners and with probability (1-p) both are placed in public domain. With the joint randomization the inventions are valued on the contingency that both inventions and future substitutes will stay in private domain.

Notice that no bureaucracy is necessary to implement the system. Every claim that an invention is substitute to another one would be accepted, because it causes no harm and has the benefit that another invention may be placed in public domain.

Another use for joint randomization is when complementary patents are sold to the government. The patent value is higher when a complement to a patent is or will be in public domain. Under these circumstances, separate auctions may cause the government to pay more than the social value of inventions. This may incentive inventors to break their inventions in various complementary patents before selling them to the government.

Kremer (1998) provides a simple example. Suppose two inventions with private value 0.1π each if separated. And the value of both inventions together is π . So, considering a markup M = 2 the social value of these inventions is 2π . If one of these inventions is in public domain, the expected buyout price of the other is 0.9π times the markup.

The problem is that in separate buyouts each inventor can expect to receive around 0.9π times the markup for the patent. This happens because in the first auction buyers expect that the other invention will be placed in public domain. And in the second auction, the first invention will already be in public domain. The government would pay approximately 3.6π for inventions with social value 2π .

To prevent this, the government should not buy complementary inventions separately. If they belong to a single owner, the government should offer to buy all complements. If the owner refuses the government should offer to buy a single invention randomly chosen, but the inventor cannot offer to sell the other inventions to the government later. And this inventor will have a waiting period before he or she can sell future developed compliments of his or her invention to the government.

If inventions belong to different owners the government should ask for bids to each owner patents separately and for the whole set of complimentary patents. If owners fail to joint sell, the government should buy the patent of only one randomly chosen seller, with probability proportional to the expected value of the seller's patents. In both situations, sellers will be better off than under the current patent system.

7.1.8 Mechanisms for Preventing Collusion

One great problem of the patent buyout mechanism is possibility of collusion. While the bidder only pays the bid with probability p, the seller always receives the benefit of a higher bid. To prevent that, the author presented a list of what the government should do to prevent collusion, or at least make it more difficult.

- 1. When the government uses the third bid to calculate buyout price, it is very hard to the inventor cheat on the auction because it is necessary that three buyers take part on collusion.
- 2. The government should be able to call the bluff when it suspects that bids are higher than the invention's value. Suppose the government with information extracted from other bidders conclude that the invention's value is approximately π , but the highest bid is $\pi + x$. The government could, in this situation, pay $\pi + \$1$ to the inventor and charge $\pi + x$ to the auction's winner for the invention. Then the government would make a profit of x - 1 from the attempt of fraud.
- 3. The government should have list of suspects of fraud and prohibit them to participate. Should not be hard to elaborate such list, because these participants will have great losses when they buy the patent.
- 4. The government should investigate inventor financial ties with bidders and punish inventors who fail to disclose their ties. This should avoid the use of front companies.

- 5. If there is a fee or if companies had to make a deposit to participate in auctions then it would become unprofitable to inventors create dummy companies to bid in their products. Alternatively, government could focus on drugs, because firms in the industry are already known, making frauds more difficult.
- 6. The government should prohibit inventors to buy back their inventions and to make side payments to bidders. The later is, in the author's opinion, the most difficult aspect to control to avoid collusion.

7.1.9 Ceiling Prices

While the private value is a floor to patent buyout prices, there is no ceiling. The author suggests ceiling prices to avoid to high prices when the mechanisms presented before do not work.

- 1. First suggestion is a waiting period. The government would let inventions under patents over several years before buyout. This would give more information about patents' value and ceiling price would be a multiple of annual revenues before buyout. A problem is the incentive to inventors try to raise sales artificially. Another ceiling price could be prebuyout price times postbuyout consumption.
- Another option could be capping the buyout price by total sales times the estimated social value per dose of drug. The government should do this estimation.
- 3. One last suggestion is a mechanism where the price is capped by profits from product. This mechanism is the same as before until randomization. But what happens after randomization is different. Now, inventor receives $(M/p) \min(\text{bid}, \pi)$ for invention only if the invention is sold to the highest bidder. If the invention is placed in public domain, the inventor receives nothing. The expected value of buyout price in this case is $M \min(\text{bid}, \pi)$. The inventor could insure the risk of receiving nothing in this situation without great difficulties.

7.1.10 Conclusion

Kremer (1998) concludes by suggesting that patent buyouts should be tried and that pharmaceuticals would be a natural area for such trials. A private foundation could conduct an initial trial and if it succeeds, then the government should try it by appropriating \$100 million from general revenue for patent buyouts.

7.2 Boldrin and Levine (2001)

Boldrin and Levine (2001) elaborated a model in which innovation occurs under perfect competition. Their motivation is that historically there was no intellectual property, but yet innovation took place.

One fundamental hypothesis of their model is that ideas do not spillover. Ideas only have value embodied in goods or people. This implies that for someone to learn the idea, he or she needs access to people or goods that embody the idea. The authors argument that ideas are rival because people or goods embodying it are rival.

7.2.1 Innovation Under Competition

Boldrin and Levine (2001) define innovation as the first time a good is actually produced or an activity is employed. Then they suppose that one innovation was produced and there is k > 0 units of product. This product is such that every copy of it is a perfect substitute of the original. The copying process of the product demands only time. Then $0 < c \leq k$ units are consumed and k - c are used to make copies. These k - c units result in $\beta(k - c)$ units in next period, where $\beta > 1$. Since the good may be durable, there are another ζc units on next period. $\zeta \leq 1$ because of depreciation and $\zeta \leq \beta$ because it is not easier to copy the product while using it. u(c) is the representative consumer's utility function, u is strictly increasing, concave, and bounded below. The representative consumer lives forever and discounts the future at rate $0 \leq \delta < 1$. The authors assume that technology and preferences are such that feasible utility is bounded above.

The solution of this problem is a concave value function v(k), the unique solution

of

$$v(k) = \max_{0 \le c \le k} \{ u(c) + \delta v(\beta k - (\beta - \zeta)c) \}.$$

In equilibrium $p_t = u'(c_t)$. From the resource constraint

$$c_t = \frac{\beta k_t - k_{t+1}}{\beta - \zeta}.$$

If ζ is large enough relative to β it may be optimal not to invest.

The price q_t of the durable good k_t is

$$q_t = v'(k_t) = p_t \frac{\beta}{\beta - \zeta}$$

Since $p_t > 0$, $q_t > 0$ for all t. The zero profit condition implies that q_t decreases at a rate $1/\beta$ per period of time.

When an innovator creates something he or she has $k_0 = 1$ units of the new product. In a competitive market this unit sells for q_0 . Assuming a cost C > 0 to create the first unit of the good, innovation will occur if $c \leq q_0$.

The difference between this model and those in which innovations are non rival is that $\beta < \infty$, meaning that the number of copies made in a period is limited. But there is no limit on the number of units that can be produced and there is no cost to produce these units. The authors believe that non rivalry is only an approximation to the fact that reproduction costs are very small.

When the reproduction costs diminish and there is no intellectual property, innovations cease to exist in traditional models. That happens because the inventor will not be able to receive for his or her invention more than the production cost. But under Boldrin and Levine's model this is not necessarily true. In the first period the inventor has the only copy of his or her invention and its price is $q_0 \ge u'(c_0)$, which is bounded below by u'(1). Therefore the first copy price will never fall to zero if consumers are impatient. And under this framework a reduction in reproduction costs may even raise the price of the first unit.

Notice that $\partial q_0 / \partial p_0 > 0$ and

$$rac{dq_{0}}{deta} = u^{''}(c_{0})rac{dc_{0}}{deta} - u^{'}(c_{0})rac{\zeta}{(eta-\zeta)^{2}}.$$

When β is sufficiently large relative to ζ the first term dominates. In this case the result depends on whether consumption is substitute or complement across time periods. If it is substitute, then a raise in β diminishes consumption and consequently raises the first unit price. If it is complementary, then the opposite happens and rents fall.

The authors provide an example where the utility function has the CES form $u(c) = -(1/\theta)(c)^{-\theta}, \ \theta > -1$. If demand is inelastic then $\theta > 0$ and there is little substitutability across periods. As $\beta \to \infty$ the initial consumption $c_0 \to \bar{c} < 1$. Thus in this case the rents fall, but not toward zero and innovation will happen under a competitive framework if $\bar{p} = u'(\bar{c}) > C$.

If demand is elastic, $\theta \in (-1, 0]$ then there is a high intertemporal substitution in consumption. In this situation utility becomes unbounded as $\beta \to \delta^{1/\theta}$. As β approaches this limit, $c_0 \to 0$ and the invention price becomes infinite. Hence if β is large enough in this case, every social desirable invention will occur.

One case not discussed yet is $\zeta = \beta$. In this situation, capital grows at rate β and the initial rent is

$$q_{t} = \sum_{i=0}^{\infty} (\beta \rho)^{i} p_{t+i} = \sum_{i=0}^{\infty} (\beta \delta)^{i} u^{'} (\beta^{i} k_{t}).$$

Again, price is bounded below by marginal utility of the first unit and the initial rent becomes infinite as β increases.

The authors question if the reproduction rate is becoming larger. They do not believe that this is happening for patentable ideas because the knowledge necessary to understand and reproduce these ideas is increasing, since ideas are becoming more complex. But for copyrightable creations, they believe that electronic reproduction over the Internet makes β to increase. Computers also reduce indivisibility C. One example is that a music studio is much cheaper today than a decade ago.

