

Trading Up: How Much Should Poor Countries Pay to Support Pharmaceutical Innovation?

By Jean O. Lanjouw and William Jack *

Summary: The most contentious issue in the pharmaceutical sector is not about whether, or how much, to support private research. Most people recognize the major contributions to global health that have come from private sector research efforts, and the fact that price-cost margins supported by the patent system have been pivotal in supporting that research. The conflicts arise over how the financing of R&D incentives should be shared among consumers. How much should a U.S. retiree, a French worker, and an Ethiopian peasant be expected to contribute by paying higher drug prices? Should the burden be spread evenly across countries? Or should rich country consumers provide most, or even all, of the incentive?

This brief outlines how a global structure of pharmaceutical prices may be determined to balance both the *efficiency* and the social *equity* concerns that arise in dealing with countries with widely disparate needs and incomes. Both concerns can be brought into a simple unified framework to determine optimal prices; this basic framework supports a number of important principles with relevance to countries at all levels of development:

- Drug prices should not be the same in all countries — the price of a drug should be similar among countries with similar demand patterns and income levels.
- Poorer countries should pay prices that are close to marginal cost.
- In the very poorest countries, drugs should be made available free of charge.
- The only situation where poor countries arguably should contribute to R&D arises in the case of diseases specific to these countries, for which alternative financing sources have not been forthcoming.

Dissatisfaction with drug prices

Tension over drug prices continues to grow. In the U.S., senior citizen outrage over high drug payments recently drove legislation through Congress to create a massive Medicare prescription drug benefit, shifting costs from pharmaceutical consumers to taxpayers at large. A similar sense of outrage has led to repeated efforts to legalize the importation of lower-priced Canadian drugs into the U.S. The effect of such “parallel imports” would be to reduce the cost of pharmaceutical research for Americans. In a similar vein, an increasing number of voices support the view recently expressed by Mark McClellan, then-Commissioner of the U.S. FDA, in Cancún, Mexico, that

the main reason [U.S.] prices are higher is that our country is paying the bulk of the costs of developing new treatments. That’s got many Americans angry...I know that many are complacent with the current situation, in which the United States has borne the bulk of costs. I

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know it is not clear how to work together internationally to create better ways to share the burden than are provided by our current trade agreements. But it is clear to me that we cannot carry the lion's share of this burden for much longer.¹

Once again the goal is, at least implicitly, to shift more of the costs of pharmaceutical research onto Europeans (who are relatively shielded by price controls) and others.

These conflicts within and between the rich countries are, at heart, the same battle that has raged for years over drug pricing in the developing world. The issue there is again distributional: given a desire to support private sector research, to what extent should allowing innovative firms to set prices in poor countries be a part of the effort? One side argues that it is crucial for firms to have this freedom worldwide if it is to explore valuable research opportunities. The focus is squarely on protecting incentives. A related position views it as only "fair" for consumers in all countries to contribute something to the discovery of new drugs. Those on the other side of the debate see poor people dying, children orphaned, and the reversal of years of development progress. Their main imperative is to keep prices in the developing countries down, as part of the larger effort to improve access.

For developing countries, the primary battle has been over the minimum standards for patent protection set forth for members of the World Trade Organization in the so-called TRIPS Agreement², in particular the requirement that all member countries offer protection for pharmaceutical innovations for 20 years. These disagreements have in turn fueled confrontations between developing country governments and firms over the pricing and sale of generics, with persistent and focused campaigning by non-governmental organizations on the side of governments to force price concessions for poor countries. Efficiency and equity considerations are common to all of these debates.

Given a desire to support private sector research, to what extent should allowing innovative firms to set prices in poor countries be a part of the effort?

