

Economic Justifications for Open Access to Essential Medicine Patents in Developing Countries

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Abstract

This paper explains an economic rationale for compulsory licensing of needed medicines in developing countries. The patent system is based on a trade-off between the “deadweight losses” caused by market power and the incentive to innovate created by profits. However, markets for essential medicines under patents in developing countries with high income inequality are characterized by highly convex demand curves, producing large deadweight losses relative to potential profits when monopoly firms exercise profit-maximizing pricing strategies. As a result, these markets are systematically ill-suited to exclusive marketing rights, a problem which can be corrected through compulsory licensing. Open licenses that permit any qualified firm to supply the market on the same terms, such as may be available under licenses of right or essential facility legal standards, are well suited toward correcting the worst effects of exclusive patent rights without compromising the goal of providing a just level of compensation for the innovative acts of the originating firm.

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paper expands on a small set of scholarship that employs an economic approach to the analysis of patents on needed medicines in developing countries.¹⁰

Our contribution is to note that, in many poor countries, markets for needed medicines are characterized by extreme inequalities of wealth that create incentives for patent holders to maximize profits by pricing their products to serve only the wealthiest segment of the population. Such pricing creates massive social costs through lack of treatment for the poor majority. In the balance of benefits and costs of such a system, the costs are likely to be disproportionately large. Fundamentally, we argue that owing to this *systematic* failure of the exclusive right based patent systems for needed medicines in developing countries, compulsory licensing to create open access to patents on needed medicines may be justified on a broad scale.

II. Balancing costs and benefits of patent monopolies

A patent is a government-created right to the exclusive use of an innovation for a fixed period of time, subject to various limitations designed to protect public interests. It is granted as an imperfect incentive to create and share new inventions.¹¹ 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. Granting exclusive use of an innovation creates costs: typically, the monopoly price of a product will be higher than if it were competitively provided. In the case of essential medicines in developing countries, the typical costs and

¹⁰ See Jean Lanjouw, *Patents, Price Controls and Access to New Drugs: How Policy Affects Global Market Entry* (Ctr. for Global Dev, Working Paper No. 61, 2005); F.M. Scherer & Jayashree Watal, *Post-TRIPS Options for Access to Patented Medicines in Developing Countries* (WHO Comm'n on Macroeconomics & Health, Working Paper No. WG4:1, 2001) [hereinafter Scherer & Watal, WHO Working Paper]; Jayashree Watal, *Pharmaceutical Patents, Prices and Welfare Losses: Policy Options for India Under the WTO TRIPS Agreement*, 23 WORLD ECON. 733 (2000); SCHERER, COMPULSORY LICENSING, *supra* note 9.

¹¹ See F.M. SCHERER & DAVID ROSS, INDUSTRIAL MARKET STRUCTURE AND ECONOMIC PERFORMANCE 621-630 (Houghton Mifflin Co., 3rd ed. 1990); *c.f.* U.S. Constitution, art. 1, § 8 (giving Congress the power “To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries”).

benefits of exclusive rights are skewed. High inequality in the demand side of the market creates profit maximizing incentives for patent holders to price out the large majority of the population from access to the good. Recognition of this problem as systemic – not cabined to a few specific diseases such as AIDS, tuberculosis and malaria – is a key step toward developing appropriate policy responses.

A. Monopoly Economics

Patents do not always create monopolies. Many patents give the holder an exclusive right to produce a product that has many substitutes and therefore normal competitive markets will restrain the patent holders' pricing. In a perfectly competitive market, each firm is a price "taker," and must accept the market price, which competitors drive down until it is approximately equal to the firm's marginal cost. Patented items in an imperfectly, but still highly competitive, market will be restrained by the same market forces to a greater or lesser extent depending on the degree to which substitutes are functionally equivalent. Indeed, there is no guarantee that a patented item will not be functionally inferior to substitutes, denying the patent any real market value.

Patents may create monopolies where there is no equally effective substitute for the patented product. This may be the case when the patent covers the active ingredient for a needed medicine if other medicines cannot be readily substituted for it in all of its applications. Such a patent gives its holder the ability to set price for the good without regard to competitive substitutes. To maximize its profits, the monopoly will raise its price above the level that would exist in a competitive market, thus serving a smaller segment of the potential demand (i.e. it will reduce its output), until resulting losses of sales make further price increases unprofitable.¹² The

¹² See MICHAEL PARKIN, MICROECONOMICS 262-67 (Addison-Wesley, 7th ed. 2005).

more the demand for the good is inelastic (meaning that consumers are less likely to decrease consumption with each price increase), the higher the price that can be profitably demanded by the monopolist.

Pricing above marginal costs creates two losses for consumers. The first loss is a wealth transfer from consumers to the monopolist, since every unit purchased is at a higher price than consumers would pay a competitive producer. In the case of an innovative monopolist, including a monopoly created by a patent, such a transfer from consumers to the monopolist may be thought to be the reward for innovation.

The second loss from monopoly pricing is a “deadweight loss” from forgone transactions which would have taken place at the lower competitive price. These lost sales are known as “deadweight” because they do not create surplus for the buyer or seller; the surplus benefit that would have gone to consumers simply disappears, and is not compensated by any gain to the monopolist. In pharmaceutical markets, this deadweight loss is often referred to as the problem of “access”: the poor may not purchase a drug product because of its high price, and as a result are untreated. Had the price been lower, they would have been able to afford the drug and would have been treated. Thus, for drugs that are essential to life and health, the term deadweight loss created by patented drug pricing takes on added significance.

