An Alternative Patent Mechanism for Pharmaceutical Drugs for Tropical Diseases

Abdülkadir Civan*

ABSTRACT

It is obvious that there is so little R&D on diseases disproportionably affecting underdeveloped countries while there is so much need for them. Unfortunately proposed solutions in the literature have not eliminated the problem completely. In this paper I try to answer why there is so little R&D on poor country diseases question and propose an alternative patent mechanism to encourage more R&D. Increasing the patent length from its current 20 year period for the diseases which are disproportionally affecting the poor countries would certainly increase R&D investments and can be socially optimal. Thus I suggest that in contrast to the current and past practice the poor countries should provide a higher patent protection for pharmaceutical drugs than developed countries.

Key Words:

Pharmaceuticals, Patents, Research and Development, Drug Innovation.

* Department of Economics, Fatih University, B. Cekmece, Istanbul, TURKEY, kcivan@fatih.edu.tr

Introduction

The types of health problems faced by different countries vary substantially. Many health problems which are basically eradicated in developed countries long times ago, still claims of millions of lives in underdeveloped regions. Three major diseases malaria, HIV, and tuberculosis kill approximately five million people each year, almost all of them in poor countries. Beyond well known malaria, HIV and tuberculosis examples; there are other significant infectious diseases especially in Africa and Southeast Asia Table 1 lists the mortality and morbidity burdens of different health problems on country groups by income level. Infectious and parasitic diseases account for more than 25 percent of the disease burden in low- and middle-income countries, compared to only 2,5 percent in high-income countries. On the other hand cancers and cardiovascular diseases claims more than 60 percent of all deaths in the high income countries while the same health problems cause only 25 percent of deaths in the poorest countries.

There are numerous other diseases which practically nonexistent in developed countries while causing millions of deaths in poor countries. Table 2 presents these diseases concentrated on poor countries. For some of these diseases there are well known and cheap treatment alternatives. Since these countries struggle with significant political, social, and economic problems, even those cheap treatments are not affordable. International organizations and charitable foundations are working to provide treatment options for them. However for some of those health problems there are no known effective treatments yet.

The last century has been filled with success stories of medical care discoveries. Significant portion of health improvement in developed countries is presumed to be due to the development in medical knowledge and technology. Moreover; there is a growing empirical evidence that new drugs have played a central role in increased longevity, enhanced quality of life and improved labor force participation and productivity. In other words the pharmaceutical drugs can be very effective on either treating or immunizing against diseases[1]. So it can be argued that if enough resources are spent on finding new treatments for diseases like malaria there would be substantial mortality and morbidity gains. However even a casual observation suggests that not enough resources are spent on finding cures for these diseases which are disproportionally affecting poor countries. Relative to this enormous social need, very little R&D is targeted toward developing new drugs for diseases concentrated in poor countries. According to Pecoul et al (1999), of the 1233 drugs licensed worldwide between 1975 and 1997, only 13 were for tropical diseases. Of these 13, five came from veterinary research, two were modifications of existing medicines, and two were produced for the US military operating abroad; only four were developed by pharmaceutical companies for tropical diseases of humans.

It is obvious that there is so little R&D on diseases disproportionably affecting underdeveloped countries while there is so much need for them. Unfortunately proposed solutions have not eliminated the problem completely. In this paper I try to answer why there is so little R&D on poor country disease question and propose an alternative patent mech-

anism to encourage more R&D. Specifically I suggest that in contrast to the current and past practice the poor countries should provide a higher patent protection for pharmaceutical drugs than developed countries.

I propose a differential patent system for the diseases affecting developed countries and for the diseases affecting underdeveloped countries. Currently World Trade Organization requires all countries to provide 20 years of patent protection for all patentable goods. However there is no economic rationale for this uniform patent period across countries and across goods. It can be shown that optimal patent period would be different for the products in different sectors. A long period of patent protection would be needed if the fixed costs are substantial while a shorter patent protection period would be required to recoup fixed costs if they are small. Similarly if a product has a significant sale potential for a given time period; a relatively shorter period of patent protection would be enough to recoup fixed costs. However in order to convince entrepreneurs to invest in products that have smaller sale potential for a given time period, governments should provide longer patent protection. In other words if a higher R&D investment is wanted on certain diseases, providing longer patent protection would convince investors to concentrate their efforts on those areas. Since the potential customers for the drugs for tropical diseases are poor, their sales potential per unit time period is necessarily smaller than other drugs.

Background and Previous Studies

Since these diseases still claim millions of lives each year, the issue became the subject of intense global attention. Several potential solutions are proposed to develop new drugs for these diseases.

A significant portion of pharmaceutical R&D investments is made by private firms. As the firms in other industries drug companies are motivated by potential profits. Decisions on innovation (R&D) are based on expected profits due to a temporary competitive advantage originating from the innovation. (Schumpeter, 1942) Pharmaceutical companies are investing resources in new drugs due to potential profit opportunities. However; since citizens of poor countries are poor, patients living there do not have ability and willingness to pay for high prices for the new drugs. Thus profit opportunities are limited for these diseases. Numerous studies have shown that drug companies had little interest on R&D investments to develop drugs for diseases of poor nations.

