

**From Drug-Purchasing Trips to Canada
To Fighting AIDS in Africa
– Reform Patent Protection to Reduce Drug Prices**

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Abstract:

The high prices for prescription drugs have negatively impacted people from all walks of life: from AIDS/HIV patients in Africa to the poor and retirees in the United States. A variety of proposals have emerged as to how to reduce drug prices and most of them are short-term solutions that fail to fundamentally change the drug pricing structure. This paper proposes a series of measures to reform the patent protection for drugs and achieve more sustainable drug price reduction.

Introduction

The high prices for prescription drugs have become one of the most controversial issues in the pharmaceutical industry today. Poor countries have long complained about their inability to afford life-saving drugs such as AIDS/HIV drugs. On the other hand, people in the United States have begun to feel the pressure of high drug prices and have turned to neighboring Canada for cheaper drugs.

The high prices for prescription drugs are the combined result of the current drug research and development process, the patent protection for prescription drugs and the ensuing monopolistic market for these drugs. On the one hand, there is the argument for maintaining a certain price level to support pharmaceutical companies' bottom-line; on the other hand, there is the ethical issue of saving lives.

Pharmaceutical companies claim that the stringent FDA approval process in the U.S. is elongating the time it takes to get drugs to the market and at the same time significantly increasing the amount of money needed to develop a drug. The patent protection for drugs has come out of the widely recognized need to protect the investment of the pharmaceutical companies and to encourage innovation. The high prices of drugs are therefore maintained during the patent term so that drug companies can recover their investment and make a profit.

Opponents to high drug prices have argued that the current drug pricing system is not rational either in an economic or ethical analysis. They argue that pharmaceutical companies make way too much monopolistic profit and severely hurt the welfare of the people in developing countries who cannot afford the high-priced drugs.

A variety of "solutions" to this problem have been proposed and experimented with. The classic ones include the concepts of compulsory licensing and parallel importing. These two approaches have become even more

relevant with the worsening of the AIDS epidemic in some parts of the world. They are viewed by some as the shortcut to resolving the drug-pricing problem. Other measures include Therapeutic Value Pricing, etc. This paper critically examines these proposals and demonstrate that they may address some of the drug pricing problems in developing countries in the short run, but do not resolve the long term fundamental issue of high drug pricing.

The paper illustrates a methodology of examining the severity of the high drug pricing issue and how to alleviate the problem through reforming the patent protection of prescription drugs. It proposes and recommends a series of measures that will address the problem from a more fundamental level, achieving sustainable drug price reduction. The measures will not necessarily resolve all the issues in the current drug pricing crisis, but will provide a basis for improvement.

1.

Patent Protection for Drugs: Rationale and Effects

United States is the country where Intellectual Property is most comprehensively legislated and strictly enforced. In the area of drug patents, because of the vast number of pharmaceutical companies and their research and development activity, patent protection has been especially strong. Patent terms, which used to last seventeen years from the date of grant of the patent, are now twenty years from the date of filing.

The rationale for patent protection comes in two forms. First, there is the argument of natural rights, where drug rights are seen as property rights belonging to the companies that develop them. The protection is there to prevent other companies or people from free riding. The theoretical basis for such rights is strong. Consistent with Locke's theory of labor and property, in an industry that is labor (intellectual labor) intensive, where generics can easily take the profit away from the companies that made the investment, the fruits of labor are entitled to strong property rights.

The second and more practical argument is that such protection enables pharmaceutical companies to recoup their investment in the research and development of new drugs and therefore offers the right incentives for these companies to continue their innovation and investment. It is reasoned that such a policy will lead to the maximum social benefits.

The high cost of drug development is real. The development in biotechnology and gene technology means that modern medicine can do what we could not even imagine before; but it also means that to achieve these results, large amount of money has to be poured into research and development. At the same time, United States has one of the most stringent FDA approval process, in order to ensure the safety and efficacy of drugs. The three clinical trials usually last between five and seven years. Less than one percent of all drugs

make it to clinical trials and four percent of those make it to the market.¹ Therefore, the cost of one drug in the market also includes, and should include the development costs for the several drugs that never made it to the market. The U.S. government in 1990 estimated that a new drug took ten to twelve years to come to market at a cost of \$359M.² Such money and time commitment, it is argued, justifies the pharmaceutical companies' need for a relatively long time of exclusive market monopoly to make some profits.