7.2.2 Innovation Chains

Boldrin and Levine (2001) also models innovations that occur in sequence. Now there are many qualities of capital beginning with quantity zero. Capital of type i is k_i and each unit of k_i allocated to production of consumption results in $(\gamma)^i$ units of output, where $\gamma > 1$. That means that higher quality capital is more efficient. Every capital used to produce consumption is depreciated at rate $(1 - \zeta)$. If c_i is produced using type *i* capital then there is $k_i - c_i/\gamma^i$ units available to produce capital. As before each unit of type *i* capital may be used to produce $\beta > 1$ units of the same type of capital. But now there is an option to produce type i+1 capital and h_i is the investment on it. Each unit invested results in ρh_i units of i+1 capital. It is assumed that $\rho < \beta$ and there is a minimum of $\underline{h} > 0$ that needs to be invested on the ρ technology before getting any output. This represents indivisibility in innovation, which was the role of *C* in the previous model. Therefore there will be investment in higher quality capital only if the rents of introducing k_{i+1} are large enough to compensate the investment of at least \underline{h}/ρ units of k_i . To make sure that sustained growth is possible it is assumed $\delta(\beta - \zeta) > 1$.

One case analysed is $\underline{h} = 0$. When $\rho\gamma > \beta$, one never uses β technology because ρ technology is dominant. The optimal consumption under competition is obtained when

$$u'(c_t) = \delta(\rho \gamma - \zeta) u'(c_{t+1}).$$
(7.3)

Since the utility function is strictly concave, u' is strictly decreasing. Thus $c_{t+1} > c_t$ and if -cu''(c)/u'(c) is bounded above as $c \to \infty$ then applying Taylor's theorem, one can show that not only $c_{t+1} > c_t$, but also $(c_{t+1} - c_t)/c_t > \Delta > 0$ and, in this case, c_t grows without bound. So in this model the occurrence of innovations is possible under a competitive scenario.

Another case analysed is if $(\underline{h}) > 0$. When \underline{h} is large enough there will be no investment in innovation and no equilibrium. But if \underline{h} is small enough, it may not be binding at social optimum. In this case, the competitive equilibrium with innovations exists, and the welfare theorems apply.

Based on that fact, one important question is, What happens to investment in the newest technology asymptotically? If it is either constant or increasing, a small enough indivisibility will not be binding, but if it is diminishing any indivisibility will be binding. Assuming that utility has a CES form, $u(c) = -(1/\theta)(c)^{-\theta}, \theta > -1$ the first-order condition (7.3) may be used to find the growth rate of consumption g

$$g = \frac{c_{t+1}}{c_t} = (\delta(\rho\gamma - \zeta))^{1/(1+\theta)}$$

There is no difference in which capital type is used to produce consumption and

which is used to innovate in the case without indivisibility. This is no longer necessarily true. The optimal plan now may involve using ρ technology in some periods and β in others because of the threshold <u>h</u>. These complications make the full characterization of the equilibrium beyond the scope of the paper. But Boldrin and Levine (2001) provide a sufficient condition for the class of production plans in which old capital is used only to produce consumption.

The necessary and sufficient condition for physical investment to be nondecreasing asymptotically is

$$g - \left(\frac{\rho\gamma - g}{\rho\gamma - \zeta}\right) \left(\frac{g - \zeta}{\rho\gamma - \zeta}\right) \zeta \ge \gamma.$$

Note that $(\rho\gamma - g)/(\rho\gamma - \zeta) + (g - \zeta)/(\rho\gamma - \zeta) = 1$. Thus the restriction is satisfied if $g - \zeta/4 \ge \gamma$. If this condition is satisfied, it is probably satisfied strictly, which is a sufficient condition for asymptotic growth of investment in this class of production plans. Therefore even if in early periods the indivisibility is binding, as time goes by investment grows and the indivisibility will become irrelevant. The authors associate this characteristic to simultaneous discovery in advanced economies. Their view is that even if part of innovations occurs because of patents, another part cannot be explained in the same way, e.g. basic science, where patent law does not apply, open source software, where innovators do not restrict downstream licensing agreements, and fashion industry, where labels are protected but the designs can be reproduced without large costs.

7.2.3 Does Monopoly Innovate More Than Competition?

According to this model innovations can thrive in a competitive environment. While conventional theories argue the existence of a fixed cost to produce a nonrivalrous good, this theory argues there exists sunk costs to produce a rivalrous good. In the former situation, since there are increasing returns to scale, competition cannot thrive. In the later one, sunk costs pose no threat to competition, but indivisibility is the great problem.

One competition problem is that rents may not cover the costs to innovate even if the invention is socially desirable. Another one is that the indivisibility may bind and there is no adequate theory of competitive equilibrium with binding indivisibilities. The authors defend the view that competition is a powerful force and it may find its way through indivisibilities.

But even in the case where some socially desirable innovations are not produced under competition, Boldrin and Levine (2001) do not believe that monopoly will have a better output because while a monopolist has incentive to produce one innovation, once that happens he or she has incentive to hold up other innovations.

To show this possibility they elaborate the following example. Commodities and activities are as before and now there is a transferable commodity m. Consumer utility is $m + \sum_{t=0}^{\infty} \delta^t u(c_t)$, where m is a transferable commodity, and the monopolist utility is m. The consumer has an endowment of \bar{m} unities of transferable commodity and the monopolist has an endowment of zero unities of transferable commodity and all initial capital (k_0^0) . The monopolist also has full patent protection over the β , ρ and γ activities. At the beginning of each period, the monopolist chooses a production plan and then price is determined by the consumer's willingness to pay.

Suppose that the period utility function is

$$u(c) = \begin{cases} -(1/\theta_1)c^{-\theta_1} & c \le 1\\ 2 - (1/\theta_2)c^{-\theta_2} & c > 1 \end{cases}$$

where $\theta_1 < 0$ and $\theta_2 > 0$. Thus this is an elastic CES below c = 1 and an inelastic CES above this level of consumption. Suppose for now that there is no indivisibility, no depreciation and the initial capital stock is $k_0^0 = 1$. The asymptotic competitive growth rate in this case is

$$g = (\delta(\rho\gamma - 1))^{1/(1+\theta_2)}$$

and the capital stock will grow over time if

$$g - \left(\frac{\rho\gamma - g}{\rho\gamma - 1}\right) \left(\frac{g - 1}{\rho\gamma - 1}\right) \ge \gamma.$$

Assuming, for example, $\theta_2 = 0.10$, $\rho = 2.20$, $\gamma = 1.05$ and $\delta = 0.98$ this condition holds and the parameters will satisfy the condition for asymptotically non-decreasing investment in innovation. Therefore there will be sustained innovation on competitive equilibrium, even with positive depreciation and a small indivisibility.

A monopolist in this scenario will have maximum revenue (u'(c)c) when he or she produces one unit. As he or she starts with one unit of capital that does not depreciate, he or she can produce one unit of consumption in each period, and this is the best he or she can do in this situation, because if he or she decides to innovate it is necessary to produce a suboptimal quantity in one period to make innovation possible. But this innovation will not result in higher profits on future periods, and then the monopolist will choose not to invest, and as he or she has patent protection, the monopolist will prohibit everyone else to innovate.

So under monopoly the result is a constant output and no innovation at all, while under competition there are successive innovations and the output grows without bound. This result is significantly dependent on the durability of capital, because without indivisibility the optimal method to replace depreciated capital is innovation, even for the monopolist. Although this would not result in output growth under monopoly, at least it would result in successive innovations.

Therefore, when a small amount of depreciation is introduced into the model, the first best is still the competitive equilibrium because the monopoly results in deadweight loss. But now monopoly is as innovative as competition, introducing a new quality of capital every period because of depreciation.

When a small indivisibility is introduced, competition is still the first best while monopoly may cease to innovate. This happens if investment to cover depreciation is less than the amount necessary to create a new quality of capital.

Boldrin and Levine (2001) point that this is an important result because it shows the incentives to innovate in both regimes. Under competition, the industry has incentive to produce innovations beyond the rate of depreciation. As the marginal valuation of the good is sufficient to cover costs of production under competition, the industry will raise output and total stock of capital. This will make it easier to reach the threshold required to innovate. When innovations happen under monopoly, they will be just enough to cover depreciation. The authors suggest that this was the situation before and after the breakup of national monopolies of the telecommunication industry.

If a monopolist receives a patent with k-periods duration, he or she has incentive to suppress invention during this time. In the case where patents are awarded by a patent race, outcome is even worse. The monopolists, except the first, will not invest to cover depreciation of capital stock or will even destroy it, because this raises their revenues. If the monopolist controls β but not ρ technology, consumers would have incentive to become a monopolist buying sufficient k_t^i to use ρ technology. Thus the monopolist would keep the amount of k_t^i available to consumers below \underline{k} , avoiding the introduction of an innovation by consumers. The higher the indivisibility, the easier to prevent consumer innovation.

7.2.4 The New Economy and the Superstars

The Boldrin and Levine (2001) model also predicts the superstandom phenomenon. This phenomenon occurs when indivisibilities and technological advances in reproduction of "information goods" are present in a competitive environment. Worlds of sports, entertainment, and arts and letters are examples given by the authors of markets where these conditions apply.

Now, consumption happens in just one period and the two goods are consumed. One of them is the information good and the other is a composite good of pre-existing goods. Utility is u(c) + m, where c is the information good.

There are two types of potential producers A and B, each with one unit of labor. They are equally productive on the information goods sector, where one unit of labor produces one unit of information good that will be called second good. Their productivities differ on composite good. While producer A produces $(1 + \varepsilon)\beta$ units of c with one unit of labor, B produces only β units of c.