The effect of potential profits on pharmaceutical R&D has been analyzed by various scholars. Acemoglu and Linn (2004) find a large effect of potential market size on the entry of new drugs. Lichtenberg (2005) concludes that drug development is positively related to the burden of disease in developed countries but not the burden of disease in underdeveloped nations. Similarly Civan and Maloney (2006, 2007) find that research in the drug industry is driven by the demand from the United States and the disease burden in underdeveloped countries has no impact on pharmaceutical R&D.

Finding new drugs and conducting necessary tests to prove them ''safe'' and ''effective'' is very expensive. Dimasi et all (2003) estimate that developing a new drug costs approximately $800 million in the United States. Part of the reason for the high cost is that most new chemical entities fail to reach the market. Less than 1 percent of the new chemical compounds examined are used in human testing and approximately 20 percent of those compounds finally gain FDA approval. On the other hand the marginal production costs are relatively small. Moreover, unlike some other high fixed cost industries, the imitation of the existing drugs is relatively low-tech and cheap. Thus patent protection is crucial in motivating profit maximizing companies to invest in R&D projects. The special significance of patents to pharmaceutical companies has been shown in by Levin, et al, (1987) and Cohen et al, (2000) studies. They conducted surveys of R&D managers in various industries to identify which factors are most important in appropriating the benefits from their innovations. Both studies find that the pharmaceutical industry placed the highest importance on patents. By contrast, many other high tech industries, such as computers and semiconductors, placed greater importance on factors like lead-time and learning by doing efficiencies. In a survey study Mansfield (1986) concludes that in the absence of patent protection 60% of developed pharmaceutical products would not have been developed. Similarly According to Taylor and Silberston (1973) pharmaceutical R&D in UK would be reduced by 64 percent in the absence of patent protection.

However prior to 1995, there were more than 50 countries that did not provide any patent protection to the pharmaceuticals. Most of those were underdeveloped countries. It has been argued by many that was the main reason why pharmaceutical companies are not investing on poor country diseases and if patent protection is strengthened they would invest more on these diseases. In this environment the member countries of World Trade Organization signed a treaty (TRIPS) which requires all countries to provide a relatively strong patent protection to the pharmaceuticals in 1995. The proponents of the treaty anticipated a rise on pharmaceutical R&D for tropical diseases. However; many were opposed to the TRIPS, underdeveloped countries were simply too poor to pay the necessary prices to recover the huge fixed R&D costs. According to opponents patent protection is irrelevant; these countries would never be potential profitable markets for new drugs with patents or without patents. Two influential theoretical papers by On Chinn and Grossman (1990) and Deardoff (1992) conclude that under most circumstances the TRIPS would have negative effects on welfares of poor countries..

Lanjouw and Cockburn (2001) find no significant increase in research for developing country diseases such as malaria after TRIPS. In the follow-up study Lanjouw and MacLeod (2005) find that the level of innovative activity related to diseases specific to poor countries remains very low relative to pharmaceutical research overall. However the study shows a small but positive effect of TRIPS. The diseases which still in need of better low-cost treatments have seen a trend increase in its share of patenting and bibliometric citation after TRIPS. In the case of patenting, a possible beginning of a speeding up of trend increase in the early 2000's is observed, but it is too early to be confident that it will persist.

Moreover after TRIPS countries like India, Brazil and South Africa with relatively established domestic drug industry were expected to develop new drugs for the under-developed country diseases. However, a survey study by Lanjouw and Macleod (2005) suggests that Indian pharmaceutical companies still focus on the diseases with potential markets in developed world. TRIPS agreement did not provide enough incentives for Indian firms to invest on tropical diseases.

Many considers this relatively disappointing evidence on the effects of TRIPS as treaty as very troublesome. They believe that it is still too soon to observe the impact considering how long it takes to develop a new drug to the market. In addition to that, in 1995 when TRIPS was signed, full implementation was not certain. Thus it is normal that pharmaceutical companies did not immediately start to invest on tropical diseases.

The experience showed that market system alone is not able to make enough R&D investments for technological innovations to solve the health problems of poor countries; thus public involvement is required to accelerate the innovations. Public institutions and non-profit organizations can help the innovation on these neglected diseases by funding for basic research through grants to academics, public investments in development, research and development tax credits, and work in government laboratories or rewarding developers for innovating new drugs. A non-trivial portion of R&D expenditures on pharmaceutical companies is sponsored by government agencies. So et al (2005) concludes that between 60 and 75% of innovative new drugs developed in the last decades in US would not have been developed or would have been delayed significantly absent public sector research. However, as expected governments of poor countries do not and cannot be active on these sponsorship activities. Governments of developed countries naturally prioritize the diseases which are more relevant for their own citizens. It is not politically feasible for European or US governments to spend too much on tropical diseases.