B. Patents and Standard Demand Curves

Patents on ordinary goods lead to higher prices – but not necessarily to unreasonably high prices. A monopolist is usually constrained by the overall market demand when he or she is setting price and output. If prices become too high, then the monopolist loses too many customers who may make a decision not to buy the product or to use a substitute.

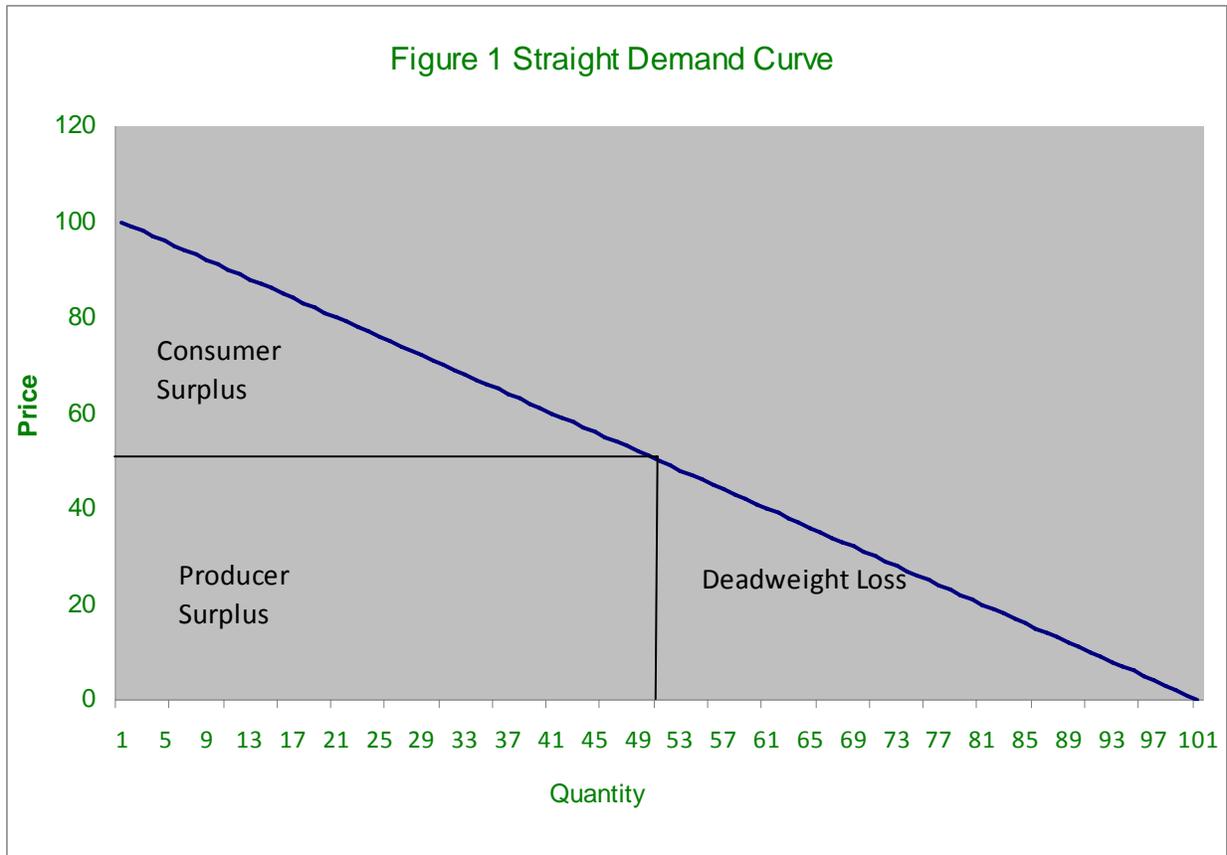


Figure 1 shows the type of demand curve typically drawn in economics textbooks, with price shown on the vertical axis, and the quantity of products sold on the horizontal. To keep things simple, it is assumed that the cost of production is approximately zero.¹³ If the good were competitively produced, it would have a price of about zero. There would be zero profits, but all consumers who valued it above its average cost of production would buy it, and there would be no deadweight loss. The total surplus under a competitive market structure would be 5000.

¹³ Normally, a diagram of monopoly pricing would include a marginal cost curve. The equation of marginal cost to zero approximates a simplified pharmaceutical market characterized by high fixed costs of R&D, but relatively small production costs (including the Active Pharmaceutical Ingredients used to manufacture medicines). The marginal cost of production in the pharmaceutical industry is typically close to constant, since for most drugs inputs are available in competitive global markets. This is not true of all drugs. For example, Taxol uses a natural ingredient derived from the yew tree and so there are biological limits to the amount that can be harvested, but for most other drugs, the costs of manufacturing are more or less constant, and therefore the incorporation of a marginal cost curve would of change the basic economic analysis.