Without indivisibility there is no superstars because price of type A labor is $1 + \varepsilon$ times price of type B labor. Since type A labor is more efficient producing c than type B, the latter will only be used to produce c after all labor of type A is used on that sector. If this is the case, let l_2 be the amount of type B labor employed for production of information goods. Thus the equilibrium condition is $\beta u'(\beta(1 + \varepsilon) + \beta l_2) = 1$. If u' is eventually inelastic, producer B will be excluded from production of c as β rises. The earnings will be 1 to producer B and $1 + \varepsilon$ to produce A, using second good as numeraire.

When there is indivisibility, the earnings are different. Now there exists a minimum threshold C to produce the information good. Thus when l_2 falls below C only producer A will produce c. This occurs when $C \beta u'(\beta(1+\varepsilon+\beta C)) = 1$ and producer B still earns 1. But now prices in information goods market are $\beta u'(\beta(1+\varepsilon))$, therefore the earns of producer A are $\beta u'(\beta(1+\varepsilon))(1+\varepsilon)$, which are greater than $1+\varepsilon$.

Therefore advances in reproduction technology initially are beneficial to both producers and wages increases at uniform rates. Eventually, further improvements lead to a "crowding-out" of the least efficient workers. For large values of β the most efficient workers will capture the whole market and earn a value that is not proportional to the skill differential ε .

7.2.5 Conclusion

Boldrin and Levine (2001) argue that "... when its functioning is carefully modeled, competition is a potent and socially beneficial mechanism even in markets for innovations and creative work." This casts doubt on the necessity of patents and copyrights to incentive innovation. The analysis of the case with innovation chains is even harsher on patents, because it shows that a monopolist has incentive to hold innovation when he or she detains a patent.

7.3 Kremer (2001)

Kremer (2001) presents a mechanism to incentive the development of vaccines. He argues that an advance commitment to buy a large quantity of these vaccines could incentive their development. Around 3 million people die every year from malaria and tuberculosis. Despite these numbers, there is not much research on vaccines for these diseases and HIV, specially on clades most common in Africa.

7.3.1 Failures in the Markets for Vaccines and Vaccine Research

These diseases affect mainly poor countries, and this is one reason why there is no intense research on vaccines for them. But that is not the only reason. There is an externality on vaccine consumption. People that take vaccines benefits the rest of the population, but these benefits are ignored by individuals. Since vaccines benefit primarily children, another problem arises. Children cannot choose to take vaccines nor pay for them with their future wages.

Monopoly pricing joins these factors that cause underconsumption of vaccines. Government can reduce this last factor, buying large quantities of vaccines for a lower price. Government intervention may increase both consumer and producer surplus. But there is risk of reducing incentives to vaccine research, because interventions reduce the producer's profit.

An additional problem is the possibility of competitors design around the original patent, which causes a reduction of the innovator's profit.

Moreover, vaccine development is a global public good. That allows many countries to free ride on others research. This is a more severe problem in small countries. To illustrate this point pharmaceutical prices in the European Union are about half of those in the United States. In Japan they are about a quarter.

The problem is that malaria, tuberculosis and some clades of HIV are diseases that affect many small developing countries. This aggravates the free rider problem. Besides, these countries do not have a tradition on protecting intellectual property rights for pharmaceuticals.

Currently, research on vaccines is driven by the demand of developed countries. Profits obtained from small developing countries represent only a little incentive to the development of vaccines.

If pharmaceutical companies could charge the amount each nation is willing to pay and intellectual property rights were respected globally, then the market could achieve efficient size to incentive the production of these vaccines.

The author argues that the benefits from a 80 percent effective malaria vaccine could be cost-effective even at a price of \$41 per immunized person on a total of 42.1 million people immunized every year. The revenues to the producer would be more than \$1.7 billion annually.

This value shows that the research towards a malaria vaccine could recover the costs of development and generate a large profit, increasing social welfare. But a private company is not able to recover its costs because even vaccines that cost a dollar or two per dose do not reach most children. Private benefits are much lower than social ones and this causes under investment on malaria vaccine research.

7.3.2 The Roles of Push and Pull Programs in Encouraging Vaccine Research

The author proposes some alternative ways to incentive vaccine research. There are two classes of programs: push and pull programs. A push program funds research through public investment, tax credits for R&D, grants, etc.. A pull program gives an extra reward to the developer of a vaccine (e.g. through purchase promises of a vaccine after its approval).

The rise of biotech industry and existence of venture capital favor pull programs. This happens specially on later stages of vaccine development and despite the fact development is made though push programs historically. The main advantage of a pull program is that the government pays only for a vaccine that is actually developed. "This creates strong incentives for researchers to 1) carefully select research projects and 2) focus on developing viable vaccines, rather than pursuing other goals." (Kremer 2000).

It is hard to select the promising research projects. Researchers are over optimistic about their own line of research and it is difficult to answer if the investment would improve social welfare.

Public-sector equity investments have a selection problem because only firms less confident in their research would seek public investments. Firms highly confident will refuse public investment since this would reduce their share on profits.

Public directed research has problems in selection of research projects and in the process of shutting down disappointing projects. It is easier for private companies to shut down projects that are shown not to be worth pursuing anymore.

Pull programs avoid investment that is not welfare improving. Since the payment is made only when a vaccine is ready, it avoids waste of public resources. The program rewards only successful projects. In this case, the amount of payments measures how much a country values the vaccine.

Once a pull program is in place, biotech and venture capital companies are encouraged to select promising projects and target a marketable vaccine. Researchers will be paid to make the final steps of development. When this stage is done through push programs it is hard to monitor if researchers are focusing on developing the vaccine.

Subsidizing private research through tax credits has problems too because even firms that research subjects with little relation to the diseases that can be used to ask for credits will claim eligibility. On the other hand, credits linked to vaccine sales are a better mechanism to obtain a private developed vaccine because it avoids this type of problem.

To illustrate problems in push programs the author cites the work of Desowitz (1991) that relates the history of the push program of the U.S. Agency for International Development (USAID) on 1980s that tried to develop a malaria vaccine.

Three teams of researchers were funded by that program and only one of them developed a candidate vaccine. This candidate vaccine was tested in 9 volunteers and only 2 were protected against malaria while the test pointed side effects. These results caused a claim by USAID in 1984 that a vaccine against malaria should be ready in five years. Despite this claim, until today there is no such vaccine. The other teams had worse results on preliminary work but they continued to receive funding. The principal investigators of both teams transferred grant funds to their personal accounts and were later indicted for theft.

USAID spent over \$60 million funding malaria research with little results. The project director of USAID's malaria vaccine, James Erickson, pleaded guilty on some charges after the discovery of a contract to acquire monkeys from an associate who paid Erickson a kickback.

Erickson was oversight by the American Institute of Biological Science, but he and the project manager responsible for the oversight were lovers.

This is an extreme case of failure in push projects. But it illustrates how a researcher may deviate resources away from what they were given for. Another point is that the three groups of researchers were over optimistic about the possible results of their research.

Push programs also have several advantages. The main advantage is that they work even when the output is unknown. In this case a pull program would be of little help. But this do not apply to vaccine research because it is relative easy to define what is an efficacious and safe vaccine. There are other advantages to push programs. The risk of failure is transferred from researching firms to society at large, which is beneficial when the shareholders of these firms cannot diversify this risk in stock markets. The spillovers from results of intermediate steps on vaccine development shared among researchers are another advantage.

The combination of push and pull programs may be more effective because the work on less intellectual rewarding levels of research would have monetary reward. This would incentive a faster development of vaccines.

7.3.3 Alternative Pull Programs

There are other types of pull programs besides advance purchase commitment. Prizes, tournaments, patent extensions to other products and signaling are examples.

Kremer (2001) argues that advance purchase commitment is the best mechanism to vaccine development.

Patent extension to other products would be a very good source of resources to pay for the successful development of a vaccine. But the cost is efficiency and equitably, because those who pay for the development would not receive the benefits. Moreover, people that needs the product with the extended patent may not be able to get it.

Another important reason against patent extension is the fact that it would give different incentives to firms that have patents of distinct values in their portfolios. Companies with more valuable patents would have more incentive to develop a vaccine but they might not be the ones in the best situation to do so. This problem may be solved creating a market for patent extensions, but this solution is not perfect because firms owing the patents would receive some share of profits from the development of a vaccine.

Cash prizes are another type of pull program. Economically, they are very similar to purchase commitments, but the latter has some important advantages. First, purchase commitments provide a better link between payments and quality of a vaccine. Moreover, they are more politically attractive, which make them more credible. There is a link between payments and quality. Suppose a cash prize is awarded at the date of regulatory approval, and latter side effects are discovered. It would be difficult to recover the money prize, while purchases could be suspended.

It is easier to justify an expense of 50 million doses of vaccine for children at \$5 per dose for 10 years than a prize of \$2.5 billion to the vaccine developer. This makes advanced purchase commitments politically attractive.

The main advantage of a prize over an advanced purchase commitment is that consumers may choose details of the good they wish to buy. This advantage has less importance in the case of a vaccine because it is a very uniform good and the government must regulate its use anyway.

Tournaments are another option of pull program. However, Kremer (2001) believes that it has several limitations to vaccine development. First, in a tournament a prize is paid even if a vaccine is not fully developed. Researchers have incentive to try to win the contest, but this is not the same as to advance on the most promising research topics, because results may take time. There are collusion problems, and that may be really harmful in such events, since contestants may receive the prize doing low effort on research.