Another mechanism to encourage innovation for the diseases that are disproportionally affecting the poor countries is 'Advance Purchase Commitments'. These programs are trying to increase profit potentials for innovating firms. The basic structure of an advance market commitment is that sponsors commit (prior to product development) to fully or partially finance purchases of drugs for poor countries at a pre-specified price. Sponsors would sign a contract underwriting a guaranteed price for the drug supplier. A purchase guarantee would provide the establishment of a fund to purchase a pre-determined amount of a new drug or other medical product meeting a given therapeutic profile for a neglected disease. Once the drug is developed poor countries would buy it at a low price, and sponsors (aid agencies etc…) would guarantee to top-up to a higher price. Thus a normal market return for the developer is provided. Once the full number of treatments has been purchased at the guaranteed price, the supplier would be required to either selling further treatments at an affordable price, or to licensing the technology to other companies.[2] This type of commitment would allow for a return on expected R&D out-

2 See Kremer (2000) for a very detailed discussion of advance purchase commitments for vaccines.

lays. As discussed on the preceding sections normally the potential consumers of the new drugs for neglected diseases are very poor; the expected profits are very low or even negative for the investors in these new drugs. Even if international organizations and other NGOs allocate considerable amount of resources to neglected diseases time-inconsistency problems make drug companies to be very reluctant on investing on these diseases. Once private pharmaceutical companies develop new drugs, governments and aid institutions often use their power as dominant purchasers and regulators to keep prices at very low levels in the interest of increasing access. Contractual bindings of advance purchase commitments would reduce the political risk that firms would be forced to sell their product at a very low price, and thus would give investors confidence about the returns they could expect if the new drugs are developed. Berndt et al (2007) studies theoretical and practical design issues of the advance purchase commitment in the context of vaccines. They estimate that the net present value of revenues that a vaccine advance market commitment would need to offer in order to match existing commercial products would be $3.1 billion, in year 2004 dollars. They also estimate potential benefits of advance commitment purchases for malaria tuberculosis and HIV/AIDS in terms of saved DALY[3]. Advance commitments of $15, $31, and $17 per DALY saved are estimated for malaria, tuberculosis and HIV/AIDS vaccines. They also note that these are very cost-effective relative to alternatives.

Many believes that patent rights for a drug developed for a neglected disease is likely to provide a very weak incentive in developing countries; it would be much stronger incentive if companies were able to transfer patent rights from the neglected disease drug to a drug prevalent in rich countries. Jonathan Mann, founding director of WHO Global Program on AIDS, suggested compensating the developer of an HIV vaccine with a ten year patent extension on another drug. Transferable intellectual property rights would allow companies benefit from an extended period of patent life for a drug of their choice in high income markets in exchange for developing for a neglected disease in poor countries. Towse and Renowden (2004) calculate the required extension period for profit-maximizing companies to develop new drugs for neglected diseases. They conclude that if European Union countries implement this mechanism, 1-6 years of patent extension on the drugs marketed in EU would be sufficient incentive for drug companies to invest in neglected diseases. Of course if the same drug was able to get patent extension in other developed country markets (US, Japan etc..) then a much shorter extension would be needed.

Lanjouw (2002, 2004) proposed an alternative patent mechanism to increase the access to drugs in developing countries. According to this scheme inventor of new drugs in developed countries makes commitments to their own governments that they will not enforce patent rights in developing countries. However; this mechanism is unlikely to create enough incentives for R&D on neglected disease drugs though it could be used alongside with other pull mechanisms as complementary.

3 DALYs are estimates of years of life lost or lived with a disability, adjusted for its severity.

Another possible solution to the problem is to reduce the fixed costs of drug innovation. Reducing the costs of basic science is not likely though costs of clinical trials can be changed in a cost-saving manner. The heavy emphasis on 'safety' and 'efficacy' of new drugs might be reasonable for developed countries since the situation is generally not that desperate. There are alternative treatments and methods to save the patients' lives or ease their pains. So it is not rational to introduce unsafe or ineffective drugs to the market. However for the relevant diseases the situation is indeed desperate. It might not be such a bad idea to take risks of unsafe and ineffective drugs. Reducing clinical trial requirements almost certainly would reduce the R&D costs. Because a substantial portion of developing costs of drugs is due to clinical trials. Thus reducing clinical trial requirements might motivate drug companies to undertake more R&D projects for these diseases. However to explain this rational cost-benefit analysis to the public would be very difficult. It would seem that the lives in rich countries are more important and more valuable than lives in poor countries. It would be a public relations disaster for a multinational pharmaceutical company if one of its drugs introduced in an African country is proven unsafe. Thus it is highly unlikely that this solution could be implemented in practice.

