

EXPERT REPORT WJ

ECONOMIC ANALYSIS OF PRICES AND ROYALTIES FOR ARVS IN SOUTH AFRICA

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This note presents an economic analysis that suggests how the distributional impacts of ARV pricing may be incorporated into competition policy, including in interpretation of the Competition Act's mandates. I prepared this report at the request of the Consumer Project on Technology (CPTech) in relation to the complaint against GlaxoSmithKline et al. pending before the South Africa Competition Commission. I am not being compensated for my work in preparing the statement.

My CV is enclosed. To summarize, I teach microeconomic theory at Georgetown University where my research interests include public economics and health economics. I have worked in academia, including the Australian National University and Georgetown, and in policy-making institutions, including the US Congress, the World Bank, and the IMF. I am the author of "Principles of Health Economics for Developing Countries," in addition to articles in peer-reviewed journals.

This analysis adopts an economic approach to the question at hand, not a legal one. It should be interpreted as a way to think about how the legal framework governing intellectual property rights can be used to achieve economically and ethically desirable outcomes. The analysis assumes that a finding of anticompetitive behavior will enable a remedy of a compulsory license allowing multiple firms to compete for the supply of medicines to South African markets.

Costs and benefits of compulsory licensing

The benefits of allowing the sale at low prices of generic AIDS drugs in South Africa are relatively uncontroversial: the prevalence of the disease is high, the drugs are effective, without them infected individuals face a certain death sentence, and the poverty status of many people in need precludes them from having access to existing marketed medications.

The potential costs of issuing a compulsory license are more debatable. The primary concern appears to be that, although TRIPS regulations permit countries to issue compulsory licenses, low royalties could attenuate current and future R&D incentives.

For drugs like those that are the subject of the Complaint, with global markets – that is, with potential consumers in both rich and poor countries – monopoly prices in poor countries are unlikely to constitute a large share of world-wide profits for the patent holder.¹ It is therefore the contention of this analysis that any reduction in profits from South African sales (which would, in any case, be limited due to a resulting expansion in sales volume) would not have a significant effect on world-wide firm profits, and thus would be unlikely to deter future R&D investment for drugs with global markets.

Economic value and excessive prices

In the case of ARVs, and most other pharmaceutical products, the definition of the cost of production is subtle, as it includes not only the costs of the materials used in the construction of the medication, but also the significant resources devoted to research and development. At one extreme, one could claim that the cost of making an additional dose of the given ARV (the “marginal cost”) is virtually zero, so any price above a token amount would be “excessive”. On the other hand, one might argue that the cost of making any given pill includes all the costs of discovering and testing the procedure by which the pill is made, so that even a price per pill in the millions of dollars would not be excessive.

In general, prices above the marginal cost of production are necessary to afford pharmaceutical companies the prospect of covering their R&D expenditures. An important issue to consider in the context of global pharmaceutical research however, is *which* prices should be above marginal production costs, and by how much? In particular, when drugs are sold in many different countries with different income levels, how should prices differ across countries? I suggest that in order to examine the appropriate ARV price in South Africa, one must also consider concurrently what prices should be in other countries.

In light of the forgoing discussion, to address the question of how high an ARV price in South Africa would need to be for it to be considered excessive, I present a framework for evaluating what the “right” prices might be.² Based on this analysis, my main conclusion is that ARV prices in South Africa should not bear any particular relationship

¹ See COMMISSION ON INTELLECTUAL PROPERTY RIGHTS (CIPR), Integrating Intellectual Property Rights and Development Policy 32 (2002) (reporting that “In 2002, the world drug market is valued at \$406 billion, of which the developing world accounts for 20%, and low income countries very much less.”); WHO press release (July 9, 2002), available at <http://www.who.int/inf/en/pr-2002-58.html> (reporting that fewer than 5% of people living with AIDS in developing countries who require ARV treatment are receiving it, half of whom live in Brazil and receive generic treatment); CIPR at 32-34 (concluding from a review of evidence that HIV/AIDS research is robust because it is a disease common to both developed and developing countries and that “[r]egardless of the intellectual property regime prevailing in developing countries, in reality there is little commercial incentive for the private sector to undertake research of specific relevance to the majority of poor people living in low income countries”).

