EXPERT REPORT AH

ECONOMIC ANALYSIS OF THE NEED FOR A COMPULSORY LICENSE REMEDY TO PROMOTE ACCESS TO ESSENTIAL MEDICINES UNDER SECTION 8(c) OF THE SOUTH AFRICAN COMPETITION ACT

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Introduction

This brief paper proposes an economic methodology for establishing when a dominant (patent holding) essential medicines supplier may be found to have engaged "in an exclusionary act . . . the anti-competitive effect of [which] outweighs its technological, efficiency or other pro-competitive gain" in violation of section 8(c) of the South African Competition Act. The framework assumes that the exclusionary act in question is a refusal to license a competitive supplier to enter the market and that the remedy for the violation would be a compulsory license allowing any qualified competitor to supply the market on competitive terms.

Balancing costs and benefits of patent monopolies

The most logical starting point for considering when a patent holder's refusal to license patent rights to a third party constitutes a violation of section 8(c) is the economic basis for patent rights. A patent is a government-created right to the exclusive use of an innovation for a fixed period of time, subject to various limitations of the right to protect public interests, such those articulated in the Competition Act. It is granted as an imperfect incentive for innovators first to innovate and second to disclose their innovation. The reason that a period of exclusive use is an incentive to innovate is that it may enable the patentee to obtain some monopoly profits during the period of the patent. Unfortunately, this exclusive use of the innovation creates costs: typically, the monopoly price of a product will be higher than if it were competitively provided, leading to two types of effects on consumers.

The first effect of higher prices for patented products is that consumers who continue to buy will pay a higher price than under competition. This higher price increases the profits

of the firm – so that in effect there is a transfer of wealth from consumers to the firm. (Notice that this has in itself no impact on health outcomes.)

The second effect of higher prices is that some consumers who would have bought at the competitive price do not buy it at the monopoly price. This is an entirely negative outcome, since the firm does not profit from these consumers, and the consumers are worse off. This effect is called by economists the "deadweight loss" of monopoly prices. Governments permit the transfer from consumers and the deadweight loss created by patents because the profits (created by the transfer from consumers) may stimulate future innovation. The rules relating to patents – including their twenty year term – have grown in developed countries to reflect their willingness to trade-off current for future welfare.

An alternative to allowing deadweight loss from refusals of a patent holder to permit competition is the grant of a compulsory license, e.g. as an "appropriate order" under section 58 to remedy a violation of section 8(c).[1] A compulsory license is the limitation of a specific right granted under patent laws, giving the state the choice of limiting the exclusive exploitation of a patented discovery. Under compulsory licensing, the patent holder is forced to license its innovation to one or more firms, which pay the patent holder a licensing fee determined by the government. Naturally, this limits the profits obtained by the patentee, while increasing the benefits to consumers. This reduction in profits, unfortunately, leads to a reduced incentive for innovation, which in turn can harm consumers. Choosing to compulsory license therefore involves a difficult trade-off between consumer benefits today (through lower prices) and consumer benefits in the future (through greater innovation). Compulsory licensing becomes desirable when the former is much greater than the latter.

Based on the foregoing, one articulation of a standard under section 8(c) for finding a violation through a failure to license competitors -- triggering the remedy of a compulsory license -- would be when the consumer benefit from lower prices today is greater than the future consumer benefits in the form of increased innovation that would result from maintenance of the monopoly price. As shown below, in the case of essential medicines in countries such as South Africa, benefits from lower prices most likely are far greater than any potential losses owing to reduced future innovation, because demand for essential medicines has very special properties. This paper explores why essential medicines have these special properties and how that leads to the conclusion that compulsory licensing of patents related to such essential medicines is necessary in some cases under the balancing standard articulated in section 8(c).

