Financing Pharmaceutical Innovation: How Much Should Poor Countries Contribute?

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A public economics framework is used to consider how pharmaceuticals should be priced when at least some of the research and development incentive comes from sales revenues. Familiar techniques of public finance are used to relax some of the restrictions implied in the standard use of Ramsey pricing. Under the more general model, poor countries should not necessarily cover even their own marginal costs, and the pricing structure is not related to that which would be chosen by a monopolist in a simple way. This framework is then used to examine ongoing debates regarding the international patent system as embodied in the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights.

The most contentious issue in the pharmaceutical sector is not whether or how much to support private research. Most observers recognize the major contributions to global health that have come from private research efforts and the fact that price-cost margins supported by the patent system have been pivotal in stimulating that research. Conflicts arise instead over how the financing of research and development (R&D) incentives should be shared among consumers. How much of the total cost should a U.S. retiree, a French worker, or an Ethiopian peasant be expected to contribute?

Today the tensions are clearly on display. Senior citizen outrage over high drug costs in the United States has driven legislation through Congress to create a massive Medicare prescription drug benefit that will shift costs from pharmaceutical consumers to taxpayers at large. Similar outrage has led to repeated efforts to legalize the importation of lower priced Canadian drugs into the

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United States. The goal: to shift some of the costs of pharmaceutical research from Americans to Canadians. In a similar vein, an increasing number of voices support the view expressed by Mark McClellen, then commissioner of the U.S. Food and Drug Administration, in Cancún 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 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]

The goal is, at least implicitly, to shift more of the costs of pharmaceutical research to Europeans and others.

These conflicts within and between rich countries reflect the same debate that has been raging for years over drug pricing in the developing world. The heart of the controversy is distributional: Given a desire to support private research, to what extent should industry control of sales in poor countries be part of the effort? The developing economy debate has focused mainly on the minimum standards for patent protection set forth for members of the World Trade Organization (WTO) in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS),[2] in particular the requirement that member countries offer protection for pharmaceutical innovations.

The institutional apparatus embodied by TRIPS is a significant factor in determining the prices at which pharmaceutical products (or licenses to produce them) are sold in different countries. More generally, these prices and license payments are the result of negotiations between governments and firms, within a legal and regulatory framework that seeks to both stimulate appropriate levels of R&D and promote broad access to available drugs. The public debate over the suitability of the international pharmaceutical prices that emerge from this process tends to be polarized between those who focus on the incentive effects and those who concentrate on other social objectives. The purpose of this article is to provide a framework for determining a policy that respects both objectives. To this end, most of the legal aspects of the debate are abstracted and well-established techniques of applied public finance are employed to integrate both efficiency and distributional concerns.

Although the analysis here accounts for the need to provide incentives to develop new products, it does not formally address the question of how much incentive should be provided. Furthermore, a variety of policy options can be used to support research and address distributional concerns. The broad composition of these policies is taken as given, and the focus is on how to best

1. See www.fda.gov/oc/speeches/2003/genericdrug0925.html (accessed April 20, 2005).

2. Agreement on Trade-Related Aspects of Intellectual Property Rights, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C. Available online at www.wto.org/english/tratop_e/trips_e/trips_e.htm (accessed April 20, 2005).

structure pharmaceutical prices. Specifically the concern is how the burden of generating any given profit from sales should be shared across countries. The basic principles of optimal pricing presented here are consistent with broadly defined social objectives. These principles have come to be known as Ramsey pricing, after the seminal work of Frank Ramsey (1927).[3]

The techniques reviewed in this article are not new. Indeed, some of the literature on pharmaceutical pricing has employed them already (see Danzon 1997, 2001). In most of this literature, however, the assumptions that underlie the derivation of standard Ramsey prices are very restrictive. In particular, they require either that concerns about the global distribution of well-being be suitably addressed through other policies or that policymakers have no such concerns.

The characterization here of social objectives—which is general enough to encompass a broad range of distributional preferences—will be familiar to students and practitioners of applied public economics, although it does not appear to have been explicitly employed in formal analyses of international pharmaceutical pricing. Once one departs from the restrictive assumptions imposed by the standard (distributionally neutral) Ramsey pricing model, the pricing rules are replaced by so-called many-person Ramsey rules (Diamond 1975). Ramsey prices calculated in the standard way are a special case.

The analysis here highlights two common prescriptions derived from the standard Ramsey pricing model that are not valid once one allows for more broadly defined social objectives. First is that prices should at least cover marginal costs in each country—that is, countries should pay at least for the direct costs of delivering drugs—a conclusion valid only when distributional concerns are not incorporated into the analysis. Second is that pricing structures should be closely related to those that would arise under monopoly pricing in each country. Again, this does not carry over to optimal policies in the presence of distributionally sensitive objectives. In addition, using a natural formulation of health needs, the standard model prescribes higher prices in countries with greater need for drugs. Rationalizing such a policy when equity is a concern would be difficult.

Section I discusses how the problem examined in this article fits into the more general problem of the provision of incentives for R&D. Section II presents the intuition for and derivation of the many-person Ramsey rule and relates it directly to the determination of reasonable royalty rates on compulsory licenses. In the light of this analysis, section III reviews the more standard Ramsey pricing rule and illustrates how policy implications drawn from the standard model can differ from those derived from the more general framework. Section IV illustrates the tradeoffs between pricing, welfare, and R&D investment and explores several recent controversies.

3. This work enjoyed a renaissance in the early 1970s with the work of Baumol and Bradford (1970) and Diamond and Mirrlees (1971). The same tools have been extensively applied to the question of public enterprise pricing, as exposited by Bös (1986), for example.

I. Financing R&D Incentives

The formulation of public policy regarding pharmaceutical pricing can be usefully thought of as proceeding in three steps: establishing the total amount of resources that society should devote to research, identifying the broad mechanisms by which such funds are raised and allocated, and designing each broad mechanism. Although the focus of this article is the third step, for clarity each part of the process is briefly discussed.

