Patent Races, “Me-Too” Drugs, and Generics: A Developing-World Perspective

by

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PATENT RACES, “ME-TOO DRUGS, AND GENERICS: A DEVELOPING-WORLD PERSPECTIVE*

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Abstract: We build a model of pharmaceutical markets in the light of a patent race among competing firms. The incentive for R&D is the patent on either the breakthrough or the me-too drug. A feature of our model that has not been analyzed before is the prevalence of insurance in developed countries as opposed to developing countries, such that the true burden of financing R&D falls to a greater extent on the former than the latter. We suggest that generics drugs be allowed in low-income countries, particularly since most of them do not have a well-established and functioning pharmaceutical industry.

1. INTRODUCTION

There continues a raging debate on the extension of pharmaceutical product patents rights to developing countries, given the disparities in health spending across different regions of the world, in general, and low purchasing power of consumers in developing countries, in particular. Product patents for pharmaceuticals were adopted in

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the developed world slowly and that too after reaching a high level of per capita income but developing countries now extending protection to pharmaceutical products are at a much lower level of income than those adopting earlier. Since stricter patent rights translate into higher drug prices, this adversely affects the welfare of poor consumers in low-income countries. In fact, the Doha Declaration on TRIPs and Public Health has extended the deadline for the implementation of pharmaceutical patent protection in 49 least developed countries from 2006 to 2016. These recent steps implicitly recognize that the trade-offs between pricing and incentives associated with patents are different for different countries.

Undoubtedly patents stimulate R&D investments for lifesaving drugs, but at the same time patents also raise pharmaceutical prices for consumers in low-income countries, denying them access to medicine. The incentives to invest in research on global diseases in developed and developing countries are different from those for neglected diseases (like malaria and tuberculosis) that primarily affect developing countries. For global diseases, the prime mover for R&D is the market in developed countries so that extending patent rights to developing countries only raises prices while contributing little to incentives. Thus, the main policy issue is to stimulate R&D for orphan drugs and neglected diseases since purchasing power in poor countries is low with very little spending on health care.

With low purchasing powers, sales of drugs in developing countries have remained much below the level found in affluent countries. In 2000, sales in the U.S., E.U and Japan were huge at $150, $74 billion and $57 billion as compared to the sales in the rest of the world worth $81 billion only (Lewis, 2001). Growth estimates for 2005
also reflect the same scenario with North America, Europe and Japan accounting for 83 percent of the global sales, and Southeast Asia, China, India, Latin America and the rest of the world including Africa contributing to only 17 percent of sales despite being the most densely populated regions of the world.

Even after the signing of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs) under the World Trade Organization (WTO) regime established in 1995 and its enforcement in developing countries by January 2005, there is a question mark on the relevance of a uniform patent system across the world. Given that developing countries and least developed countries not only have low purchasing power but are also home to many diseases and epidemics, different proposals have been put forward for the reform of the patent system. These include the proposal for foreign filing licenses by Lanjouw (2003) and differential pricing by Danzon (2002). Lanjouw (2003) proposes the foreign filing license solution such that an innovator firm cannot claim patent rights worldwide but is required to choose patent protection either in high-income countries or in low-income countries except when the patent relates to orphan drugs for neglected diseases. Danzon (2002) advocates differential pricing for pharmaceuticals to make drugs affordable in developing countries. Differential pricing entails charging different prices in different markets based on “Ramsey pricing” such that prices are inversely related to the elasticity of demand. Price differentials could be such that prices in high-income countries exceed the costs of production and distribution to cover joint costs of R&D and prices in low-income countries cover their marginal cost. From the viewpoint of efficiency and equity, differential pricing can be welfare-improving if more
new drugs are developed and distributed in developing countries and lower prices are charged in low-income countries.

In this paper, we propose that developing countries be exempt from TRIPs obligations regarding product patents for pharmaceuticals. We propose alternative ways to recoup R&D investments through global R&D pools or R&D subsidies in developed countries. Thus, our policy suggestion is to allow the availability of generic substitutes in low-income countries, particularly since most of these countries, do not have a well-established and functioning pharmaceutical industry.

The rest of the paper is organized as follows. Section 2 outlines the background for setting up the model. In section 3, we specify the model and solve for the equilibrium configuration on the assumption that there is a harmonization of patent laws according to TRIPs so that patent protection is similar in both developed and developing countries. In section 4, we find the solution under the alternative assumption where developing countries have a weaker patent legislation that allows generics to compete with the breakthrough drug from the outset and show the difference this makes to the returns to pharmaceutical research, and to the consumer surplus in developed and developing countries. Section 5 is an extension where we endogenize the time taken for a me-too drug to enter the market. Section 6 concludes with some policy suggestions.

2. BACKGROUND

In this paper, we build a theoretical model to consider certain aspects of the supply and pricing of new pharmaceuticals in the world. Given that pharmaceutical research has the nature of a public good and most of the cost is sunk, the first-best
efficient pricing is not feasible with marginal cost near zero. The second-best solution is a
time-limited monopoly pricing in the form of patents. Thus, our paper analyzes the
pricing of pharmaceuticals in the light of the international patent system as per the
provisions of the TRIPs.

While knowledge is a public good, patent legislations for rewarding innovations
are national. In order to do away with the national incentive to free-ride on R&D
conducted elsewhere in the world, TRIPs was signed in 1994 under the aegis of the
WTO. Before 1995, many developing economies had different patent regimes, often
involving weaker forms of patent legislation and shorter periods of protection, than in the
developed countries. However, TRIPs regulations call for a harmonization of patent laws
such that developing countries are required to enforce the same patent laws as prevalent
in developed countries which include both product and process\(^1\) patents together with a
longer patent term.