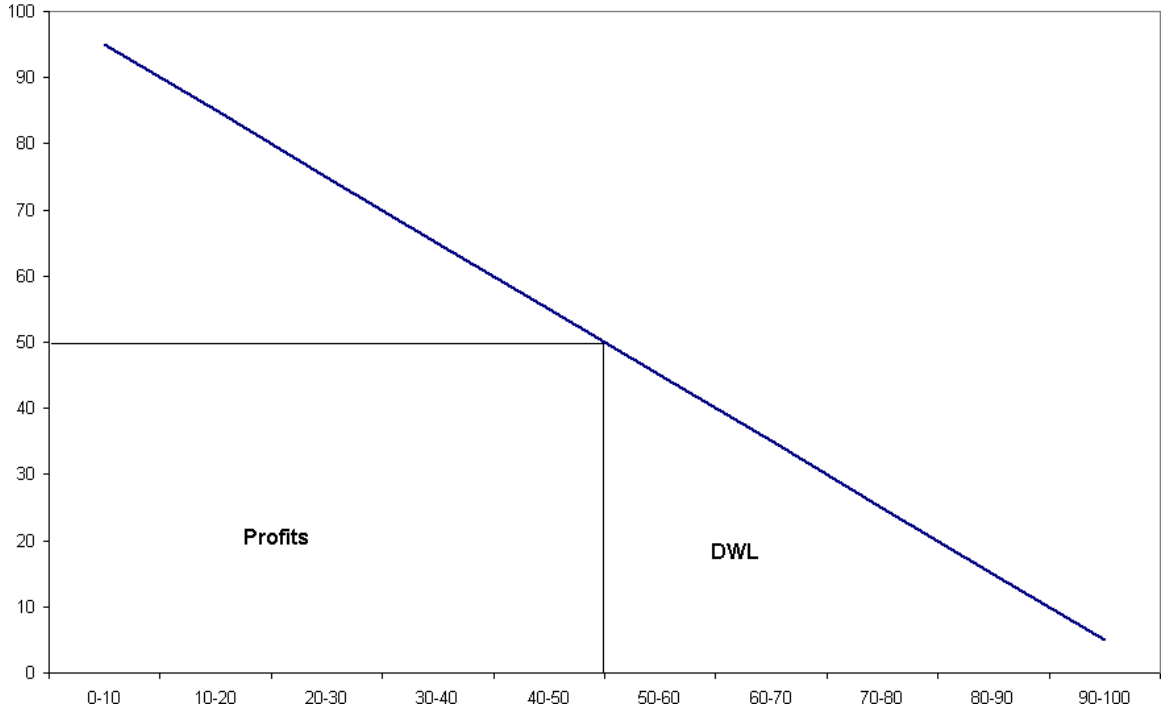
[1] Compulsory licenses as a remedy for anti-competetive conduct has a long history, dating back to the orginal requirement in the Paris Convention of 1883 that patent holders "work" the relevant invention in the country granting the patent. *See* Jerome Reichman with Catherine Hasenzahl, *Non-voluntary Licensing of Patented Inventions: Historical Perspective, Legal Framework under TRIPS, and an Overview of the Practice in Canada and the Uited States of America*, UNCTAD/ICTSD Capacity Building Project on Intellectual Property Rights and Sustainable Development, 4-5 (September 2002); CARLOS CORREA, INTEGRATING PUBLIC HEALTH CONCERNS INTO PATENT LEGISLATION IN DEVELOPING COUNTRIES 91-98.

Patents on ordinary goods

Patents on ordinary goods lead to higher prices than would be expected in their absence – but not necessarily unreasonably high prices. A monopolist is usually constrained in what she will charge by the market. Typically, the monopolist will want to raise prices until an increase in price will increase revenues by the same amount as it raises costs. The reason for the limit on how far prices will increase is that if prices go up too much, then the monopolist loses too many customers. Thus the profit-maximizing price will be above the cost of production, but not normally vastly above it.