How Big an Incentive to Provide for Innovation

It is widely believed that under a laissez-faire policy, incentives for investment in R&D are severely attenuated and the aggregate amount of R&D investment is far less than what would be socially desirable. This is because the production of new drugs (like many other innovations) exhibits significant returns to scale due to the presence of sometimes enormous fixed costs, and competition leading to marginal cost pricing results in negative profits. Exactly what level of R&D is optimal depends on several factors. In general, the right level of R&D depends on its expected benefits and costs in the obvious way. The extent to which research investment leads to the discovery of new products, coupled with an evaluation of the benefits of these new products, must be weighed against the value of other goods that could otherwise have been obtained. Making these tradeoffs requires careful attention to such factors as the rate of time preference (because research pays off in the longer run) and the cost of stimulating different levels of innovation. These topics are not pursued further in this article.[4]

How to Support Innovation

A variety of mechanisms exist for providing R&D incentives in the presence of increasing returns to scale. The patent system promises future profits on sales. Various tax credits and subsidies (such as the orphan drug legislation in the United States) provide returns not so much for successful innovation but for attempts at innovation (that is, at the research stage). Alternatively, some R&D is funded directly by the government through public institutions (such as the U.S. National Institutes of Health). The relevant distinction here is between research support derived from profits on sales of successful innovations and research support provided through the general tax system.

Suppose that total R&D funding is the sum of R, funding from sales revenues in excess of marginal costs, and T, funding from general taxes. An important finding of Atkinson and Stiglitz (1976) is that under certain conditions, if a government wants to raise a certain amount of revenue with both efficiency and

4. See Nordhaus (1969) and Scherer (1972, 2003) for discussion of some of the tradeoffs involved in this decision.

equity objectives in mind, it should implement a suitably designed income tax and avoid taxing the consumption of goods and services separately.[5] In the context of pharmaceutical pricing, this would mean that drug prices should be set equal to marginal cost (that is, very close to zero) and that *R* would be zero.

However, in practice there are many sound reasons why sales revenues in excess of marginal costs might be a useful source of financing. First, the form of research support can affect the productivity of the investment. In particular, support from sales of products gives researchers a larger incentive to find products that address consumer needs than to, say, work on projects that are primarily of scientific interest. It might be politically easier for governments to allow a firm to charge certain prices than to hand over a large sum of tax revenue. Governments can thus maintain support for the overall R&D incentive if at least some of the funding does not come from explicit tax increases.[6]

More important, even if all other conditions are satisfied, the Atkinson-Stiglitz result requires a sophisticated (nonlinear) worldwide income tax. Clearly, the global institutions are not in place to implement such a tax, with good reasons, including institutional and political constraints and corruption. When equity concerns cannot be directly addressed, it is important to take into account the distributional implications of all policies. Drug pricing may well be one of the more effective tools for redistribution because it targets a basic human need and provides resources in a form more difficult to divert than, say, direct transfers to country governments.

Pricing to Yield R

Having established the size of the research support that society is willing to provide and the division of this incentive between taxes, *T*, and net sales revenues, *R*, the last issue to address is the design of the price structure that will yield *R*, the primary subject of this article. The results will apply to any level of *R*: As the choices made in the first two steps change, the pricing formulas remain unaffected (although the actual prices prescribed will change). That is, the general insights into the structure of prices conditional on *R* remain informative as *R* changes.

The design of the price structure, and possible practical limitations on it, will inform and feed back into the decisions made in the first two steps. For example, if certain constraints mean that feasible prices differ from prices that would otherwise be considered optimal, then policymakers might want

5. This result is in the context of a static model with no savings. Under an intertemporal model with savings the result indicates the optimality of a (nonlinear) consumption tax. See Atkinson and Stiglitz (1980).

6. Of course, this is not to suggest that prices above marginal cost are not taxes, rather that they are perceived differently by voters.

to shift more financing into taxes and pursue other avenues for attaining distributional goals. Furthermore, the total resources that should be devoted to research may be revised if otherwise desirable pricing policies are unavailable.

With this in mind, readers should interpret the findings here as the first input (working backward) in the solution to the three-part problem of finding ways to induce R&D when policymakers care about dynamic efficiency (that is, R&D incentives), static efficiency (such as the distortionary costs of monopoly pricing), and equity.

II. Ramsey Pricing

The analysis here starts by considering the simplest model with two countries, north and south.[7] It also assumes that both countries have the same number of residents and that they are identical within each country.[8] Thus for simplicity each country, $i = n, s$, is assumed to have a single consumer[9] with income, m_i,[10] who chooses between two goods, x, which represents all other goods and whose price is normalized to 1, and a drug, y, available in country i at a price, p_i. Incomes can vary across countries. The consumption preferences of the consumer in country i are represented by a function, $u_i(x, y)$. The consumers in both countries are assumed to have the same preferences for the two goods. However, in the next section preferences for drugs will be allowed to differ in north and south, due, say, to differences in disease conditions and health needs.

These preferences can be used to determine the highest level of utility that the consumer can attain with income m_i and drug price p_i. Because there is no saving in this simple model, consumers will spend their entire incomes so that $x + p_i y = m_i$. Then consumer i's maximum utility level (indirect utility function) for any price and income can be written

$$v_i(p_i, m_i) = \max_{x,y} u_i(x, y) \quad \text{subject to } x + p_i y = m_i. \tag{1}$$

7. The analysis would hold for any number of countries.

8. The assumption that individuals in a given country are identical is clearly contrary to fact and made to highlight the ways pharmaceutical prices should vary across countries. In addition, differential drug pricing within a country is likely to be more difficult to implement than differential pricing across countries, and other means of redistribution are likely to exist within countries that are not available for redistribution across countries.

9. The optimal pricing rules are the same for any distribution of population across countries, although the level of prices would differ.

10. m_i is income net of any contributions, t_i, to tax-financed R&D incentives, T. Taking the t_i as given, only the distribution of m_i across countries matters, not the distribution of t_i. Since the t_i are small relative to the m_i, this distinction is of little practical importance.

To formalize the policy objective, drug prices are assumed to be chosen to make some concept of global aggregate well-being as large as possible.[11] Extending in a natural way a long tradition of applied public economics for determining country-level tax policies, this goal is described in terms of global social welfare, which depends on the utility of consumers in both countries. That is, social welfare is a function, $W(v_n, v_s)$.[12] How much a small increase in the utility of consumer i contributes to social welfare depends on how W is defined and on consumer i's starting level of utility, as well as the utility levels of other consumers. The incremental effect of an increase in consumer i's utility is denoted by $\gamma_i = \partial W/\partial v_i$.

