Innovation, Parallel Trade, and the Pharmaceutical Industry

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Abstract

This paper discusses the pharmaceutical industry's effect on national and international welfare issues from the perspective of developed countries. Welfare is gauged by the extent to which treatments are available to potential consumers whose willingness to pay is at or above the marginal cost of production. The discussed trade scenarios generally refer to trade between developed nations. Although issues arise regarding the development and distribution of medications to low-income individuals and nations, these discussions are beyond the scope of the paper.

1. Introduction

Many governments seek to reduce the prices of prescription drugs by instituting price caps or sanctioning parallel trade with other countries.[2] In their efforts to affect immediate changes, proponents of these plans pay little attention to the long-run national and international welfare implications of these policies. This paper begins with a brief discussion of Intellectual Property Rights (IPR) and the patent system's relevance to the pharmaceutical industry. I continue by investigating government-instituted price caps and the various manifestations of parallel trade in pharmaceutical goods. Through this, I work to identify what if any benefits these practices offer. The paper concludes with a discussion of the potential benefits of replacing current IPR policies with a reward or patent-buyout system to increase social welfare by decreasing the deadweight loss associated with patenting.

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[2] Parallel trade occurs when a patented good is exported from one country to another without the patent owner's expressed permission (Grossman and Lai, August 2006).

2. Literature Review

Scherer and Ross (1990) note that patenting is of particular importance to the pharmaceutical industry due to the exceptionally high cost of product development versus the exceptionally low cost of product duplication. A survey of industry research and development (R&D) managers by Henry Grabowski (2002) estimates that pharmaceutical R&D expenditures would be reduced by 64% in the absence of patent protection. Grossman and Lai (January 2002) demonstrate that the rewards which are offered by patenting further incentivize additional R&D, and thus increase future welfare. However, many problems arise from the monopolies that accompany pharmaceutical patenting. Lanjouw (May 2005) explores the rate at which firms with patented drugs choose to enter new markets. Empirical evidence clearly demonstrates that patents cause a significant deadweight loss due to the pharmaceutical company's ability to operate as a monopolist.

The practices of price discrimination and differential pricing particularly upset developed countries, which are burdened with relatively high prices compared to the rest of the world. Kremer (Autumn 2002) as well as Danzon and Towse (September 2003) study these practices from a global welfare perspective by examining the extent to which new treatments are both available and affordable. Upon conducting their own study of the effects of differential pricing and price caps in Europe, Grossman and Lai (August 2006) advocate the implementation of parallel importation policies by governments in order to provide greater access to pharmaceuticals while disincentivizing the implementation of unreasonably low price caps. Kyle (March 2007) in turn articulates the ways in which pharmaceutical companies react to excessive government interference, and suggests that mechanisms such as increased product differentiation counteract the perceived benefits of

parallel imports. Furthermore, Kyle (March 2007) notes that many consumers, particularly in Europe, are indifferent to drug prices due to government-sponsored prescription drug plans.

In light of the patent system's many shortcomings, there is significant support for the implementation of other measures in its place. Shavell (May 2003) provides an excellent summary of the patent system's faults, as well as a brief overview of potential alternatives. Of the possibilities, either a reward or patent-buyout system seems most likely to continue to incentivize innovation while eliminating some of the deadweight loss associated with patenting. Maurer and Scotchmer (August 2003) examine the merits of these competing mechanisms in comparison to the current intellectual property system. From this relatively simple investigation, Michael Kremer's (November 1998) paper on patent buyouts lays out the mechanisms by which the government could gain the information necessary to purchase a patent at the correct price. Similarly, Shavell and Ypersele (February 1999) forward an "optional rewards system" in which an inventor could either sell his innovation to the government or keep it if he deems the government's offer to be unsatisfactory.

3. A Brief Discussion of Pharmaceutical Patenting

There is little argument that the current patent system creates inefficiencies by granting innovating firms short-term monopolies. It is also generally accepted that patents (and other types of IPR) are necessary to incentivize innovation in the pharmaceutical industry. The pharmaceutical industry is unique in that development of new drugs is exceptionally costly, while the marginal cost of producing these drugs once developed is

exceptionally low. One study showed that a representative new product cost over $400 million to be developed, while the development of a representative generic compound required only $1 to $2 million (Grabowski, 2002). Although patents grant protection for 20 years, the average drug takes between 10 and 12 years to reach the market (Moors and Faber, February 2007). Therefore, although some provisions are offered to extend patent protection due to development time, the ability of a pharmaceutical to charge prices above marginal cost is crucial in recouping costs sunk in product development. Unfortunately, since pharmaceutical research is a global public good, an incentive exists for some countries to free-ride on the R&D of others (Kremer, Autumn 2002). This opportunity for free-riding frequently manifests itself in government-implemented price caps or sub-optimal protection of IPR. Both of these measures interfere with the pharmaceutical supplier's ability to recoup its development costs and earn profits. Such difficulties in achieving profitability discourage future R&D and make other endeavors look more enticing in the eyes of the pharmaceutical corporation. Thus, attempts to free-ride often lead to a tradeoff between the short-run benefits of lower prices and the long-run welfare reductions due to a lack of innovation spending.