Figure 1 shows a demand curve for a typical, "textbook" economics market, with price shown on the vertical axis, and the quantity of products sold on the horizontal. Suppose also, to keep things simple, that the cost of production is approximately zero. If the good were competitively produced, it would have a price of about zero. There would be zero profits, but all consumers who valued it above its cost of production would buy it, and there would be no deadweight loss. If the good were sold by a monopolist, then the profit-maximizing price, given this demand curve, would be about $50. Those consumers with a valuation of the product under $50 would not buy it. The deadweight loss in this case is marked as the area "DWL", while the area marked "profits" is the profits earned by the monopolist. An important point is that profit is about twice as large as the DWL, so that it provides a strong incentive for future innovation, compared to current welfare losses owing to the DWL.

Figure 1
The shape of the "standard" demand curve



Essential medicines

Now we wish to compare this "standard" case with the case of patented essential medicines in a country such as South Africa, and in particular, those essential medicines that are essential for continuing survival. In theory, the willingness to pay is essentially infinite for anyone who has the disease. The ability to pay, however, will be less than infinite. Indeed, in a country such as South Africa, ability to pay is limited either by wealth of a family or the financial capabilities of the state, in the case that the drug is government-provided. So we need to consider two cases. First, then, consider the case in which individuals must pay for the essential medicine themselves; and later we will consider the case in which government pays for the medicine and distributes it to all individuals who qualify medically.

Privately funded essential medicines

For privately funded essential medicines, the ability to pay, as measured by wealth, and the incidence of the disease together determine the demand curve. The distribution of wealth in a country such as South Africa is extremely uneven. There are a few very wealthy families, with extensive holdings; and at the other extreme a large number of households have essentially no wealth. Certainly most individuals with AIDS will have little income and no wealth. They may have a possibility of future income generation, provided they get the life-saving drug required. Otherwise, they will die. In principle, such sick individuals could borrow against expected future earnings to finance purchasing the drug today. But banks will not in general lend on that kind of basis, and so no such borrowing is possible. (At the extreme, antiretroviral drugs to prevent transmission from mother to fetus are cost-effective, but the future child's income cannot form any kind of security for the purposes of lending.)