To determine appropriate prices across countries, it is useful to observe that the way in which a price increase in country i affects social welfare can be decomposed into two parts. First, increasing the drug price will generally lower consumer i's utility (assuming the drug was already being consumed). If consumer i's drug consumption was y_i initially and remained at that level after a small increase in the drug price, Δp_i, the effect of the price increase would be the same as if consumer i's income had been reduced by $\Delta m_i = \Delta p_i \times y_i$. Thus, knowing what effect a reduction in income would have on consumer utility allows an assessment of the first impact of a price increase in country i. This marginal utility of income is typically denoted by $\alpha_i = \partial v_i/\partial m_i$. Studies of behavior under conditions of uncertainty indicate that α_i is very likely to decline as income increases. That is, people get less benefit from an extra dollar as they become richer.[13]

Second, as discussed earlier, the reduction in consumer utility in country i (Δv_i) will have an effect on social welfare. The two pieces together give the total effect on social welfare of a change of income in country i. This is denoted β_i:

$$\begin{aligned} \beta_i &= (\partial W/\partial v_i)(\partial v_i/\partial m_i) \\ &= \gamma_i \alpha_i. \end{aligned} \tag{2}$$

With the relationship between price and income changes, $\Delta m_i = \Delta p_i \times y_i$, changing the drug price in country i would have the following effect on social welfare:

11. Exactly who determines priorities at the global level is not addressed here. The purpose is simply to ask how prices should be chosen, given some criterion that is global in nature because it incorporates the well-being of consumers in different countries.

12. This article assumes that competition drives rents in the pharmaceutical industry to zero, so that all net revenue is invested in R&D. More generally, if pharmaceutical companies earn positive rents (that is, profits in excess of the cost of capital), static social welfare can be defined as a function of consumer utilities and profits, where the weight on profits depends on how they are distributed. Allowing for positive profits would affect the choice of the optimal level of R&D incentive, but not the pricing rules conditional on R focused on here.

13. The value of α indicates how a given consumer would view an extra dollar if the consumer were poor compared with if the same individual were rich. A declining α does not necessarily imply that an extra dollar would give every rich consumer less utility than it would give to a poor consumer—only if they derive the same utility from consumption, as assumed in this section.

$$(3) \qquad (\partial W/\partial p_i) = (\partial W/\partial v_i)(\partial v_i/\partial p_i) = -\beta_i y_i.$$

Thus lowering the price of the drug in country i tends to be most beneficial when β_i is large. The value of β_i is large when extra income is particularly valuable to the consumer in country i (large α_i) and when boosting the well-being of those in country i is viewed as particularly important (large γ_i). For example, if extra income is more valuable to poor consumers and if south is the poorer country, $\alpha_s > \alpha_n$. Second, a preference for a more equal distribution of well-being implies that $\gamma_s > \gamma_n$.[14] Thus on both accounts one might expect $\beta_s > \beta_n$. One objective of this article is to bring attention to the fact that the use of public economics in the policy debate on international drug pricing has implicitly assumed a very special (and arguably unrepresentative) case: one in which both α_i and γ_i, and hence β_i, are constant across all countries at all incomes.

Derivation of Ramsey Prices

The model described earlier is used to characterize the optimal drug price in each country. It is assumed that the marginal cost of producing and distributing the drug is constant within a country but can vary across countries and is equal to c_i in country i.[15] Now, suppose that for a given product the innovator firm is permitted to generate sales revenue over costs of R. The optimal set of drug prices p_n and p_s are those that give the highest social welfare, W, subject to this revenue constraint. It is assumed that profits (or losses) on sales accrue to the firm, either because the firm sells the drug directly or because it controls and sets the terms of licenses to alternative manufactures. If licensing is compulsory, there must be enough competition among generics manufacturers that they do not profit from sales. It also means that there are no import or sales taxes. Formally, these prices solve the problem

$$(4) \qquad \max_{p_n, p_s} \; W(v_n, v_s) \quad \text{subject to} \quad \sum_i (p_i - c_i) y_i = R.$$

A Lagrange multiplier, λ, is introduced on the constraint, so that the first-order conditions satisfied at the optimal prices are

14. The welfare function is usually assumed to be anonymous, that is, it does not discriminate directly among consumers. But, for example, if one cared less about the well-being of consumers from the south, then all else equal, γ_s would tend to be lower than γ_n. A strong enough preference for northerners could imply a desire to redistribute from the poorer south to the richer north.

15. The marginal cost of delivery could vary within a country. This is ignored here, and it is assumed that the costs of launching a product in an additional country (obtaining marketing approval, advertising to doctors, arranging distribution, and the like) are negligible.

$$(5) \qquad (\partial W/\partial v_i)/(\partial v_i/\partial p_i) + \lambda[y_i + (p_i - c_i)(\partial y_i/\partial p_i)] = 0 \quad \ldots \; i = n, s.$$

The (negative of the) first term is the marginal social cost (that is, the incremental reduction in social welfare) associated with a price increase in country i, MSC_i. The bracketed part of the second term is the marginal revenue earned from a price increase in country i, MR_i. The condition then says that for each country

$$(6) \qquad MSC_i/MR_i = \lambda.$$

The ratio on the left side is the reduction in welfare as revenue generated by sales in country i increases. Because λ is the same for both countries, the marginal social cost of revenue generation is equalized across countries. That is, at the optimum prices, raising an extra dollar from either country should have the same (negative) effect on social welfare: if the marginal welfare loss per unit of net revenue differed between countries, the amount earned from each could be adjusted, keeping aggregate net revenue constant at R, while reducing the total social cost.

Using equation 3, equation 5 can be rearranged as

$$(7) \qquad \left(p_i^* - c_i\right)/p_i^* = [(\lambda - \beta_i)/\lambda]\ 1/\eta_i,$$

where p_i^* is the optimal (Ramsey) price in country i and $\eta_i = -(p_i/y_i)\ (\partial y_i/\partial p_i) > 0$ is the elasticity of demand for the drug in that country.[16] It measures how sensitively consumers react by adjusting their consumption of drugs when prices change. The Lagrange multiplier, λ, measures the social value of relaxing the financing constraint by a dollar—that is, the gain in social welfare that would accrue if the revenue allowed the firm, R, was marginally reduced. As discussed earlier, β_i, measures the increase in social welfare associated with a \$1 increase in the income of the consumer in country i.

For a given elasticity of demand, the markup as a share of the final price is smaller the larger β_i is. As argued, β_i might be expected to be larger in a poor country, which would suggest lower markups. In general, though, there is no reason to expect that at the optimum prices, $\beta_i < \lambda$ for all countries i (although it must be the case that $\beta_i < \lambda$ for at least one country for revenue to be nonnegative). That is, the term in brackets could even be negative. This means that Ramsey prices do not necessarily cover marginal costs in all countries, because if

16. It is assumed that optimal prices, including Ramsey and monopoly prices, are unique. Equation 7 is closely related to Diamond's (1975) many-person Ramsey rule. Despite the mathematical similarity, however, there is a slight difference in interpretation. Diamond's analysis considers the optimal tax rates applied to several different goods, under the constraint that these tax rates must be the same for all individuals. Under the model here there is just one taxed good, the drug, but it is assumed to be possible to apply different tax rates (prices different to marginal cost) to it in different countries, that is, tax rates that depend on who buys the drug.

the right side of equation 7 is negative, $p_i^* < c_i$. This possibility is illustrated graphically in the appendix. (Whether such prices can be attained given available policy tools is considered in section IV.)