We take the stylized facts regarding the current system to be as follows. Most the
of the R&D that leads to a flow of new drugs is undertaken by a small group of large
multinational firms, owned principally by investors in developed countries. The firms
compete with each other, and when one of them achieves a “breakthrough” leading to the
discovery of a significant new drug, the others try to produce their own versions or “me-
too” drugs in the same therapeutic class. However, the me-too drugs are sufficiently
different from the breakthrough drugs so that they can be patented in their own right\(^2\).

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\(^1\) Process patents are granted for a novel way of manufacturing a given product using a different production
process.
\(^2\) This brings into focus the breadth of the patent which is defined as the area in a vertically differentiated
product space that is protected by a patent. Thus, it is in the interest of the innovator to claim the broadest
scope of patent protection.
Patent legislation in the developed countries ensure that the firms owning the patents have monopoly rights for a period of 20 years, although for breakthrough drugs the period of effective patent protection is smaller as there is a substantial lag between the time when the relevant patent is registered and the time when the drug can be marketed. When the product patent on the breakthrough drug expires, other firms are free to use the technology to produce a generic version that is protected by process patents. Typically, because generic versions of brandname drugs must be aggressively marketed, the market for the generic version tends to be dominated by a single seller for a period of time after the product patent has expired. Finally, a key feature of the patent legislation in most countries is that national legislation prohibits “parallel imports”. Thus the patent owner in each country faces no competition from independent imports from low-price to high-price countries by retailers.

Economic efficiency in this system depends in a complex way on the length of patent protection, the breadth or scope of patents that determine how different a new version of a drug has to be in order to be patented as a different drug, and on the nature of the competition among different versions of a drug. As has been well described in the literature, economic efficiency in this market involves a tension between static efficiency (which is promoted by pricing drugs at their marginal cost of production once they have been invented) and dynamic efficiency (ensuring that the expected profitability of inventing new drugs is high enough which requires prices above marginal production cost). The tension arises because the implicit optimum is inherently second-best in

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3 See Graboswki and Vernon (2000).
4 See Frank and Salkever (1997) and Scott Morton (1999).
5 Parallel imports occur when goods produced or sold abroad with the consent of the owner of the applicable intellectual property right (IPR) - copyright, patent or trademark - are imported into the domestic market without the consent of the IPR owner.
comparison with one in which marginal-cost pricing is used to attain static efficiency, and incentive to undertake R&D is provided through public subsidies. Thus, the rationale for strengthening the international patent system through TRIPs lies in economic efficiency, such that by increasing the potential profitability of the worldwide marketing of new drugs, it enhances dynamic efficiency by providing incentives for pharmaceutical companies to undertake R&D.

However, in this paper, we argue that this Agreement in its simple form is rather tenuous. In fact, it has been shown that even though monopoly rents should induce inventive efforts, the costs of disclosure of the details of the patented innovation can more than offset the gains from patenting (Arora et al., 2003). Further, the effects of “stronger” patent rights imply that the patent for rivals also become stronger. For instance, increasing the patent scope does not necessarily result in higher expected rents since a rival may forestall the ability of a firm to commercialize its innovation (Jaffe, 2000; Gallini, 2002). This is particularly true of pharmaceuticals where firms are engaged in patent races to develop drugs in the same therapeutic class. Moreover, it has been argued by Merges and Nelson (1990) and Scotchmer (1991) that broader patents may even decelerate the rate of innovation by curtailing subsequent innovations when the technology is cumulative and builds on existing technology (as is the case with generic pharmaceuticals). In addition, for cumulative technologies, firms may even file patents for strategic reasons so that they are able to negotiate access to other firm’s technology on more favourable terms (Hall and Zeidonis, 2001).

In this paper, we add to the literature on patents by building a model of a patent race for patents where the world is separated into two markets for developed and
developing countries. If a given firm wins the race in developing a new drug, it receives product patents for that drug and the other firms are left to develop the me-too and generic versions of the drug. The paper also focuses on the issue of patent scope through the entry of me-too drugs, which are newer and better quality drugs in the same therapeutic class. While the incentive for investing in R&D comes from the patents granted to the new drug, we show that for developing countries, exclusive marketing rights granted by patents lead to welfare losses as compared to a world without patents. In fact, we go a step further and try to put some numbers on the welfare losses due to patents through simulations. Finally, we demonstrate that under reasonable assumptions, other methods to enhance the profitability of pharmaceutical R&D (such as differential pricing and public subsidies) may be more efficient. Moreover, because other things being equal, the larger static efficiency losses under the TRIPs affect individuals in low-income countries, they will lead to a highly unfavourable impact on the global distribution of real income. Thus, we suggest that developing countries should be exempt from the provisions of TRIPs regarding the enforcement of product patents for pharmaceuticals.

3. MODEL WITH TRIPs

Our analysis is based on a three-period model of the lifecycle of a breakthrough drug, starting from the time it is first marketed. Let firm $A$ be the one to develop the breakthrough drug. In period 1, firm $A$ enjoys monopoly power, since there is no other “similar” drug but competing firms carry on working to develop their own drugs in this therapeutic class. The first period comes to an end when additional versions of the drug
have been patented and begin to compete with the original one. We represent these me-too versions by a single drug, developed and produced by firm $B$. In period 2, firms $A$ and $B$ engage in a Bertrand competition with differentiated products. Period 3 begins when the patent on the breakthrough drug expires. At this point, an early generic competitor, firm $G$, enters the market that is covered by process patent. Period 3 lasts till the process patent on the generic drug expires and there is free entry in the market. Thus, in all three periods, the drugs are protected by some form of intellectual property rights (IPRs) because even if the product patent expires, the brandname drugs are still covered by trademarks.

In each period, the different drugs are marketed throughout the world. For simplicity, we distinguish only two sub-markets, one in the developed world (denoted by $H$), and the other in the developing world (denoted by $L$). In each market, individuals buy either one or zero units. Individuals' willingness to pay (henceforth WTP) for the original breakthrough drug is denoted by $X$, and ranges from zero to $X^H$ in $H$ and from zero to $X^L$ in $L$. Again for simplicity, we assume that potential buyers are uniformly distributed on the intervals $[0, X^H]$ and $[0, X^L]$, and that the marginal cost of producing any version of the drug is zero, once it is developed. The mass of potential buyers with positive WTP in market $H$ is $\lambda^H$ while the size of the market in $L$ is denoted by $\lambda^L$.