The Proposal

In this section I propose that increasing the patent length from its current 20 year period for the diseases which are disproportionally affecting the poor countries can be socially optimal. This suggestion is counterintuitive. Usually it has been suggested that poor countries should provide either no protection or less protection than rich countries for pharmaceutical drugs. According to that argument poor countries' free riding on developed countries R&D investments would benefit them substantially while not hurting the rich countries significantly. Even if that argument might be valid for certain health problems it is not applicable for all of them. For the diseases which are common in both developed and underdeveloped countries there are indeed free riding opportunities. Due to potential profits in rich countries pharmaceutical companies make R&D investments. If they find a new drug treating that these they can introduce those new drugs in underdeveloped countries as well. Poor countries would get the best of the two worlds, small prices in the short run, due to lack of strong patent protection, and innovation in the long run, due to R&D investments for the rich countries. However, the case for certain drugs is completely different. There are numerous other diseases which practically nonexistent in developed countries while causing millions of deaths in poor countries. Since there is no potential market for the new drugs for those diseases in the developed world, profit maximizing companies would not invest on these diseases unless poor countries provide incentive for innovation. Since the potential consumers of these new drugs are poor and have relatively low ability and willingness to pay, the annual profits for the innovated drugs would be smaller than other drugs. Though the development costs of these drugs might be lower than the development costs of regular drugs, it is unlikely. Thus underdeveloped countries can increase innovative activity on those areas by providing a higher patent length than customary 20 years.

In this section I summarize the two models in the literature which derive these conclusions formally and show that they are indeed applicable in the pharmaceutical markets for poor countries. Two models emphasize two different aspects of the market. In the first model a closed economy is modeled and optimal patent length is derived. In the second model the optimal patent protection level is derived for open economy.

Optimum Patent Length in a Closed Economy

In a recent paper Kotowitz and Schure (2006) derived the optimal patent length for a closed economy. The model assumes that eventual innovation is assured but the timing is uncertain. Timing depends on the amount of innovative activity. The more research units try to find the new drug simultaneously, the sooner the innovation takes places. So increasing research efforts is beneficial. The details of the model can be accessed from the paper but below are their main results.

$$T = T(y,u), \qquad \frac{dT}{dy} \langle 0 \ , \qquad \frac{dT}{du} \rangle 0^{4}$$

Where T is the socially optimum patent length, y is the proxy for the profitability of patented product which mainly depends on the demand and u is the degree of uncertainty of the innovation process.

The results make intuitive sense, if a product is more profitable (for a given time period) once it is developed, the less time is required to make up for R&D costs. So for relatively unprofitable (for a given time period) products in order to speed up the development the policy makers should provide lengthier patent protection. Similarly if the uncertainty of innovation rises the present value of total profits to convince investors would rise; thus lengthier patent protection is warranted.

Obviously the expected profitability of the drugs treating diseases which are affecting mainly poor countries is smaller than profitability of drugs treating other diseases. So in order for profit maximizing companies to undertake R&D for those diseases, the patent life should be more than 20 years. Moreover there is some anecdotal evidence that for many of those tropical diseases specifically malaria, science behind finding drugs is extremely difficult, indeed more difficult than other drugs. Thus since the uncertainty of success is higher and optimum patent length could be higher.

According to authors results optimal patent length there is proportional with the square root of profitability and profitability is proportional with the square of the reservation price.

3 The exact formula for optimum patent length is that: $T = 1.15\sqrt{\frac{1}{y}(1-\frac{1}{u})}$ where $y = \frac{\lambda}{(\lambda + r)}\frac{\delta h^2}{4r}\, u = \frac{\lambda + r}{\lambda}$ where λ is the probability of discovery for a given research investment, h h is the difference between consumers' reservation price, r is the discount rate, and marginal cost of production and δ which is assumed to have $P = A - \frac{Q}{\delta}$ form.

(see footnote 5) Thus if patients in developed countries are willing to pay twice as much patients in poor countries, patent length should be twice as much in poor countries.

The parameters chosen and assumptions made on this model might be influencing the conclusions[5]. Indeed in some other models sometimes it has been concluded that current patent regime is providing too much innovative activities and wasteful thus patent length should be reduced. On theoretical ground they might have valid points. However as Pecoul's study strikingly shows that there is almost no R&D on these disease, so it is impossible that current patent regime is providing too much innovation.

Optimum Patent Length in the North-South Framework

At that point I would like to summarize the results of another theoretical paper by Diwan and Rodrik (1991) which explicitly models the optimal patent regime in the North-South (developed-underdeveloped) framework.

They analyze the differential incentives of the North and the South to provide patent protection to innovating firms. Unlike the previous models they consider the possibility of two region to have a different preferences and thus have different technological needs. That property of the model is particularly significant for our purposes since we are analyzing the innovation for the diseases which has no relevance to North whatsoever. In fact they specifically mention that:

> ''…the North would like to develop drugs against cancer and heart disease, whereas the South benefits more from drugs against tropical diseases…''

as the motivation for their paper.

In the model there is an infinite supply of potential innovating firms. However they assume that all innovation activity is made in North by northern firms. That is indeed parallel to what happens in pharmaceutical markets[6]. There is a constant fixed cost required to develop each technology. Their first conclusion is not very new or counterintuitive. According to the model when the technological preferences of the two countries become more similar, the level of optimum patent protection in the South is smaller. That is usual free riding argument, South can free ride on R&D investments of North. Since relative market size of South is small that free riding would not have substantial effect on R&D investments by the innovating firms. However, the policy makers in the South have to trade off between the free-riding benefits and the losses because of reduced levels of investment in technologies that are particularly appropriate to them. As the technological needs of

5 Indeed the optimal patent life estimated by the authors is less than 5 years. However, the parameters chosen in the model are about patents in general industries. The high R&D costs and relatively long time period between R&D expenditures and market introduction due to clinical trials in pharmaceutical markets should make optimal patent length higher than numbers estimated in the paper.