Finally, note that the condition refers to the markup over cost as a share of price. If the marginal cost of producing and distributing the drug, c_i, is the same across countries, a lower markup in country i also implies a lower price in country i. If it is not the same, the final price, p_i, could be higher in the country with the lower markup.

Ramsey-Reasonable Royalty Rates

The TRIPS agreement allows for the compulsory licensing of patented innovations in some circumstances. These licenses give manufacturers the right to produce and sell a patented product in the country issuing the license in return for adequate remuneration to the patent holder (TRIPS, articles 31h and 31k). In general, when compensation is due a patentee, it is commonly in the form of royalty payments per unit of sales, and laws requiring compensation are sometimes directly specified in relation to reasonable royalties.[17] What is "reasonable" is not clearly stated and is open to interpretation.[18] One natural approach to this problem in the international context is to follow the same line of reasoning used here, asking what royalty rates would generate the highest level of social welfare.

Royalty payments are typically defined as a share of the final sale price. Thus, if the royalty rate to be paid to the inventor on sales in country i is, say, r_i, the marginal cost of production to the manufacturing firm becomes $c_i + r_i p_i$. If the market is competitive—that is, with several generics producers operating under compulsory license—the price will equal the marginal cost of production, $p_i = c_i + r_i p_i$. In this case

$$r_i = (p_i - c_i)/p_i \tag{8}$$

and the royalty rate in country i will determine the markup as a share of price in that country.[19] Thus, given competition, it follows directly that the Ramsey-reasonable royalty rate is defined by equation 7.

III. STANDARD RAMSEY PRICES

This section presents the special case of the model illustrated earlier that has been used in the discussion of international drug prices. Two common prescrip-

17. In assessing damages in infringement cases, for example, 35 U.S.C. §284 provides that damages should be "in no event less than a reasonable royalty for the use made of the invention."

18. See Scherer and Watal (2002) for an interesting discussion of historical practice within countries.

19. Without competition and price controls the price would be higher. Some of the resulting revenue would go to the inventor as royalty payments and some would go to the generics producer as profit.

tions derived from this special model are highlighted to show how they are at odds with those drawn from the more general formulation discussed earlier. The first is that prices should at least cover marginal costs in each country. The second is that the pricing structure should be closely related to what would arise if monopoly prices were charged in each country. The special model also suggests that prices should be higher in countries with a greater need for drugs. This inference is not typically noted.

Consumer Surplus, Ramsey Prices, and "Fair" Prices

The standard approach does not incorporate any concern for the distributional effect of drug prices. There are two interpretations of this treatment. First, it could mean that distribution simply does not matter. This requires assuming that an extra dollar gives the same amount of additional utility to a consumer regardless of that person's starting income level. That is, the marginal utility of income, α_i, is constant. Furthermore, it requires that the way any total amount of utility is distributed between the two consumers is not given any particular importance. Formally, a social welfare function is implicitly assumed, and it is utilitarian:

$$W(v_n, v_s) = v_n + v_s. \tag{9}$$

With the utilitarian social welfare function, $\gamma_s = \gamma_n = 1$. Together with the constant marginal utility of income, this means that $\beta_i = \beta$ is also constant.

The second interpretation is that distribution does matter, but that it is expected to be dealt with in other ways. If there are other (unused but nevertheless effective) avenues for bringing all consumers in the world to a similar level of well-being, distributional concerns can be safely ignored when pricing drugs. In either interpretation, β_i can be treated as constant across countries, and the optimal pricing conditions from equation 7 simplify to

$$(\bar{p}_i - c_i)/\bar{p}_i = [(\lambda - \beta)/\lambda]\ 1/\eta_i, \tag{10}$$

where $\bar{p}_i$ is the optimal price and $\beta = \alpha\gamma = \alpha$.[20]

The term in brackets, $(\lambda - \beta)/\lambda$, is now constant across countries. Thus prices should differ across countries in such a way that the proportional markup as a share of price is inversely related to the elasticity of demand at those prices—the standard result. This rule implies higher prices for those who change their consumption less, and it is efficient because it causes the least distortion to consumption patterns. Finally, it can be argued in this special case that at the optimal prices,

20. It is common in the literature on regulation and utility pricing, and in some accounts of international drug pricing, to adopt the maximization of a measure of aggregate consumer surplus as the policy objective. This approach can be reconciled with the one adopted here, with $\alpha_i = \alpha$ for $i = n$ and s, and a utilitarian social welfare function.

$\lambda > \beta$, so that the price in each country is at least as high as c_i, the marginal cost of production and distribution there. This is shown graphically in the appendix.

It is tempting to interpret the condition that each country cover at least its own marginal costs as fair. But this can be fair only in a procedural sense. Putting such a condition on prices only emerges as a general policy prescription when concern for equity is ruled out.

Comparison with Monopoly Pricing

If a single firm were producing and selling the drug, and if the firm could freely choose prices in separate country markets, it would set prices to maximize net revenue, $R = \Sigma_i(p_i - c_i)y_i$. The first order condition for this problem is simply

$$y_i + (p_i - c_i)(\partial y_i / \partial p_i) = 0, \tag{11}$$

which is the same as equation 5, except that it does not have a term giving weight to social welfare. The monopolist would thus choose prices p_i^m in different countries to satisfy

$$\left(p_i^m - c_i\right)/p_i^m = 1/\eta_i. \tag{12}$$

When compared with equation 10, the relative price-cost markups derived in the special case are proportional to what would be chosen by a price-discriminating monopolist. That is, if $\mu_i = (p_i - c_i)/p_i$ is the markup as a share of price in country i,

$$\mu_s^m / \mu_n^m = \eta_n / \eta_s = \bar{\mu}_s / \bar{\mu}_n. \tag{13}$$

These can be compared with the ratio of price-cost markups under the optimal Ramsey prices characterized in equation 7:

$$\mu_s^* / \mu_n^* = [(\lambda - \beta_s)/(\lambda - \beta_n)]\ \mu_s^m / \mu_n^m. \tag{14}$$

If $\beta_s > \beta_n$, the relative markup in country s is smaller than the relative markup that would be chosen by a price-discriminating monopolist.

