Rationalizing the drug patent system

Health & Medicine, Drugs

Abstract:

Pharmaceuticals and drug markets functioning poorly because, system of patent does not effectively stimulate drug research and development. Instead, it is inducing large amounts of research into therapeutics with relatively low incremental therapeutic index, while providing inadequate incentives to innovate in some areas of great therapeutic value life saving drugs. As a result, patents lead to high prices which exclude many users from access to potentially life-saving drugs and anti-retroviral. In this essay, I supported to proposed novel reward system for pharmaceutical innovation, in which innovators are rewarded based on the incremental therapeutic outcomes of their innovation. This may align innovators' incentives with social objectives i. e., public interest of affordable price of drugs and lead to the best possible allocation of R&D investment. When rewards given directly to innovators, patents could be compulsorily licensed to enable competitive drug pricing, thus solving problems of drug access. Government expenditures on rewards could be largely derived through reduced expenditures on patented drugs, and pharmaceutical innovators could continue to earn a good return on their R&D investments.

1. Introduction

The patent system was designed to foster the research, development and cater the need of the society by using it for the public welfare. The members of the WTO have to follow the minimum standards of the intellectual property protection laid by the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). The WTO-TRIPS try to create a common platform for countries of different economic caliber to have a common

trading platform. The idea is to provide all the essential products like drugs to be made available at an affordable price.

In this assignment the first part deals with global efforts of international organizations and domestic legislations of developed nations to achieve the above purpose and the pharmaceutical lobby to curtail it. It also deals with the generic drugs and their availability . The latter part will also discuss the policy considerations, reforms and alternatives to make the pharmaceutical patent system a more effective and strong structure by creating a striking balance between the interests of the brand drug pharmaceutical companies on one side and the public interest on the other side.

2. Patent Protection for Drugs:

2. 1 Rationale

General rationale for patent system comes in two forms. There is the argument of natural rights, where product (drugs) rights are seen as property rights owned to the companies that develop them. The protection is there to prevent other companies from free riding. The theoretical basis is strong, Consistent with Locke’s theory of labor and property rights, 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 pragmatic view is that such system enables pharmaceutical companies to recoup their investment in the R&D of new drugs and therefore offers the right incentives for those manufactures to

continue their innovation and investment. It is reasoned that such a policy will reap the maximum social benefits.

The high cost of drug R&D is real; United States has one of the most stringent FDA approval protocols, in order to ensure the safety and efficacy. 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 R&D costs for the several drugs that never made it to the market. 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] Suchmoneyand time commitment, it is argued, justifies the pharmaceutical companies' need for a relatively long time of exclusive market monopoly to make some profits.

2. 2 Effects: Are generics at stake of malady of public health?

The generic medicine is what comes to market after the patent term expires. [3] Currently, this is the only legal way for consumers in most parts of the globe to get a medicine for a cheaper price. Because of the low price of generic medicines, they constitute only a small portion of the overall pharmaceutical revenue. In 1997, the dollar sales of branded drugs in the United States amounted to $71. 8 billion, and 90% comes from brand name prescription drugs.[4] Sooner the generic medicine comes into the market, greater the financial loss to the branded pharmaceutical companies. Therefore the R&D pharmaceutical companies have employed a variety tactics to elongate their term of patent protection. At the same time, generic drugs are the saviors of some of the under developed nations in the world

that are also burdened with the highest HIV infection rate. Without generic medicines coming to them sooner, the horrible situation there will get worse.

3. Measures adopted to address the drug pricing problem

The issue of consumer access to generic drugs through the Drug Price Competition and Patent Term Restoration Act of1984[5], (the Hatch-Waxman Act) was trying to do two things: it reduces the burden on generic drug companies in their effort to get FDA approval; and it compensates R&D pharmaceutical companies for their time spent in the FDA approval process with more patent protection time.

The Hatch-Waxman Act has not achieved its intended purpose, it has been reported that pharmaceutical companies have designed strategies to take unfair advantage of this act to maximize their profits. These strategies include applying for patents over a period of time that covers different aspects of a drug so that new patents become active as old patents expire. [6]

It is extensively acknowledged that some patent legislation do serve remarkable public interest. The Orphan Drug Act[7] 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. The pediatric exclusivity clause of theFoodand Drug Administration Modernization Act of 1997 also uses patent protection to promote overall social benefits.[8]

Similarly, the European Parliament gave a fillip to the Bolar-type exception by its 16 April 1996 resolution which supported the measure, albeit in a much narrower sense.[9] Specifically, European Community Directive 2001/83/EC on medicinal products for human use, provides for the Bolar-type exemption provisions.[10] This exception is particular relevance to generic drug manufacturers who wish seeking regulatory approval for their products, modeled on patented pharmaceuticals that are in their twilight.