The Pricing Problem in Context

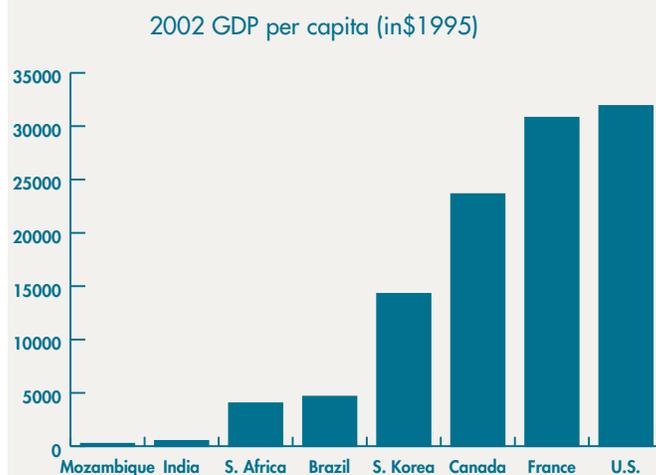
Creating an environment in which firms can earn a profit margin on sales of innovative products by selling at a price higher than the marginal cost of production and distribution is one of the

most common ways to encourage research investment. A patent system, for example, does this. Currently much of the R&D investment in the pharmaceutical sector is induced by the expectation of earning profits during the years that patents are in force.

We start from the assumption that some amount of R&D incentive is to be generated by global profits, and focus on the key policy question of how drug prices should be determined to share the burden. One benchmark is uniform pricing across countries, which can result from choices made by pharmaceutical firms, illegal arbitrage, or free trade in pharmaceuticals (as within the European Union). But charging the same price in rich and poor countries is, roughly speaking, like a regressive tax: \$10 to someone with a \$500 income means something very different from \$10 to someone with a \$10,000 income. Allowing different drug prices could be more progressive, but how different should these prices be? A second benchmark in recent discussions has been country-specific monopoly pricing, which would result when firms have patent control and total discretion on setting prices. Indeed, a restrictive version of the so-called Ramsey pricing framework — one that does not allow for equity concerns justifies monopoly pricing as a reasonable benchmark.

What is needed is a coherent framework for global pricing that explicitly incorporates the distributional concerns driving debate over drug patents and price controls. We adapt a model originally developed for pricing goods across rich and poor

Box 1: Income Differences between Countries in the Spotlight



Source: The World Bank: World Development Indicators online (accessed 8/04)

Box 2: Income Levels on Adoption of Pharmaceutical Product Patents

Panel A: OECD Adopters

Country	Year of Adoption	GDP per capita in year of adoption (\$1995)
Switzerland	1977	36,965
Italy	1978	13,429
Holland	1978	20,722
Sweden	1978	22,178
Canada	1983	16,447
Denmark	1983	28,010
Austria	1987	24,844
Spain	1992	14,384
Portugal	1992	10,538
Greece	1992	11,114
Norway	1992	30,598

Panel B: Recent Adopters

Country	Year of Adoption	GDP per capita in year of adoption (\$1995)
China	1992/3	426
Brazil	1996	4,474
Argentina	2000	8,174
Guatemala	2000	1,563
Uruguay	2001	6,193
Egypt	(2005)	1,250
Pakistan	(2005)	518
India	(2005)	493
Malawi	(2016)	157

Note: China GDP is for 1992. Parentheses indicate an expected future date of adoption. For these countries the GDP figure is for 2002. Sources: Years of adoption, Santoro (1995) "Pfizer: Global Protection of Intellectual Property," *Harvard Business School Case Study no. 9-392-073*, country representations to the WTO at <http://www.wto.org> (accessed 9/04), Richard Wilder and Marco Antonio Palacios, personal communications, 2002 and 9/04; GDP statistics, *The World Bank: World Development Indicators* online (accessed 8/04).

consumers within a single country to the problem of optimally pricing pharmaceuticals across rich and poor countries (many-person Ramsey³ pricing). Because the international policy discussion and the legal and regulatory infrastructure related to pricing are largely at the national level, an analysis at this level seems a useful starting point. In adapting the model, of course, we ignore great inequality within countries.