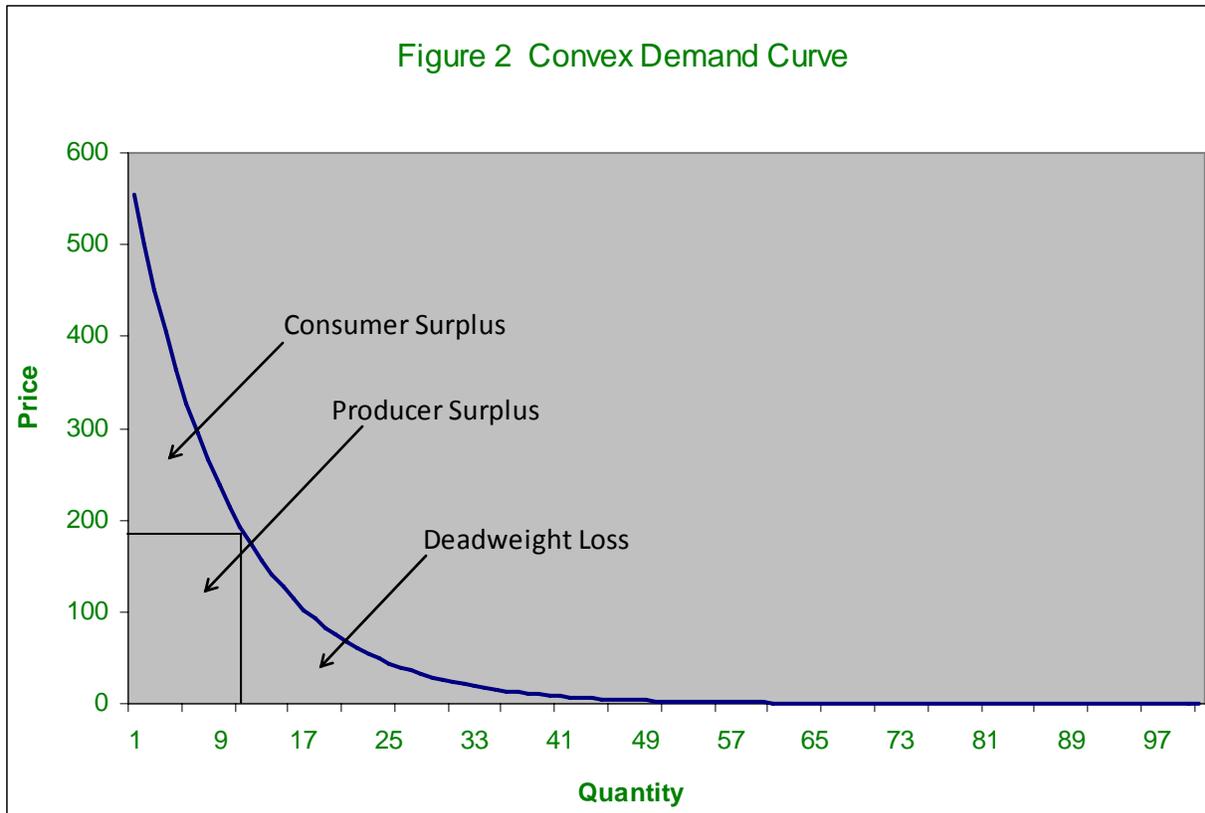
The monopolist will pick the profit-maximizing output for any given demand curve. In this scenario, the seller could sell a quantity of 99 goods for 1 unit of currency (hereafter, USD), yielding sales of \$99. He or she can raise the price to \$2 loose one sale (selling 98 goods instead of 99), but the resulting increase in income per sale more than makes up for the loss of demand (enabling earnings of \$196). The seller will continue increasing prices and lowering total sales in the market until the raise in price and resulting loss of sales negatively impacts its revenue. Here, the monopolist will stop raising prices when it sells 50 goods for \$50, earning \$2500 in sales. Beyond this point, the seller loses money by the lost sales at higher prices. Thus, 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 (2500) is about twice as large as the DWL (1250), so that it provides a strong incentive for future innovation, compared to current welfare losses owing to the DWL.

C. Patents and Highly Convex Demand Curves

The profit maximizing pricing strategies for a firm with a monopoly are altered by the shape and slope of the demand curve. The slope of the demand curve may be affected by the elasticity of demand. A monopolist will be more restrained if consumers will be more willing to shift to an inferior substitute or do without the good as prices rise. More elasticity in the demand market results in a demand curve that is more flat on the horizontal plane; less elasticity results in steeper demand curve. A perfectly inelastic demand curve, meaning that consumers will not curb their demand at any price, will be vertical. A horizontal demand curve would mean that the smallest price increase would eliminate all consumer purchases.

Most demand curves are not perfectly horizontal or vertical, but rather have some element of convexity. Convexity indicates that some segment of the market (the flatter part of the demand curve) will be highly elastic – giving up the purchase with a slight price increase. Another segment of the market is likely to be more inelastic – willing to pay much higher prices for access. And the bulk of the market will exist on points along the curve between these two extremes.

Suppose that the demand market for a good is highly convex, as illustrated in Figure 2. This figure is drawn with a convex demand curve and so that the area under the demand curve is the same as the area under the demand curve in Figure 1. (The equation for inverse demand is $p = 555(0.9^q)$.) Given this demand curve, if the product were offered competitively, the surplus in the market would be 5000, just the same as the competitive market given the demand curve drawn in Figure 1.



The shape of the demand curve changes the profit-maximizing price in a predictable way. Attempting to capture a significant portion of the flat/elastic part of the demand curve is unprofitable. There, small price increases knock large numbers of consumers out of the market. The monopolist will target its price toward the steep end of the curve where large price increases will cause minimal decreases in additional sales. Thus, profit-maximizing price given the demand curve in Figure 2 would be almost 200, four times higher than the case of the linear demand curve, and causing a much higher amount of deadweight loss. The result is that only a small proportion of the possible purchasers (about 10%) would buy the product. The profits to be obtained from this market are considerably smaller comparative to the deadweight loss created. For the case above, the profits would be about 1900, while deadweight loss is

approximately 1700. Deadweight loss in this market is almost as large as profits, where in the linear example it was half as large as profits.

To help illustrate the effect of convexity on the deadweight loss to profit ratio, consider a demand curve of the form $p = 1 - q^n$, where $p \in (0,1)$. As shown in the Appendix, the ratio of deadweight loss to profit increases as n decreases (i.e. as the demand curve becomes more convex). The converse also holds, so that the ratio of deadweight loss to profit decreases as n increases. For more complicated real-world demand curves, there will not generally be a single measure of convexity, but the general principle applies that greater convexity will typically drive the monopolist to serve a much smaller (more inelastic) segment of the market and produce comparatively large deadweight losses.