4. WTO –TRIPS and Traditional Methods to the Address the Problem through Compulsory Licensure and Parallel Imports

The context of access to life saving medicines in developing countries, the WTO Trade Related Aspects of Intellectual Property Rights (TRIPS) Doha Declaration on PublicHealth[11] provides for special provisions ranging from parallel import, government use, to compulsory licensing, to facilitate and improve access to affordable life-saving drugs.[12] However, it has been noted that Article 31bis, the arrowhead of the new amendment to TRIPS, that is especially ratified to facilitate access to essential drugs by developing countries that have limited or no manufacturing capacity, is encumbered with administrative barriers that could hamper its effectiveness. Furthermore, the proliferation of bilateral trade agreements requiring stronger intellectual property protection than TRIPS does, are generally perceived as obstacle to the implementation of TRIPS' flexibilities by developing countries.[13]

With essence, even with exceptions to pharmaceutical patent exclusivity, the current patent system is by no means, weak, and there is an ample evidence

of a causal link between the current system of stronger patent protection and higher pharmaceutical prices.[14] One major concern is proliferation of patented research tools, which can potentially up the costs of pharmaceutical R&D.[15] The ambiguous and perennially shrinking scope of research or experimental use exception offers little space for unfettered use of patented research tools.[16] This arguably informed the recent report of the Commission on Intellectual Property Rights, Innovation and Health (CIPIH) of the World Health Organization, urging developing countries to, inter alia; devise appropriate national legal frameworks to facilitate access to affordable prescription drugs.[17] This essay also reiterates, inter alia, the virtues of the rewards system, and open source approaches to pharmaceutical R&D, with a view to easing patents' stranglehold on pharmaceuticals.[18] Other major issues of Patent Monopoly System and Pharmaceuticals

4. 1 Misdirected innovation

Since prices in pharmaceutical markets do not necessarily satisfy value to consumers, profits are not expected to be proportional to the social value of an innovation. There are four types of problems which arise here, which are. First, the pricing of branded (pioneer) drugs may bear no particular relationship to social value. Second, " me-too" drugs may be able to yield large profits even though they offer little or no therapeutic advantage over prior existed therapies. Third, firms may find it very profitable to develop minor modifications to their own prior existing drugs, as a sort of ever greening strategy. Fourth, profits from R&D and showing new uses for non-

patented compounds will be small and may not support investing in clinical trials to demonstrate efficacy.

4. 2 Me-too drugs

Many commentators have been very critical of what appears to be an accelerating number of " me-too" drugs (also called " follow-on" drugs). Me-too drugs are products which largely duplicate the action of existing drug. For example, there are now many " statins" to help fight cholesterol, and, as some commentators have observed, it is not evident that there is much social benefit from so much variety.[19] Me-too drugs can be precious in providing therapeutic choice, and perhaps also benefits from competition; but they also may harm the returns available to the break-through drug in a class by capturing market share[20]. It is arguable that firms have devoted an excessive share of innovative research into developing me-too drugs, which have relatively little incremental therapeutic value, but which harms the returns available to the first drug in the market.

4. 3 " Deadweight losses"

The current implemented patent system also causes substantial welfare losses because consumers who would buy the product if it were priced at somewhere nearer production cost do not buy it at the monopoly price.[21] The welfare loss caused by this is called the " deadweight loss" (DWL) of monopoly pricing, since there is a pure loss to society when consumers do not obtain a product which they value more than the cost of manufacturing it.[22] Using highly aggregated data, claim that the scale of deadweight loss in the US drug market is on the order of $3bn- $30bn annually; the same authors estimate deadweight losses of $5bn on $8bn of sales, which

indicates very large DWL for the market overall.[23] Globally, the DWL is clear, because in many markets, drug insurance is unavailable and so consumers are more price-sensitive.

The following section will briefly review the literature on the possible alternatives to the patent system, and how best to deploy them to mitigate the costs of patents.