Factors Determining the Elasticity of Demand

The standard Ramsey and monopoly pricing rules, equations 10 and 12, have been loosely interpreted as requiring prices to be higher in countries with lower demand elasticities, because the elasticity of demand is typically not constant as a function of price. Indeed, when marginal costs are zero, these rules collapse to $\eta_i = (\lambda - \beta)/\lambda$ or $\eta_i = 1$, that is, prices should be set so that the elasticity of demand is equal across countries. In general, this requires differential prices if the relationship between price and elasticity differs by country. This begs the question of how demand elasticities are likely to vary across countries. This section offers two illustrative answers to this question. Two important dimensions along which countries differ are income and health

needs. Consumers in countries in the south are assumed, on average, to be poorer and sicker than consumers in countries in the north.

THE EFFECT OF INCOME ON DEMAND ELASTICITY. Suppose consumer demand for a drug in country i is a linear function of its price and the consumer's income,

$$y(p_i, m_i) = \begin{cases} y_0 - b(p_i/m_i) & \text{if } p_i < y_0 m/u, \\ 0 & \text{otherwise} \end{cases} \tag{15}$$

where y_0 is the same for both countries and measures the amount of the drug that would be consumed if it were free and b is a constant. Note that for any price at which demand is positive, demand is increasing in income and decreasing in price. But there is no difference between the countries in terms of their health needs, that is, if consumers in the two countries had the same income and faced the same prices, their demand for the drug would be the same.

It is easy to show that the elasticity of demand in country i is

$$\eta_i = (y_0 - y)/y. \tag{16}$$

This elasticity is decreasing in income and increasing in price. These two properties together imply that prices should be higher in the north than in the south, even with distributionally insensitive social objectives. If equity is a concern, the optimal price differential between north and south will increase further.

THE EFFECT OF HEALTH NEEDS ON DEMAND ELASTICITY. Disease prevalence and the susceptibility of people to disease differ markedly across countries, so some pharmaceutical products will be in higher demand in some countries than in others. Demand for pharmaceuticals may also be higher in some countries because alternative medical treatments are unavailable or more costly. Perhaps the easiest way to incorporate these country differences into the Ramsey pricing analysis is to suppose that the utility that consumers in country i obtain from the consumption of a drug, y, and other products, x, can be written

$$u_i(x, y) = \phi[x + \upsilon(\theta_i y)], \tag{17}$$

where θ_i measures the value of the drug relative to other consumption in country i.[21] Assuming a constant elasticity functional form for function υ, demand elasticities in this case are

21. This specification can be interpreted as follows: Consumers care about the composite good, x, and their level of health attainment, h, according to $u(x, h) = x + \upsilon(h)$. In practice, health attainment is a complicated and not well-understood function of many variables, but here suppose it is a simple linear function of the consumer's consumption of the drug, $h = \theta y$, so that utility is $u(x, y) = x + \upsilon(\theta y)$. A simple way to model heterogeneous health needs is to assume that consumers with greater health needs have a higher value of θ, so that the effect of the drug on their health attainment is larger.

$$\eta_i = 1/\rho\theta_i. \tag{18}$$

Countries with greater need for drugs (higher θ_i) have lower demand elasticities.[22]

The Ramsey pricing rule, equation 7, now becomes

$$(p_i - c_i)/p_i = \rho[(\lambda - \beta_i)/\lambda]\theta_i. \tag{19}$$

This means that the markup is greater, the greater are health needs (as measured by θ_i) and the smaller is β_i. In the special case of a utilitarian social welfare function and constant marginal utility of income ($\phi' = 1$), so that $\beta_i = \beta$ for all i, only the first effect is relevant, and equation 19 prescribes that countries with greater needs should face higher prices. This result again highlights the inadequacy of distributionally insensitive pricing rules, because it is likely that countries with greater need for pharmaceuticals will also be relatively poorer.

IV. Policy Illustrations

The Ramsey prices described earlier give the highest level of social welfare while allowing an innovative firm to earn a given net revenue. How do these prices compare with the prices expected under various regulatory and patent regimes? This section uses a graphical tool to conveniently compare alternative policy choices with each other and with the benchmark Ramsey prices. The model now allows for many countries.

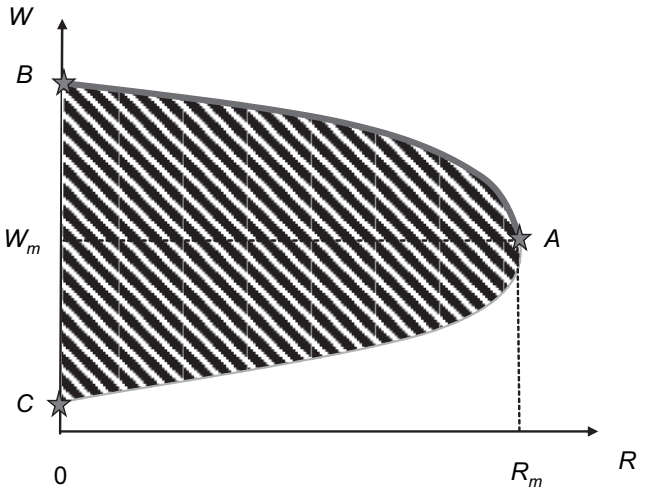
In many cases a given net revenue target, R, can be reached with a variety of international price structures. Some might result in much of the revenue being raised in richer countries, while others might have it raised in poorer countries. With each set of prices an associated level of global welfare, W, is attained. The shaded area in figure 1 depicts all the combinations of net revenue and welfare (R, W) that can be obtained with different sets of global drug prices.

At point A, the sales revenue raised by the firm in excess of marginal costs, R_m, is the amount that would be raised by a profit-maximizing monopolist able to separate markets. This maximum net revenue target can be reached only if the price in each country is the monopoly price for that country, p_i^m. When monopoly prices are charged in each country, social welfare is W_m.

At the other extreme, the firm receives no revenue in excess of marginal costs and $R = 0$. There is a set of Ramsey prices associated with this revenue target, and these prices yield the highest level of social welfare, shown as point B. To

22. Given the utility function in (17), at any price p_i, consumers in country i have a demand for drugs $y_i(p_i\ ;\ \theta_i)$ that satisfies the condition $\theta_i v'(\theta_i y_i) = p_i$. This condition implies that demand for the drug depends on its price and consumer needs, θ_i, but not on income (admittedly an extreme assumption). The elasticity of demand is then $\eta_i\ (y_i\ ;\ \theta_i) = -(1/\theta_i)\ [v'(\theta_i y_i)/y_i v''(\theta_i y_i)]$. In the special case where $v(h) = (h^{1-\rho})/(1-\rho)$, for $\rho \in (-\infty,1)$ then $-yv''/v' = \rho$ and equation 18 follows.