The trade-off between incentives for innovation vs. current deadweight losses for convex demand curves is not as favorable for the patent system as in cases with linear demand curves. That is, traditional patent protection will have a smaller effect on innovation than in the linear demand case; and at the same time the deadweight losses are larger.

There is no established ratio of deadweight losses to profit at which economists would all agree that unrestrained monopoly pricing of the patented product undesirable. The straight-line demand curve drawn in Figure 1 might be thought to be somehow “average.” The rules relating to patents – including their twenty-year term – have grown in developed countries to reflect a societal willingness to trade-off incentives for innovation (via profits) with deadweight loss in the average case. In effect, the balance has been established that, on average, twenty years of exclusive exploitation of an innovation grants enough incentive to innovate; the implication is that longer patent duration would increase deadweight losses more than it would spur on

innovation.¹⁴ For markets which have much less favorable DWL/profits ratios, however, the marginal cost of extending patent protection is much higher for a given amount of benefit, and the optimal period of patent protection – or the type of protection offered – must be less. Indeed, if the DWL/profit ratio is sufficiently unfavorable, the optimal period of exclusion through patent protection will be zero.

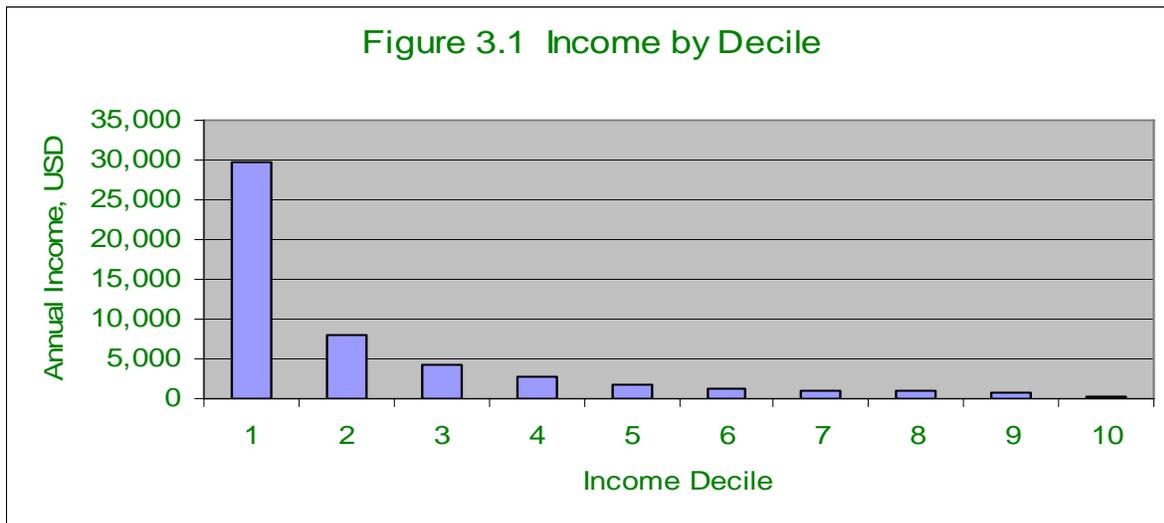
It is well known that the optimal patent design should vary depending on market demand and cost characteristics,¹⁵ and therefore the conclusion that the standard patent rules are maladapted to markets with convex demand curves will not be surprising. However, if one could identify an important class of markets characterized *systematically* by highly convex demand curves, there would be a strong case for altering the operation of patents in those markets. As we show in the next section, markets for needed medicines in developing countries constitute precisely such a class.

¹⁴ See James W. Hughes, Michael J. Moore & Edward A. Snyder, '*Napsterizing*' *Pharmaceuticals: Access Innovation and Consumer Welfare* (Nat'l Bureau of Econ. Research, Working Paper No. 9229, 2002); John Duffy, A Minimum Optimal Patent Term (2003) (unpublished manuscript, available at SSRN: <http://ssrn.com/abstract=354282> or DOI: 10.2139/ssrn.354282)

¹⁵ Wright, D., 1999, "Optimal patent breadth and length with costly imitation," *International Journal of Industrial Organization*. 17:419-436.

D. Essential Medicine Patents in Developing Countries

An essential medicine patent may be defined as a patent on a medicine that is (1) essential to life or health, and (2) for which there are limited or no actual substitutes.¹⁶ The lack of substitutes means that the patent creates an effective monopoly. The essential nature of the medicine for life or health means that people requiring the medicine will generally be willing to spend whatever resources are available to them to buy that medicine.¹⁷ The relative unlimited willingness of patients to pay for the drug means that, in the sector of the population that must pay for the medicine through private means (which is large in developing countries),¹⁸ the demand curve is likely to be a function of their ability to pay.¹⁹ (In the case that the drug is government-provided, the financial capabilities of the state and its willingness to pay for a given therapy become the relevant constraints.)



¹⁶ World Health Organization [WHO], *The Selection and Use of Essential Medicines: Report of the WHO Expert Committee*, WHO Technical Report Series/ 914 (2002) (16-24) (defining “Essential Medicines” as “those that satisfy the priority health care needs of the population.”).

¹⁷ See Watal, *supra* note 10.

¹⁸ WHO Regional Office of the Western Pacific, *TRIPS, Intellectual Property Rights and Access to Medicines*, HIV/AIDS ANTIRETROVIRAL NEWSL., Dec. 2002 (reporting that patients themselves pay for 50% - 95% of medicines in developing countries).