5. New Reward System for Pharmaceutical Innovation: Reward Contests as a Primer for Innovation

As seen above, the patent monopoly system doesn’t serve the pharmaceuticals market very well – it leads to misdirected innovation[24], to substantial deadweight losses[25], to counterfeit drugs[26], to price controls[27], and arguably to excessive marketing and unnecessary risks to patients. These features are not observed in other markets.[28] This suggests that there are two crucial requirements for an effective system of funding innovation in pharmaceuticals.

First, the rewards for innovation in pharmaceuticals should be proportional to the social value of the innovation.

Second, prices should be near average production cost, in order to minimize deadweight losses and counterfeit drugs, and to eliminate the need for price controls. The following section details a proposal for a system which meets these requirements.

5. 1 The proposed reward system and its implementation: Generics a New stand

Method for rewarding patented pharmaceuticals with payments or rewards paid out of a government-financed Pharmaceutical Innovation Fund (PIF). When a drug is approved for use in a country, it would be registered by a firm, normally by the owner of related patents required in the production of the drug.[29] PIF would make payments to registrants, and in exchange for such payments, registrants would be compelled to grant zero-priced licenses for all listed patents when used to make and sell the drug. The payments would be annual during the period in which the registrant’s drugs were patented. Rewards might also be paid for patented cost-reducing process innovations, and for court verdicts of invalidity or non-infringement which allowed for generic production without a compulsory license. The aim of this section is to outline how the fund should determine the reward for a given innovation.

Each patented drug would given points reflecting gain in average therapeutic value less costs of treatment over that of the next best pre-existing treatment, for all units of the drug sold by the registrant and by other manufacturers in a given year.

Drugs that improve health would get reward = Incremental value of QALY[30] ? Dollar value of QALY (Quality Adjusted Life Years)[31]. This will be determined on the therapeutic value determinant of the drugs. Better the therapeutic value more the reward. This put simply means that the pleasure drug like Viagra would enjoy less reward than the life saving essential drug.

Cost reducing innovations should be given the points that have been achieved by using the patentedtechnology= Average price of the medicine set by all sellers using patented innovations – Average price not using the patented innovation ? number of pills sold. This can be a parameter for the successful invention as the number of drugs sold will generate more revenue and this parameter can be used for determining successful invention.

Registrant would get points for every sale of its drug, no matter who produced or sold the product, so that the reward is really for the innovation, clinical testing, and marketing of the product. In principal, the innovator need not produce/sell the drug, though it would have an incentive to market the drug so as to increase the volume of sales on which it could earn points. In many instances, drugs are given for a variety of different conditions, and so the therapeutic value, as well as the next best therapies, would be different for different conditions. This implies that it would be useful to obtain evidence from prescribing doctors on what conditions drugs were prescribed for, through random sampling of doctors.[32]

5. 2 Significances of the proposed system

The potential significance of the proposal are immense, including making drugs more widely accessible, eliminating over pricing, improving the direction of research spending, and marketing incentives more efficient.

5. 2. 1 Better direction of research expenditures

This proposed system would make the incentives to innovate proportional in a meaningful way to social value, since the award given to the drug registrant would be appropriate with the net benefit created by the drug.

This would increase the incentives to find new drugs with large incremental therapeutic value, and decrease the incentives to find new products which offered little extra benefit. (And with fewer me-too products, and less incentive to advertise them, profits of pioneer innovators would be even higher.) And it could become profitable to demonstrate the therapeutic value of old, unpatented compounds for new uses, if rewards were paid to patentees who had shown the therapeutic value of the patented use of the drug

5. 2. 2 Elimination of “ Deadweight Loss” (DWL)

Prices of drugs under this proposal would fall to approximately the average cost of production. Based on experience with medicines facing generic competition today, this implies that patented drug prices would decrease by on average 50% to 80%. This would obviously be beneficial for consumers, with total savings in the US of on the order of $100bn annually. Global, savings might be on the order of $200bn. Much of this saving would be used up in paying for rewards.

Aside from the reduction in total expense to consumers, there would be a welfare gain from increased consumption of lower-priced medicines. Deadweight loss (DWL) from the current patent system is certainly immense in pharmaceutical markets.

The efficiency gains from reducing drug prices to approximately the average cost of production could easily be over $100bn, and the gains in terms of saved lives would likely be very good in number.