A key assumption in the paper is that demand conditions are such that $X^H > X^L$. We justify this assumption by two considerations. First, incomes are higher in $H$, so that in general, the WTP for any good, including drugs that contribute to better health, is higher in the developed than in the developing countries. Second, most individuals in
developed countries are covered by some form of health insurance\(^6\); insurance can either be private or mandated by the government under a social-insurance or national health service model. In developing countries, in contrast, most buyers have to pay out of pocket for the drugs they use.

3.A Period 1: Monopoly of breakthrough drug

In period 1, firm \( A \) is a monopolist in both markets. Due to linear demand curves and marginal cost equal to zero, firm \( A \) sets prices \( P_{A,\lambda} = X^j / 2, \; j = H, L \) (superscripts \( H \) and \( L \) denote the two markets). Profits per unit of time are \( \lambda^H \cdot X^H / 4 \) and \( \lambda^L \cdot X^L / 4 \) respectively, and consumer surpluses in the two markets are \( \lambda^H \cdot X^H / 8 \) and \( \lambda^L \cdot X^L / 8 \).

Period 1 lasts from time 0 to \( t_1 \) which is endogenously determined since it is defined by the time at which drug \( B \), the me-too version of the breakthrough drug \( A \), becomes available in the markets. We assume that during period 1, firm \( B \) engaged in research to produce drug \( B \).

3.B. Period 2: Me-too drug enters the market

In period 2, firms \( A \) and \( B \) compete in both markets. Period 2 begins from \( t_1 \) and lasts till \( t_2 \), where \( t_2 \) is the time when the patent protection on the breakthrough drug \( A \) expires.

Here \( t_2 \) is determined by the common patent legislation in the two markets. To reflect the fact that drug \( B \) has to be sufficiently different from \( A \) in order to be separately

\(^6\) The RAND Health Insurance Experiment headed by Newhouse (1993) showed that patients with greater insurance coverage bought more prescription drugs. For other empirical studies that found similar evidence, see Leibowitz et al. (1985), Lundin (2000), Scott Morton (2000), Pavnic (2002) and Buchmueller et al. (2004).
patentable, we introduce the parameter \( s > 1 \) which denotes the extent to which drug \( B \) is more effective than drug \( A \) (for example, by having fewer side effects or smaller dosage like once-a-day instead of thrice-a-day). We assume that this superior effectiveness is reflected in consumers’ WTP for one unit. Specifically, if a patient has WTP, \( X \) for a unit of drug \( A \), we assume that she has WTP, \( sX \) for a unit of drug \( B \). Further, we assume that till the time the patent on drug \( A \) expires, firm \( A \) does not engage in competition with firm \( B \) by bringing out another drug that is superior to drug \( B \) since that would result in reducing the market for its own drug \( A \).

A consumer in either market will purchase at most one unit of either drug \( A \) or drug \( B \) or nothing. For a consumer in market \( j \) with WTP \( X \), utility is:

\[
U = \begin{cases} 
X - P_{A,2}^j & \text{if buys } A, \text{ the breakthrough drug} \\
X - P_{B,2}^j & \text{if buys } B, \text{ the me-too drug} \\
0 & \text{otherwise}
\end{cases}
\]

Prices are set by a simultaneous-move Bertrand game. The reaction functions in each market are (see Appendix 1 for the method of derivation):

\[
P_{B,2}^j = \frac{X^j(s-1) + P_{A,2}^j}{2}, \quad P_{A,2}^j = \frac{P_{B,2}^j}{2s}, \quad j=H,L.
\]  

yielding Nash equilibrium prices:

\[
P_{B,2}^* = \frac{2X^j(s-1)}{4s-1}, \quad P_{A,2}^* = \frac{X^j(s-1)}{4s-1}, \quad j=H,L.
\]

The respective demands are:

\[
D_{B,2}^* = \lambda^j \cdot \frac{2s}{4s-1}, \quad D_{A,2}^* = \lambda^j \cdot \frac{s}{4s-1}, \quad j=H,L
\]
As before, the gross profits of firms A and B, and the consumer surplus of buyers in both markets can be computed in a straightforward way. Assuming continuous discounting at an exponential rate $r$, we can also compute the present values of these variables, for given lengths $t_1$ and $t_2$ of periods 1 and 2.

**Proposition 1:** The price and demand of the me-too drug is higher than that of the breakthrough drug or $P_{B,2}^* > P_{A,2}^*$ and $D_{B,2}^* > D_{A,2}^*$. Since $X^H > X^L$, the results support differential pricing.

Since $P_{B,2}^* > P_{A,2}^*$, it means that if the quality of the me-too drug is sufficiently high, it is optimal to charge a higher price for the me-too drug than the breakthrough drug instead of engaging in price-cutting competition\(^7\). Also, $D_{B,2}^* > D_{A,2}^*$ so that the me-too drug captures double the market share of the original breakthrough drug in both the markets. This suggests that those who value quality are willing to buy the better quality drug even if it is more expensive\(^8\). Thus, for products like drugs where the demand is inelastic and mostly influenced by the prescriptions of physicians, patients prefer to buy the better-quality drug even if it costs more. Finally, the equilibrium prices for brandname drugs are higher in developed countries than in developing countries. Thus, optimal pricing supports differential pricing for the drugs in different markets depending on the ability to pay of patients in each market.

\(^7\) This finding is consistent with empirical studies that show that newer drugs are priced at a higher level than existing drugs (Mullins et al., 2001 and Danzon and Ketcham, 2004).