4. Problems With Parallel Trade

Generally speaking, parallel trade results from price differences due to price-discriminating suppliers, government-imposed price caps, or differences in IPR (Danzon and Towse, September 2003). Each of these scenarios results in questionable short-run benefits to the trading countries in exchange for long-run welfare decreases due to lower levels of future R&D.

Despite the advantages of global price discrimination in balancing access to treatments with rapid cost recovery, some countries still choose to seek short-run welfare boosts by fighting both domestically and globally differentiated prices. For example, in response to pharmaceutical "competitive discounting" which offered discounted rates to customers with certain insurance packages, in 1991 Medicaid instituted a "best price" provision. The policy required pharmaceutical companies to give Medicaid customers the largest discount given to any private customer (Danzon and Towse, September 2003). This provision reduced the ability of suppliers to selectively discount their products, which resulted in a baseline price only slightly lower than the former Medicaid rate for all consumers. Thus, by attempting to legislate a solution for pharmaceutical prices the United States Government caused a net welfare decline for its citizens while reducing pharmaceutical revenues (Danzon and Towse, September 2003).

A similar situation arises when parallel trade is incentivized by price differences between neighboring countries due to price discrimination. Generally speaking, pharmaceutical companies offer higher prices to countries of larger size, greater prosperity, and with more inelastic demand. This allows suppliers to sell in more countries where willingness to pay is above the marginal cost of production, but below a potential global monopoly price. In hopes of lowering prices and thus improving welfare, these countries begin to import prescription drugs from neighbors with lower prices. Theoretically, the immediate result of this policy will be lower prices in the larger country. While the empirical evidence to support this claim is mixed at best (Kyle, March 2007), if parallel trade becomes pervasive enough to significantly undermine price differentials between the two countries, the pharmaceutical corporation will be forced to

offer one set price to all participating countries.[3] Under this new scenario, the larger country experiences a short-term welfare boost in the form of lower prices at the expense of decreased access and higher prices in the smaller country. While some justify this process as eliminating cost shifting, others appropriately consider it free-riding by the price-inelastic consumers of the large, prosperous country on the relatively price-elastic consumers of the small country (Danzon and Towse, September 2003). Aside from the detrimental effect this scenario has on current access to treatments, such a free-riding policy between developed nations is welfare-decreasing in the long-run and morally questionable from a global perspective.

Government-instituted price caps frequently create another incentive for parallel trade. When examining the effect of price-caps and subsequent parallel trade on national and global welfare, one must consider two independent cases. The first case is a two country scenario in which one country has price caps and the other does not. For the sake of generalization, we will say that Country A has price caps on prescription drugs while Country B allows the pharmaceutical company to set the price. In an attempt to lower prescription drug prices, Country B creates a program through which citizens can purchase drugs at lower prices from Country A. As this program takes effect, suppliers lose potential profits from Country B on top of already lost potential profits due to price caps in Country A. In order to stem this parallel trade, the pharmaceutical company will likely move to limit the quantity supplied to Country A (Grossman and Lai, August

[3] A pharmaceutical supplier facing increased levels of parallel trade could also withdraw from the smaller country altogether in hopes of maintaining higher prices in the larger country. Generally speaking the moral implications of such a strategy prevent its implementation, but often the threat alone is enough to pressure governments into taking some type of action to reduce parallel trade.

2006).[4] While this decreased supply does not affect prices, it does affect overall availability, and Country A experiences a net welfare decrease. The effect of parallel trade on Country B is much more difficult to identify, as many contend that large portions of price differentials are absorbed by intermediate suppliers and never reach consumers (Kyle, March 2007). Thus, in this case parallel trade has a questionably positive short-run effect on Country B, a negative short-run effect on Country A, and an undeniably negative long-run effect on both countries due to decreased spending on future R&D by the pharmaceutical company.