The generic drug is what comes to market after the patent term expires. This is the stage when the drugs that are almost equivalent in substance and efficacy to the original drugs can be sold for a fraction of the original price. Currently, this is the only legal way for consumers in most parts of the world to get a drug for a cheaper price. Because of the low price of generics, they constitute only a small portion of the overall drug revenue. In 1997, the dollar sales of prescription drugs in the United States amounted to \$71.8 billion, and 90% comes from brand name prescription drugs.³ The sooner the generic drugs come into the market, the greater the financial loss to the R&D pharmaceutical companies. Therefore the pharmaceutical companies have employed a variety tactics to elongate their patent protection. At the same time, generic drugs are the saviors of some of the poorest nations in the world that are also burdened with the highest HIV/AIDS infection rate. Without generic drugs coming to them sooner, the dire situation there will get worse.

Congress has tried to address the drug pricing problem, as well as the issue of consumer access to generic drugs, through the Drug Price Competition and Patent Term Restoration Act of 1984, commonly known

¹Elyse Tanouye & Robert Langreth, *Times Up: with Patents Expiring on Big Prescriptions, Drug Industry Quakes*, The Wall Street Journal, Aug 12, 1997.

²George Foster, *Opposing Forces in a Revolution in International Patent Protection: the U.S. and India in the Uruguay Round and Its Aftermath*, 3 UCLA J. Int'l L & For. Aff. 283, 1998.

³The Gale Group, *Intellectual Property Rules: A Delicate Balancing Act for Drug Development*, 23 Chain Drug Rev. RX13 2001.

as the Hatch-Waxman Act. The Act was trying to do two things: on the one hand, it reduces the burden on generic drug companies in their effort to get FDA approval; on the other hand, it compensates R&D pharmaceutical companies for their time spent in the FDA approval process with more patent protection time.

However, the Hatch-Waxman Act has not achieved its intended purpose and has not alleviated the problem of high drug prices. It has been reported that pharmaceutical companies have designed numerous strategies to take unfair advantage of this act to maximize their profits from patent protection. These strategies include applying for a series of patents over a period of time that cover different aspects of a drug so that new patents become active as old patents expire.⁴ For example, Bristol-Myers secured a new patent that was closely related to its original patent on the anti-cancer drug Taxol months before its original patent expired in 1997.⁵ Other methods include patent litigation and mergers and acquisition for the purpose of extending patent protection, etc. The effects of the Hatch-Waxman Act can be summarized by Congressman Henry Waxman as follows: the act “has been used to delay competition, rather than foster it.”⁶

On the other hand, it is widely acknowledged that some patent legislations do serve tremendous public interest. The Orphan Drug Act⁷ grants exclusivity to drugs that affect fewer than 200,000 people where pharmaceutical companies that develop them would otherwise not be able to realize a profit at all. An example of this system working is that Merck, Sharp & Dome, Inc. is developing drugs to treat Wilson’s disease, where only about one hundred Americans can potentially benefit from such a drug. Without proper patent protection, such development would not have taken place in the first place and people who suffer from the disease would be the ones to lose.

⁴Lara Glasgow, *Stretching the Limits of Intellectual Property Rights: Has the Pharmaceutical Industry Gone Too Far?*, 41 J.L.&Tech, 227 2001.

⁵Robert Langreth & Victoria Murphy, *Perennial Patents*, Forbes, Apr 2, 2001.

⁶American Health line, *Rx Drugs II: FTC Probes Brand Name Generic Drug Deals*, 6 Am. Health Line 4 (Oct. 12, 2000).

⁷§360aa-360ee (FDCA §525-528)

The pediatric exclusivity section of the Food and Drug Administration Modernization Act of 1997 also uses patent protection to promote overall social benefits. There an exclusive period of six months following a patent term is offered to pioneer companies to conduct clinical investigations to determine safe and effective doses for children. However, opponents points out this does nothing in terms of helping with reducing drug prices; in fact it further increases the monopolistic profits for pharmaceutical companies. Extending the patent life of Claritin by six months means earnings of almost \$1 billion for the pharmaceutical company that developed it.