¹⁹ See Eina V. Wong, *Inequality and Pharmaceutical Drug Pricing: An Empirical Exercise* (Ctr. for Econ. Analysis, Econ. Dep’t, Univ. of Colo. at Boulder, Working Paper No. 02-19, 2002)

The distribution of income and wealth in developing countries tends to be extremely uneven. There are a few very wealthy families, with extensive holdings and high income; at the other extreme a large number of households have essentially no wealth and low incomes.²⁰ Figure 3.1 shows the distribution of income in South Africa in the form of average per capita income for each decile of the population in 2000.^{21 22} The richest 10% earned 58 percent of all income. Put another way, the richest 10% earned an average of \$29,626 a year, more than eighty times the average income of the poorest 10% (only \$362).

High inequality in ability to pay in a country will produce highly convex demand curves. Figure 4.1 is a demand curve for AIDS medicine in South Africa constructed according to the assumptions that ability to pay is proportional to annual income and that incidence of the disease is equal among all income levels. This, in turn, implies a demand curve having proportions very similar to that in Figure 2, for which we demonstrated that the deadweight loss created by monopoly pricing of the good are very large compared to the incentives for innovation enabled by such pricing.²³

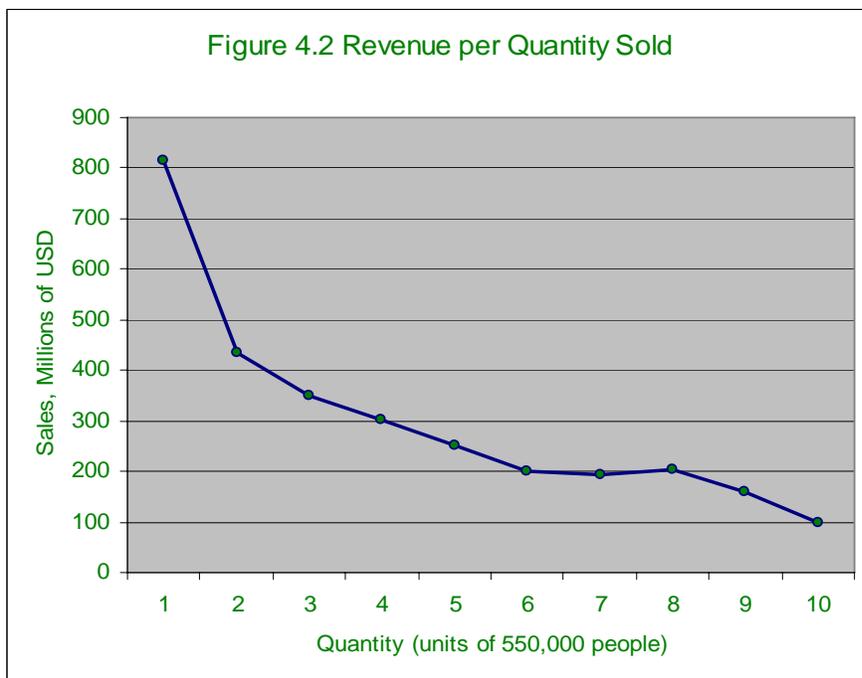
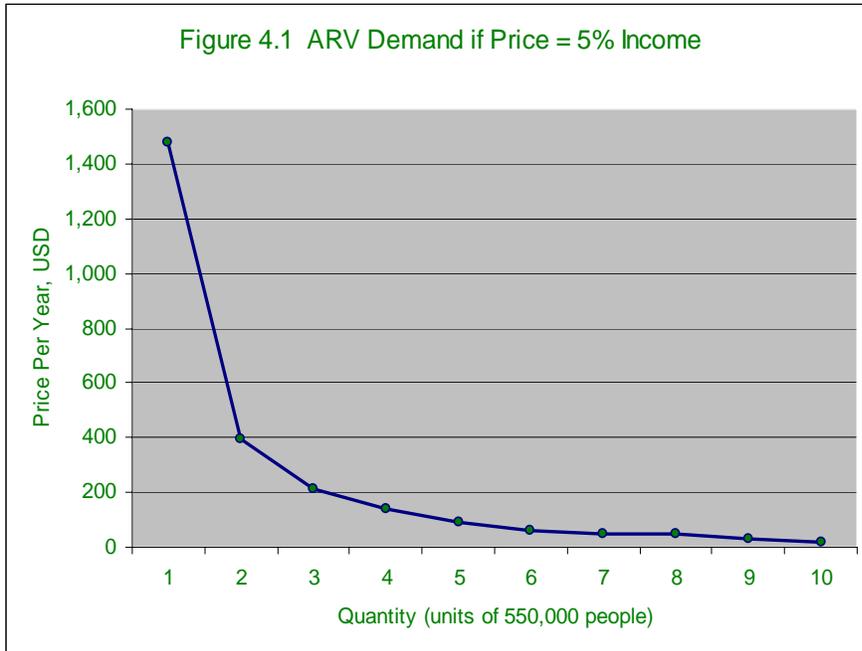
²⁰ In principle, sick individuals could borrow against expected future earnings to finance purchasing the drug today. But banks will not in general lend on that kind of basis, and so no such borrowing is possible.

²¹ Data from Statistics South Africa's 2000 Income and Expenditure Survey, as reported by the South African Regional Poverty Network.

http://www.sarpn.org.za/documents/d0001062/P1175-simkins_Nov2004.pdf

²² A more complete analysis would include examination of the distribution of wealth as well. But we do not know of an available estimate of the true distribution of wealth in South Africa. Typically wealth distribution is more unequal than income distribution. Poor households with a survival income typically have virtually no accumulated wealth.