² This discussion is based on William Jack and Jean O. Lanjouw, “Financing Pharmaceutical Innovation: How much should poor countries contribute?” Center for Global Development, Working Paper #28, 2003, available at www.cgdev.org/fellows/lanjouw.html.

to monopoly prices chosen by a profit-maximizing firm.³ Indeed, in a country with a large number of poor people (the median income in South Africa is around \$1000 per year), prices significantly below monopoly level are warranted.⁴

What is a reasonable royalty rate?

At an international level, royalty rates (which is the same as the mark-up of price over marginal production cost as a share of the final sales price), and thereby prices, would ideally be set so as to advance the well-being of consumers throughout the world, while maintaining R&D incentives for new products. One interpretation of “reasonableness” could be that, whatever the price *level*, all consumers pay the *same* price, so that royalty rates are equalized across countries. This could be expressed in an excessive pricing standard that looks primarily to comparisons between prices in South Africa and those in other countries to determine the reasonable value of the good. This concept has weak welfare foundations, however, and is not observed in unregulated markets in any case: in practice, pharmaceutical companies tend to charge different prices in different markets.⁵ The approach adopted here to defining reasonable royalty rates is to ask not if, but how prices should differ across countries.

This approach requires the comparison of the effects of different royalty rates on the well-being of individuals in different countries. Conditional on reaching some level of global profits from drug sales, the structure of royalty rates and prices should vary across countries in a way that balances the losses in consumer well-being from incremental, or marginal, price increases in each country: countries that suffered a relatively high loss from such price increases would have lower royalty rates than others. “Reasonable” prices and royalties would be ones that exhibited such general patterns across countries.

Formally, the royalty should be lower in countries that exhibit the following characteristics:

- (i) demand is sensitive to price – that is, the elasticity of demand is high.
This parameter is denoted by η ;
- (ii) the additional private well-being derived from extra income (delivered through low prices) is high for the individuals who will obtain the drug.
This evaluation is denoted α ; and

³ For explanations of monopoly pricing by a profit seeking firm, see Aidan Hollis, *The Need For A Compulsory License Remedy To Promote Access To Essential Medicines* (2003) and F. M. Scherer, *Global Welfare in Pharmaceutical Patent Policy* (2003).

⁴ I recognize that average income in South Africa is significantly higher than the median, and that domestic redistributive policies could be used to reduce poverty rates in. For this reason, I do not recommend that prices there should be as low as they might be in some other extremely poor countries, without access to the same domestic resources. This said, I would anticipate that a formal analysis of desirable prices (not royalties) in such poverty-stricken countries would be close to zero.

⁵ Brand name pharmaceutical companies have offered lower prices to developing countries only since 2001. Before that, prices were the same in developed and developing countries: between \$10,000 - \$12,000 a year for a triple therapy HAART regime. See MSF, *Untangling the web of price reductions: a pricing guide for the purchase of ARVs for developing countries* (Fourth Edition, June 2003)

- (iii) the social value of additional well-being is high for the individuals who will obtain the drug. This value is denoted γ .

It is noted that the parameters η and α can be estimated from data on demand for drugs and insurance. While the *level* of demand at a given price is low in poor countries, the *responsiveness* of demand (η) is less obvious: people desperate for treatment might respond little to price changes, but poor people are often desperate for food and shelter in addition to treatment, so they might be more responsive. The empirical evidence on how η varies across countries is thus not entirely clear. On the other hand, common sense suggests that α tends to be higher for poorer people.⁶

Unlike η and α , the parameter γ represents a value judgment by policy-makers. If there is a particular desire to improve the well-being of the poor, this variable would favor lower prices in countries with high concentrations of poverty. In fact, what matters for defining reasonable royalties turns out to be the product of α and γ , which is denoted $\beta = \alpha\gamma$. Unless policy-makers explicitly place higher weight on the well-being of those with higher incomes, it is likely that β will be higher for poorer countries.⁷

With this structure, it is possible to show that reasonable royalty rates satisfy the following condition:⁸

$$\text{Royalty} = \left[\frac{p - c}{p} \right] = \left[\frac{\lambda - \beta}{\lambda} \right] \frac{1}{\eta}.$$

Here, p is the price of the drug in the country, and c is the marginal production (and delivery) cost, so $(p-c)/p$ is by definition the royalty rate.⁹ This condition illustrates that the royalty rate should be lower for a country with high values of β and η .