The second case in which price caps incentivize parallel imports involves two countries with price caps at different levels. While less desirable than full price discrimination, a case can be made for the institution of parallel imports in this scenario. In this case, Country A has exceptionally high price caps while Country B's price caps are unreasonably low. This price difference causes Country A to import drugs from Country B, and thus effectively import Country B's lower price caps. As was the case with the previous scenario, if this trade volume becomes significant the pharmaceutical company begins by limiting supplies to Country B. Theoretically, in order to prevent losing access to these treatments, Country B will proactively raise its price caps, bringing its prices more into line with regional standards and disincentivizing parallel trade. However, on the flip side of this, Country A will also likely be forced to lower its price caps in order to further disincentivize trade. Although parallel trade is beneficial in this case, in light of price capping's negative effects on future innovation as well as global

[4] Again, in this scenario the strategy of full withdrawal from the smaller market exists, but is rarely chosen in light of other options to stem the flow of parallel trade.

access to treatments; we can only state that this type of parallel trade makes an undesirable situation slightly more palatable.[5]

Finally, parallel trade due to differences in IPR is much more simple to address. Due to the general recognition that a certain level of intellectual property (IP) protection is necessary to incentivize innovation, parallel trade in unauthorized generics between developed countries occurs with relative infrequency. Under the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) of 1994, signatory countries agreed to a series of strict IPR provisions including recognition of patents granted in other countries. However, the compulsory licensing provisions of TRIPS still allow limited circumstances in which a government can disregard patent protections and allow production of pharmaceuticals near marginal cost by generic producers. When a country allows the premature entry of generics into the market, the opportunity for parallel trade is present with almost any other country. Again, this scenario leads to the familiar tradeoff between short-run gains from lower prices and long-run losses due to decreased incentives for innovation. However, such blatant free-riding behavior is likely to be met with international backlash in all but the most extreme national emergencies.

5. Potential Alternatives to Intellectual Property Rights

As discussed above, the monopolies created by the patent system are inherently inefficient in making new products available to potential consumers. The need to recoup high development costs by charging prices well above marginal costs creates a significant deadweight loss. This deadweight loss is especially troubling when the products in

[5] For a more complete explanation of scenarios in which parallel trade can be beneficial to global welfare, see Grossman and Lai (August, 2006).

question are capable of enhancing and saving lives. The need to balance incentives for innovation with maximizing access has led many to search for alternative methods which reduce inefficiency.

Two similar systems, referred to as rewards and patent buyouts, have been proposed in hopes of replacing the current system of IPR. Under both plans, governments pay innovators a lump sum rather than granting the monopoly power that accompanies a patent. In a reward system, the pharmaceutical company is then able to produce and sell the new drug at or near marginal costs, thus eliminating almost all deadweight loss. Under a patent buyout system, upon paying a lump sum to the innovating party, the government gains the rights to the patent and puts it in the public domain, thus allowing production of generics as well as fostering increased innovation (Kremer, November 1998).

The main weakness of these alternatives lies in the government's lack of access to adequate pricing information. In order to calculate a fair reward or buyout price, it is necessary to accurately estimate the social surplus created by a new drug's introduction (Philipson and Mechoulan, April 2003). To remedy this information gap, Kremer (November 1998) proposes a system in which new innovations are put up for auction and rival firms bid on the patents. In order to prevent collusion and encourage honesty, a small number of these innovations would actually be sold to the highest bidder, while the data from the remaining auctions would be used to calculate a fair reward for the innovator. Shavell and Ypersele (February 1999) propose a similar auction system, but upon receiving the government's offer the innovating party is able to choose whether to take the up front reward or keep the patent. Either approach at least theoretically appears

to remedy the government's lack of information in offering a reward which will maximize efficiency.

Unfortunately, a second problem which goes nearly unaddressed in the literature relates to the nature of pharmaceutical innovations as global public goods. In the aforementioned pieces on rewards and buyouts, the models make no allowance for how reward burdens would be distributed among the governments of the world. The absence of a clear and binding system by which all affected countries contribute a share to rewards and buyouts creates the incentive for free-riding. The current IP situation in which many nations free-ride on the IPR standards of others provides a glimpse into the future of any system without robust compliance measures. Of all the problems with rewards and buy-out system, the complete lack of attention paid to this issue is startling given the situation the pharmaceutical industry faces in the current IPR regime.

6. Conclusion

In the current IPR climate, markets in which producers are able to price discriminate freely without government interference are most beneficial to both short-term and long-term global welfare. Although certain anomalies exist, parallel trade generally results in questionable short-run benefits and consistently negative long-run welfare effects for all parties involved. Finally, this paper finds that the potential exists for new incentive systems to replace current IPR regimes and reduce the inefficiencies which are so troubling in the pharmaceutical industry. However, more work regarding reward funding and global participation is required before any of these systems are ready for testing and implementation.

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