Figure 2
Income and Wealth Distribution for South Africa

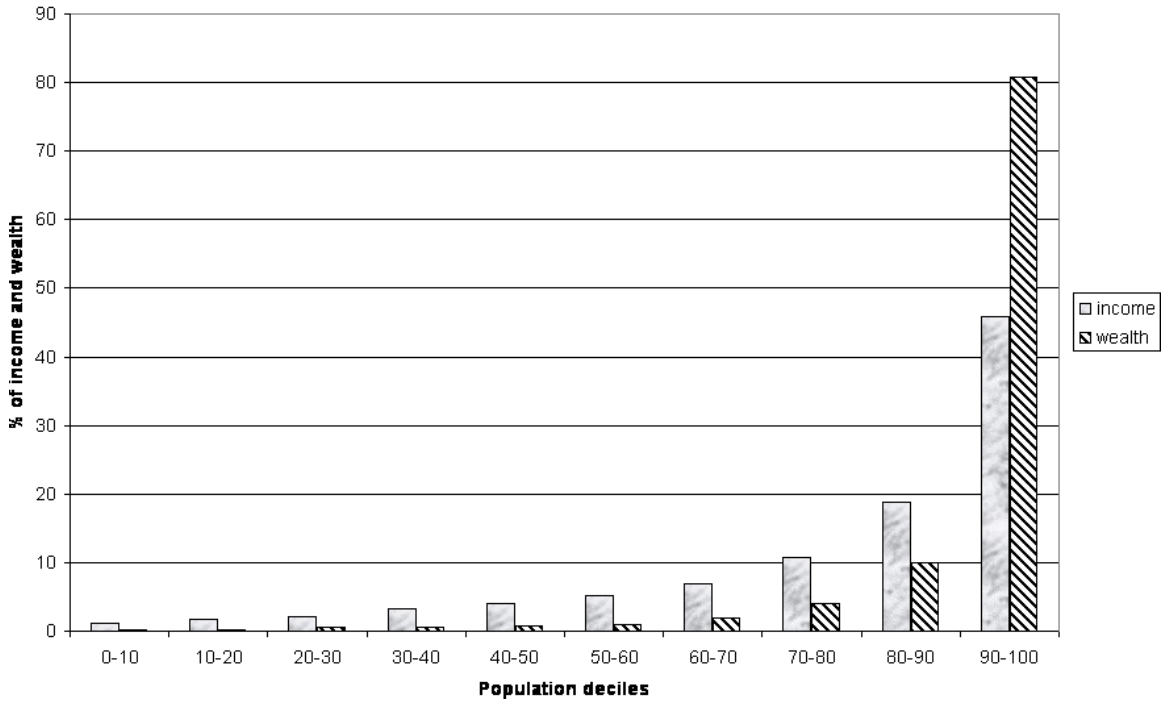
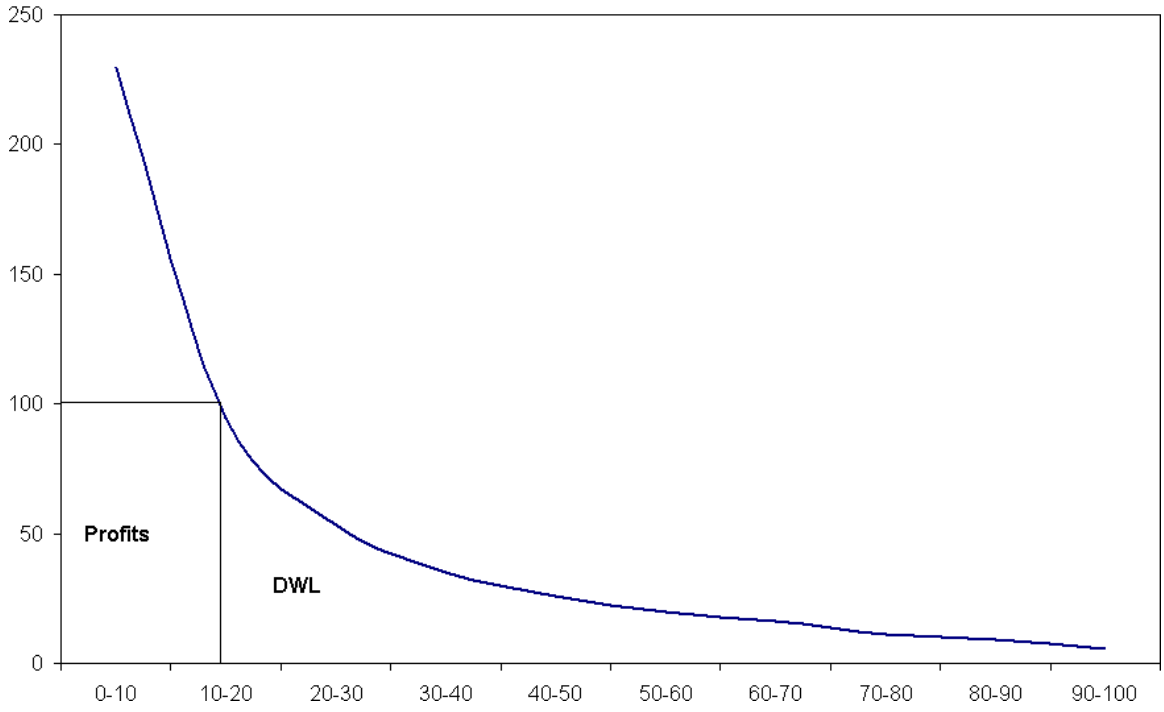


Figure 2 shows estimates of the distribution of income and wealth in S. Africa, by population decile.[2] It shows that the richest 10% of the population earns about 46% of all income in a given year and owns about 80% of all wealth. Since ability to pay, and incidence of disease determine the demand curve, the demand curve should simply reflect that. Suppose that the incidence of the disease is equal among all income levels; then to get a demand curve, we can simply assume that each affected individual is willing to pay the same proportion of his entire income (or wealth) in order to get the essential life-saving drug. Thus, using the data on income distribution, the demand curve would have the shape presented in Figure 3. Figure 3 is a transformation of the income distribution so that the area under the demand curve is approximately the same as the area under the demand curve in Figure 1. As we show here, the shape of the demand curve is important in determining the price as well as profits and deadweight losses.