\(^8\) For $s > 1$, there is partial market coverage such that some consumers are left out of the market.
3.C. Period 3: Generic entry

The third period of the game begins at time $t_2$ when the patent on the breakthrough drug expires and it becomes legal to market a generic version of drug $A$. We assume that the technology for the generic drug can be copied from the technology inherent in drug $A$, but that only one firm in each market wins the race for process patents for distributing the generic version$^9$.

In general, while generic versions of previously patented drugs are supposed to be “bio-equivalent” to the originals, evidence suggests that consumers do not value them equally and treat the brandname drugs as better quality products. To reflect this, we assume that consumers’ WTP for generic and brandname versions are not the same and introduce another parameter $v < 1^{10}$. Specifically, a consumer who values a unit of drug $A$ at $X$ will only value the generic version at $vX$. Thus, given prices, consumers’ utility in each market is given by:

$$U = sX^j - P_{B,3}^j \quad \text{if buys the me-too drug}$$
$$= X^j - P_{A,3}^j \quad \text{if buys the breakthrough drug}$$
$$= vX^j - P_{G,3}^j \quad \text{if buys the generic drug}$$
$$= 0 \quad \text{otherwise}$$

$^9$ We assume that the brandname drug manufacturers do not enter the market for generic drugs since it has been found that there are no market-level strategic synergies between the brandname and generic products due to the different nature of the products (see Scott Morton, 2002).

$^{10}$ Many studies on the response of brandname drugs to generic entry have shown that brandname drugs create brand loyalty based on the perception of their better quality (Grabowski and Vernon, 1992; Caves et al., 1991; Frank and Salkever, 1992 and 1997; Suh et al., 2000; Ellison and Ellison, 2000; Danzon and Chao, 2000; Danzon and Pauly, 2002).
We again assume that prices in each market are established through a Bertrand competition. Expressions for the equilibrium prices and demands are derived in Appendix 1. As before, we can find the present values of all variables for given $t_1$ and $t_2$.

**Proposition 2:** In equilibrium, $P_{B,3}^* > P_{A,3}^* > P_{G,3}^*$ and $D_{B,3}^* > D_{A,3}^* > D_{G,3}^*$. Therefore, brandname drugs are able to carve a niche market for themselves and continue to charge higher prices even in the presence of a cheaper generic substitute.

*Proof:*

(i) $P_{B,3}^* > P_{A,3}^*$ because $v < \frac{4s - 2}{s + 1}$ always holds for $s > 1$. $P_{A,3}^* > P_{G,3}^*$ since it is can be easily seen that $P_{A,3}^* = \frac{2P_{G,3}^*}{v}$.

(ii) $D_{B,3}^* > D_{A,3}^*$ since $s > \frac{v}{2 - v}$ and $D_{A,3}^* > D_{G,3}^*$ since $v < \frac{s + 1}{2}$.

Even though generic versions are sold at lower prices than the brandname drugs, sales of the brandname drugs do not go to zero. This is because although the product patent on the breakthrough drug expires, it is still able to differentiate itself from the generic drug through trademarks and brandnames. Further, as long as the valuation for the generic drug remains low compared to the brandname drugs, the latter can maintain their market share. This feature of our model is consistent with the idea that patients are unlikely to take chances when purchasing drugs that directly affect their health. Further, since we assume the difference in WTP between developed and developing countries, the prices of all the drugs are again higher in the former than the latter, supporting differential pricing.
4. THE COUNTERFACTUAL: A WORLD WITHOUT TRIPs

In this section, we consider the welfare consequences of a system in which developing countries were not committed to providing the same level of patent protection as developed countries, but instead could allow firms to produce and sell generic versions of patented drugs from the outset. Evaluating the effects of this requires a consideration of both the static and dynamic consequences of changing patent rules. This would require estimates of not only the changes in profits and consumer surplus from the sale of a given breakthrough drug, but also the estimates of the long-term consequences of changes in the profitability of devoting R&D resources to the development of new kinds of drugs. The framework we have outlined above is not sufficient for this purpose, since we have not explicitly modeled the process through which new breakthrough drugs are developed.

To circumvent this problem, we consider instead a somewhat less general problem, namely that of the cost of alternative methods for providing a given level of incentive for the development of breakthrough drugs. We measure this incentive by the combined profits from the sale of breakthrough drugs, and the net profits on the development and sale of the derivative me-too drugs that result when a new breakthrough drug is introduced. The rationale for this measure is the assumption that at any given time, there are several different firms that are engaged in R&D aiming at developing a given kind of breakthrough drug. However, only one of them will be successful in doing so and obtaining patent protection; the remaining ones will only develop the me-too versions. But ex ante, it is not known who the successful one will be. Thus, the incentive to engage in R&D will consist in the expected profit of either becoming the patent holder for the new breakthrough drug, or to developing and marketing a me-too version.
Assuming for simplicity that there is symmetry among the contestants, the relevant incentive level is then equal to the sum of the profits from the breakthrough drug and the net profits from the me-too drug. The value of this incentive measure in the baseline case can be computed using the methods outlined in Appendix 1. Our initial approach then is to compute the amount by which the combined incentive changes in a counterfactual experiment in which developing countries are allowed to use generics throughout. One way of compensating for this would of course be direct public subsidies from the public purse. Alternative methods would involve lengthening the period of patent protection in the developed world, or changing the rules governing patentability of me-too drugs.

4.A. Equilibrium without TRIPS

In the following modified version of the model, the environment in which the three firms A, B, and G compete is the same for the developed country market (H) in all three periods. However, in the developing country market (L), the breakthrough drug A is no longer a monopolist in period 1, but instead competes with a generic; there will thus be a new equilibrium price \( P_{G,1}^L \), with \( P_{G,1}^L < P_{A,1}^L \), and firm G will earn some of the profits in market L. Similarly, in period 2 all three firms will compete in market L to establish prices \( P_{B,2}^L > P_{A,2}^L > P_{G,2}^L \). The methods used to establish the equilibrium prices are the same as outlined in Appendix 1.