The last pull program discussed by Kremer (2001) is an expansion of existing vaccines market. There are some vaccines that are available but they are not widely used. While to purchase these vaccines at higher prices could incentive the development of new ones, the cost is less resources to save lives.

One problem with this approach is that this program do not assure to research firms a reward for developing a vaccine. The development process takes time and to recover the investment the product needs to generate revenues for a long time. Since health policy of developing countries changes frequently, companies will find difficult to believe that this program would still being applied ten years after the new vaccine reaches the market.

Besides, when companies develop the vaccines already in market, they did not expect large profits from developing countries. This program would increase firms profits without guaranteeing the development of new vaccines. Some people argue that as R&D funding also depends of current revenues, this program would help vaccine development. But changes on the way revenues are obtained may change funding policy inside firms.

Kremer (2001) finds that a purchase program is a cost-effective way of saving lives, although he does not believe that it is necessary to incentive the development of new vaccines.

7.3.4 Conclusion

The author concludes that the social value of new vaccines may be much higher than private incentives. This causes potential vaccine developers to pass up socially desirable research on vaccines.

Even if these vaccines were developed, they would not be widely available because they would be sold at monopoly prices.

Commitments to purchase future developed vaccines to distribution on developing countries provides incentives to vaccine research and guarantees that they will reach people who needs them. And taxpayers only would pay when a vaccine is developed.

7.4 Shavell and Ypersele (2001)

In this paper the authors compare reward systems to intellectual property rights. Under a reward system, government pays innovators for innovations that pass to public domain immediately. In that way the deadweight loss caused by property rights like patents and copyrights disappears. They suggest that an optional reward system is superior to intellectual property rights. In this system, innovators can choose between a reward or intellectual property rights.

They build a model in which a single innovator decides his or her investment in research. While he or she knows the demand curve for the innovation before investment, the government knows only the probability distribution of demand curves. Decision depends on the system of innovation incentives. Under the patent system he or she will earn monopoly profits and under the reward system he or she will earn the reward chosen by the government.

Shavell and Ypersele assume that a risk neutral potential innovator chooses in-

vestment in research k. The probability of an innovation is p(k), and it increases on k; p'(k) > 0; p''(k) < 0. If an innovation is discovered, it generates a product that can be produced at cost c. The inverse demand curve for the product is d(q;t)where q is the quantity of product and t is a parameter in $[t_a, t_b]$. The probability density of t is g(t) > 0 on $[t_a, t_b]$. As usual $d_q(q;t) < 0$. The authors assume that at t_a there is positive monopoly profits, deadweight losses and social surplus, and they are increasing in t. Social welfare is the expected value of utility obtained from the product by individuals, minus production costs, and minus research investment. With the exception of t, every function and variable described above is common knowledge. Only the innovator knows the value of t.

7.4.1 First-Best Outcome

When an innovation occurs the optimal quantity on a competitive market is q(t)such that d(q(t); t) = c. Consumers surplus is

$$s^{*}(t) = \int_{0}^{q(t)} (d(q;t) - c) dq.$$
(7.4)

First-best research investment maximizes

$$p(k)s^*(t) - k,$$
 (7.5)

so that

$$p'(k)s^*(t) = 1,$$
(7.6)

identifies the first-best level of k. Let k(z) be the value of k chosen when z is the payoff from an innovation. In this case, the first-best k is $k(s^*(t))$ and the first-best social welfare as a function of t is

$$W^{*}(t) = p(k(s^{*}(t))s^{*}(t) - k(s^{*}(t)).$$
(7.7)

7.4.2 Patent Regime

As usual, under patent regime, when an innovation occurs, the innovator holds exclusive rights over the product. Assuming profit maximization, he or she sells the monopoly quantity $q_m(t)$ and earn monopoly profits $\pi(t)$. The innovator will choose k to maximize

$$p(k)\pi(t) - k. \tag{7.8}$$

As $\pi(t)$ is the payoff from an innovation, he or she will choose $k(\pi(t))$.

The authors compare the patent outcome to the first-best one. Because $q_m(t) < q(t)$ there is a deadweight loss

$$l(t) = \int_{q_m(t)}^{q(t)} (d(q;t) - c) dq$$
(7.9)

Social welfare under patents is then

$$W_P(t) = p(k(\pi(t)))[(s^*(t) - l(t)] - k(\pi(t)).$$
(7.10)

The difference between social welfare in the first-best and in the patent regime is

$$W^{*}(t) - W_{P}(t) = \{ [p(k(s^{*}(t)))s^{*}(t) - k(s^{*}(t))] - [p(k(\pi(t)))s^{*}(t) - k(\pi(t))] \} + p(k(\pi(t)))l(t).$$
(7.11)

The term in braces is the welfare loss from inadequate investment in research under the patent regime because $\pi(t) < s^*(t)$. In words, an innovator has less incentive to invest under the patent regime then $k(B(t)) < k(s^*(t))$. The other term is the expected deadweight loss due to monopoly pricing.

7.4.3 Reward Regime

Under reward regime, the innovator receives a reward from the government for his or her innovation that passes to public domain immediately. Other firms can use the innovation and market the resulting product. Assuming perfect competition, the product will be sold at marginal cost c and the total quantity sold will be q(t). So firms make no profit selling the product and there is no deadweight loss on this market. If the government had perfect information about the market, the firstbest solution could be implemented. Government would just set the reward equal to social surplus generated by the invention $s^*(t)$. But governments do not have perfect information. It fixes reward r for an innovation and, because profits from products sold is zero, that is the only incentive to innovate. The innovator maximizes

$$p(k)r - k, (7.12)$$

so will choose k(r). The government does not know the value of t and tries to maximize social welfare

$$W_R(r) = \int_{t_a}^{t_b} p(k(r))s^*(t)g(t)dt - k(r) = p(k(r))E(s^*) - k(r),$$
(7.13)

where $E(s^*)$ is the expected value of $s^*(t)$. Social welfare is maximal if $r = E(s^*)$, as can be seen through (7.12), that is, optimal reward r^* is the expected social surplus from an innovation.

Comparing to the first-best outcome, the reward system achieves the same quantity when an innovation happens. But the investment now does not depend on t, being constant $k(E(s^*))$, which falls short when $s^*(t)$ exceeds $E(s^*)$ and is excessive when $s^*(t)$ is below $E(s^*)$.

Note that the government does not need any information about the probability function p(k) in order to calculate the optimal reward.

7.4.4 Patent versus Reward

Subtracting the social welfare under patent from that under reward the authors obtain

$$W_{R}(r) - W_{P} = W_{R}(r) - \int_{t_{a}}^{t_{b}} W_{P}(t)g(t)dt$$

= $\int_{t_{a}}^{t_{b}} \{ [p(k(E(s^{*})))s^{*}(t) - k(E(s^{*}))] - [p(k(\pi(t)))(s^{*}(t) - l(t)) - k(\pi(t))] \} g(t)dt.$ (7.14)

This equation shows the difference between reward and patent systems. There are two main factors that explains it. First, the deadweight loss l(t) from the monopoly caused by patents. Significant deadweight loss favors the reward system. The other factor is that incentives to invest under the reward system are fixed, given by $r = E(s^*)$, while under patent the incentive depends on t.

While larger deadweight losses favor the choice of a reward system, the later factor depends on the first-best optimal. The role of incentives is clearer in figure 5. Let t^* be such that $s^*(t) = E(s^*)$. If t is close enough to t^* , rewards are better than patents for both reasons, i.e. the reward system has no deadweight loss and

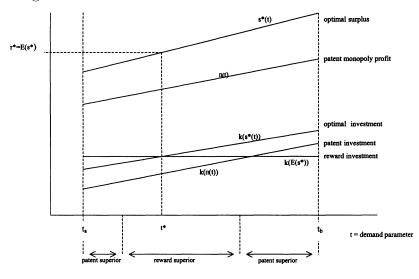


Figure 5: Patent and Reward: Investment and Incentives

Source: Shavell and Ypersele (2001)

incentives to invest are closer to the fist-best than patents. If t far enough from t^* , patents dominate rewards because deadweight loss is less important than distortion on incentives. On the left region, patents are superior and rewards cause over investment on innovations. On right side, rewards are insufficient to provide optimal investment. On both regions, investment under the patent system is closer to optimal than under the reward system and this compensates the deadweight loss from monopoly under patent.

This means that the question about the best system has no unambiguous answer. In the example on figure 5 it depends on t.

7.4.5 Optional Reward Regime

Under the optional reward regime the innovator chooses if he or she wants to patent his or her invention or if he or she prefers to receive a reward for it. He will pick the one with highest expected value. Thus he or she will choose patent if and only if $r < \pi(t)$. This is illustrated in figure 6.