Patent protection of drugs is also a worldwide issue. Pharmaceutical companies have been pushing for the worldwide adoption of U.S. style patent protection of drugs. One hundred and seventeen countries signed the Uruguay Round Agreements in 1994. As part of the Uruguay Round, The Agreement on Trade-related Aspects of Intellectual Property (TRIPS) requires that all member nations grant patents for drugs. The tension among different countries concerning drug patent rules has been high, especially between the US/Europe and developing countries. On the one hand, the United States has strong incentives to protect the domestic pharmaceutical industry and has used a variety of financial pressures to entice strong patent rules in developing countries. On the other hand, developing countries want less stringent patent protection for drugs, the resulting lower drug prices, and in certain situations, the ability to resort to compulsory licensing and parallel importing. The developed world has had some success in enforcing patent rules in developing countries. Countries such as Thailand and a series of other countries have been forced to modify their laws on patents in order not to lose the favorable trading status with the United States. What this achieves is a seemingly more orderly world, where intellectual property is widely respected and pharmaceutical companies can conduct

business around the world and accurately forecast their revenue/profit level. However, tremendous problems with high drug prices also follow.

2.

Problems with Current Patent System: High Prices

One of the most significant problems resulting from the monopoly granted to pharmaceutical companies is high drug prices, both domestically and abroad. This happens because with a monopoly, pharmaceutical companies no longer determine drug prices based on supply and demand in a competitive market, like the pricing of most products in a market-driven system. Instead, the patent holders can artificially stipulate a drug price that consumers have to pay. This price is therefore much higher than it would have been in a competitive market. Because these are drugs that patients have to take in order to cure diseases, the elasticity of the demand curve is small. The demand does not drop much with every price increase. Without a direct competitor for the drug or a substitute, consumers will have to pay the high prices.

The first victims of high drug pricing are patients in the U.S.. United States, being one of the richest countries in the world, seemingly can most afford the drugs produced by pharmaceutical companies. Therefore, the drug prices in the U.S. are one of the highest in the world. However, drug prices impact all walks of life, not only the richest. The middle and lower class have to spend a significant portion of their income on prescription drugs or medical insurance. The poor and elderly basically cannot afford the drugs that they need most. The irony here is that the drugs developed and produced in the United States are not affordable to some of the domestic patients.

Other countries have similar complaints, especially developing countries. On the one hand, because of the difference in living standards, even discounted drug prices in these countries still seem unaffordable. On the other hand, some of the worst epidemics, including AIDS, are most prevalent in those most indigent countries in the world. In South Africa, some 4.2 million people are infected with HIV and more than 5000 die daily. In Thailand, over one million people are infected with HIV. In fact, eighty-nine percent of the world's HIV

infected population lives in the poorest ten percent of the countries.⁸ These people cannot afford the drugs developed by western pharmaceutical companies, even though those drugs are probably their only hope of surviving.

The problem is both a financial and an ethical one. The ethical dilemma is something few can deny. On the individual level, how can we let people die when we have drugs that can save them and that have very low variable cost? The economics argument involved, on the other hand, is more on the aggregate and long-term level. How do we improve the current systems so that the drug prices in the U.S. and abroad are more rational and how can we develop contingency systems to address life-death situations when the existing pricing system does not resolve the particular crisis?

The ethical dilemma has to be addressed by all parties involved. Pharmaceutical companies should realize that besides a duty to their shareholders to maximize returns, there is also a moral and social responsibility to the welfare of all human beings when they choose to do business in the pharmaceutical industry. Developed countries should realize that helping developing countries, especially when people are dying of treatable diseases, is something they should consider when they draft legislations to regulate the economy or a particular industry. Developing countries, at the same time, should realize that a long-term solution that fundamentally resolves the pricing issue is preferable to any short-term patchwork on drug pricing.

The economic analysis seems more straightforward. A balance need to be struck for the system to work.

The system has to be able to sustain the continued growth of an industry whose goal is to promote the

⁸Margaret Duckett, *Compulsory Licensing and Parallel Importing: What Do They Mean? Will they Improve Access to Essential Drugs for People Living with HIV/AIDS?* International Council of AIDS Service Organization. (July 1999)

health welfare for all human kind; it also has to be rational in pricing, preventing pharmaceutical companies from exorbitant profits. The general lack of resources in addressing human health problems in the world will probably prevent us from ever reaching a stage when no conflict ever surfaces between the two forces; but at least a more rational system can be created to ease the tension currently in the system.