4.B. Some numerical illustrations

Preliminary calculations suggest that, as conjectured in the text, allowing developing countries to use liberal rules for the use of generics would be a potentially efficiency-
enhancing step. The simulations underlying Tables 1 and 2 were based on a set of assumed parameter values with the following characteristics. The mass of patients with positive WTP for the breakthrough drug $A$ was assumed to be the same in the developed and developing countries, but the marginal WTP for each drug, at any quantity, was assumed to be 40 percent lower in developing countries ($X^L = 0.6X^H$). The parameters $s$ and $v$ were set at 1.2 and 0.85, respectively. Thus, anyone with a positive WTP for the breakthrough drug $A$ had a 20 percent higher WTP for the improved drug $B$, but a 15 percent lower WTP for the generic drug. The effective period of patent protection $t_2$ was set at 12 years, and competition from the me-too drug $B$ was assumed to occur 6 years after the launch of drug $A$ i.e., $t_1$ was set at 6. In the base case for developed countries, it must be noted that while the demand curve is a regular demand curve from the viewpoint of the monopolists, the area under the demand curve is not a true measure of the consumer surplus due to insurance coverage, which leads to the problems of moral hazard and overutilization of drugs. To account for insurance, we assume that one-third$^{11}$ of the drug expenditure is covered by insurance and take two-thirds of the total to be the true consumer surplus.

The results for the base case are interesting (see Table 1). Although $B$, as the most valuable drug, is priced higher than $A$ in either market after it has been introduced, it is priced well below the level at which $A$ was priced when it enjoyed a monopoly in period 1. In developed countries, the losses in consumer surplus from monopoly pricing are lower since the bias arising from patents and monopoly prices is offset by the implicit

$^{11}$ The average insurance coverage for developed countries is around 50 percent of the health expenditure (see Table 2.1, pp25 in WHO (2002)). But the net insurance coverage after paying the insurance premium is expected to be around one-third.
subsidy from insurance. This also means overutilization of drugs compared to other inputs of health. In period 3 in the base case, introduction of the generic further lowers the equilibrium prices of $A$ and $B^{12}$. There is a fall in the demand for drug $B$ but not for drug $A$ with the introduction of generics, reflecting not only the brand loyalty for the breakthrough drug but also the costs involved in switching from the brandname to the generic drug.

In the counterfactual experiment, the assumption that the generic drug is allowed to compete in the $L$ market from the beginning changes the equilibrium values only in the $L$ market and only in periods 1 and 2. This is due to the fact that in the absence of parallel imports, both drugs $A$ and $B$ can be priced independently in markets $H$ and $L$ in periods 1 and 2, and even though the generic version can be legally sold in market $L$ in periods 1 and 2, it cannot be legally sold in market $H$ until period 3. The major impact of the generic competition in market $L$ is in period 1, when the price of drug $A$ in the counterfactual case is 80 percent lower than in the base case and revenue falls by around two-thirds (see Table 2). In period 2, the fall in revenue is smaller at around 50 percent.

Taking the combined present value (the discount rate was set at 5 percent) of the profits for drugs $A$ and $B$ as the basic measure of target incentive to produce breakthrough drugs, around 60 percent of the combined profits come from market $H$ in the base case.

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12 The price response of brandname drugs to generic entry has been a source of controversy. Some studies show that brandname drug prices rise after generic entry (Grabowski and Vernon, 2000 and Suh et al., 2000). Ellison and Ellison (2000) show that prices fall for the drugs where predicted entry is likely and rise for the drugs with low probability of generic entry. According to Frank and Salkever (1992), as the cross-price sensitive segment of the market grows, it would reduce the prices of brandname drugs. In general, there are two pharmaceutical submarkets such that the brandname drug manufacturers concentrate on sales in the inelastic market and give up the elastic market to generic manufacturers. Since our model does not explicitly account for these two submarkets, we find that the price of the brandname drugs fall with generic entry as opposed to the findings of some empirical studies for developed countries. In any case, in developing countries, it is more likely that the response of brandname drug manufacturers would result in a fall in prices. Even in developed countries, with the growing concern for rising health care costs and the institutional structure veering towards managed care, it is expected that the price of brandname drugs would fall.
As the model has been constructed, over 40 percent comes from the me-too drug $B$, even though it is assumed to be launched in both the markets six years later than drug $A$.

In the counterfactual case, allowing the marketing of the generic version of the drug from period 1 itself in low-income countries reduces the present value of combined profits by about 80 percent. The reduction is mostly due to a fall in the profits on the breakthrough drug $A$. By construction, the entire decrease in combined profits occurs in the developing countries. In addition, however, there is a considerable gain to the population in developing countries in the amount of consumer surplus they enjoy. In fact, the present value of the gain in consumer surplus plus the profits of the generic drug companies (we assume that they are owned by developing-country citizens in periods 1 and 2) is more than twice as large as the reduction in the profits of brandname drug manufacturers. That is, for every dollar by which these profits are reduced, citizens of the developing world gain more than two dollars ($2.05). Although the ratio becomes somewhat smaller for assumptions that imply either that the me-too drug $B$ is more similar to drug $A$ (the value of $s$ is reduced from 1.2 to 1.1), or that the generic drug $G$ is more similar to drug $A$ (the value of $v$ is raised from 0.85 to 0.90), the consumer surplus gain remains quite large relative to the reduction in combined profits (it is 98 percent and 84 percent larger, respectively).