Figure 3
The shape of the demand curve if based on income distribution



How is this demand curve different from the standard one presented in Figure 1? The principal difference is that the demand curve for the essential drug is much more extreme. While wealthy people may be willing to pay more for most ordinary goods, and buy more, than poor people, their demand is limited. In the case of essential drugs, buyers are

[2] The income distribution is for 1993 (the most recent year available) and is drawn from the World Bank World Development Report (1996). Unfortunately, there is no available estimate of the true distribution of wealth in S. Africa, and the estimate presented here is based roughly on the distribution of income. Typically wealth distribution is more extreme than income distribution. Poor households with a survival income typically have virtually no accumulated wealth.

willing to pay whatever is required to get the drug, and thus the inequality of wealth distribution will be reflected in the demand curve.

The shape of the demand curve significantly changes seller behavior. The profit-maximizing price given the demand curve in Figure 3 would be at least 100, so that only a small proportion of the possible purchasers (about 15%) would actually buy the product. Recall that the demand curves illustrated in Figures 1 and 3 have the same area underneath them, and the competitive price would in both cases yield a total surplus of 5000. The optimal price is surprisingly high, given the large numbers of low income people who wish to buy the product. The reason is that rich people, though few, are able to pay so much for the drug. The greater the inequality of the income or wealth distribution, the more severe this problem becomes, with greater individual ability to pay on the part of the very rich pushing the price up. (It is even possible that the optimal price in a poor country with very unequal distribution of wealth/income could be higher than in a rich country with a more equal distribution.)

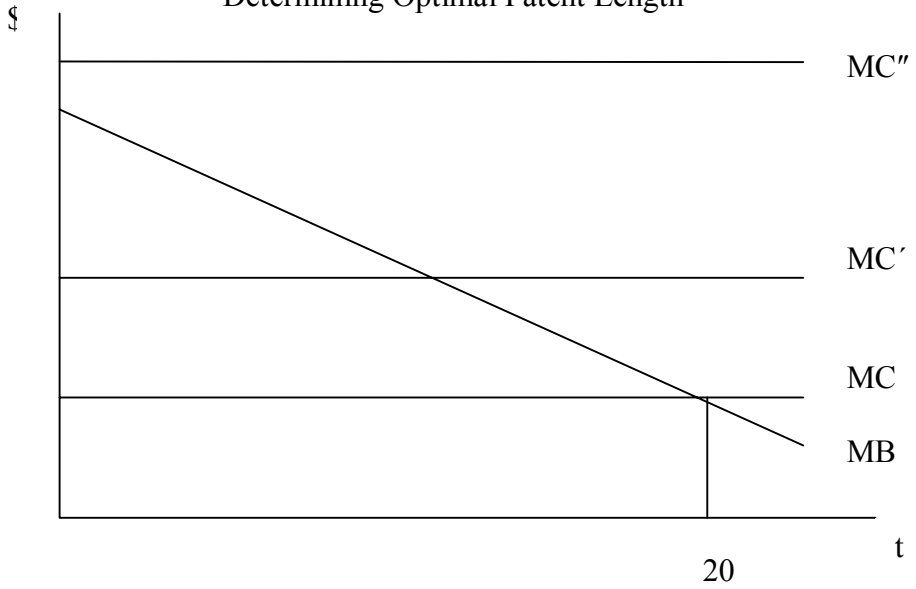
The trade-off between incentives for innovation vs. current deadweight losses for this sort of demand curve does not favor innovation. In this case, the deadweight loss is about one and half times as large as the profits (instead of only half as large). This suggests that welfare will not be well-served by the patent system in this case, since the incentive effects of patent protection (the profits) are relatively small compared to the deadweight losses. That is, patent protection will do little to stimulate innovation, but will seriously harm welfare.