3.

Traditional Proposals to Address the High Pricing Problem

A few proposals have long been in the debate about drug pricing. These proposals have been under scrutiny from a variety of parties, including politicians of both developed and developing countries, representatives of pharmaceutical companies and non-profit foundations who are trying to resolve the AIDS crisis in some parts of the world. The practicality of these proposals depends on finding a balance point where we can preserve the incentives of pharmaceutical companies to continue the innovation and invention and at the same time provide cheaper drugs and relief to the people in the world who desperately need those drugs. A critical examination of these major proposals will shed light on what solutions are only temporary patches that do not address the fundamentals and what proposals may have the potential to achieve the optimal point for innovation and cheaper drugs.

Compulsory Licensing

Compulsory licensing takes place when a state requires a patent holder to license its drugs to another manufacturer to be produced and marketed in return for some fixed royalty. This is usually forced upon the pharmaceutical company and the royalty is minimal compared with what the company could have made in a patent-protected market place.

Compulsory licensing destroys the patent protection within that country, even though theoretically there is some compensation to the patent holder. Proponents for compulsory licensing argue that under certain special situations, such as the AIDS epidemic in some countries, it is the right thing for a government to grant compulsory licensing to save lives.

Compulsory Licensing may even take the more dramatic form of completely ignoring intellectual property. In October 2001, Health Canada ordered one million doses of ciprofloxacin, the generic version of the drug

Cipro, from Apotex, a generic drug manufacturer. The Cipro patent holder, Bayer, was totally bypassed in this case.⁹

Compulsory licensing has been the subject of strong reaction and resistance from the pharmaceutical industry. When South Africa modified its patent law in 1997 to allow compulsory licensing, forty of the world's largest pharmaceutical companies filed suit to change that.¹⁰

Compulsory licensing has several drawbacks that seriously affect its applicability. First of all, a unilateral compulsory licensing and its widespread use will render the current patent protection system ineffective and therefore negatively affect the incentives involved in the drug development process. Ultimately such actions will lead to the underdevelopment of new drugs.

Secondly, selective application of compulsory licensing in certain countries does not address the fundamental issue of high drug pricing. Even within developed countries, there are people who cannot afford AIDS drugs. It does not seem fair to penalize them for living in a developed country, when it seems that if they had lived in a nation where compulsory licensing were allowed, they would have had access to the cheaper drugs.

The current state of compulsory licensing has changed a lot from years before, mainly because of the pressure from intellectual property proponents. In Canada, compulsory licensing used to be available under the patent law provision introduced in 1923. This changed when the Act was amended in 1987 and 1993.¹¹

⁹Katie Sykes, *Special Notes on Bill C-36: Patents and the Public Interest: the Cipro Controversy*, 60 U.T. Fac. L. Rev. 115 (Winter 2002).

¹⁰Robert Block, *AIDS Activists Win Skirmish in South Africa*, The Wall Street Journal, March 7, 2001.

¹¹Supra note 9.

Parallel Importing

Parallel importing has been hailed as one of the creative ways to solve the drug affordability problem in some countries. Parallel importing takes place when the distributor in one country imports drugs from a distributor in another country, rather than going directly to the actual drug manufacturer. Because of the drug price differences among countries, usually caused by difference in drug regulations, such arbitrage will result in a lower drug price in the local importing country.

Parallel importing has also been made more feasible and convenient through the development of modern technologies. Previously, only large-scale distributors can implement parallel importing economically and they still run the risks associated with crossing the border with the drugs, which is often illegal. However, the use of the Internet has enabled even ordinary individual patients to conduct their own parallel importing. Canadian drug stores, which generally get cheaper drugs than U.S. drug stores, can set up a storefront on the Web and sell drugs to individuals in the U.S. directly. The approach is very appealing to individual patients, since in the short-term it does seem to solve the affordability problem.

Parallel importing, on its face, seems to be the ultimate market-driven mechanism. The world is one big market and there should not be price differences; or if there is one, people should be allowed to price arbitrage. However, a closer examination of the market indicates that it is not the case.