If $r < \pi(t_a)$, then the optional reward system is equivalent to the patent system because the innovator will always choose patents. Hence to determine the optimal reward the authors made a restriction: $r \ge \pi(t_a)$. Let $l(r) \equiv \pi^{-1}(r)$ for r in

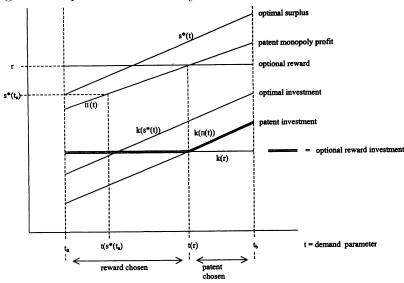


Figure 6: Optional Reward System: Investment and Incentives

Source: Shavell and Ypersele (2001)

 $\pi(t_a), \pi(t_b)$, and let $t(r) = t_b$ for $r > \pi(t_b)$. Social welfare becomes:

$$W_O(r) = \int_{t_a}^{t(r)} [p(k(r))s^*(t) - k(r)]g(t)dt + \int_{t(r)}^{t_b} [p(k(\pi(t)))(s^*(t) - l(t))k(\pi(t))]g(t)dt.$$
(7.15)

The derivative of (7.15) is

$$W'_{O}(r) = k'(r)[p'(k(r))E(s^{*}|t \le t(r)) - 1]G(t(r)) + t'(r)p(k(r))l(t(r))g(t(r)),$$
(7.16)

where G is the cumulative distribution function of g and $E(s^*|t \leq t(r))$ is the expected value of $s^*(t)$ conditional on $t \leq t(r)$. First term in (7.16) is the inframarginal effect, representing the increase in research investment when the innovator chooses reward. Second term is the marginal effect, i.e. the effect from innovators deciding to accept reward instead of to patent their products. This effect does not change investment because the reward is equal to monopoly profits when this change happens, it only eliminates deadweight loss.

First term of (7.16) is nonnegative and second term is positive when $r < E(s^*|t \le t(r))$ is positive (thus $[p'(k(r))E(s^*|t \le t(r))-1]$ is positive). Since $s^*(t_a) < E(s^*|t \le t(r))$ the optimal reward r^{**} is always greater than $s^*(t_a)$. If the optimal reward is greater than $\pi(t_b)$ the system is equivalent to a mandatory reward r^{**} .

7.4.6 Optional Reward versus Patent

Suppose an optional reward system with $r = \pi(t_a)$. In this case the innovator would choose to patent his or her invention (except on a set of measure zero, when $t = t_a$). But in this point $W'_O(r) > 0$, hence to increase the reward raises welfare. This result shows that an optional reward system is superior to a patent system.

7.4.7 Optional Reward versus Reward

Both optional reward and reward may be superior to each other. If patent is superior to reward, then optional reward is superior to reward since optional reward is superior to patent. But even when reward is superior to patent, optional reward may be superior to reward.

Reward may be superior to optional reward when the demand curve is too high and patent is chosen under optional reward. In this situation non optional reward prevents the choice of patents, avoiding deadweight losses.

7.4.8 Rewards Conditional on Quantity Sold

If government can observe quantity sold q and use this information to choose reward, the results are better. In this case, reward is now r(q) and the innovator chooses k(r(q(t))). Assuming that he or she can not influence q(t), welfare in this scenario is

$$W_{r}(r(q)) = \int_{t_{a}}^{t_{b}} [p(k(r(q(t)))s^{*}(t) - k(r(q(t)))]g(t)dt$$

=
$$\int_{q_{a}}^{q_{b}} [p(k(r(q)))E(s^{*}|q) - k(r(q))]f(q)dq,$$
 (7.17)

where $E(s^*|q)$ is the mean of $s^*(t)$ given that q(t) = q, f(q) is the density of q derived from g(t) and $q_i = q(t_i)$. From (7.17) it is easy to see that optimal r(q) is $E(s^*|q)$. Conditional optimal is usually different from unconditional optimal and therefore, it is superior. This means that an optional conditional reward is more superior to a patent system than an unconditional one.

7.4.9 Discussion

The authors discuss that one possible alternative system would be to combine patents and rewards. In this case, investment would be close to the first-best because of the underinvestment problem, which is diminished with the reward system. But this alternative is still dominated by optional reward. To see this, let the optional reward be $r + \pi(t_a)$, then just follow the same steps from section 7.4.6.

One great problem is how to determine the reward. The authors defend that the government should use sales data and, when possible, frequency of use of music, computer software and television production to define the reward. Using this system the government does not need to fear the existence of incentives to ask for rewards if the invention is not relevant. But as Kremer (1998) points: "General Motors could stick a useless piece of metal onto a Chevrolet, and as long as the automobile sold due to other attractive features, GM could argue it deserved the reward." The authors claim that the government could supplement rewards on an annual basis.

Another point is the difference between government and innovators information. They claim that ex-ante innovators' information is substantially imperfect and government's information will be reasonably good ex-post. So, as long as rewards are based on ex-post information, and the government's ex-post information is as good as the innovator's ex-ante information, not only optional rewards, but also mandatory rewards are superior to intellectual property rights.

The race to be first, subsequent innovations and administrative costs are problems that affects both rewards and patents, therefore there are no clear winner in these issues.

One point not discussed is the distortion caused by financing the reward system, which may reduce benefits from the reward system.

Shavell and Ypersele (2001) argue that optional reward has many advantages over the patent system, including practical ones. The industry should not object it because it could only raise profits. And since the system is optional, the government would not try to pay too little as rewards. They suggest that this system would have more advantages in areas where social losses caused by intellectual property rights are high, e.g. pharmaceuticals, computer software, and recorded music and visual products.

7.5 Lerner (2002)

This paper analyses impacts of changes in patent policy in sixty nation over 150 years. He is interested in the impact of these changes on quantity of patent applications. He uses two measures of fillings: domestic ones (in the country changing policy) and applications in Great Britain, a country where patent policy was relatively constant.

The author examined a number of guides to patent activity, the World Intellectual Property Office's (WIPO) publications and various national patent offices publications to determine patent policy changes and their impact on number of fillings.

The analysis shows that changes in policy that strengthen patent protection reduce the number of patent applications both in Great Britain and in the country where changes take place. Therefore, such changes did not incentive innovation.

The author also examined some predictions of theoretical literature. He finds that raise patent protection in countries with already strong patents has little impact on innovation. The same happens if its per capita GDP is much lower than other nation's. There exist endogeneity problems in this analysis, but the author employs instrumental variables to address them.

7.5.1 Theoretical Perspectives

A great part of economic literature assumed that stronger patent protection increases innovation rate. The necessary assumption for this conclusion is that patents do not affect incentives to future innovations.

When this assumption is dropped, conclusions may change. Research on sequential innovation shows that strong patents may reduce incentives to innovate and they may cause less innovation than no patent protection at all.

The strength of patent protection in a country also affects the impacts of policy changes. When patents are weak and their strength is increased, innovators receive larger rewards for their inventions. But increases in strength when patents are strong may incentive competitors to invent around the original innovation. This reduces the reward to the original inventor, thus reducing incentive to innovate.

Another factor that affects the impact of policy shifts is the nation's stage of development. One possible setting is where modest investment will probably result in substantial innovation but beyond some threshold, discoveries become much more costly. In this setting, an increase in patent protection is likely to have little effect on innovation rate. This is probably the case of developing nations.

The author exams the number of patent fillings by residents of 60 countries to evaluate effects of policy changes. The paper evaluates the quantity of patents in the country where the change happens and in Great Britain that had a stable policy during the period studied.

There is no clear mapping between innovative activity and patent applications. There are fillings for very modest innovations and there are also many important discoveries that are not patented. There is little to do about these problems since data about them are not consistently available.

Lerner (2002) analyzes differences in patent applications associated with policy changes. If the propensity to patent do not vary, this value is a good proxy for changes in innovative activity. Another way to achieve better results is examining patent fillings not only in one country, but also in Great Britain, a country that kept its patent policy relatively stable. He used the overall growth in patent applications as a control for patenting trends.

The number of fillings by foreign entities helps the identification of significant policy shifts: a policy change that increases patent protection induces foreign firms to seek patent protection.

7.5.2 Constructing the Data Set

Lerner (2002) utilized on his data set the sixty countries with highest GDP in 1997, according to the International Monetary Fund's International Financial Statistics (1999). The sample starts in 1850 or the political independence of the country, whichever comes later. The author determined significant changes on patent policy in guidebooks to the world patent systems, publications of the British Patent Office (Commissioners of Patents' Journal), the Patent Office Society (Journal of the Patent Office Society and related titles), the publisher Trade Activities (Patent and Trade Mark Review), and the WIPO (Industrial Property and La Propriete Industrielle), legal monographs on individual nations' patent systems in the collections of Harvard University and the Max Planck Institute for Foreign and International Patent, Copyright and Competition Law.

The selection of events was guided by five principles. First, governments had intention to change policy. This principle eliminated changes within five years of establishment of a nation, its restoration after being part of another nation or a revolution that changed the regime of government. Temporary policy changes during wartime were also excluded.

Second principle was date accuracy. When the author could not determine the year of change, he eliminated it from the sample.

Third principle excluded changes that altered scope of patents because it would be very difficult to interpret the dependent variable. Suppose scope of patents is broadened. Is the reduction on patent fillings caused by a decline on innovation or by the fact that a single patent now covers the equivalent to several fillings before the change?

Since the author wanted to compare reactions of domestic and foreign firms to changes, fourth principle eliminated changes that happened at the same time as policy changes that affected only foreign applicants.

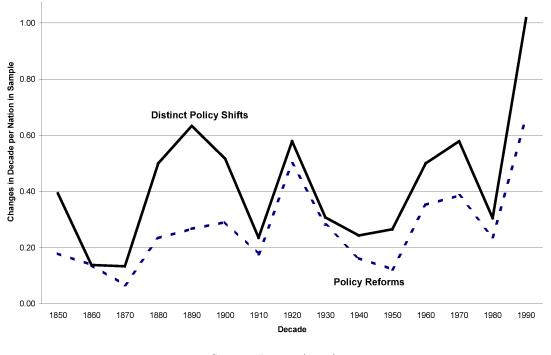
Lastly, Lerner (2002) only wanted substantive changes in patent policy. These include the following cases: when a country had no patent protection at all in general or in certain classes of discoveries, modifications on duration of patents to domestic applicants, changes on the cost of patents and modifications on the period of time after which a patent could be revoked or compulsory licensed if it was not worked.