The focus on equity in addressing burden sharing is natural given the stark inequalities between countries that have been focal points in the debate (Box 1). Mozambique (GDP per capita \$223)⁴ represents the poorest countries — the group that most clearly needs flexibility in global standards for patent protection. India (\$493) is of interest in its role as a current producer of generics, and as a large future market. It is often put together with Brazil (\$4,642), as in "countries like Brazil and India," but is clearly far poorer. South Africa (\$4,020) has been in the spotlight of controversy over the prices of patented anti-retrovirals. South Korea (\$14,280) stands out as a poor country that grew extremely rapidly — a cautionary example to the pharmaceutical industry that uninteresting markets today may well be valuable tomorrow. Canada (\$23,621), with an average income 70% of that of the U.S., is the country to which Americans are turning for cheaper drugs. Canada also recently passed legislation to allow its firms to export generics to the poorest markets under compulsory

license. France (\$30,790) is a frequent target of industry complaints over price controls. The U.S. (\$31,891), with an average annual per capita income 50 to 100 times higher than that of the poorest countries, is of primary importance to the research-based industry; its concerns inevitably influence all of the international discussion.

The inequalities that have fueled disagreement over TRIPS are also evident in Box 2, which shows the GDP per capita of countries at the time when they introduced patent protection for new pharmaceutical products. The countries adopting strong patent protection today are doing so at much lower income levels (between \$500 and \$8,000 per capita) than was the case for the developed countries (upwards of \$20,000)⁵.

While in *theory* the best way to address concerns about global inequalities would be through direct redistribution of income — e.g., through comprehensive international aid transfers, or even a worldwide income tax system — in *practice* such transfers are limited by institutional and political constraints, as well as the potential for corruption. Forced to rely on other complementary policies to tackle global equity concerns, drug pricing may well be one of the more effective tools available to address a basic human need, and to provide resources in a form more difficult to divert than, say, direct transfers to poor country governments.

What are “Optimal” Prices?⁶

An innovating firm could obtain net revenues from sales of a new drug in several countries. Suppose that, for a given drug, we would like to allow the firm a targeted level of total net revenue to encourage research investment. Recognizing that prices determine how the R&D financing burden is shared across countries, what prices will ensure that social welfare — a global aggregate of well-being — is as large as possible? Two considerations go into answering this question:

Efficiency — How do we set prices so as to keep the *sum* of well-being as high as possible?

Equity — How do we set prices so as to obtain the best *distribution* of well-being across countries?

The key concept capturing equity is the marginal social cost (MSC) of raising revenue in each country. This indicates how much global social welfare would fall if an innovator firm were to raise an extra dollar by increasing the price of a drug in a given country. The magnitude of the MSC depends on two factors. The first is the extent to which a higher price diminishes the well-being of individuals in that country, and the second is how much one wants to avoid reducing the well-being of those people. Thus the MSC for a country is large when extra income is particularly valuable to its people, and when preserving the well-being of people there is viewed as particularly important. The first consideration is a factual matter. Because the differences in income are so extreme, we can safely assume that extra income means more to poorer people, so that the MSC of raising revenue in the poorer countries would be higher. The second consideration is a value judgment. A preference for a more equal distribution of well-being across countries would also suggest a higher MSC for poor countries.

The Structure of Optimal Prices

Using well-established techniques of applied public economics, we can determine the structure of prices that gives the highest level of (global) social welfare while allowing the innovator firm the targeted net revenue. These are often called Ramsey prices. The Ramsey pricing rule shows that prices should be lower:

- when demand is very responsive to price. This implies lower mark-ups for those who would cut back most when faced with a price increase. Pricing this way is efficient because it causes the least distortion in consumption patterns, i.e., it minimizes the reduction in drug consumption because of cost.

Box 3: Ramsey Reasonable Royalties

The TRIPS Agreement allows governments to license patented innovations in some circumstances against the wishes of the patent holder. These so-called compulsory licenses give generic manufacturers the right to produce and sell a patented product locally in return for adequate remuneration to the patent holder (TRIPS, art. 31h and 31k). Another licensing variant — not quite compulsory, but less than voluntary can also arise in some circumstances, as in a recent agreement by GlaxoSmithKline and Boehringer Ingelheim to license production of their patented anti-retrovirals for distribution in South Africa, in an out of court settlement of a case before the Competition Commission.