Parallel importing takes place precisely because the world is not one open and free market. Because there

are significant differences in patent laws and government regulations, pharmaceutical companies cannot in some countries obtain the price level they want. Granted in most cases, the prices they want to achieve are monopolistic prices under the patent protection term; however, in some instances, the price they are able to obtain, if not contained within a certain geographic region, are not enough for the pharmaceutical companies to recoup their research and development investment on the drugs. Therefore, price differentials among different countries have to be maintained, so that drugs can be sold in some countries at higher prices to recover the investment and in some countries at lower levels to comply with regulations. Such differentials oftentimes also reflect the income level in different regions in the world to meet the ability to pay of the different populations.

Considering such an underlying structure, allowing parallel importing at a large scale would seriously affect the ability of pharmaceutical companies to control their revenue streams from different parts of the world. If all U.S. customers are able to purchase drugs from Canada simply because drugs there are cheaper, then pharmaceutical companies' projected revenue from the U.S. will drop significantly, potentially prompting the companies to jack up prices in other parts of the world to recoup that loss.

This analysis does not mean that the current pricing level for drugs all over the world are reasonable or optimal. Because of the monopolistic nature of the prescription drug market, pharmaceutical companies are opportunistic in their pricing, trying to achieve the maximum price they can get. Nonetheless, the point is that allowing parallel importing on a large scale will disrupt a segmented market system and is fundamentally flawed.

Therapeutic Value Pricing

Australia has adopted a therapeutic value pricing approach.¹² There an independent body determines the price for a drug based on its therapeutic value. On its face, this method seems to break new ground in drug pricing. If there is an accurate measure of the therapeutic value of each individual drug, then pricing the drugs based on that value seems like a great idea.

However, there are two problems with this approach. First of all, it is almost impossible to have an objective measure of therapeutic values. Different drugs will achieve different goals in treating illnesses. There are also differences in how difficult it is to treat different diseases. To compare therapeutic values within the same disease category might be feasible; to compare and rank them across different diseases is almost impossible. Secondly, this approach is too detached from the underlying business economics of drug development. Because of the differences in difficulties in developing different drugs, the underlying cost of each drug is not necessarily proportional to its therapeutic value. Therefore, even if we can find an objective measure of therapeutic value, pricing drugs entirely based on such therapeutic value will make it economically unwise for pharmaceutical companies to make certain drugs, even though the drugs may be desperately needed by patients. That will eventually destroy the incentives to innovate and develop new drugs.

The measures above are either difficult to implement or have significant drawbacks that impairs the particular market system that supports the pharmaceutical industry. The challenge is to find a way to work within the market driven pharmaceutical industry and to rationalize the patent protection for drugs.

¹²Duckett, *supra* note 8.

4.

A New Method of Analysis

The measures mentioned in the previous section may have generated seemingly effective results, but seldom are those long-term solutions, since they do not address the fundamental problem of how to find the balancing point where we do not overly affect the incentive of the pharmaceutical industry to develop new drugs and achieve lower pricing for drugs across the board.

Patent protection for drugs tries to achieve the harmony between private interest and public interest; between free market and protectionism. The justification for the temporary monopolistic protection lies in the belief that society will overall benefit from such protection and monopoly. However, where to draw the line is what we try to figure out as a matter of public policy. The government should not hesitate to step in when consumers are ultimately harmed by the system.

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Is There A Problem?

The first question to answer then, even though it may seem rudimentary, is whether we truly have a high pricing problem. This can be answered in two ways. Anecdotally, as indicated before, we have seen the prices for drugs here in this country so high that some subgroups of the population have a hard time affording the drugs they most need. There is a strong movement for Americans to, either through traveling north or over the Internet, purchase drugs from Canada, where drugs are considerably cheaper. Abroad, the AIDS epidemic has produced the most dramatic dilemma for drug pricing. Large numbers of people in countries like South Africa and Thailand cannot afford the AIDS drugs developed by western countries and therefore

are facing death.

There is also another way to measure the problem of drug pricing. Even though it is well recognized in the industry and among the public that drug development is a capital intensive activity and chances of developing an approved drug are slim and the time it takes to get a drug to the market is long,¹³ the bottom line of drug companies has the last word about the nature of the industry and whether drug companies are overcharging consumers, or in other words whether they can afford to lower drug prices. The author conducted a survey of Fortune 100 companies and compared the profit margin of pharmaceutical companies and the Fortune 100 companies average. The result indicates that pharmaceutical companies have one of the highest profit margins as an industry.