5. AN EXTENSION: OPTIMAL TIMING FOR ENTRY OF ME-TOO DRUG

Here, we consider the time taken for a me-too drug to enter the market to be determined by the present value of the net profit flow of firm $B$. We specify the process of
developing any new drug as one that can be accelerated to some extent by more intensive research, but which requires time in an essential way. To establish the equilibrium value of \( t_1 \), we write the net profits of firm \( B \) as a function of \( t_1 \). The time and resources required also depend on \( s \): the higher the quality of the new drug \( B \) in comparison with drug \( A \), the more time and resources it will require to develop. In particular, we assume that the relation between \( M \), \( s \), and \( t_1 \) is given by \( s = kM^\alpha \cdot t_1 \), where \( M \) denotes the spending on R&D, \( 0 < \alpha < 1 \) measures the extent to which the completion time for a drug of quality \( s \) can be accelerated by a higher rate of R&D spending, and \( k \) is a constant. In full equilibrium, \( t_1 \) will be determined by this cost function and the expected profit stream from drug \( B \); the latter depends not only on conditions in period 1 but also on the nature of competition in periods 2 and 3. When the rate of interest is very close to zero, the optimal solution to the timing of the entry of the me-too drug is very close to the following (see Appendix 2)

\[
\tau^*_1 = \left( \frac{s}{k} \right) \left[ \frac{\alpha \Pi_{B,2}}{1 - \alpha} \right]^{-\alpha}
\] (4)

**Proposition 3:** The higher the quality of the me-too drug \( s \), the greater the time it takes for the me-too drug to enter the market but higher the R&D spending \( M \), the lower the time taken to introduce the me-too drug.

The higher the quality of the me-too drug that is given exogenously by the scope of the patent, that firm \( B \) seeks to introduce in the market, the greater the time it takes for the
me-too drug to enter the market and end the monopoly of the breakthrough drug. However, if firm B intensifies R&D efforts by expending more resources in a shorter period of time instead of over a longer period of time, the lower the time taken to introduce the me-too drug.

From Figure 2 in Appendix 2, it is clear that while the present value of profits falls all through as $t_1$ rises, the present value of the R&D cost initially falls and then rises with $t_1$ as diminishing returns set in. Thus, the present value of the net profit flow rises as long as the profits outweigh the costs and then starts falling.

6. CONCLUSION

The paper suggests that developed and developing countries require different patent legislations. This would require alternative forms of rewards and prizes that are less socially harmful for stimulating R&D for developing countries such as differential pricing and basic research funded by the government. If TRIPs is to be retained for developing countries, then at least governments should allow differential pricing for drugs in low-income markets. But, if developing countries are to be exempted from TRIPs, then a crucial concern is who would compensate pharmaceutical firms for the loss of revenue. It could be done either by taxpayers in developing countries or by taxpayers in developed countries in the form of foreign aid. Given that developing countries generally have weak tax systems, the real cost of raising a dollar’s worth of tax revenue has a social cost well in excess of one dollar. If we substitute patent revenue by tax funding for R&D in developed countries, then even if the excess burden is as high as 85-95 cents or more per dollar of revenue, it is still possible to have net gains.
Alternatively, compensation in the form of foreign aid by developed countries entails payment by taxpayers of developed countries (that is, donor government funding of goods or services provided by pharmaceutical multinational corporations in the donor country). A standard result in the analysis of the welfare effects of tied aid is that the real value of such aid is less than its nominal value, since the effect of tying may be to raise the cost. Thus each dollar of aid would be likely to have a real value to the citizens of the receiving country of less than one dollar. In the case of paying for an exemption from TRIPs, however, the real value would be a multiple of the nominal value of the aid: each dollar of aid would yield benefits of what would be perhaps 85-95 percent higher than their nominal value.

Finally, equity considerations are likely to further strengthen the conclusions regarding exemption from TRIPs for developing countries. On average, buyers of pharmaceuticals in low-income countries are likely to have lower incomes than the average taxpayer in the developing world, not only because drug expenditure tends to be associated with illness which by itself lowers income, but also because the incidence of illness is likely to be higher in low-income groups than in high-income groups in a country. This consideration would make a world without TRIPs even more attractive for developing countries, irrespective of who compensates the pharmaceutical firms for the loss in revenues.

References:


Table 1: Developed countries: Base Case

<table>
<thead>
<tr>
<th>Drug</th>
<th>Period 1</th>
<th>Period 2</th>
<th>Period 3</th>
<th>Present value</th>
</tr>
</thead>
<tbody>
<tr>
<td>A: Share</td>
<td>0.500</td>
<td>0.315</td>
<td>0.324</td>
<td></td>
</tr>
<tr>
<td>Revenue</td>
<td>2.500</td>
<td>0.166</td>
<td>0.090</td>
<td>14.585</td>
</tr>
<tr>
<td>Cons surplus</td>
<td>0.837</td>
<td>0.055</td>
<td>0.072</td>
<td>5.355</td>
</tr>
<tr>
<td>B: Share</td>
<td></td>
<td>0.631</td>
<td>0.569</td>
<td></td>
</tr>
<tr>
<td>Revenue</td>
<td></td>
<td>0.797</td>
<td>0.648</td>
<td>10.182</td>
</tr>
<tr>
<td>Cons surplus</td>
<td></td>
<td>2.271</td>
<td>2.071</td>
<td>31.465</td>
</tr>
<tr>
<td>G: Share</td>
<td></td>
<td></td>
<td>0.092</td>
<td></td>
</tr>
<tr>
<td>Revenue</td>
<td></td>
<td></td>
<td>0.010</td>
<td>0.119</td>
</tr>
<tr>
<td>Cons surplus</td>
<td></td>
<td></td>
<td>0.005</td>
<td>0.040</td>
</tr>
</tbody>
</table>

Notes: “Share” is the proportion of unit mass of potential buyers opting for each drug. Note that shares do not sum to unity since some potential buyers do not actually buy. “Revenue” and “Cons surplus” is annual revenue and consumer surplus for each drug. “Present value” is discounted present value of revenue and consumer surplus over all three periods. Parameter values are: $X^H = 10, X^L = 6, s = 1.2, v = 0.85, r = 0.05, t_i = 6, \lambda^H = \lambda^L = 1$. We assume that insurance coverage is provided to consumers in developed countries up to one-third of their drug expenditure, so the true measure of consumer surplus is calculated as 0.67 of the total consumer surplus.
## Table 2: Developing countries: Base Case compared to Counterfactual Case