Typically, compensation to the patentee is defined as a royalty payment per unit of sales, and laws requiring compensation sometimes refer to “reasonable” royalties. However, “reasonable” can mean many things. Deciding on its interpretation is likely to be a new area of international dispute when compensation rules span countries at both ends of the income spectrum. One natural way to approach the problem would be to follow the same line of reasoning used here and to ask what royalty rates would generate the highest level of social welfare. The resulting “Ramsey reasonable royalty rates” would have precisely the same structure as Ramsey prices.

- on this account, optimal prices would be lower in poorer countries (assuming consumers there are more price sensitive), but also higher in countries with more pressing health needs.
- when the marginal social cost (MSC) of raising revenue in a country is high, i.e., when there is a relatively large social cost to removing income from the hands of consumers. On this account, one would likely want to have lower prices in poorer countries.

Four clear conclusions arise from the analysis:

- Monopoly pricing in every country is not an obvious benchmark. Contrary to what has been suggested, there is no reason to expect optimal pharmaceutical prices to be closely related to monopoly prices.

- The price of a drug should *not* be the same in every country.
- The price of a drug should be similar among countries with similar demand patterns and income levels.
- With sufficient concern for global equity, Ramsey prices could imply that some countries would be allowed to pay less than marginal production costs. The optimal mark-up on pharmaceuticals in these countries could thus be negative.

Within this framework, it becomes clear that the same arguments that suggest that Americans, Canadians, and Europeans pay similar prices for drugs also support allowing very low prices in poor countries.

Policy and Pricing Implications of TRIPS

Ramsey prices are socially optimal prices. They may or may not be possible to achieve in practice, but they can provide a useful benchmark against which actual prices can be measured, and are worth bearing in mind when examining the effect of TRIPS on drug costs.

Because developed countries already offered strong protection for pharmaceuticals, the main result of the harmonization of standards required by TRIPS is to strengthen pharmaceutical patent rights in a group of poorer countries. Thus TRIPS:

- increases total pharmaceutical profits, and thus the level of financing for R&D
- changes the distribution of financing so that a greater share is shifted to poorer countries.

Profit increases. By adding patent rights in some developing countries and strengthening them in others, TRIPS increases the net revenue generated from sales on any given product. However, for most drugs it increases very little because the markets in poor countries are exceedingly small, even though they have large numbers of people. One study by Lanjouw estimates, for example, that countries with half the world's population represent less than two percent of spending on cardiovascular drugs. In fact, firms often find it unprofitable to exercise their option to patent in poor countries.

The distribution of financing. The contribution from sales in poorer countries to the total net revenue received by firms is increased under TRIPS. Note that while prices in some countries

become higher, assuming that the new patent rights are exercised, nowhere does TRIPS cause prices to become lower. Therefore global social welfare certainly declines. How much one considers it to have fallen, however, depends on how one assesses social welfare. Because it is relatively poor countries that have higher prices as a result of TRIPS, any aversion to inequality would suggest that welfare could fall steeply.

This illustrates an important question regarding the purpose of TRIPS. Most pharmaceutical research creates products that are beneficial to people in both rich and poor countries. If the purpose of TRIPS is to allocate more of the research cost to poorer countries in the interest of "fairness" (with everyone contributing toward cost), then it would seem reasonable to keep worldwide net revenue at the pre-TRIPS level. This could be done, say, by combining the new patent regime with stronger price controls in the rich countries.

Alternatively, if the purpose is to increase the net revenue received by an innovating firm on a given product, it might be worth reconsidering whether strengthening patent rights in poorer countries is the best way to do this, especially given how small an increase it yields. There are, after all, many alternatives. One could, for example, move prices on new drugs in rich countries into closer correspondence with Ramsey prices. At the most basic level, this would mean that countries with similar income levels and demand patterns would have similar mark-ups. Thus moving to Ramsey prices would require prices to go up in some of the high-income countries that have restrictive controls (such as France) and to come down in some of the countries with relatively high drug prices (such as the U.S.).

The same arguments that suggest that Americans, Canadians, and Europeans pay similar prices for drugs also support allowing very low prices in poor countries.

The situation differs for a product that is specific to developing countries — one where any sales revenue must come almost entirely from poor country markets. If public (non-revenue) sources of research support are sufficient to generate the innovation then there is no reason to allow a profit margin on sales. This may be feasible for a few targeted health needs, such as a malaria vaccine, where the need can be relatively clearly specified in an R&D contract and the public encouraged to support the effort. However, given past experience, it seems unrealistic to expect that most products that could specifically benefit poor patients will be invented on the basis of non-revenue sources alone.