For comparative purposes, we note that if the price was set to maximize profits (as is presumably the strategy of the patent holder), it would satisfy the condition

$$\left[\frac{p - c}{p} \right] = \frac{1}{\eta}.$$

⁶ Empirical evidence on insurance choices also supports this contention. For example, suppose an individual's income is uncertain, and can be either high or low. Buying insurance is a way to increase income when it is low, in return for letting it fall a little when it would be high. This is beneficial if the value of the extra money (what we have called α) when income is low is higher than it is when income is high. Because we see that individuals *do* in fact purchase insurance, we can infer that α tends to fall with income. For a more complete discussion of insurance concepts, see William Jack, *Principles of Health Economics for Developing Countries*, Chapter 5, World Bank Institute, Washington, DC, 1999.

⁷ See F. M. Scherer, *Global Welfare in Pharmaceutical Patent Policy* 3 (2003) ("If one accepts the notion dating back at least to Alfred Marshall that 'the richer a man becomes the less is the marginal utility of money to him,' one needs to assign greater weight to the benefits realized by poor nation citizens than to those of rich nation inhabitants.").

⁸ Op. cit.

⁹ The constant parameter λ is the same for all countries and can be safely ignored in interpreting the condition.

Since λ and β are both positive, $(\lambda - \beta)/\lambda < 1$, and the socially desirable mark-up is smaller than that chosen by a monopolist.¹⁰ In particular, the monopoly price should be considered excessive. How much lower than the monopoly choice the permitted price should be in a given country depends on the sizes of η and β .

What does this condition suggest about reasonable royalty rates for AIDS therapy in South Africa? It is argued that royalty rates should be low, because the negative effects on consumer welfare of increasing prices to cover a greater share of R&D costs (and lowering prices in other countries) are potentially large in South Africa for two reasons:

- (i) many people who would use the drugs (but do not do so now) are poor;
and
- (ii) health “needs” are great.

The first observation means that taking a dollar from a person by raising the royalty rate will, on average, have a significant detrimental effect on the representative consumer’s well-being – that is, α (and thereby β) is large. It is true of course that some well-off South Africans may benefit from lower drug prices, but the huge number of infected poor individuals suggests that most of a dollar transferred to South African AIDS sufferers through lower prices would accrue to people for whom the value of the transfer was large.

The second observation means that transferring a dollar through reduced AIDS drugs prices is a very effective way to help the poor. Simply stated, offering cheap AIDS drugs to a country with so many AIDS sufferers would have a large impact on average consumer well-being. Due to the alarming prevalence of AIDS in South Africa, and prospects for its continued spread, South Africans would see a large benefit from a dollar transferred via lower drug prices than residents of some less afflicted region.

These arguments, coupled with the contention that R&D incentives would be little affected because of the current distribution of drug sales, suggest that the royalty rate in South Africa should be quite low if the distributional impact of the price reduction is acknowledged. A strong implication of my formal analysis with Lanjouw¹¹ is that royalty rates under a regulatory regime that accounts for the distributional effects should lead to consumer prices that bear little formal resemblance to monopoly prices.

In fact, there is nothing in our formal analysis that even requires that reasonable royalty rates be positive. That is, the reasonable price might not be above the marginal cost of production. This is for two reasons. First, once social objectives include distributional concerns, as in our analysis, desirable prices can fall to nearly zero, if a country is poor enough.¹² The other reason is more practical: when the patent-holding firm’s marginal costs of production are higher than those of willing competitors, the relevant marginal cost upon which to base the reasonable price is the lowest amongst the potential

¹⁰ For details, see Jack and Lanjouw, op cit.