FIGURE 1. Revenue-Welfare Options



Note: All points in the shaded region, representing revenue-welfare pairs (*R, W*), are attainable. Those on the upper boundary are attained by setting Ramsey prices.

the right of point *B*, the revenue target increases, which means prices must rise. Thus the highest attainable welfare falls until point *A* is reached, with welfare W_m. These maximum welfare levels, reached when Ramsey pricing is used to generate any given net revenue target, are depicted by the bold line.[23]

There is also a minimum level of welfare than can be reached for a given revenue target. These "worst possible" welfare and revenue combinations form the bottom edge of the shaded area in figure 1. For any given *R* there are prices that can generate any intermediate levels of welfare between these bounds (assuming continuity). Thus all combinations of *R* and *W* in the shaded area can be attained by setting different drug prices.

Finally, point *C* has two interpretations. If the drug is developed, point *C* is where the drug is priced so high everywhere that demand is zero and consequently welfare is very low. Point *C* also represents the sales revenue (zero) and welfare that would be obtained if the drug fails to be developed.

Limitations on Implementable Prices: Voluntary Participation

In the discussion of Ramsey pricing thus far it has been assumed that any price could be set in any country. However, policymakers often control prices only indirectly, and their options may be limited by the available policy tools and the ways prices in one country affect prices elsewhere. This section considers what prices could be implemented in practice.

23. If no value is put on the well-being of some countries, their prices can be raised first without affecting the level of social welfare and the bold line would be horizonal at low *R*.

If firms can separate markets, the country-specific monopoly price can be reached in each country by granting firms strong and well-enforced patent rights—in particular, rights that are not compromised by compulsory licensing. Prices below the monopoly level can be reached by granting firms patent rights and then regulating price levels. Most developed economies follow this strategy, and price controls come in a wide variety of forms.

Arriving at price equal to marginal cost can in principle be managed in two ways. First, the price can be directly set at that level through regulation. This, however, assumes that regulators have enough information to determine marginal cost, which is unlikely, and that firms would not respond by refusing to enter the market. Second, the price can be controlled indirectly by allowing entry by competitive generics firms. Given current TRIPS obligations, this could be ensured only through government grant of nonexclusive compulsory licenses. Of course, generics firms would need to enter the market for competition to be effective, which cannot be assumed.[24] In many countries, other features of the market or regulation unrelated to patents may limit competitive entry.

What about prices below marginal cost? As seen earlier, Ramsey prices may be less than marginal cost in some countries. Firms may be willing to sell at a loss in limited circumstances. Drug donation programs are an example, although they do not fit the model here precisely because some part of the cost to the firm is offset by tax deductions. One way to implement such prices is to link sales across countries through a bulk purchase arrangement, in the spirit of the large-scale procurement of vaccine by the United Nations Children's Fund. Firms would bid to sell a given quantity of a pharmaceutical at a given uniform unit price to the intermediary, which would then sell the product to individual countries at differentiated Ramsey prices.[25] Such systems, however, require an administrative infrastructure that would be costly to expand to a broad range of pharmaceuticals. Furthermore, richer countries in the arrangement effectively subsidize losses in the poorer ones, creating a clear incentive for firms and richer countries to interact outside of the scheme.[26] Even if these difficulties could be overcome, it would be hard for governments to credibly commit now to providing these sales arrangements for future new drugs and therefore difficult to use them to encourage the right level of investment today.

24. In August 2003 an agreement was reached on rules governing the export of drugs under compulsory license to supply countries lacking the ability to manufacture their own (resolving the "paragraph 6" debate). How this agreement is implemented will influence the sources of generic supply for poorer countries and thus competition among suppliers.

25. The United Nations Children's Fund purchases vaccines primarily for distribution in developing areas, so the potential cross-subsidy from richer countries is limited.

26. The obligation sometimes imposed on providers, such as the postal service, to serve unprofitable locations or consumers at subsidized prices to obtain a larger contract is an example of such an arrangement. The implicit subsidy from one group of consumers to another sometimes induces the former to opt out and purchase services from alternative suppliers, such as private postal services.

Thus, as a practical matter, it may not be possible to implement prices lower than marginal costs. Figure 2 shows what this limitation on pricing implies for the options. At point *A* the Ramsey price in each country is the monopoly price, which is greater than marginal cost, so this point remains feasible.

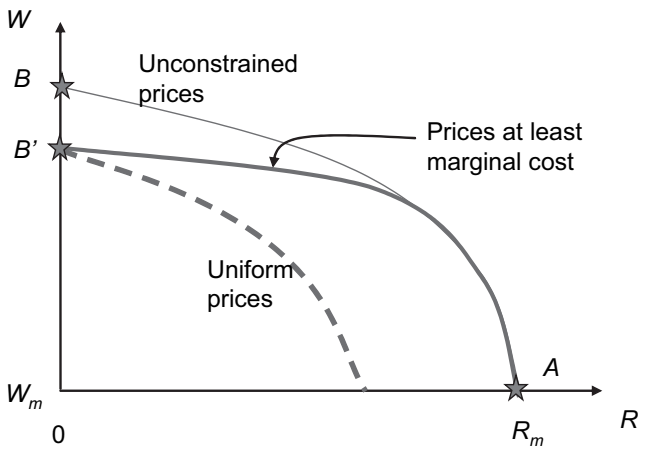
When the net revenue target is zero, for all countries welfare-maximizing prices equal marginal cost only when $\beta_i = \beta$ (see section III and the appendix). On the other hand, if there is a concern for distribution, Ramsey prices may be higher than marginal cost in some countries and lower in others. If so, restricting prices to be at least as high as marginal cost in all countries would lower welfare in comparison with the welfare attained with Ramsey prices, and point *B* would no longer be feasible. Figure 2 depicts the top portion of figure 1. The upper boundary of the feasible area in figure 2 now starts at point B' and indicates the highest level of welfare possible with each revenue target when all countries must cover their marginal costs. It is below the previous boundary, implying less attractive options, until the point where the required net revenue is sufficiently high that Ramsey prices also imply $p_i \geq c_i$ in all countries.