Similar results have also been reached elsewhere: “The pharmaceutical industry has the highest level of net profit as a percentage of revenue than any industry in the United states.”¹⁴ Statistics reveal that the after tax rate of return on the average stockholder’s equity has been higher for the pharmaceutical industry than for the general manufacturing industry in every year from 1956 to 1979.¹⁵ In 1999, the pharmaceutical industry realized on average an 18.6 percent return on revenues.¹⁶ Over the past thirty years, the overall price increase to consumers for drugs has been three to four times greater than the increase in prices for all other items.¹⁷ All these statistics mean that even though pharmaceutical companies are constantly investing huge amounts of money in research and development, even though much money is constantly being written off by

¹³John Harrelson, *Trips, Pharmaceutical Patents and the HIV/AIDS Crisis: Finding the Proper Balance between Intellectual Property Rights and Compassion*. 7 Wid. L. Symp. J. 175 (2001)

¹⁴Stephen Schondelmeyer, *Patent Extension of Pipeline Drugs: Impact on U.S. Health Care Expenditures*, PRIME INSTITUTE, College of Pharmacy, July 28, 1999.

¹⁵Patent Term Extension and Pharmaceutical Innovation: Hearing Before the Subcommittee on Investigations and Oversight of the Committee on Science and Technology, 97th Cong. , 2d Sess. 18 (1982)

¹⁶Marcia Angell, *The Pharmaceutical Industry: To Whom Is It Accountable?* 342 New Eng. J. Med. 1902 (2000).

¹⁷Mary T. Griffin, *AIDS Drugs & the Pharmaceutical Industry: A Need For Reform*. American Journal of Law and Medicine, 17 Am. J. L and Med. 363, 1991.

pharmaceutical companies because a large percentage of the drugs they are developing do not go anywhere and are “wasted”, pharmaceutical companies still make much more money than most other industries in the world. The conclusion is therefore obvious: the exclusivity of the monopoly granted by patent law to these companies not only fully compensates pharmaceutical companies, it may actually have overcompensated them.

One further argument that pharmaceutical companies have the capacity to lower drug prices is that the reduction actually may not negatively affect pharmaceutical companies’ top-line at all. The overall revenue/profit for pharmaceutical companies depends on two factors, the price of the drugs and the amount of drug they are able to sell. The decrease in drug price per unit may well be compensated through the increased volume. This will be most evident in some countries that could not have afforded drugs in the first place. A study from a U.S. consumer project on technology found that lower drug prices in South Africa would increase the sales income from that country.¹⁸

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Shortening Patent Term

The findings above are not a total rejection of the current patent protection of drugs. Abandoning the patent system will destroy the incentives in drug development and probably bankrupt all of the major pharmaceutical companies. However, further statistical studies could be conducted to measure quantitatively what degree of patent protection is appropriate for the pharmaceutical industry.

¹⁸Someshwar Singh, *Compulsory Licensing Good for U.S. Public, not Others*. Third World Network, October 29, 1999

One obvious solution is to shorten the terms of the patent protection. Currently, in the United States and most parts of the world, drugs enjoy a twenty-year protection from competition from generics. Congress, alarmed by the long time it takes to get drugs to the market, has enacted a few acts that further grant drug companies extra time for the time they spend getting the drugs through FDA. However, by examining the profit margin of the drug companies, it is obvious that such general concerns are unwarranted. By shortening the length of the patent protection, we can lower the overall amount of money that drug companies can make from any one drug. And by moving ahead the time point when consumers can have access to generic drugs that are much cheaper, we are one step closer to alleviating the drug pricing problem.

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Appropriate Government Regulations

However, such an adjustment in patent term may even have the opposite effect if not done properly. Because they are facing a shorter exclusivity period, pharmaceutical companies may have the incentives to jack up the prices even further during that shorter patent term period. Government regulation may be necessary here. Government should have a more involved role in the regulation of the pharmaceutical industry, especially in terms of pricing. The theory behind this is that government regulation of certain industries “more effectively controls business behavior than market competition”¹⁹ The government could impose an artificial cap on drug pricing, calculated based on the current level of pricing, which is already on the high end or “a [legislative cap] on prices which may be charged for drugs, perhaps tied to the actual expense put into the research.”²⁰ The practice of government regulations has actually been in effect in some countries already.