¹¹ *ibid.*

¹² I note that it would of course be difficult to compel a firm to sell drugs at a loss in a given country.

suppliers. A reasonable royalty would then be a mark-up over the marginal costs of the lowest cost generic producer, assuming identical chemical composition, adequate quality standards, and other similar features (including packaging, ease of consumption, etc.)¹³

Anti-competitive behavior and sleeping patents

Opening the drugs market to generic competition does not of course mean that a patent holder must sell its product at the generic price. Even in the context of bioequivalent agents, there could be good reasons – brand loyalty, consumer preferences for certain production locations (e.g., Europe versus Asia), etc. – why the patent holder could continue to earn positive profits even in the presence of competition. In the case under consideration, failure to issue a voluntary license might be construed as an anti-competitive strategy that limits consumer choice. That is, the patentee’s branded drug might well co-exist with a generic product, just as often occurs in the US when a drug goes off patent. One segment of the market would continue to purchase the branded drug, while the generic producer would supply another, more price-sensitive, segment. The failure to permit generic producers to supply the price-sensitive segment of the private market may be motivated by an anti-competitive desire to preclude competitors from gaining a foothold in the low-end of the market that would erode the market power the patent holder would otherwise enjoy after the expiration of the patent.

There are many instances of related behavior facilitated by the patent system in other countries, wherein a firm will hold a large number of “sleeping patents” – patents that it leaves dormant, thereby excluding other producers from some segments of a market even though it does not enter those segments itself.¹⁴ While it is not claimed that the patentee holds a formal sleeping patent on alternative drugs in the case under consideration, the economic and welfare effects of the firm’s actions are similar to those that would transpire if it did.

With its great needs and low incomes, South Africa can arguably not afford to restrict itself to branded medicines with accompanying price premiums: it needs variety, so that those who desire brand-name drugs can purchase them, but those with more limited means can purchase a different, though still medically effective, products. It is argued that the current patent holder effectively, though not formally, holds a sleeping patent over generic, non-brand-name drugs, and that this can be interpreted as an anti-competitive strategy, in a wider sense than simple monopoly pricing would entail.

Summary

¹³ Note that in this case, while the price is less than the patent holder’s marginal cost, if the dominant firm does not produce the drugs for sale, then in contrast to the preceding footnote, it earns positive royalties from the generic manufacturer.

¹⁴ Probably the most impressive example was that of ATT before the anti-trust case that led to its break-up: ATT had approximately 50,000(!) patents that it did not use directly, but which precluded entry by other firms.

For some, the human tragedy of AIDS in South Africa is enough to justify issuing a compulsory license with low associated royalty rate. But even abstracting from this motivation, there are clear economic arguments in favor of such a move.

First, reducing prices of AIDS drugs in developing countries will have little impact on future R&D incentives. Second, transferring a dollar to South Africans via lower AIDS drug prices is likely to be socially efficient, since there are many sufferers of the disease, the drugs are effective, and the recipients of the cheaper drugs would, on average, be relatively poor. And third, refusal to grant a license can be interpreted as a restriction on the variety of products in the market, and the closure of the market to lower-income individuals. These reasons all support the granting of a compulsory license with only a nominal (positive) royalty rate.

Based on the foregoing analysis, it is my opinion that the following standard for justifying a compulsory license remedy would be warranted by an economic analysis that recognizes the distributional impact of competition policy in South Africa, while seeking to maintain global incentives to conduct research and development for new drugs:

- (1) The “reasonable value” of an essential medical good is that which yields the highest social benefits while maintaining R&D incentives. What this standard implies will vary across countries, and will be lower in a country with a high poverty rate, and a high incidence of the treatable disease (HIV/AIDS). In South Africa, in practical terms, the reasonable value can be considered the price that would result from full competition among numerous suppliers.
- (2) A dominant supplier of a needed medicine should be found to be in breach of competition standards when it blocks competition and prices its good higher than that indicated in (1).
- (3) Reasonable royalty rates for licenses for ARV therapy in South Africa should be nominal – i.e. at or close to zero. If positive, the royalty rate should be calculated as the mark-up of price over the marginal cost of the most efficient producer of the drug.