Limitations on Price Differentiation: Arbitrage and Reference Pricing

A second and far more restrictive limitation on pricing is a global uniformity constraint. Completely uniform prices are unlikely, but there are two reasons why it might be difficult for a firm to charge markedly different prices for the same drug in different countries.

The first is arbitrage. *The Washington Post* described how $18 million worth of reduced-price antiretroviral drugs meant for Africa were diverted back to the

FIGURE 2. Revenue-Welfare Options with Constraints



Note: Limitations on prices shrink the feasible set of (*R*, *W*) pairs. At $R = 0$, the highest attainable welfare is at B', below *B*. Along the bold line, price must be at least as high as marginal cost, and along the dashed line, prices must be uniform across countries.

European market by black marketeers (October 3, 2002). Competition among intermediaries tends to narrow the differences in prices across countries. Without competition between intermediaries, prices may stay high in the high-priced countries with some part of the profit going to the intermediary. Either way revenue to the innovative firm falls.[27]

The second factor pushing global prices together is regulatory practice. In particular, many countries' price control boards refer to prices in other countries when determining their own price ceilings (so-called reference pricing; see Jacobzone 2000).

Figure 2 illustrates how options are constrained and welfare diminished if countries are limited to a uniform price. With this restriction on pricing, the available combinations of welfare and revenue are largely limited to those on the dashed line drawn inside the constrained boundary (in bold).[28] The monopoly revenue, R_m, is no longer possible because it requires different prices across countries.[29]

TRIPS

As a result of the TRIPS component of the treaty establishing the WTO, all member countries are expected to grant and enforce 20-year patents on pharmaceutical innovation. Because most rich countries already offer such protection, the main result of TRIPS is to strengthen pharmaceutical patent rights in a group of poorer countries.

Point *D* in figure 3 indicates a possible "pre-TRIPS" location for a pharmaceutical treating a disease with global incidence (for example, cancer). Firms have patent rights (often with price control) in most countries, with generic competition in some poor countries. Both regulation and competition push firm net revenue below R_m, where welfare is also lower than it need be, given R, because the global prices that result from the current system of uncoordinated national price regulation and free market pricing are unlikely to correspond to Ramsey prices for any social welfare function.[30] The introduction of TRIPS results in a move to one of the points denoted E_i, $i = 1,2,3$. Stronger patent rights increase the net revenue on drug sales. R grows very little, however, because markets in

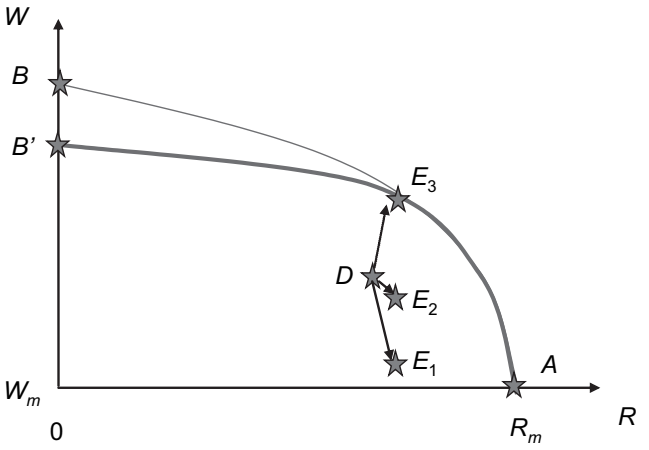
27. In practice, costs of intermediation allow for some limited differentiations even when arbitrage is legal (see Ganslandt and Maskus 2004 for evidence within the European Union). Intermediation becomes considerably more difficult if transshipments are illegal.

28. In addition, the set of possible (R, W) points will include some single points below the boundary, because the nonmonotone relationship between profit and price varies across countries.

29. The European Union initiated an enforcement effort to enable firms to differentiate ("tier") prices to the benefit of poor countries without being damaged by illegal arbitrage. It allows firms to register approved tier-priced drugs and mark them with an identificable logo. Customs authorities are directed to detain market products as they come into the European Union. See http://europa.eu.int/comm/trade/csc/med08_en.htm (accessed May 26, 2003).

30. See Scherer and Watal (2002) on antiretroviral drugs. Prices may not correspond closely to income levels because price regulations are less effective in poorer countries or because it can be profitable for a firm to target only the upper class in a poor country with a very unequal income distribution.

FIGURE 3. Revenue-Welfare Implications of TRIPS



Note: The effect of TRIPS is to induce a move from pont D to a point like either E_1 or E_2, where welfare is lower and revenue is marginally higher. An alternative would be to move to a point like E_3, which allows the same increase in revenue, but with a positive impact on welfare.

poor countries are exceedingly small despite having large numbers of people. Lanjouw (2002) estimates, for example, that countries with half the world's population account for less than 2 percent of spending on cardiovascular drugs. For this reason firms often choose not to obtain patents in poor countries even when they are able to (Attaran and Gillespie-White 2001).

TRIPS also changes the structure of contributions so that a greater share of total net revenue comes from sales in poorer countries. Because in some countries prices are higher with TRIPS but nowhere are prices lower, welfare certainly decreases. How much welfare has fallen, however, depends on the social welfare function used. Because relatively poor countries have higher prices as a result of TRIPS, a welfare function with any aversion to inequality would suggest that welfare falls steeply, as indicated by point E_1 in figure 3. But if there is little concern for distribution, the welfare fall may be moderate, as indicated by point E_2.

Figure 3 illustrates an important question regarding the purpose of TRIPS. If the goal is to increase the relative share of global research costs paid by poor countries to be somehow fair, it seems reasonable to keep net revenue at the pre-TRIPS level of point D by pairing the new patent regime with stronger price control in the rich countries (that is, lower prices). Alternatively, if the purpose is to slightly increase the net revenue received by an innovative firm from a given product, it seems worthwhile to consider whether strengthening patent rights in poorer countries is the best option. There are, after all, many alternatives: Targeting point E_3, for example, would move prices in rich countries closer to Ramsey prices. At the most basic level, this means that countries with similar income levels and demand patterns should have similar markups.

Tradeoffs for a product that is specific to developing economies must also be considered. Suppose, for simplicity, that a product, such as a vaccine for malaria, does not yet exist and would have no market outside of developing areas (point *C* in figure 1). Clearly, if nonsales revenue sources of research support are enough to have the product invented (that is, if *T* is large enough), there is no reason to allow a profit margin on sales, and optimal prices would lead to point *B*. In this situation granting patent rights in developing economics would be damaging to welfare.