5. 2. 3 Efficient marketing

The proposed system of rewards would not prevent marketing by the drug registrant. Indeed, promotions which prolonged demand could be profitable, since the registrant obtains points for more sales, based on the average net benefit. However, the effect of this marketing would be wholly profitable: marketing with increased sales such that the net benefit was negative would decrease the reward obtained. So manufacturers would have an incentive to promote the drug to obtain the largest number of consumers with a positive net profit. However, the amount of promotional activity would be declined under this proposal because there would be lesser copycat drugs competing to attract a restricted number of prescriptions.

5. 3 Possible global implications of the proposed system

This system is ideal for enabling wide international access to life saving drugs, while eliminating ineffective parallel imports between nations having different prices. Innovator could be resident anywhere; and with prices equal to the average cost of production, even developing nations would be well served. However, if not all states adopted this model, then one could expect substantial parallel imports into the non-adopting states. The asymmetries could lead to some problems of coordination between adopting and non-adopting nations withrespectto pharmaceutical trade and commerce. But the system if adopted by many nations could be designed to allow for small contributions in developing nations, basically by assigning them a small dollar value for each QALY.

6. Discussion and conclusion

The proposal outlined in this essay presents an effective method of rewarding pharmaceutical innovation which yields two major benefits. First, it aligns private research incentives with social objectives i. e. as much focused issues of high drug prices by rewarding innovations based on their assessed therapeutic value. This is an improvement over the ordinary implementation of the current monopoly patent system, which cannot be efficient in bringing out pharmaceutical innovation given that pharmaceutical markets are extraordinarily dysfunctional. The proposed system can therefore be used to increase the rate of drug development cycle. Second, it allows for medicines to be priced at near the average cost of production, enabling widespread access to life saving drugs. It is possible to achieve both of thesegoalswithout increased government expenditures on drugs, since governments are already large buyers of high-priced medicines. The proposed system is not intended to be an assault on the pharmaceutical industry: on the contrary, it continues to offer healthy benefits to pharmaceutical manufacturers which successfully bring valuable, innovative drugs to market, while removing the spectre of poorly-conceived, arbitrary price controls and satisfying the public interest. These significances suggest that this system deserves serious investigation.

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[1] Elyse Tanouye & Robert Langreth, ‘ Times Up: with Patents Expiring on Big Prescriptions, Drug Industry Quakes’, (Aug 12, 1997), The Wall Street Journal.

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

[3] 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.

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

[5] See Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585. Codified as 35 USC.

[6] Lara Glasgow, Stretching the Limits of Intellectual Property Rights: Has the Pharmaceutical Industry Gone Too Far?, (2001), 41 J. L.&Tech, 227.(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)

[7] §360aa-360ee (Food Drug Cosmetic Act §525-528); 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.

[8] 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.

[9] Paragraph 17 of the European Parliament 1996 Resolution provides as follows: “ Measures should be introduced which enable pharmaceutical companies to begin, in advance of patent or supplementary protection certificate (SPC) expiry, such laboratory experiments and regulatory preparations as may be required only for the registration of generic pharmaceuticals developed in the EU, to be available on the market immediately, but only after the expiry of a patent or SPC for a proprietary product.”

[10] See Article 10 (1), (a), (i), (ii), (iii), Directive 2001/83/EC on the Community code relating to medicinal products for human use, (as amended).

[11] See Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, at http://www. wto. org/English/thwto_e/minist_e/min01_e/mindec_trips_e. htm (accessed on May 20, 2011).

[12] See Frederick M. Abbott and Jerome H. Reichman, “ The Doha Round’s Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines under the Amended TRIPS Provisions,” (December 2007), vol. 10, No. 4, Journal of International Economic Law, at 929-957.

[13] See for example, Carlos Maria Correa, “ Implications of bilateral free trade agreements on access to medicines,” (2006), vol. 84, No. 5, Bulletin of the World Health Organization, at 399-404.

[14] See Oxfam, “ Fatal Side Effects: Medicine Patents Under the Microscope.” In Brigitte Granville, ed., The Economics of Essential Medicines, (London: Royal Institute of International Affairs, 2002) at 81-99, (noting that patented drugs are more expensive than off-patent drugs); Kumariah Balasubramaniam, “ Access to Medicines: Patents, Prices and Public Policy – Consumer Perspectives.” In Peter Drahos and Ruth Mayne, Global Intellectual Property Rights: Knowledge, Access and Development, eds., (New York: Palgrave Macmillan, 2002) at 90-107.