Indeed, those closely involved in trying to better health conditions in the developing world often stress the enormous gap between the human suffering caused by developing-country-specific diseases and the relatively low level of public and philanthropic investment to discover products to treat them. While it is likely to be small, there may need to be some contribution from sales in poor consuming countries to reach the level of incentive required for the desired innovation to occur.

Conclusion

Allowing firms to profit from the sale of new products will continue to be one of the important ways in which society supports and encourages private pharmaceutical research. But intense disagreement continues over how the costs of this R&D incentive should be shared across countries, in particular over the share borne by consumers in the developing world. Monopoly pricing has been put forward as a reasonable benchmark for global prices, but it addresses only efficiency issues, while ignoring much of the public debate driven by equity concerns.

Research incentives provided through profit margins on pharmaceutical sales will inevitably produce distributional consequences. Using global pricing arrangements, the same (or stronger) incentives could be provided to innovative firms in many different ways, placing a larger or smaller burden on consumers in certain countries than in others. Lengthening patent protection for a couple of weeks in rich countries, for

The same (or stronger) incentives could be provided to innovative firms in many different ways, placing a larger or smaller burden on consumers in certain countries than in others.

While some pricing arrangements may be out of reach given the current process of international negotiation, it is important to be clear about goals and tradeoffs.

Employing standard tools of public economics, we provide conditions for pricing that can be used to assess alternatives. The framework can incorporate any degree of aversion to inequality (including none) and also differences across countries in demand conditions and income levels. Assuming some concern for global equity, we believe the pricing conditions can usefully be simplified to three cases:

- Moderate-to-upper income countries should pay a price proportional to their monopoly prices. Within this group, countries with similar demand patterns and income levels should have similar prices. Patents should be enforced and parallel imports from poorer countries forbidden. Price controls could be used to ensure that the overall incentives provided to innovative firms through profit margins stay in line with targeted levels.
- In poorer countries, generic competition should be allowed to lead to marginal cost pricing. These countries should not be expected to contribute to global R&D financing. The exception would be in the case of new products invented by the private sector to satisfy a need specific to developing countries, when the prospect of net revenue on sales in these markets might be important. Such sales could be financed locally (through patent protection) or with donor support.
- In the very poorest countries, certain drugs should be made available free of charge. Many pharmaceutical firms already donate their products to the poorest countries, supported by tax codes that encourage such donations.

example, could provide returns equivalent to the introduction of 20-year patents in the developing world. Edging rich country prices closer together could have a similar effect on the profitability of a new drug as would raising prices in poorer countries.

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Notes

- ¹ Speech before the First International Colloquium on Generic Medicine. September 25, 2003, Cancún, Mexico. Available at <http://www.fda.gov/oc/speeches/2003/genericdrug0925.html> (accessed 12/28/03).
- ² "Trade-Related Aspects of Intellectual Property Rights," Annex 1C of the *Agreement Establishing the World Trade Organization*.
- ³ Frank Ramsey (1927): "A Contribution to the Theory of Taxation," *Economic Journal*. Vol. 37, pp. 47-61.
- ⁴ Figures in parentheses are GDP per capita for 2002 in 1995 U.S. dollars. *World Bank World Development Indicators* online (accessed 8/04).
- ⁵ Malawi is a Least Developed Country qualifying for a delay to 2016 under the Doha Declaration.
- ⁶ A full derivation of the results outlined here is available in Jack and Lanjouw (2004) "Financing Pharmaceutical Innovation: How Much Should Poor Countries Contribute?". CGD working paper 28.
- ⁷ Lanjouw, J.O. (2002) "Beyond TRIPS: A New Global Patent Regime," Policy Brief. The Center for Global Development. Vol. 1, issue 3. July, 2002. Available at <http://www.cgdev.org/fellows/lanjouw.html>
- ⁸ For a practical mechanism to allow patent protection in poor countries only for products specific to their markets, see Lanjouw (2002), cited above.

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