²³ Figure 2 is indeed exactly based on this income distribution.



The shape of the demand curve can be used to estimate the profit maximizing behavior of monopoly in this market. Figure 4.1 assumes that people needing AIDS treatment in South Africa will purchase an antiretroviral if the cost is 5% of their income.²⁴ According to 2006 UNAIDS data, 5.5 million people live with HIV/AIDS in South Africa.²⁵ If we assume that HIV prevalence is uniform across income deciles,²⁶ then each decile

²⁴ Statistics South Africa. *Income and Expenditure Survey*. 2000. The choice of 5% is somewhat arbitrary. However, exactly the same results occur for any percentage of income, and so the argument being made here is not reliant on the choice of 5%.

²⁵ Joint United Nations Programme on HIV/AIDS, *Epidemiological Fact Sheets on HIV/AIDS and Sexually Transmitted Infections: South Africa* (December 2006)

http://www.who.int/GlobalAtlas/predefinedReports/EFS2006/EFS_PDFs/EFS2006_ZA.pdf

²⁶ The prevalence of HIV/AIDS is not uniform across deciles, but higher among South Africans with higher incomes. We assume uniformity in order to simplify our demonstration that a firm will maximize sales by selling exclusively to the elite. If we were to weigh demand at each income decile to account for differences in prevalence

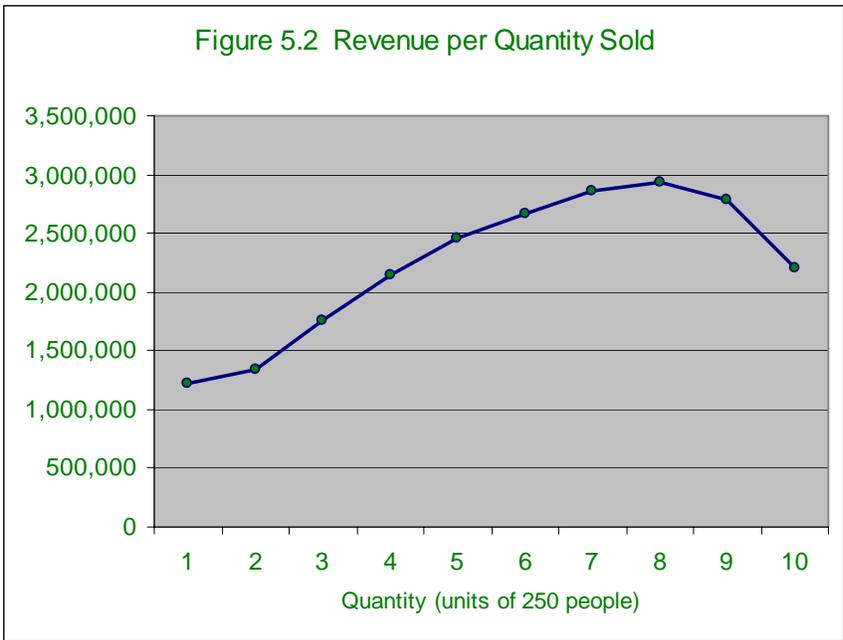
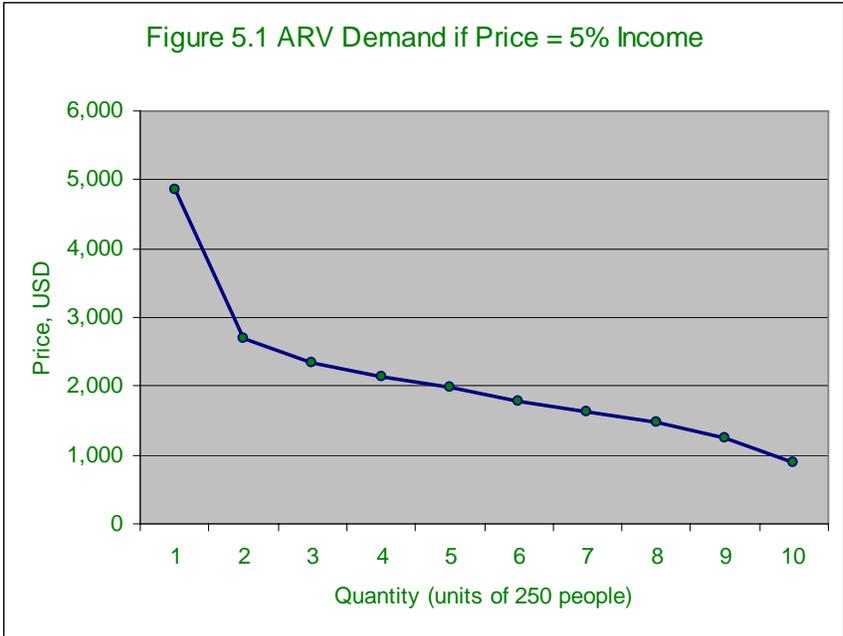
contains 550,000 people who will need antiretroviral treatment. If a firm prices its antiretroviral at \$1,481 per patient per year (5% of the per capita GDP distributed to the top income-decile)²⁷ then 550,000 people will buy it. In order to sell to a greater proportion of the population, the price must fall considerably – people in need of treatment in the second-top income decile will buy the medicine if it is priced at \$396, and half of the people in need of treatment can purchase an antiretroviral if it is priced at \$92. In order to sell to all people with AIDS who need treatment, the price would have to be lowered to \$18 per patient per year. (Since the marginal cost of production is usually very low and nearly constant across production levels,²⁸ we are showing total revenue instead of marginal revenue and marginal cost.)