Changes in patent costs are considered only when the raise was higher than 100% or the new cost was lower than 50% of previous one. When several payments were required, net present value was considered.

The sample includes a total of 177 events in 51 out of the 60 countries. There are cases where the change affected several elements of patent policy and where two bills about patents passed in the same year. These are counted as one event.

Figure 7 shows the number of events and policy changes during each decade, normalized by the number of active countries at the beginning of the decade.

Figure 7: Number of changes in patent policy over time. The sample consists of the sixty largest countries (by gross domestic product) at the end of 1997, observed from 1850 (or the date of inception as an independent entity) to 1999. The chart presents the number of policy reforms, as well as that of distinct policy shifts, in each decade, normalized by the number of active countries in the sample at the beginning of the decade.



Source: Lerner (2002)

The author then measures how many patent applications residents of a country where an event happened filled in Great Britain, in their own country and foreign residents filled in a country where a change happened. Only traditional patents are counted, when it is possible to determine their number without other types of prizes.

Lerner (2002) found data on domestic and foreign applications in the country for 145 event windows and British application data for 171 windows. These windows are periods from five years before to five years after policy change. The author collected information about population of countries, per capita GDP and occurrence of war during more than 3 months within the country affecting more than 10% of its territory, or changes of more than 10% in population or area of the country caused by changes in a country's borders.

7.5.3 Analysis of Patent Protection

Panel A from table 7 shows changes in patent fillings from two years before to two years after a policy change. Missing observations are replaced by data from one or three years before or after to raise the number of observations.

Observations are divided into two groups according to the type of policy change. Changes that increased patent protection (64%) constitute a group and changes that are either ambiguous (12%) or diminished patent protection (24%) constitute another group.

Domestic and foreign applications increased in countries that enhanced patent protection, while British fillings did not. But these numbers are not controlled by the propensity to patent in the period.

The same data is reported on panels B and C adjusted by two indexes used to capture trends. These indexes use data from the ten nations with the longest time series of patent application data. First one assigns equal weight to every nation, and second weights each observation by patent applications. The adjusted observations are computed by

$$A_{+2} - A_{-2} - \left[\frac{I_{+2} - I_{-2}}{I_{-2}} * A_{-2}\right], \qquad (7.18)$$

A represents the number of fillings and I represents the level of the index.

After adjustment, a change in policy that strengthened patents caused the decline of patent applications by residents of the country where the change took place both in the country itself and in Great Britain while foreign patent raised. Changes in fillings had much lower magnitude when policy changes were ambiguous or protectionreducing.

Table 7 also shows results for the three most frequent types of changes: enhancements of patent's coverage, length of patents and length of the working period. These changes represent 56%, 50% and 21% respectively of the total of changes. Table 7: Impact of a change in patent policy on patenting activity. The sample consists of 177 changes in patent policy between 1852 and 1998 in 60 nations. Panel A displays the change in the number of unadjusted patent applications filed from two years before the event to two years after the event by domestic entities residents of the country undertaking the policy change in Great Britain and in the country undertaking the change, and foreign entities filling in the country undertaking the change. In Panels B and C, these changes are shown net of equal-weighted and value-weighted indexes of patenting in the ten nations with the longest time series of application data. Underneath each adjusted change, the absolute t-statistic of the difference of the change from zero is displayed. In all tests, each observation is weighted by the inverse of its standard deviation of the annual change in patenting from 20 to five years before the policy change.

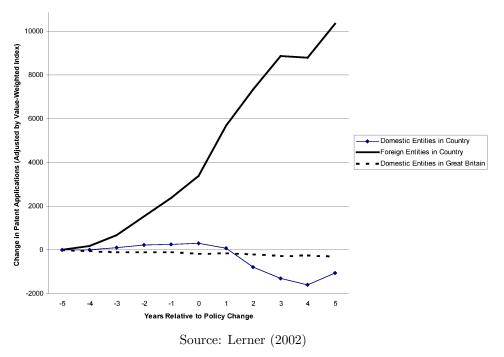
| Panel A: Unadjusted Changes in Patenting Around Policy Changes | | | | |
|--|--------------------|---------------------|--------------|--|
| U | Residents' | Domestic Entities | Foreign | |
| | Patenting in | Patenting | Patenting | |
| | United Kingdom | in Country | in Country | |
| Positive Patent Policy Changes | -27 | +2424 | +8662 | |
| Ambiguous/Negative Changes | +210 | +529 | +1401 | |
| Positive Changes Involving Coverage | -63 | +2233 | +9739 | |
| Positive Changes Involving Duration | -80 | +2399 | +10957 | |
| Positive Changes Involving Working Periods | -34 | -1081 | +3191 | |
| Panel B: Changes in Patenting Around | Policy Changes, Ad | ljusted by Equal-We | ighted Index | |
| | Residents' | Domestic Entities | Foreign | |
| | Patenting in | Patenting | Patenting | |
| | United Kingdom | in Country | in Country | |
| Positive Patent Policy Changes | -101 | -1617 | +4979 | |
| | ***[4.61] | *[1.86] | **[2.41] | |
| Ambiguous/Negative Changes | -217 | -525 | +390 | |
| | ***[3.19] | [0.34] | [1.28] | |
| Positive Changes Involving Coverage | -98 | +1915 | +7704 | |
| | ***[5.13] | [1.03] | **[2.58] | |
| Positive Changes Involving Duration | -190 | -4714 | +5699 | |
| | ***[4.68] | **[2.22] | *[1.84] | |
| Positive Changes Involving Working Periods | -27 | -1239 | +2772 | |
| | [1.33] | *[1.84] | [1.31] | |
| Panel C: Changes in Patenting Around | | | | |
| | Residents' | Domestic Entities | Foreign | |
| | Patenting in | Patenting | Patenting | |
| | United Kingdom | in Country | in Country | |
| Positive Patent Policy Changes | -100 | -932 | +5617 | |
| | ***[4.52] | *[1.69] | ***[2.85] | |
| Ambiguous/Negative Changes | -137 | -408 | +501 | |
| | **[2.40] | [0.07] | [1.65] | |
| Positive Changes Involving Coverage | -111 | +1781 | +7963 | |
| | ***[5.12] | [0.94] | **[2.57] | |
| Positive Changes Involving Duration | -186 | -3347 | +6690 | |
| | ***[4.63] | **[2.14] | **[2.36] | |
| Positive Changes Involving Working Periods | -27 | -1289 | +2809 | |
| | [1.29] | *[1.89] | [1.27] | |

* = Significant at the 10% confidence level; ** = significant at the 5% level; *** = significant at the 1% level.

Lerner (2002) also reports the statistical significance of these changes following a method used in finance literature. The author calculates standard deviations of changes in patent applications from 20 years before to 5 years before the policy change and then weighted t-tests and regression analyses by the inverse of standard deviation. This method shows that the fall of patent fillings by residents in response to an increase in patents protection is significant. The increase in patent applications by foreigners is also significant which suggest that the set of changes is significant.

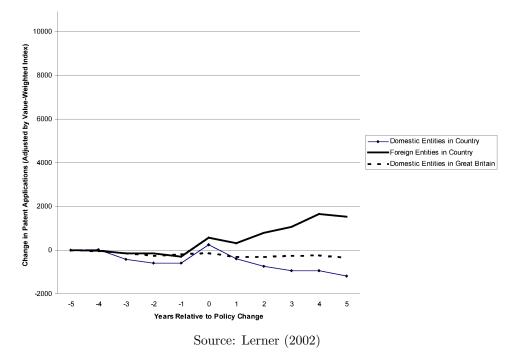
Figure 8 shows average change in patent fillings around changes that increase patent protection and figure 9 shows average for other policy modifications. They confirm what table 7 reports.

Figure 8: Patenting changes around the time of patent protection-enhancing policy changes. The sample consists of 177 changes in patent policy between 1852 and 1998 in the sixty largest countries (by gross domestic product) at the end of 1997. The figure displays the change in the number of patent applications filed between five years before the event and five years after the event by domestic entities filing in the country undertaking the change, foreign entities filing in the country undertaking the change, and residents of the country undertaking the policy change in Great Britain. These changes are shown net of a value-weighted index of patenting in the ten nations with the longest time series of application data.



The author also constructs indexes for each class of number of applications, but

Figure 9: Patenting changes around the time of patent protection-reducing or ambiguous policy changes. The sample consists of 177 changes in patent policy between 1852 and 1998 in the sixty largest countries (by gross domestic product) at the end of 1997. The figure displays the change in the number of patent applications filed between five years before the event and five years after the event by domestic entities filing in the country undertaking the change, foreign entities filing in the country undertaking the change, and residents of the country undertaking the policy change in Great Britain. These changes are shown net of a value-weighted index of patenting in the ten nations with the longest time series of application data.



no significant changes are reported. He also adjusts the index restricting it at all times to nations whose per capita GDP was below 75% of that of the wealthiest nation to avoid distortions caused by developed nations in the index. Again, no significant changes are reported.

Lerner (2002) also analyses cross-sectional differences in the sample. He estimates regressions of adjusted growth in patent applications as dependent variable. The main independent variables are a dummy denoting a change that increases patent protection and a dummy denoting if protection before policy change was strong; a dummy denoting if protection was weak before the change or per capita GDP of the country relative to the wealthiest nation at the time of change. Strong policies have patent life of eighteen or more years while weak ones have patent life of ten years or less. Interactions between these variables are also included in regression.