6 Indian pharmaceutical companies can be considered an exception to this general rule.

South and North part apart the benefits of free riding decline. Thus it could be expected that South should provide equal patent protection with North. In fact authors formally derive that when Southern preferences for technology differ substantially from those of the North, the optimum patent protection in South is higher than in North. Their simulations results suggest that patent protection in South can be as much as one and half times patent protection in North.

This situation is a good picture of what happens in pharmaceutical drugs market for tropical diseases. The technological needs of South and North are substantially different and thus it is very likely that optimum patent protection in the poor countries should be higher than patent protection level in the North.

However it should be noted that both Kotowitz and Schure (2006) and Diwan and Rodrik (1991) are static models. Introducing dynamic effects might change the conclusions in the long run. In fact Helpman (1993) establishes that increased protection augments the availability of new products in the short run, but decreases it in the long run. Even though dynamic models are more appropriate for policy recommendations particular aspects of the issue make a case for static models. In the next section some of these aspects are discussed.

Other Considerations

Health and Income Growth

For the very poor countries the resources available for health care is very limited. Millions of lives are lost each year due to diseases which have cheap and readily available treatments for decades. However, many of those countries cannot guarantee their citizens even those very cheap off patent drugs which are sold with prices close to marginal costs. Thus it can be argued that those countries can never be profitable regardless of the patent length. However, it is probable that those poor countries can be relatively well of in the near future and provide profit potentials for these innovative companies. Even though very poor counties have not experienced substantial income growth in the last several decades, that trend is not universal even among very poor countries. Suppose patent protection is increased from its current level of 20 years to 40 years for those diseases. This might reduce the welfares of the future patients who would be buying the drugs for cheaper prices if the patent term is not extended. However, if the current trend continues there is not going to be any drugs for many of those diseases, cheap or expensive. Pharmaceutical companies will make substantial investments on these only when they see profit potentials which strongly depend on the income levels of these poor countries. If poor countries start to be relatively rich then drug companies will start investments. Considering how long it takes to make scientific research and clinical trials to introduce a drug to the market, millions will still suffer in the meantime. Moreover currently international organizations and NGOs have relative success on providing vital drugs to very poor countries. If the drugs are developed for these diseases, the same organiza-

tions might finance the purchase of drugs. As discussed in the literature section public funding for R&D is not as effective as funding for purchases.[7]

Moreover it has been argued that one of the main reasons of low level of income in underdeveloped countries is their unhealthiness. Productivity of unhealthy individuals is lower, the absenteeism is higher, and their physical and physiological strengths are not enough for the job requirements. Long lives also motivate to saving more which in return helps economy to grow faster. Moreover long lives increase the returns to education and investments on human capital. Thus with increased health status people invest more on human capital and education and become more productive workers. Indeed Gallup and et all (2001) finds that eradicating malaria in Sub-Saharan Africa would increase per capita income growth rate by 2.6%. Many other studies in the economics literature including Bloom and Sachs [2001], Alleyne and Cohen [2002], Lorentzon, Wacziarg ve Mcmillan [2005] confirms the general belief that healthier nations also grow faster economically[8]. Thus it could be argued that poor countries are stuck in the low health-low income vicious cyle. New drugs by providing means to improve their health can also help to break away from this vicious sycle. Then since income level of these countries rise pharmaceutical companies can make profits with their patented drugs. The current situation might be just the opposite, poor countries are poor because they are unhealthy. They are unhealthy because there is no treatment for some of their health problems. Drug companies do not invest on finding treatment for those diseases. Thus poor countries stay unhealth, poor and unattractive markets for pharmacutical companies.

Welfares of Future Generations

In Industrial Organization textbooks patents are defined as tools of second best worlds. Provide incentives for long run innovative activity by increasing current prices. So some sacrifices are made for long run gains. In our analysis trade off is upside down. Patent term is extended so that new drugs are invented today and current patients get benefit but tomorrows patients pay higher prices due to extended patent terms. It could be argued that interests of future generation of poor countries prejudiced by extended patent terms. They would have to pay higher prices than their counterparts in the developed countries. First as argued before, extended patent protection helps the development of new drugs and the number of new drugs would almost certainly increase. New drugs have been shown to improve both quality of health care and reduce the total health expenditures. Civan and Koksal (2008) show that the US States which prescribe newer drugs on average spend less on total health care than states which prescribe older drugs.

7 Public funding for basic science is considered to be effective but the later stages of the proces is best managed by profit maximing firms.

8 However there are recent two studies which finds just the opposite. Acemoglu and Johnson(2006) finds that improvement in mortality rates in the 20th century had adverse effects on per capita income levels. Similarly Young (2005) concludes that HIV/AIDS episode in Africa had positive affects on per capita income.