¹⁹L. Schwartz, J. Flynn & H. First, *Free Enterprise and Economic Organization*. Antitrust 961 N. 66 (1983)

²⁰Jonathan L. Mezrich, *The Patentability and Patent Term Extension of Lifesaving Drugs: A Deadly Mistake*, 6 J.L. & Health 111, 128 (1991/1992)

The United Kingdom negotiates with pharmaceutical companies every year to determine the prices and related reimbursement issues. Germany has recently switched from a free market system to a direct price control system and has witnessed drug price increases that are comparable to inflation.

Government regulation should also address the problem of excessive marketing in the pharmaceutical industry. High drug prices have been traced to “direct manufacturing cost, research and development costs, overhead, clinical factors, marketing and distribution costs, and profit potential.”²¹ It is estimated that drug companies spend \$2.5 billion dollars on consumer advertising in 2000.²² In an efficient market, marketing expenses directly impacts companies’ bottom-line and therefore companies will conduct extensive cost-benefit analysis for any kind of marketing. Government regulation on marketing expenses is not necessary there. However, because of the monopolistic nature of prescription drugs during the patent protected time period, there is a tendency for pharmaceutical companies to spend an excessive amount of money in marketing to get the brand name to the consumers. It is hoped that such a strong branding will ensure that consumers will stick with the prescription drugs even after the generics come into the market and thereby continue the prescription drug dynasty. The problem with such excessive spending on advertising is that such marketing expenses are incorporated into the drug prices that consumers have to pay. Government should be able to step in in this situation and control the cost of drug prices through examining the marketing expenses of pharmaceutical companies. A certain guideline can be stipulated so that pharmaceutical companies will at least absorb some of the expenses themselves.

Price control through reduced patent protection period and associated government regulation also has a positive effect on innovation. Currently, because of the twenty-year protection, pharmaceutical companies

²¹Supra Note 17.

²²Stephen Hall, *Prescription for Profit*, N.Y Times Magazine, March 11, 2001

do not necessarily have incentives to maximize the speed of new drug development, since they can sit on their existing portfolio to wait for the cash to come in. With reduced revenue and profit level on individual drugs, pharmaceutical companies will be ever more incentivized to develop new drugs faster to achieve returns for shareholders. The shortfall in the revenue per drug will have to be fulfilled through the increase in the number of drugs in the market. There may be a limit as to how fast pharmaceutical companies can get drugs to the market. However, the limit does not seem to have been reached in the current system.

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Public Venture Capital Investment and Private Funding

A further strategy to reduce drug pricing across the board is to sponsor public-funded research and development and treat such funding as venture capital investment. Currently, there is substantial public funding of the development of drugs that are vital to fighting the epidemics in the world. What can be done further is to treat such public investment as venture capital that demands a high rate of return, which can in turn be used to reduce drug prices for the public. This is not a replacement of the current funding system of drug development. Instead, such public venture capital funding will be complementary.

The mechanism works as follows. By accepting such public venture capital fund in their research and development, pharmaceutical companies are required to return a pro rata profit to the public in the future. They can do this either by returning the cash or reducing the drug prices across the board accordingly. The difference between this method and traditional thinking about public research funding is the idea that these funds will be investment that need to be returned to the public at the rate of return at the same level as private investment in the industry.

The source of the public funding can be several-fold. First, it could be the traditional research grants, including NIH funding. Basically these public funding could be repositioned as venture capital investment in

pharmaceutical companies' research and development efforts. It could also be government grants from other nations, who will ultimately enjoy the price reduction. The ability of different nations in contributing to the fund will differ dramatically, but contribution by countries that contribute more can be justified as a sort of humanitarian relief these countries give to other nations.

This method of public funding makes sense because it takes advantage of the high profit level and return on investment pharmaceutical companies enjoy. By enabling public money to enjoy similar types of returns, the public funding will play a more effective role in reducing the high prices for drugs.