The control variables are type of policy change, presence of a war within the country border, number of patent fillings two years before the change, population of nation and change in the country's border.

Results are reported on tables 8 and 9. On table 8, the dependent variable is the number of patent applications in Great Britain by residents of the country where the policy changes. Results confirm part of the theoretical basis. The interaction between the dummy variable denoting strong patent protection before the policy change and the one denoting an increase in patent protection is negative and significant at 5% level in first and second regressions. In fourth regression, the interaction between relative GDP and the dummy denoting an increase in patent protection is significantly positive. These results suggest that increases in patent protection are less effective in developing countries and when patent protection is strong before the change.

The dependent variable in table 9 is patent applications by residents in the country that promoted the policy change. Only two control variables are significant.

The author also does regressions with different event windows, additional control variables, different definition of patent protection's strength or weakness to check robustness of the results. He also estimates Heckman sample selection regressions and uses an instrumental variable to reduce endogeneity problems. None of these modifications changes significantly results, reported in table 10.

7.5.4 Conclusions

One important conclusion is that adjusted changes in patent application numbers by residents are negative when a policy change that increases patent protection is adopted. Another is the confirmation of predictions of economic theorists in crosssectional analysis.

The author points out the advantages of his methodology over other case studies in patents that analyze only a single case, while Lerner (2002) studied 177 policy changes in sixty countries over 150 years.

He also points out limitations of the analysis. One of them is that the study only

Table 8: Weighted least squares regression analyses of patenting in Great Britain by residents of the countries that underwent patent policy changes around the time of the changes. The sample consists of 177 changes in patent policy between 1852 and 1998 in the sixty largest countries (by gross domestic product) at the end of 1997. The dependent variable is the change in the number of patent applications filed by residents of the country undertaking the policy change in Great Britain from two years prior to the policy change to two years afterwards, net of either of a value-weighted (VW) or equal-weighted (EW) index of patenting in the ten nations with the longest time series of application data. The independent variables are dummy variables denoting whether the policy change entailed an unambiguous increase in protection and the aspects of patent policy that the change covered, variables denoting whether during the period the country began or ended a conflict on its territory or expanded or contracted its territory (with the former instance being coded as +1, the latter as -1, and all others as zero), the number of patent applications by domestic entities in Great Britain two years before the policy change, and the population of the nation at the time of the change. In addition, the various regressions include dummy variables denoting whether the country had a particularly strong or weak patent policy before the change, the nation's per capita gross domestic policy relative to the leading nation at the time, and the interaction of these measures with the dummy variable indicating an increase in patent protection. Each observation is weighted by the inverse of the standard deviation of the annual change in patent applications in Great Britain from twenty to five years before the policy change. Absolute t-statistics in parentheses.

| | Dependent Variable: Change in U.K. Patent Applications Net of | | | | |
|-------------------------------------|---|-------------------|--------------------|--------------------|--|
| | VW Index | EW Index | VW Index | EW Index | |
| Positive Patent Policy Change? | 165.94 [0.87] | ***598.53 [3.24] | 19.13 [0.11] | -333.42 [0.88] | |
| Strong Protection Prior to Change? | -249.34 [0.96] | 86.93 [0.35] | | | |
| Weak Protection Prior to Change? | | | 273.22 [0.32] | | |
| GDP as Percent of Leading Nation | | | | ***-1561.76 [2.92] | |
| Strong Protection * Positive Change | **-602.57 [1.99] | ***-980.07 [3.34] | | | |
| Weak Protection * Positive Change | | | -133.66 [0.14] | | |
| Relative GDP * Positive Change | | | | **1292.27 [2.15] | |
| Change Involving Coverage? | 50.74 [0.37] | 216.92 [1.65] | 32.63 [0.22] | 61.80 [0.42] | |
| Change Involving Duration? | -199.37 [1.41] | -79.30 [0.58] | -171.04 [1.06] | -135.68 [0.91] | |
| Change Involving Cost? | ***1014.88 [4.42] | ***1137.36 [5.12] | ***1059.91 [4.24] | ***1252.63 [5.26] | |
| Change Involving Working Periods? | *-335.37 [1.78] | -192.88 [1.06] | -249.62 [1.22] | -117.16 [0.61] | |
| Inception of Conflict? | -10.97 [0.04] | -332.82 [1.09] | 80.75 [0.24] | -118.82 [0.36] | |
| Change in Territory? | ***-1058.54 [3.37] | 130.20 [0.43] | ***-1042.61 [3.03] | -118.22 [0.35] | |
| Applications Two Years before Event | ***-0.12 [11.63] | ***-0.13 [13.14] | ***-0.12 [10.13] | ***-0.12 [10.03] | |
| Population of Nation | 0.07 [0.07] | 0.27 [0.29] | -0.14 [0.14] | -0.96 [0.94] | |
| Constant | 21.18 [0.09] | -523.10 [2.21] | -117.27 [0.50] | 428.65 [1.10] | |
| Number of Observations | 159 | 159 | 159 | 159 | |
| F-Statistic | 17.10 | 23.14 | 12.06 | 18.08 | |
| p-Value | 0.000 | 0.000 | 0.000 | 0.000 | |
| Adjusted R ² | 0.53 | 0.61 | 0.44 | 0.54 | |

* = Significant at the 10% confidence level; ** = significant at the 5% level; *** = significant at the 1% level.

Table 9: Weighted least squares regression analyses of domestic patenting by residents of nations undergoing patent policy changes. The sample consists of 177 changes in patent policy between 1852 and 1998 in the sixty largest countries (by gross domestic product) at the end of 1997. The dependent variable is the change in the number of patent applications filed by domestic entities in the country undergoing the policy change from two years prior to the policy change to two years afterwards, net of either a value-weighted (VW) or equal-weighted (EW) index of patenting in the ten nations with the longest time series of application data. The independent variables are dummy variables denoting whether the policy change entailed an unambiguous increase in protection and the aspects of patent policy that the change covered, variables denoting whether during the period the country began or ended a conflict on its territory or expanded or contracted its territory (with the former instance being coded as +1, the latter as -1, and all others as zero), the number of patent applications by domestic entities two years before the policy change, and the population of the nation at the time of the change. In addition, the various regressions include dummy variables denoting whether the country had a particularly strong or weak patent policy before the change, the nation's per capita gross domestic policy relative to the leading nation at the time, and the interaction of these measures with the dummy variable indicating an increase in patent protection. Each observation is weighted by the inverse of the standard deviation of the annual change in domestic patent applications from twenty to five years before the policy change. Absolute t-statistics in parentheses.

| | Dependent Variable: Change in Domestic Patent Applications Net of | | | | |
|-------------------------------------|---|------------------|------------------|------------------|--|
| | VW Index | EW Index | VW Index | EW Index | |
| Positive Patent Policy Change? | 1862.87 [0.76] | 2361.31 [0.82] | 2727.11 [1.32] | 2887.20 [0.59] | |
| Strong Protection Prior to Change? | -1079.46 [0.30] | -717.08 [0.17] | | | |
| Weak Protection Prior to Change? | | | -2018.17 [0.12] | | |
| GDP as Percent of Leading Nation | | | | 4630.29 [0.63] | |
| Strong Protection * Positive Change | 1657.97 [0.42] | 1230.48 [0.27] | | | |
| Weak Protection * Positive Change | | | -611.87 [0.04] | | |
| Relative GDP * Positive Change | | | | -615.17 [0.08] | |
| Change Involving Coverage? | 1153.91 [0.63] | 1311.54 [0.61] | 1423.43 [0.80] | 1861.75 [0.88] | |
| Change Involving Duration? | -373.71 [0.21] | -566.56 [0.27] | -746.30 [0.41] | -387.44 [0.19] | |
| Change Involving Cost? | 1979.52 [0.59] | 1872.51 [0.48] | 1580.56 [0.48] | 1226.20 [0.32] | |
| Change Involving Working Periods? | 1485.56 [0.53] | 1620.48 [0.50] | 1473.81 [0.53] | 1758.43 [0.54] | |
| Inception of Conflict? | -1639.60 [0.41] | -1523.63 [0.33] | -1999.77 [0.51] | -2125.00 [0.46] | |
| Change in Territory? | -1231.93 [0.36] | -934.01 [0.23] | -1215.29 [0.35] | 322.75 [0.08] | |
| Applications Two Years before Event | ***-0.23 [16.53] | ***-0.31 [18.95] | ***-0.24 [16.65] | ***-0.32 [18.64] | |
| Population of Nation | ***25.20 [3.05] | ***26.56 [2.74] | ***26.46 [3.22] | ***30.19 [2.94] | |
| Constant | -1449.71 [0.43] | -1500.72 [0.38] | -1756.58 [0.60] | -4797.64 [0.88] | |
| Number of Observations | 132 | 132 | 132 | 132 | |
| F-Statistic | 27.83 | 36.82 | 28.05 | 37.29 | |
| p-Value | 0.000 | 0.000 | 0.000 | 0.000 | |
| Adjusted R ² | 0.69 | 0.75 | 0.69 | 0.75 | |

* = Significant at the 10% confidence level; ** = significant at the 5% level; *** = significant at the 1% level.