Authors argue that new drugs are so effective such that even if their prices are higher they reduce the demand for other health care services and total expenditures. Lichtenberg (1996) reaches the same conclusion. Moreover he shows that newer drugs also improve the health status more than older drugs. Considering that unlike other health care services most drugs do not require developed health care infrastructure which is non-existent in almost any poor countries. Thus newer drugs can be more expensive due to patent term extension but benefits of increase in number of new drugs would outweigh the costs.

Second the historical data in developed countries shows that for the most innovations the patent rights are not exercised till the end of patent term. In most developed countries maintaining patent rights require regular renewals fee payments. Generally the amount of renewal fee increases with each renewal. Thus patent owners compare the potential benefits of maintaining patent rights with the renewal fees. Lemley (2001) finds that for only one third of US patents the patent rights are maintained by the owners till the end of patent term; half of the patents cannot even reach the half-life of patent term. Lanjouw (1993) and Schankerman (1998) find a similar result for German and French patents. Pakes and Simpson (1989) show that patent renewal trends are similar in Finland and Norway. Christie and Rotstein (2007) note that in Australia renewal rates at the end of the statutory period of patent protection for the various industries range from 15% to 23%. Even though the studies show that pharmaceuticals drug patents' renewal rate is one of the highest[9] it is still true that for most patents the rights are not exercised till the end of statutory period. Presumably patent renewal fees play a significant role in here. These renewal fees can also provide hedging opportunity for poor countries. If we assume patent renewals follow a similar pattern in poor countries many drugs could be free of patent protection before the full patent term. Thus potential welfare loses due to extended patent statutory would be less than we anticipate. Poor countries can implement increasing fees for subsequent renewals like in the developed countries. Patent renewal fees can be introduced to the patent systems of very poor countries. Thus drug companies would maintain only the most profitable (in other words most valuable and most needed) patent rights. Presumably to the poor countries the benefits of those drugs greatly outweigh the costs.

Coordination between Nations and Concerted Action

Considering the substantial opposition to the TRIPS agreement it should not be a big surprise if poor countries do not fully embrace the increasing patent period longer than in developed countries. However, developed countries can increase the patent term in their own countries for the drugs treating tropical diseases. It is true that those diseases are indeed very rare in developed countries but not inexistent. Moreover developed countries generally purchase substantial amount of those types of drugs for their consular and military staff. Since these make only a tiny portion of developed countries health expendi-

9 See Pakes and Simpson (1989) and Christie and Rotstein (2007)

tures, paying relatively higher prices due to extended patents would not hurt them much. However, they would substantially increase the potential markets for these new drugs. Moreover it would make increasing the patent length much easier in political sense. The net effect of increasing patent term can also be positive for developed countries.

Conclusion

There are numerous diseases which practically nonexistent in developed countries while causing millions of deaths and cause enormous suffering in poor countries. For many of these diseases there is no known treatment. For most of those diseases no treatment is anticipated in the near future either. Simply put these diseases are not promising profits for the pharmaceutical market so they don't invest in finding a cure for them. This is especially sad because pharmaceutical drugs could be administered even if there is no strong public health infrastructure which is the general case in poor countries. I propose extension of the patents for the drugs for the tropical diseases which are disproportionally affecting the poor countries.

In order for that extension to create enough momentum for the R&D investments for new drugs, it has to be implemented by many countries. If only one or few countries extend patent term that would not create enough profit potentials for pharmaceutical companies. In addition to that, it would be politically infeasible for countries to implement unless others are also extending. Thus it has to be a coordinated and concerted action by national governments and international organizations. In fact without strong support and leadership by international organizations like WHO, UN, World Bank or World Trade Organization, that kind of extension can never be realized.

Maybe it is also useful to emphasize that the patent extension can improve poor countries welfare only on diseases which are putting the biggest burden on underdeveloped countries. For the diseases which are affecting both poor and rich countries like diabetes, célèbre vascular diseases or cancers, extending the patent term in poor countries would almost certainly reduce their welfare. In fact many studies conclude that signing TRIPS agreement, i.e. increasing the patent protection of the drugs to the patent protection levels in developed countries, reduced poor countries welfare.

10 Chinn and Grossman (1990) and Deardoff (1992)

REFERENCES

Acemoglu, D., and Linn, J. (2004). Market size in innovation: Theory and evidence from the pharmaceutical industry. *The Quarterly Journal of Economics*, 119 (3) August, 1049-1090

Acemoglu, D., and Johnson S. (2006). Disease and development: The effect of life expectancy on economic growth. NBER Working Paper 12269

Alleyne, G. and Cohen, D. (2002). The report of working group of the commission on macroeconomics and health. WHO Commission on Macroeconomics and Health, (April).

Berndt, R.E., Glennerster, R., Kremer, M., Lee, J., Levine, R., Weizsacker, G., and Williams, H. (2007). Advance market commitments for vaccines against neglected diseases: estimating costs and effectiveness. *Health Economics*, 16(1):491-511, January

Bloom, D. E., and Sachs, J. (1998). Geography, demography and economic growth in Africa. *Brookings Papers Econ. Activity*, (2): 207-295.