Unfortunately, there is no established ratio of deadweight losses to profit at which economists would all agree that patent protection is undesirable. In markets where the curvature of the demand curve goes the other way (*concave* to the origin), patents are a very efficient mechanism for inducing innovation. When the demand curve is convex to the origin, then patents become relatively inefficient, as in the case of the market for essential drugs in South Africa. The straight-line demand curve drawn in Figure 1 might be thought to be about average, and is, perhaps, the basis for establishing the 20 year patent term, a point we explore below.

Suppose that the 20 year patent term has been established in order to maximize welfare given that the *average* market is characterized by a profit/DWL ratio of two (as in the linear demand curve case). Then the implication is that the marginal benefit in terms of innovation from the twentieth year of patent protection is just equal to the marginal cost of patent protection in the twentieth year. This is pictured diagrammatically in Figure 4, in which MB indicates the marginal benefit of patent protection in terms of inducing new innovation; and MC indicates the marginal cost of patent protection in terms of deadweight losses *for the average market*. The marginal benefit is drawn as falling over time (and what is required is that it be falling more quickly than marginal cost). The 20 year patent term is determined by the intersection of MB and MC, and patents are granted since they create more benefits than costs. For markets such as those for essential drugs in developing countries, however, the marginal costs of extending patent protection are much higher than average for a given amount of benefit, because of the large deadweight

loss to profit ratio. MC' and MC'' represent the marginal costs of extending patent protection for different levels of this DWL to profit ratio. In the case of MC', the optimal patent should be shorter than 20 years; in the case of MC", the optimal patent should be zero years. In either case, compulsory licensing could be seen as a suitable solution to the problem that that marginal cost of patent exclusivity exceeds its marginal benefits.

Figure 4
Determining Optimal Patent Length



The economic value of essential medicines

Another perspective on this issue is that demand curves for essential medicines reflect ability to pay, not any sort of underlying value.[3] In the case of essential medicines, an individual's low ability to pay at the time of purchasing a drug may not reflect social value from the individual's receiving of the drug. For instance, if an infant receives a life-saving drug, the individual may grow up to be a productive member of society. However, the child is unlikely to be able to pay for the drug. Thus there are certainly important issues to be considered about whether the demand curve (which reflects ability to pay) should be used to measure value in these cases. It is possible that the real deadweight losses from high drug prices are much higher than given by integrating under the demand curve. Most likely there are very substantial inefficiencies created by the inability of sick people to afford medicines which will enable them to regain their health.

A third point to be made is that the high price that will be set by a monopoly seller of an essential drug in South Africa may be similar to the high price set in other countries. Globally, the distribution of income is rather similar to that in S. Africa, with a small number of people who are very rich and a large number who are extremely poor. As in

[3] This point is different from – and complementary to – one often made in the literature on compulsory licensing that the marginal utility of income may be much higher in developing countries than in developed countries (see eg . W. Jack and J. Lanjouw, "Financing Pharmaceutical Innovation: When Should Poor Countries Contribute?" mimeo, Georgetown University, 2003, and F. M. Scherer, *Global Welfare in Pharmaceutical Patent Policy* (2003))

the case of South Africa, the profit-maximizing global monopoly price is therefore going to be so high as to put it out of the reach of the vast majority of potential consumers. This provides little incentive for drug firms to offer different prices in different countries. (This contrasts with the prescription offered by Danzon and Towse (2003)[4], who suggests that Ramsey pricing with confidential pricing will be enough to lower prices. It won't, because most developing countries happen to have relatively unequal wealth distributions in which the profit-maximizing monopoly price is high.)

In these circumstances, the use of compulsory licensing becomes an obvious remedy to problems created by the existence of patent rights in situations where they do not increase social welfare. The compulsory license eliminates most of the deadweight loss. Moreover, some of the drop in price will result in higher demand, generating additional royalty payments from the consumers who are not now participating in the market. Thus while there may be some reduction in profits from compulsory licensing, it may be relatively small compared to the huge benefits created for very poor people.