Table 10: Instrumental variable regression analyses of patenting in Great Britain and domestically by residents of nations undergoing patent policy changes. The sample consists of 177 changes in patent policy between 1852 and 1998 in the sixty largest countries (by gross domestic product) at the end of 1997. The dependent variable is the change in the number of patent applications filed in Great Britain and domestically by residents of the nation undergoing the policy change from two years prior to the policy change to two years afterwards, net of an equal-weighted index of patenting in the ten nations with the longest time series of application data. The independent variables are dummy variables denoting whether the policy change entailed an unambiguous increase in protection and the aspects of patent policy that the change covered, variables denoting whether during the period the country began or ended a conflict on its territory or expanded or contracted its territory (with the former instance being coded as +1, the latter as -1, and all others as zero), the number of patent applications by domestic entities in Great Britain and domestically two years before the policy change, and the population of the nation at the time of the change. In addition, the various regressions include dummy variables denoting whether the country had a particularly strong patent policy before the change, the nation's per capita gross domestic policy relative to the leading nation at the time, and the interaction of these measures with the dummy variable indicating an increase in patent protection. A dummy variable denoting that the policy change took place in the ten years following the signing of the Paris Convention of 1883 and the preliminary version of the TRIPs agreement of 1993 is used as instrument for the measure of positive patent policy changes. Each observation is weighted by the inverse of the standard deviation of the annual change in patent applications in Great Britain and domestically from twenty to five years before the policy change. Absolute t-statistics in parentheses.

| | Dependent Varia | ble: Change in Paten | t Applications, Net of E | qual-Weighted Index | |
|-------------------------------------|-------------------|----------------------|--------------------------|---------------------|--|
| | Applications in | n Great Britain | Domestic Applications | | |
| Positive Patent Policy Change? | ***7737.47 [3.00] | -3342.62 [0.87] | -7243.45 [0.37] | 6075.96 [0.19] | |
| Strong Protection Prior to Change? | **4546.50 [2.28] | | -3062.68 [0.16] | | |
| GDP as Percent of Leading Nation | | **-9152.71 [2.48] | | 15135.62 [0.57] | |
| Strong Protection * Positive Change | **-6671.86 [2.48] | | 1621.90 [0.07] | | |
| Relative GDP * Positive Change | | **10667.92 [2.06] | | -18925.80 [0.49] | |
| Change Involving Coverage? | **1137.27 [2.15] | -115.15 [0.31] | 202.25 [0.07] | 1569.60 [0.56] | |
| Change Involving Duration? | 133.54 [0.29] | -529.23 [1.50] | -1912.28 [0.86] | -926.64 [0.39] | |
| Change Involving Cost? | **2655.75 [2.12] | **2128.94 [2.56] | -2480.94 [0.44] | -1792.07 [0.28] | |
| Change Involving Working Periods? | **3322.78 [2.26] | 1438.40 [1.57] | -5693.91 [0.58] | -4964.26 [0.77] | |
| Inception of Conflict? | *-2221.32 [1.79] | -202.12 [0.23] | -104.44 [0.02] | -627.54 [0.11] | |
| Change in Territory? | -1380.91 [1.17] | **-2111.38 [2.14] | 1875.57 [0.29] | 4339.82 [0.66] | |
| Applications Two Years before Event | -0.12 [3.52] | ***-0.08 [2.79] | ***-0.24 [9.49] | ***-0.24 [9.84] | |
| Population of Nation | 3.45 [1.08] | -4.12 [1.55] | 22.52 [1.41] | 30.62 [1.64] | |
| Constant | ***-7283.29 | 2883.99 [1.01] | 8720.00 [0.47] | -3886.16 [0.16] | |
| | [2.94] | | | | |
| Number of Observations | 159 | 159 | 132 | 132 | |
| F-Statistic | 3.08 | 5.34 | 11.29 | 11.34 | |
| p-Value | 0.001 | 0.000 | 0.000 | 0.000 | |

* = Significant at the 10% confidence level; ** = significant at the 5% level; *** = significant at the 1% level.

considers patents. How do trade secrecy, prizes for discoverers, tournament behave at the time of patent policy change? Another important question is how the judicial system interprets new policies: does it actually apply the changes?

Another important limitation is the measure of innovation utilized. The long time frame did not allow to use other measures, e.g. R&D spending, total factor productivity growth and innovations' counts.

7.6 DiMasi, Hansen, and Grabowski (2003)

In this paper, the authors estimated the average cost of develop a new drug. They found that capitalized average cost is US\$ 802 million (2000 dollars) per new drug.

The estimation is based on micro-level data, obtained from pharmaceutical firms though confidential surveys. These surveys asked about a random sample of drugs developed by the firm. Drugs in the sample were initially tested in human beings during the period 1983-1994. In order to obtain an accurate estimation of the expected cost of development, costs of projects that resulted in failure had to be allocated to the successful ones.

The drug development process goes through several phases: discovery of the compound, preclinical development, clinical testing and application for marketing approval. In this study, it is not possible to separate costs of discovery of the compound from costs of preclinical development.

Clinical testing has three successive phases. In phase I, a few healthy volunteers are tested to obtain information about dosage, absorption, distribution, metabolic effects, excretion and toxicity of the compound.

In phase II, subjects with the disease targeted by the compound are tested to verify its safety and to obtain preliminary data about efficacy. This phase may involve hundreds of subjects. In the last phase, subjects are tested to firmly establish efficacy and uncover infrequent side effects. To gather these information, thousands of subjects may be necessary.

Because the development cost is highly dependent on time and on the development phase in which it is abandoned, data are stratified on the length of time of clinical testing and whether or not an application for market approval was filled in the FDA. This application may be a new drug application (NDA) or a biological license application(BLA).

The expected clinical cost is:

$$C = E(c) = p_I \mu_{I|e} + p_{II} \mu_{II|e} + p_{III} \mu_{III|e} + p_A \mu_{A|e},$$

where p_I, p_{II} and p_{III} are the probabilities of a random selected compound enter phases I-III respectively and p_A is the probability of long term animal testing be conducted during the clinical phase. The μ 's are conditional expectations, i.e. the population mean costs for drugs that enter each phase. If one assumes that p's and μ 's are stochastically independent, the expected value C is an unbiased estimate of the population's expected value.

Estimation of parameters p's is done though a two-stage statistical process using drugs in the Tufts Center for the Study of Drug Development (CSDD) database that were first tested in humans between 1983 and 1994.

Preclinical costs are obtained from aggregate data at firm level on spending prior to human testing and on human testing from 1980 to 1999. These data are used to obtain a ratio of R&D expenditures prior to human testing and on human testing using a lag structure because expenditure prior to human testing should occur before the associated human testing cost. This ratio is then multiplied by estimated clinical cost to obtain the estimated pre-human R&D cost.

A cost timeline is established and expenditures are capitalized at an adequate discount rate. In this study the authors use 11% as real cost of capital baseline value. This value is obtained by the difference between nominal cost of capital and inflation rate.

Results of out-of-pocket cost in clinical period are reported in table 11. Mean cost, median cost, standard deviation, N, probability of entering the testing phase and expected cost are presented for each phase.

Table 12 presents the results of mean phase lengths, mean time between successive phases, capitalized mean phase cost and capitalized expected phase cost.

The estimated ratio of preclinical to total R&D expenditure is 30%. This ratio

| Testing phase | Mean cost | Median cost | Standard deviation | N ^b | Probability of entering phase (%) | Expected cost |
|------------------|-----------|-------------|--------------------|----------------|--------------------------------------|---------------|
| Phase I | 15.2 | 13.9 | 12.8 | 66 | 100.0 | 15.2 |
| Phase II | 23.5 | 17.0 | 22.1 | 53 | 71.0 | 16.7 |
| Phase III | 86.3 | 62.0 | 60.6 | 33 | 31.4 | 27.1 |
| Long-term animal | 5.2 | 3.1 | 4.8 | 20 | 31.4 | 1.6 |
| Total | | | | | | 60.6 |

Table 11: Average out-of-pocket clinical period costs for investigational compounds (in millions of 2000 dollars)^a

^a All costs were deflated using the GDP Implicit Price Deflator. Weighted values were used in calculating means, medians, and standard deviations.

^b N: number of compounds with full cost data for the phase.

Source: DiMasi, Hansen, and Grabowski (2003)

Table 12: Average phase times and clinical period costs for investigational compounds (in millions of 2000 dollars)^a

| Testing phase | Mean phase length | Mean time to next phase | Capitalized mean phase cost ^{b,c} | Capitalized expected phase cost ^{b,c} |
|------------------|----------------------|----------------------------|---|--|
| Phase I | 21.6 | 12.3 | 30.5 | 30.5 |
| Phase II | 25.7 | 26.0 | 41.6 | 29.5 |
| Phase III | 30.5 | 33.8 | 119.2 | 37.4 |
| Long-term animal | 36.5 | _ | 9.5 | 3.0 |
| Total | | | | 100.4 |

^a All costs were deflated using the GDP Implicit Price Deflator. Weighted values were used in calculating means, medians, and standard deviations for costs and phase times. Phase times are given in months.

^b The NDA approval phase was estimated to be 18.2 months. Animal testing was estimated to begin 4.2 months after the initiation of phase I.

^c Costs were capitalized at an 11% real discount rate.

Source: DiMasi, Hansen, and Grabowski (2003)

was used to estimate preclinical out-of-pocket and capitalized cost per approved new drug as US\$ 121 and 335 million, respectively.

Therefore full out-of-pocket estimate is US\$ 403 million and the capitalized estimate is US\$ 802 million.

There are several diseases with social costs larger than the values found and yet no effective treatment or vaccine, as patents alone cannot generate the necessary incentives to their development.

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