Chin J., Grossman, G. (1990). Intellectual property rights and North-South trade. in Jones, R., and Krueger (Ed.) *The Political Economy of International Trade: Essays in Honor of Robert E. Baldwin* (pp. 90-108). Cambridge: Basil Blackwell

Christie, A. F. and Rotstein F. (2007). Duration of patent protection: Does one size fit all? University of Melbourne Legal Studies Research Paper No. 245; Intellectual Property Research Institute of Australia Working Paper No. 04.07. Available at SSRN: http://ssrn.com/abstract=1012214

Civan, A., and Maloney, M. (2006). The determinants of pharmaceutical research & development investments. *Contributions to Economic Analysis & Policy*, No. 1, Jan

Civan, A., Maloney, M. (2007). The effect of price on pharmaceutical R&D. *manuscript* (2007).

Civan, A., and Koksal, B. (2008). The effect of newer drugs on health spending: Do they really increase the costs? Available at SSRN: http://ssrn.com/abstract=1068909

Cohen, R., , Nelson, R., and Walsh, J. (2000). Appropriability conditions and why firms patent and why they do not in the American manufacturing sector. NBER Working Paper 7552

Deardoff A.V. (1992). Welfare effects of world patent protection. *Economica*, 59(233) February, 33-51.

DiMasi, J.A., Hansen, R.W., and Grabowski, H.G. (2003). The price of innovation: New estimates of drug development costs. *Journal of Health Economics*, 22(2) March, 151-85.

Pécoul, B., Chirac, P., Trouiller P., Pinel, J. (1999). Access to essential drugs in poor countries: A lost battle? *Journal of American Medical Association*, 281

Diwan, I., and Rodrik, D. (1991). Patents, appropriate technology and North-South trade. *Journal of International Economics*, 30(1-2) February, 27-47

Gallup, J.L., and Sachs, J.D. (2001). The economic burden of malaria. *Amer. J. Tropical Medicine and Hygiene*, 64, 1 Suppl. : 85-96.

Helpman, E. (1993). Innovation, imitation and intellectual property rights. *Econometrica*, 61(6) November, 1247- 1280.

Kremer, M. (2000). *Creating markets for new vaccines. Part I: rationale*. Cambridge: Harvard University

Kotowitz, Y., and Schure, P. (2006). The optimal patent length. University of Victoria, Canada, available at http://economics.huji.ac.il/seminars/seminars%2005-06/schure.pdf.

Lanjouw, J. (1993). Patent protection in the shadow of infringement: Simulation estimations of patent value', Mimeograph, Department of Economics, Yale University, cited in T. O'Donoghue, S. Scotchmer and J-F Thisse, Patent breadth, patent life and the pace of technological progress. *Journal of Economics and Management Strategy* 7(1)

Lanjouw, J.O. (2002). A patent policy for global diseases: US and international legal issues. *Harvard Journal of Law and Technology*, 16(1):85-124.

Lanjouw, J.O. (2004). *Outline of the foreign filing license approach*. Washington: Brookings Institution.

Lanjouw, J.O., and Cockburn, I.M. (2001). New pills for poor people? Empirical evidence after GATT. *World Development*, 29(2) February, 265-289.

Lanjouw, J.O., and MacLeod, M. (2005). Statistical trends in pharmaceutical research for poor countries. CIPIH Working Paper

Lemley, M. (2001). Rational ignorance at the patent office. *Northwestern University Law Review*, 1495-1503.

Levin, C.T., Klevorick, A.K., Nelson, R.R., and Winter, S.G. (1987). Appropriating the returns from industrial R&D. *Brookings Papers on Economic Activity*, 3: pp. 783-820

Lichtenberg, F. (1996). Do (more and better) drugs keep people out of hospitals? *The American Economic Review Papers and Proceeding*, 86(2), 384-388.

Lichtenberg, F. (2001). Are the benefits of newer drugs worth their cost? Evidence from the 1996 MEPS. *Health Affairs*, 20(5), 241-51.

Lichtenberg, F. (2005). Pharmaceutical innovation and the burden of disease in developing and developed countries. *Journal of Medicine and Philosophy*, 30(6), December

Lorentzon, P., McMillan, J., and Wacziarg, R. (2005). Death and development. NBER Working Paper 11620

Mansfield, E. (1986). Patents and innovation: An empirical study. *Management Science*, 31

Pakes, A., and Simpson, M. (1989). Patent renewal data. *Brookings Papers on Economic Activity: Microeconomics*, 331, 391.

Schankerman, M. (1998). How valuable is patent protection? Estimates by technology Field. *The RAND Journal of Economics*, 29(1)

Schumpeter, J. (1942). *Capitalism, Socialism, and Democracy*. New York: Harper & Row

So, A., Rai, Arti, K., and Cook-Deegan, Robert M. (2005). *Intellectual property rights and technology transfer: enabling access for developing countries.* (Commissioned Report, World Health Organization).

Taylor, C.T., Silberston, Z.A. (1973). *The Economic Impact of the Patent System*. Cambridge, England: Cambridge University Press

Towse, A., Mestre-Ferrandiz J., and Renowden, O. (2004). Estimates of the medium-term financial resource needs for development of pharmaceuticals to combat 'neglected diseases. Geneva: The initiative on Public-Private Partnerships for Health, Global Forum for Health Research.