[15] See John H. Baton, “ Research-tool patents: issues for health in the developing world,” (2002) vol. 80, No. 2, Bulletin of the World Health Organization, at 121-125.

[16] See for example, Tao Huang, “ The Experimental Purpose Doctrine and Biomedical Research,” (2004), Vol. 11, Michigan Telecommunication & Technology Law Review, at 97-115.

[17] See Report of the Commission on Intellectual Property Rights, Innovation and Public Health, Public Health, Innovation and Intellectual Property Rights, (Geneva: WHO Press, 2006), at 175-188.

[18] Id

[19] Angell, Marcia, " The Pharmaceutical Industry: To whom is it Accountable?" New England Journal of Medicine, 2000, 342: 1902-1904. p. 90) argues that many me-too drugs are never tested at equivalent doses to show that there are significant differences in outcomes for some patients, and claims that " the idea that patients respond differently to me-too drugs is merely an untested – and self-serving – hypothesis."

[20] DiMasi J and C Paquette, " The Economics of Follow-on Drug Research and Development Trends in Entry Rates and the Timing of Development" Pharmaco-economics 22 (Suppl. 2), 2004: 1-14.

[21] Avorn, Jerry, Powerful medicines. (New York, 2004): Knopf. p. 262(discusses how deadweight losses can occur even when there is full insurance. Insurers may be unwilling to cover certain medicines, such as osteoporosis drugs, whose benefits mainly appear only after some years.); the patent system as now implemented also causes substantial welfare losses because consumers who would buy the product if it were priced at somewhere nearer production cost do not buy it at the monopoly price. The welfare loss caused by this is called by economists the " deadweight loss" (DWL) of monopoly pricing.

[22] Guell R. and M. Fischbaum, “ Toward allocative efficiency in the prescription drug industry.” Milbank Quarterly, 1995, 73: 213-229.

[23] Douglas and Guell (2004) use US and Canadian data to argue that the DWL in the US market for a large number of drugs is at least 25% of sales.

[24] It is well known that monopoly exploitation of innovations under the patent system can reduce the benefits or “ surplus” available to society from an innovation.

[25] Supra note 21.

[26] A recent statement of the US Assistant Attorney General in a vaccine price-gouging case claimed that an “ exorbitant market price … may increase the incentive for counterfeiters to manufacture fake, ineffective, and potentially unsafe” drugs. (Statement of Interest of the United States, in Office of the Florida Attorney General v. ASAP Meds, Inc., Broward County Circuit Court, October 22, 2004.)

[27] Supra note 20

[28] For example, in automobile markets, consumers are relatively competent to assess product quality and to make informed decisions about purchasing based on prices, quality, and their own budgets. Automobile makers therefore have incentives to develop differentiated products which respond to consumers’ demands. Deadweight losses are relatively small in automobile markets because prices are close to the average cost of production, counterfeits are relatively rare, and price controls are not used.

[29] It is possible that a registrant might not own all the required patents, in which case registration would require the registrant to obtain a license to the patents from the patentee.

[30]Quality-adjusted life year(QALY) is a measure of disease burden, including both the quality and the quantity of life lived. It is used in assessing the value for money of a medical intervention. The QALY is based on the number of years of life that would be added by the intervention. Each year in perfect health is assigned the value of 1. 0 down to a value of 0. 0 for death. If the extra years would not be lived in full health, for example if the patient would lose a limb, or be blind or have to use a wheelchair, then the extra life-years are given a value between 0 and 1 to account for this. In a worst possible health state it will be from 0 to negative value.

[31] Drugs which advance health should be given points reflecting the gain in average therapeutic value less costs of treatment over that of the next best pre-existing treatment. It will determine the net benefit of a drug, and then compare it to the net benefit of the next most effective pre-existing therapy, and award points based on the improvement. These points would be awarded to the registrant for each year in which the registrant’s patents would, in the absence of compulsory licensing, be sufficient to prevent other firms from producing bio-equivalent products.

[32] This would be particularly important for some drugs which have extensive off-label uses (uses for which the FDA has not approved the product). There are claims that up to half of all prescriptions are written for off-label uses. “ How Drug Directory Helps Raise Tab for Medicaid and

Insurers", Wall Street Journal Oct. 23, 2003. IMS Health already conducts in the US a survey of this sort entitled the " National Disease and Therapeutic Index."