Figure 4.2 shows the total sales revenue a firm will gain if it sells at each price on the demand curve. The firm maximizes its sales in South Africa by selling at the price that only the top 10% can afford. At this price, the firm makes \$814.6 million in total revenue. If the firm lowers its price to be able to make sales to 20% of the affected individuals (at \$396 per patient), then it will sell twice as many medicines at a price less than half of the profit-maximizing price, earning substantially less (\$435.6 million). As the monopolist continues to cut prices and raise production, revenues fall further at almost every level of output and corresponding price. In other words, the firm will maximize its profits by setting a price unaffordable for at least 90% of people in need.

of HIV/AIDS, it would lead to an even greater difference between demand and sales at the upper and lower income deciles (firms would be less likely to sell to the middle and lower classes).

²⁷ World Bank, World Development Indicators Database <http://devdata.worldbank.org/query/> (Constant GDP in 2000 USD and population statistics for the year 2000 were taken from the data base for South Africa, Norway, and all of the countries listed in Annex 2).

²⁸ See PARKIN, *supra* note 12.



To understand the effect that South Africa's inequitable income distribution has on the pricing and output decision of a monopolist in that country, compare it to the corresponding figures for Norway, which has one of the most equitable income distributions.²⁹

Constructing a similar demand curve based on the assumption that people will buy a medicine at prices up to 5% of their income yields a flatter, less convex demand curve (Figure 5.1).

^{30,31,32,33}

²⁹ Norway also has an excellent health insurance system so that in principle income need not be a barrier for anyone to obtain needed drugs there. Also, we are once again assuming uniformity in HIV/AIDS prevalence across income deciles.

³⁰ Data on income distribution in Norway for 2000 was taken from Statistics Norway, which is under the Norwegian Ministry of Finance (www.ssb.no). GDP data from the World Bank. According to UNAIDS data, there are 2500 people with HIV/AIDS in Norway, far less than South Africa. Figures 5.1 and 5.2 still assume that HIV is distributed evenly across income deciles, so each 10th of the HIV+ population represented in the graphs represents 250 potential consumers.

The less convex demand curve produces incentives for the firm to serve a larger percentage of the population through its pricing. Figure 5.2 shows the total revenue a firm will receive if it sells at the price affordable to each decile of the population. If it sets a price that only the top 10% of Norwegians could afford, it will earn total revenues that are much lower than it will receive if it lowers its price to one which a higher percentage of the population can afford. The seller will maximize profits by selling at the price affordable to all but the poorest 20% of the population.

Because the monopolist's demand curve is flatter, (more elastic overall) the firm cannot make up lost consumption by the majority of the population with very high price increases at the steeper (less elastic) end of the curve. Thus, the monopolist in this economy will maximize profits by selling at the price where 80% of the HIV+ population will purchase the product (Figure 5.2).³⁴

³¹ Statistics Norway, Norwegian Ministry of Finance, *Income Distribution: More Equal Income Distribution* (Mar. 7, 2008)) http://www.ssb.no/english/subjects/05/01/iffor_en/.

³² Joint United Nations Programme on HIV/AIDS, *Epidemiological Fact Sheets on HIV/AIDS and Sexually Transmitted Infections: Norway* (December 2006) http://www.who.int/GlobalAtlas/predefinedReports/EFS2006/EFS_PDFs/EFS2006_NO.pdf

³³ See World Bank, *supra* note 27.

³⁴ Indeed, because of universal drug insurance, the monopolist will wish to sell to all consumers.

South Africa

Affordable P (if this = 5%Y)	Q Sold at Each Price	Total Sales at Each Price
1,481	550,000	814,550,000
396	1,100,000	435,600,000
213	1,650,000	351,450,000
138	2,200,000	303,600,000
92	2,750,000	253,000,000
61	3,300,000	201,300,000
50	3,850,000	192,500,000
46	4,400,000	202,400,000
32	4,950,000	158,400,000
18	5,500,000	99,000,000

Sources: Statistics South Africa; UNAIDS

Norway

Affordable P (if this = 5%Y)	Q Sold at Each Price	Total Sales at Each Price
4,864	250	1,215,960
2,683	500	1,341,748
2,348	750	1,761,045
2,138	1000	2,138,412
1,971	1250	2,463,366
1,782	1500	2,673,014
1,635	1750	2,861,698
1,468	2000	2,935,075
1,237	2250	2,783,080
881	2500	2,201,306

Sources: Statistics Norway; UNAIDS.

The table above shows the data used for graphs 4.1 through 5.2. Although at every income decile the affordable price in Norway exceeds that in South Africa, this does not mean that the profit-maximizing price is below that of South Africa. As the table shows, the profit-maximizing price in South Africa is \$1,481, slightly *higher* than the profit-maximizing price in Norway. Of course, at this price in South Africa, only the wealthiest 10% would be able to afford the medicine; while in Norway 80% of the population would have access.