Young, A. (2005). The gift of the dying: The tragedy of AIDS and the welfare of future African generations. *Quarterly Journal of Economics*, 120(2), 423-466.

Table 1: Diseases of Low- and Middle-income Countries

Disease	Lower-income Country Share of Total DALYs Lost	DALYs Lost (thousands)	Annual Deaths (thousands)
Chagas Disease	100	667	14
Dengue	100	616	19
Diphtheria	100	Na	5
Lymphatic Filariasis	100	5,777	0
Malaria	100	46,486	1,272
Onchocerciasis-river blindness	100	484	0
Polio	100	151	1
Trichuriasis	100	1,006	3
Trypanosomiasis	99.8	1,525	48
Ascariasis	99.8	1,817	3
Japanese Encephalitis	99.8	709	14
Leishmaniasis	99.8	2,090	51
Schistosomiasis	99.8	1,702	15
Syphilis	99.8	4,200	157
Tetanus	99.8	7,074	214
Diarrhoeal Diseases	99.5	61,966	1,798
Leprosy	99.5	199	6
Measles	99.4	21,475	611
Trachoma	99.4	2,329	0

Notes: DALYs are estimates of years of life lost or lived with a disability, adjusted for its severity.
Source: Lanjouw and MacLeod (2005)

Table 2a: DALYs (000s) by cause, and income group (a), estimates for 2004

Cause	WORLD (b)		HIGH INCOME	UPPER MIDDLE INCOME	LOWER MIDDLE INCOME	LOW INCOME
Population (000)	*6 436 826*		*977 189*	*579 621*	*2 464 976*	*2 412 669*
	(000)	*% total*	*(000)*	*(000)*	*(000)*	*(000)*
DEATHS UNPOP DIVISION 98 REV	*51 949*		*27 447*	*24 502*	*2 529*	*2 529*
TOTAL DALYs	1 523 259	100.0	122 092	121 032	451 827	827 669
Infectious and parasitic diseases	302 144	19.8	2 754	16 272	41 856	241 099
Respiratory infections	97 786	6.4	1 374	2 377	15 188	78 807
Maternal conditions	38 936	2.6	667	1 277	7 950	29 022
Perinatal conditions (e)	126 423	8.3	1 770	3 890	27 401	93 331
Nutritional deficiencies	38 703	2.5	775	2 099	9 263	26 553
Malignant neoplasms	77 812	5.1	17 826	8 589	32 386	18 982
Diabetes mellitus	19 705	1.3	3 623	2 520	7 560	5 991
Nutritional/endocrine disorders	10 446	0.7	1 927	929	3 831	3 753
Neuropsychiatric disorders	199 280	13.1	31 558	19 613	75 209	72 824
Cardiovascular diseases	151 377	9.9	17 853	21 399	54 805	57 258
Respiratory diseases	59 039	3.9	7 266	4 174	24 871	22 706
Digestive diseases	42 498	2.8	4 714	4 872	14 387	18 508
Diseases of the genitourinary system	14 754	1.0	1 248	1 189	5 818	6 491
Skin diseases	3 879	0.3	230	390	1 419	1 838
Musculoskeletal diseases	30 869	2.0	5 237	3 409	12 879	9 332

Source: WHO Global Burden of Disease available at: http://www.who.int/healthinfo/global_burden_disease/en/index.html

Table 2b: Deaths (000s) by cause, and income group (a), estimates for 2004

Cause	WORLD (b)		HIGH INCOME	UPPER MIDDLE INCOME	LOWER MIDDLE INCOME	LOW INCOME
Population (000)	*6 436 826*		*977 189*	*579 621*	*2 464 976*	*2 412 669*
	(000)	*% total*	*(000)*	*(000)*	*(000)*	*(000)*
DEATHS UNPOP DIVISION 98 REV	*51 949*		*27 447*	*24 502*	*2 529*	*2 529*
TOTAL Deaths	58 772	100.0	8 144	5 556	18 793	26 251
Infectious and parasitic diseases	9 519	16.2	171	546	1 401	7 395
Respiratory infections	4 259	7.2	311	150	805	2 990
Maternal conditions	527	0.9	2	9	66	449
Perinatal conditions (e)	3 180	5.4	37	95	650	2 397
Nutritional deficiencies	487	0.8	19	18	106	344
Malignant neoplasms	7 424	12.6	2 163	805	2 893	1 560
Diabetes mellitus	1 141	1.9	224	142	381	393
Nutritional/endocrine disorders	303	0.5	76	22	110	94
Neuropsychiatric disorders	1 263	2.1	453	90	315	404
Cardiovascular diseases	17 073	29.0	3 027	2 422	6 474	5 142
Respiratory diseases	4 036	6.9	476	219	2 012	1 328
Digestive diseases	2 045	3.5	349	253	712	730
Diseases of the genitourinary system	928	1.6	173	76	325	353
Skin diseases	68	0.1	16	7	16	29
Musculoskeletal diseases	127	0.2	46	11	41	29

Source: WHO Global Burden of Disease available at: http://www.who.int/healthinfo/global_burden_disease/en/index.html