State-funded essential medicines

Medicines are in some cases paid for by the state and provided to all individuals whose medical condition indicates treatment with the medicine. This creates a very different sort of demand curve: now the demand curve is fixed at the number of doses required for all individuals deemed to require it, and the price does not affect the demand curve at all. In the case that the government has an obligation to pay for drugs, the demand curve is simply a vertical line. In the extreme, this can create an impossible situation: the patent holder can set any price it wishes, and the government must purchase the product. This situation creates enormous deadweight losses through the tax system, since the government must pay very high prices for the drug.

If the government does not have an absolute obligation to purchase medically necessary medicines, it may nevertheless be somewhat constrained. In South Africa, sections 27 and 28 of the Constitution give individuals (and especially children) rights to health care. This right is limited in that the state is recognized to have limits on its ability to pay for access, and the courts have carefully considered what obligations are imposed on the state by these sections of the Constitution (most recently in Treatment Action Campaign v. Minister of Health). Recognizing that there are limits on what the state can be forced to provide, this does nevertheless imply that the government is at least somewhat constrained in its negotiations with any company selling an essential medicine: the government may be forced to purchase the product. That is say, sections 27 and 28 remove some of the bargaining or negotiating room that the government would otherwise have when dealing with pharmaceutical companies. This would not be such a problem, except that when the pharmaceutical company holds a patent-monopoly, then the government's weak negotiating position will likely push up the price of the essential medicine.

[4] Danzon P, Towse A, "Differential Pricing for Pharmaceuticals: Economics and Policy." Mimeo, Wharton School, 2003.

Setting an obligation to license competitors when the high price of the patented drug creates unacceptable deadweight loss through the tax system is therefore applicable when the purchaser is the state. Compulsory licensing is a way to bring some balance back to negotiations in such a situation, as shown in Hollis (2002).[5] The government can restore its negotiating position by imposing – or threatening to impose – compulsory licensing in case the monopolist attempts to abuse its monopoly position.

Conclusions

Whether essential medicines are state-provided or privately purchased, unusual characteristics of the demand for essential medicines provide a strong justification for the use of compulsory licensing. In the case of privately purchased essential medicines, the demand curve is likely to have the sort of shape shown in Figure 3, which means that patent protection has very weak effects on stimulating innovation but large effects in terms of harming poor consumers. In such a case, government-granted compulsory licenses can be used to mitigate the negative effects of government-granted patents. In the case of government-funded essential drugs, the government may find itself hostage to a combination of patent laws and constitutional imperatives which allows drug firms to charge virtually unlimited prices. The taxation required to fund expensive government-provided drugs will again create large deadweight losses. In this case, compulsory licensing can again be used to restore balance to negotiating positions, reasonableness to pricing, and a better trade-off between the incentive to innovate and current welfare losses.

Based on this analysis, the balancing test under section 8(c) of the Competition Act suggests that a violation should be found, and a compulsory license for all qualified suppliers issued, whenever (1) patent holders have failed to license multiple suppliers at reasonable royalty rates, (2) prices remain above that which would result in a competitive market and (3) the result of these facts is that access to needed medicines is limited to substantial numbers of people (i.e. there is substantial deadweight loss). In such cases in South Africa, it can be confidently and conclusively presumed that "the anti-competitive effect" of the failure to license all qualified suppliers – the deadweight loss represented by South Africans who will die from AIDS that otherwise would have lived – far outweighs the "technological, efficiency or other pro-competitive gain" to consumers in terms of future innovation incentives from the maintenance of monopoly pricing power.[6]

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[5] Hollis AM, "The Link Between Publicly Funded Health Care and Compulsory Licensing," *Canadian Medical Association Journal,* 167: 765-767, 2002.

[6] For a supporting analysis, see F. M. Scherer, *Global Welfare in Pharmaceutical Patent Policy* (2003) (concluding from an economic analysis that, even with no royalties paid to the patent holder, "global welfare is maximized by letting low-income nations free-ride on the patented inventions of first-world nations over a wide range of negative new product development impacts if one accepts the reasonable premise that the marginal utility of income is appreciably higher in poor nations than rich nations").