Extreme income inequality exists to a greater or lesser extent in nearly every developing country, where a small minority earns salaries that compare to those of advanced industrialized countries and the majority live in poverty. This inequality leads ineluctably to high prices for drugs under the patent system, in the absence of price controls. The problem is that relatively rich people, though few, are able to pay so much more for their drugs than most of the population. 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.³⁵ While price discrimination is theoretically possible within a country, in practice it seems to be quite difficult to charge different prices for different people who live near each other but have different incomes. In practice, price discrimination happens in situations where seller is able to split the market into distinct sectors that cannot trade with each other, such as utilities.³⁶ Thus, there is commonly little or no price discrimination within the private market in developing countries.³⁷

One implication of high monopoly prices in developing countries is that they may be similar to the monopoly prices in the developed countries. With highly convex demand curves in most of the developing world, there may be little economic incentive for drug firms to offer very different prices in different countries. This helps to explain why, even though parallel trade has not been established as a major problem, drug prices in very poor countries are often not particularly low.³⁸ There are some striking examples of this. Prior to the vocal outcry of international treatment activists, for example, the price of a first-line AIDS regime was the same in developed and developing countries – over \$10,000 a year.³⁹ Hellerstien (2004) found that “ARV prices had little or no relationship to developing countries’ per-capita incomes in 2000, when there was no generics competition.”⁴⁰ In Guatemala, which has one of the world’s most unequal countries in terms of income distribution,⁴¹ the 2000 sales price of fluconazole, an

³⁵ See, Wong, *supra* “Inequality and Pharmaceutical Drug Pricing: An Empirical Exercise (Ctr. for Econ. Analysis, Econ. Dep’t, Univ. of Colo. at Boulder, Working Paper No. 02-19, 2002) Working Paper No. 02-19. October 2002.

³⁶ CHARLES F. PHILLIPS JR., *THE REGULATION OF PUBLIC UTILITIES* 61-63 (1988).

³⁷ Helena Viñes Fiestas, et al., *Investing for life: Meeting poor people’s needs for access to medicines through responsible business practices*, Page 14 (Oxfam, Briefing Paper No. 109, 2007).

³⁸ F.M.Scherer & Jayashree Watal, *Post-TRIPS Options for Access to Patented Medicines in Developing Nations* 5 *J. INT’L ECON. L.* 913 (2002) [hereinafter Scherer & Watal, *J. INT’L ECON. L.*] (showing that there was in fact very little correlation between national income and pricing of AIDS drugs in a large sample of prices from 1995-1999)

³⁹ MÉDICINS SANS FRONTIÈRES, *UNTANGLING THE WEB OF PRICE REDUCTIONS: A PRICING GUIDE FOR THE PURCHASE OF ARVs FOR DEVELOPING COUNTRIES*, Page 6. (10th ed. 2007).

⁴⁰ Rebecca Hellerstein, *Do Pharmaceutical Firms Price Discriminate Across Rich and Poor Countries? Evidence from Antiretroviral Drug Prices* (Aug. 2004) (unpublished paper *available at* <http://www.ny.frb.org/research/economists/hellerstein/JDE2.pdf>).

⁴¹ UNITED NATIONS DEVELOPMENT PROGRAMME, *HUMAN DEVELOPMENT REPORT 2007-2008* 281-84 tbl.15 (2008).

important antifungal drug used with AIDS patients, was over twice as high as in the United States (\$27.60 vs. \$12.20 per unit).⁴² A 2001 WIPO report found that Mexico and Brazil paid higher prices than the UK and Sweden for a number of top selling drugs, including amlodipine, ciprofloxacin and sertraline.⁴³ Other drugs, such as the breakthrough anti-leukemia agent imatinib, are sold in developing countries at a similar price in many poor and rich countries.⁴⁴

III. Toward Open License Strategies

Not all intellectual property rights grant the right to exclude that is indicative of ‘property rules,’ as that term was used by Calabresi and Melamed in their seminal article.⁴⁵ Some intellectual property rights are ‘liability rules,’ in which the right holder has an entitlement to compensation for use of the protected invention, not a right to preclude the use. Liability rules are the default form of protection for digital broadcasting of copyrighted music in the U.S., for example, where “certain non-interactive digital audio services [may] transmit sound recordings under a compulsory license, provided that the services pay a reasonable royalty fee and comply with the terms of the license.”⁴⁶ Liability rules are also used to compensate American agricultural chemical companies when competitors use their test data submitted to the FDA for regulatory approval under the Federal Insecticide, Fungicide, and Rodenticide Act.⁴⁷

⁴² Carmen Perez-Casas, et. al, *Access to Fluconazole in Less-Developed Countries*, 356 LANCET 2102, 2102 (2000).

⁴³ Keith Maskus, *Parallel Imports in Pharmaceuticals: Implications for Competition and Prices in Developing Countries* (Apr. 2001) (unpublished report for the World Intellectual Property Organization *available at* http://www.wipo.int/export/sites/www/about-ip/en/studies/pdf/ssa_maskus_pi.pdf).

⁴⁴ See CPTech, *Note on Gleevec Price Hike in South Korea* (January 23, 2003) (*available at* www.cptech.org/ip/health/gleevec/gleevecprice-korea01222003.html) (reporting that the price of Gleevec in South Korea was recently raised 30% to over \$1,000 /month).

⁴⁵ Guido Calabresi & A. Douglas Melamed, *Property Rules, Liability Rules, and Inalienability: One View of the Cathedral*, 85 HARV. L. REV. 1089, 1092 (1972). *See also* Robert P. Merges, *Contracting into Liability Rules: Intellectual Property Rights and Collective Rights Organizations*, 84 CAL. L. REV. 1293 (1996); J. H. Reichman, *Of Green Tulips and Legal Kudzu: Repackaging Rights in Subpatentable Innovation*, 53 VAND. L. REV. 1743 (2000).

⁴⁶ *Determination of Reasonable Rates and Terms for the Digital Performance of Sound Recordings*, 37 C.F.R. §260 (2007); *see* 17 U.S.C. 106(6) & 114(d) (2001).

⁴⁷ SHAMNAD BASHEER, *PROTECTION OF REGULATORY DATA UNDER ARTICLE 39.3 OF TRIPS: A COMPENSATORY LIABILITY MODEL?* (Intellectual Property Institute, forthcoming 2008)