<table>
<thead>
<tr>
<th>Drug</th>
<th>Period 1</th>
<th></th>
<th>Period 2</th>
<th></th>
<th>Present Value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Base Case</td>
<td>Counterfactual</td>
<td>Base Case</td>
<td>Counterfactual</td>
<td>Base Case</td>
</tr>
<tr>
<td>A: Share</td>
<td>0.500</td>
<td>0.634</td>
<td>0.315</td>
<td>0.324</td>
<td></td>
</tr>
<tr>
<td>Revenue</td>
<td>1.500</td>
<td>0.362</td>
<td>0.099</td>
<td>0.054</td>
<td>8.751</td>
</tr>
<tr>
<td>Cons Surplus</td>
<td>0.750</td>
<td>1.723</td>
<td>0.049</td>
<td>0.065</td>
<td>4.795</td>
</tr>
<tr>
<td>B: Share</td>
<td></td>
<td></td>
<td>0.631</td>
<td>0.569</td>
<td></td>
</tr>
<tr>
<td>Revenue</td>
<td></td>
<td></td>
<td>0.478</td>
<td>0.389</td>
<td>6.109</td>
</tr>
<tr>
<td>Cons Surplus</td>
<td></td>
<td></td>
<td>2.034</td>
<td>1.855</td>
<td>33.998</td>
</tr>
<tr>
<td>G: Share</td>
<td>0.317</td>
<td>0.092</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Revenue</td>
<td>0.077</td>
<td>0.006</td>
<td>0.071</td>
<td>0.496</td>
<td></td>
</tr>
<tr>
<td>Cons Surplus</td>
<td>0.038</td>
<td>0.003</td>
<td>0.035</td>
<td>0.855</td>
<td></td>
</tr>
</tbody>
</table>

Notes: Period 3 is not shown as the Base Case and the Counterfactual case are the same in period 3. Note that Cons Surplus for drug G includes profits of generic drug producers in periods 1 and 2. In the simulations, $t_i$ was fixed exogenously at 6 years.
APPENDIX 1

In Period 3, when the patent on the breakthrough drug expires, all the three drug varieties are available in the market i.e the breakthrough drug (A), the me-too drug (B) and the generic drug (G). The marginal valuation of patients for the drugs is measured by $X$. There is a perceived quality difference for the drugs which is measured by the parameters $s > 1$ for the me-too drug and $0 < v < 1$ for the generic drug. The size of Market $H$ is $\lambda^H$ and that of Market $L$ is $\lambda^L$. Depending on the patient’s choice of drugs, her utility is:

$$U = sX^j - P^{j}_{B,3} \quad \text{if buys the me-too drug}$$

$$= X^j - P^{j}_{A,3} \quad \text{if buys the breakthrough drug}$$

$$= vX^j - P^{j}_{G,3} \quad \text{if buys the generic drug}$$

$$= 0 \quad \text{otherwise}$$

Let us consider any market $j$, for which we get three critical values of $X$. These are determined by the patients who are indifferent between buying the me-too drug and the breakthrough drug, the breakthrough drug and the generic drug, and the generic drug and not buying any drug. Thus, $X_1 > X_2 > X_3$ are determined by setting

$$sX_1 - P^{j}_{B,3} = X_1 - P^{j}_{A,3} ; \quad X_2 - P^{j}_{A,3} = vX_2 - P^{j}_{G,3} ; \quad vX_3 - P^{j}_{G,3} = 0.$$  

The proportion of consumers that choose the three drugs will then be given by

$$\frac{(X^j - X_1)}{X^j}, \frac{(X_1 - X_2)}{X^j}, \frac{(X_2 - X_3)}{X^j}, \frac{(X_3)}{X^j}, \text{respectively.}$$
Given the prices, consumer surplus on purchases of the three drugs are as illustrated in Figure 1 below.

**Figure 1: Consumer surplus in Market $j$**

Valuation per unit in dollars

Profit of firm $B$ in the two markets, $j = H, L$ is

$$\pi_{B,j} = p_{B,j} \left( \frac{X^j - X_1}{X^j} \right) \lambda^j$$

$$= p_{B,j} \left( \frac{(s-1)X^j - p_{A,j} + p_{B,j}}{(s-1)X^j} \right) \lambda^j$$

Maximizing with respect to $p_{B,j}$, we get the reaction function

$$p_{B,j} = \frac{X^j (s-1) + p_{A,j}}{2} \tag{1.1}$$

Profit of firm $A$ in the two markets is,

$$\pi_{A,j} = p_{A,j} \left( \frac{X_1 - X_2}{X^j} \right) \lambda^j$$
$$P^j_{A,3} = \left[ \frac{(1-v)P^j_{B,3} - (s-v)P^j_{A,3} + (s-1)P^j_{G,3}}{(s-1)(1-v)X^j} \right] \lambda^j$$

Maximizing with respect to $P^j_{A,3}$, we get the reaction function

$$P^j_{A,3} = \frac{(1-v)P^j_{B,3} + (s-1)P^j_{G,3}}{2(s-v)} \quad (1.2)$$

Profit of firm $G$ in the two markets is

$$\pi^j_{G,3} = P^j_{G,3} \left\{ \frac{X^j_2 - X^j_3}{X^j} \right\} \lambda^j$$

$$= P^j_{A,3} \left( \frac{vP^j_{A,3} - P^j_{G,3}}{v(1-v)X^j} \right) \lambda^j$$

Maximizing with respect to $P^j_{G,3}$, we get the reaction function

$$P^j_{G,3} = \frac{vP^j_{A,3}}{2} \quad (1.3)$$

Solving the three reaction functions from equations (1.1), (1.2) and (1.3), we get the following Nash equilibrium prices:

$$P^*_{B,3} = \frac{X^j_3(s-1)(4s-3v-sv)}{2(4s^2-2v-sv-1)}$$

$$P^*_{A,3} = \frac{X^j_3(s-1)(1-v)}{(4s-2v-sv-1)}$$

$$P^*_{G,3} = \frac{X^j_3v(s-1)(1-v)}{2(4s-2v-sv-1)}$$

The respective demands for the three drugs are:

$$D^*_{B,3} = \lambda^j \cdot \frac{4s - 3v - sv}{2(4s - 2v - sv - 1)}$$
\[ D_{i,3}^{*} = \lambda^i \cdot \frac{s - v}{4s - 2v - sv - 1} \]

\[ D_{j,3}^{*} = \lambda^j \cdot \frac{s - 1}{2(4s - 2v - sv - 1)} \]

For \( s > 1 > v \), \( D_{i,3}^{*} + D_{j,3}^{*} + D_{k,3}^{*} < 1 \).