The acceptance of public money had been mixed. There had been reluctance from pharmaceutical companies in accepting such money, primarily because they wanted to maintain control for the profits. As of 1960, only 2% of the R&D budget was through government contract.²³ On the other hand, with the AIDS drug development, we have witnessed recently closer collaboration between the pharmaceutical industry and government institutions and budgets. Examples include the development of drugs such as ddI and ddC.

Private money outside the pharmaceutical industry plays an important role in promoting research and health as well and it indirectly contributes to reducing drug prices. Recently, The Bill Gates Foundation has issued a challenge to the medical world to come up with the solutions to the most urgent medical problems in the world. It has granted over \$200 million to fund this effort. A special focus of this fund is to address the diseases in developing countries. Of the \$5.5 billion that the Gates Foundation has given out so far, \$3.1 billion has been for global health problems.²⁴ With such strong funding for research, the cost of resulting drugs will be significantly reduced and therefore patients can expect to better afford the drugs they need most.

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²³Pharmaceutical Mfr. Ass'n, Prescription Drug Industry Fact Book 39, 1986.

²⁴Lawrence Altman, *Gates Announces Grant Aimed at Improving Health of the Poor*, The New York Times, January 26, 2003.

Subsidies and Debt Forgiveness

Subsidies and debt forgiveness are yet another way to directly address the issue of drug pricing for developing countries.

Recently, Glaxo Wellcome joined force with the UN Children's Fund to provide discounted antiretroviral products for the Mother-to-Child Transmission Program. Bristol-Meyers Squibb has donated \$100 million in five South African countries. Jeffrey Sachs of WHO stated that access to drugs in developing countries could only be obtained if "rich companies put up the money to buy these drugs at the discounted prices, and provide them essentially for free."²⁵

Debt forgiveness is equally effective. Some of the poorest countries are paying a significant portion of their GDP on interest expenses to developed countries. Some African nations spend up to 40% of their revenue for debt service. This has seriously hampered their ability to effectively deal with the domestic health issues. By forgiving the debt payment, developed countries will be able to help developing countries focus their attention on their most urgent health crisis.

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Tiered Pricing

Tiered pricing has been proposed as a method to further address the drug affordability issue in developing countries. This is where pharmaceutical companies specifically address the epidemics in certain countries by pricing their drugs differently for that purpose. To a certain degree, tiered pricing already exists in the global market, and that's one of the underlying reasons why some people have proposed parallel importing.

However, in this particular tiered pricing scheme, pricing is determined based on a number of factors beyond

²⁵John James, *Compulsory Licensing for Bridging the Gap-Treatment Access in Developing Countries: Interview with James Love*, *Consumer Project on Technology*, AIDS Treatment News, Mar 5, 1999.

the financial strength of a particular company. Pharmaceutical companies will lower prices for particular drugs that are particularly needed in a certain country to address an epidemic like AIDS. In order for tiered pricing to work, strict control of the drugs' distribution within that country is needed.

Recently, Pharmacia has in effect used tiered pricing in helping fighting the AIDS crisis in developing countries.²⁶ Pharmacia would license Rescriptor to a non-profit organization, International Dispensary Association of the Netherlands, who would in turn line up generic drug companies to produce the medicine for as many as 78 poor countries. Rescriptor currently sells for \$300 a month in the United States and are obviously out of reach for people in poor countries. A variety of generic manufacturers will be engaged and encouraged to compete on price, to achieve the maximum price reduction. Pharmacia will also convey knowledge beyond the patent itself; it will also transfer manufacturing expertise. Part of the agreement also includes measures to ensure that the licensing will not negatively impact Pharmacia's domestic sales. In order to achieve that, the generic versions will be of a different shape and color to make it easier for customs officials to identify them. Similar tiered-pricing moves by other companies include GlaxoSmithKline's granting a license for some HIV drugs to Aspen Pharmacare, a South African generics maker.

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²⁶Scott Hensley, *Pharmacia News Generics Deal On AIDS Drug for Poor Nations*. The Wall Street Journal, January, 24.

Conclusion

The drug pricing issue has long been a serious problem for people in all walks of life. It is time to thoroughly examine the patent protection for drugs and design a series of legal and public policy measures that will help to fundamentally resolve the problem. The optimal point for good incentive for drug companies and lower prices is always difficult to achieve, but any measures that take us in the right direction will help alleviate the problem of high drug pricing.