Note that a similar analysis gives the equilibrium results in period 2 by setting \( v = 0 \) and \( P_{G,3} = 0 \).
APPENDIX 2

Let \( \pi_{B,2}^j \) and \( \pi_{B,3}^j \) be the profits of firm B per unit of time in market \( j \) in periods 2 and 3, respectively. Then total profits for firm B are given by:

\[
\Pi_{B,2} = \pi_{B,2}^H + \pi_{B,2}^L \quad \text{and} \quad \Pi_{B,3} = \pi_{B,3}^H + \pi_{B,3}^L
\]

Given that \( t_1 \) is the time at which the me-too drug enters the market, \( t_2 \) is the time at the generic drug enters the market and \( T \) is time when period 3 ends (the drug becomes dominated by new drugs), the present value of firm B’s profit flow at a rate of interest \( r \geq 0 \) is:

\[
V(t_1) = \int_{t_1}^{t_2} e^{-rt} \Pi_{B,2} dt + \int_{t_2}^{T} e^{-rt} \Pi_{B,3} dt \quad (2.1)
\]

We postulate that the cost of inventing the me-too drug by firm B for exogenous constants \( s \) and \( k \) and research expenditure per unit of time \( M \) is given by:

\[
s = kM^\alpha t_1, \quad \text{where} \quad 0 < \alpha < 1
\]

Thus, we can express the research effort as a function of \( t_1 \):

\[
M = \left( \frac{s}{kt_1} \right)^{1/\alpha} \quad (2.2)
\]

The present value of the expenditure on R&D is

\[
C(t_1) = \int_{0}^{t_1} e^{-rt} M dt = \int_{0}^{t_1} e^{-rt} \left( \frac{s}{kt_1} \right) dt \quad (2.3)
\]

Firm B has to choose the \( t_1 \) to maximize the present value of the net profit flow:

\[
\max_{t_1} V(t_1) - C(t_1)
\]
For \( t_1^* \) as the optimal timing, the first order condition is

\[
V'(t_1^*) - C'(t_1^*) = 0
\]

and the second order condition is

\[
V''(t_1^*) - C''(t_1^*) < 0
\]

Consider two cases when \( r = 0 \) and when \( r > 0 \)

**Case A:** With \( r = 0 \), \( V(t_1) \) is simply

\[
V(t_1) = (t_2 - t_1)\Pi_{b,2} + (T - t_2)\Pi_{b,3}
\]

and \( C(t_1) \) is

\[
C(t_1) = (t_1 - 0)^\left(\frac{s}{kt_1}\right)^\alpha = t_1^{1-\frac{1}{\alpha}} \left(\frac{s}{k}\right)^\alpha
\]

Then the first order condition is

\[
V'(t_1^*) - C'(t_1^*) = -\Pi_{b,2} - \left(\frac{\alpha - 1}{\alpha}\right) t_1^{-\frac{1}{\alpha}} \left(\frac{s}{k}\right)^\frac{1}{\alpha} = 0
\]

Solving,

\[
t_1^* = \left(\frac{s}{k}\right)^\frac{\alpha \Pi_{b,2}}{1 - \alpha}
\] \hspace{1cm} (2.4)

The second order condition is satisfied since

\[
V''(t_1^*) - C''(t_1^*) = \left(\frac{s}{k}\right)^\frac{1}{\alpha} \left(\frac{\alpha - 1}{\alpha}\right) \left(\frac{1}{\alpha}\right) t_1^{-\frac{1}{\alpha}-1} < 0
\]

**Case B:** With \( r > 0 \), we have

\[
V(t_1) = \Pi_{b,2} \left[ \frac{e^{-\eta_1} - e^{-\eta_2}}{r} \right] + \Pi_{b,3} \left[ \frac{e^{-\eta_2} - e^{-\eta_T}}{r} \right]
\]
and

\[ C(t_1) = \left( \frac{s}{kt_1} \right)^{\frac{1}{\alpha}} \left( \frac{1-e^{-\frac{r t_1}{\alpha}}}{r} \right) = \left( \frac{s}{k} \right)^{\frac{1}{\alpha}} \left( \frac{1-e^{-\frac{r t_1}{\alpha}}}{r} \right) t_1^{-\frac{1}{\alpha}} \]

Then first order condition is

\[ V'(t_1^*) - C'(t_1^*) = -\Pi_{B_2} e^{-\frac{r t_1^*}{\alpha}} - \left( \frac{s}{k} \right)^{\frac{1}{\alpha}} e^{-\frac{r t_1^*}{\alpha}} t_1^{-1/\alpha} + \left( \frac{1}{\alpha} \right) \left( \frac{s}{k} \right)^{\frac{1}{\alpha}} \left( \frac{1-e^{-\frac{r t_1}{\alpha}}}{r} \right) t_1^{-1/\alpha-1} = 0 \]

Here, we cannot have an explicit solution for \( t_1^* \) but for different parameter values, we can obtain the solution numerically. In particular, if \( r \) is very close to zero, then \( t_1^* \) is very close to the solution given by equation (2.4) above.

**Figure A2.2: Profit flow of firm B**