However, it seems unrealistic to assume that this will always be the case. Indeed, health advocates often stress the enormous gap between the human suffering caused by developing area–specific diseases and the relatively low level of public and philanthropic investment to discover products to treat them.[31] That is, point *B* simply may not be possible; there may need to be some contribution from consuming countries in the form of net revenue for the desired innovation to occur. Without any additional incentive society might remain at point *C*. Thus, for products specific to the developing world there is some rationale for having patents in the poorer countries.[32]

V. Conclusion

Techniques of modern public finance have been employed to consider how pharmaceutical prices should be set in a global context. In particular, how concern about the extreme inequality in the distribution of world income leads to adjustments to standard pricing prescriptions has been considered. With these adjustments poor countries should not necessarily cover their own marginal costs of drug production and distribution. In particular, poor countries should not necessarily share in any of the costs of R&D. Also, the pricing structure is not related to what would be chosen by a monopolist in a simple (proportional) way. Both of these results are at odds with standard analyses that do not take into explicit account distributional concerns.

Care has been used here to distinguish between general tax sources for financing R&D incentives and sales revenues, although little has been said about what the split between these two sources should be. It is explicitly recognized that private R&D cannot be treated as free, and although there might be ways of limiting the economic rents earned by pharmaceutical companies (for example, through various contractual mechanisms), in the end the costs of R&D must fall either on taxpayers in general or consumers of the product.

31. See, for example, the reports of the Médecins Sans Frontières Working Group on Drugs for Neglected Diseases at www.accessmed-msf.org/dnd. It is estimated that almost a million children die each year from malaria.

32. See Lanjouw (2002, 2003) for a mechanism that allows different global patent rights for different diseases.

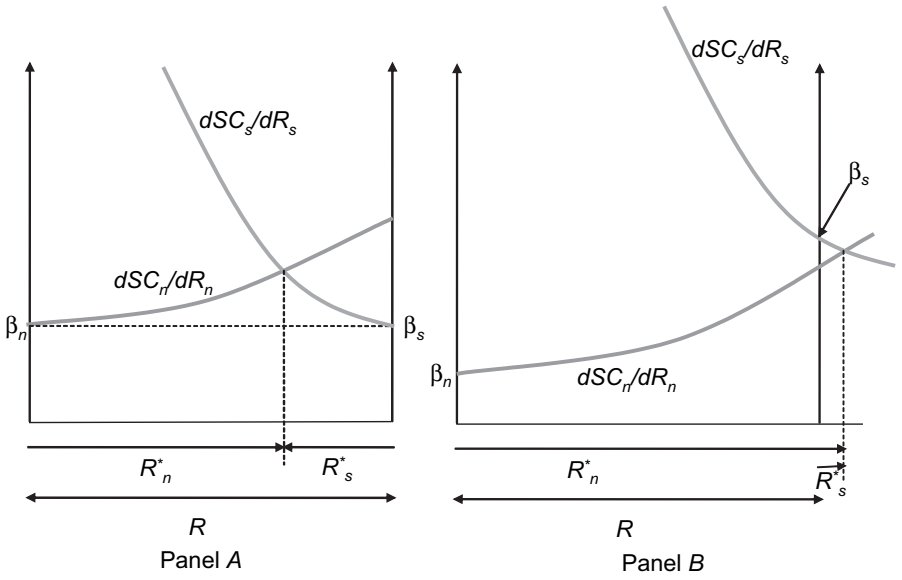
A serious problem that arises with most development assistance programs is within-country targeting. This is avoided by assuming that all individuals in a given country are identical, but in practice there is likely to be a concern that some of the benefits of low drug prices in poor countries might accrue to local elites. These benefits might accrue to them as consumers, and members of the elite might also be able to appropriate some of the benefits of lower (import) prices if they act as intermediaries. Nevertheless it is expected that significant benefits would often reach the poor, especially if low prices are implemented through competition and not by regulation.

Finally, the framework has been used to examine ongoing debates on the international patent system and global pricing. In particular, the very small net revenue increase that TRIPS might afford pharmaceutical companies (thereby strengthening R&D incentives) comes at the cost of shifting a greater share of the burden onto poorer countries. The same increase in incentives could be implemented in an alternative fashion with a positive welfare effect.

APPENDIX

Figure A1 shows that in the special case where $\beta_i = \beta$ optimal prices are such that the price in each country is at least as high as c_i, the marginal production and distribution cost. It also shows that when the β_i's are not the same across countries, the price in one country may be lower than c_i. Return to the discus-

FIGURE A1. Marginal Social Costs of Revenue Generation in Countries *n* and *s*



sion immediately following equation 5 where the marginal social cost of raising additional net revenue in country i was the ratio of $-(\partial w)/\partial v_i)\ (\partial v_i/\partial p_i)$ to $y_i + (p_i - c_i)\ (\partial y_i)/\partial p_i$. Using equation 3, this ratio is

$$MSC_i/MR_i = \beta_i y_i/(y_i + [p_i - c_i][\partial y_i/\partial p_i]). \tag{20}$$

This ratio is the change in social cost from raising an additional dollar in country i, dSC_i/dR_i, at a price, p_i. At the optimal prices, the marginal social cost of raising revenue is equalized across countries: $dSC_s/dR_s = \lambda = dSC_n/dR_n$. Note that when the price in country i is just equal to production cost c_i there, equation 20 collapses to

$$MSC_i/MR_i = dSC_i/dR_i = \beta_i. \tag{21}$$

Two cases are shown in figure A1. In panel A the length of the horizontal axis represents the total net revenue of R to be raised. The amount raised in country n is measured from the left and that in country s from the right. The horizontal dashed line is the marginal cost, which is assumed to be the same across countries: $c_n = c_s = c$. Generating revenue in either country imposes a social cost. First consider the social cost when revenue is raised in the south. When $p_s = c$, revenue from the south is zero (the right edge of the figure). Equation 21 shows that the marginal social cost of generating an additional unit of revenue at this point is β_s. The cost increases moving left, and more revenue is generated in country s through increases in p_s. The same applies for the north starting from the left edge of the figure. This gives the two marginal social cost curves. In panel A, $\beta_n = \beta_s$, so the curves cross at some point in the middle of the figure, meaning that both north and south contribute to the revenue requirement in amounts R_n^* and R_s^*, respectively, and prices in each are above marginal cost.

In panel B it assumed that $\beta_n < \beta_s$. Now the two cost curves can cross at a point outside the interval shown, meaning that the net revenue requirement, R, should be shared between the two countries by having country n contribute $R_n^* > R$, while country s receives a subsidy in the amount of $R_s^* = R_n^* - R$, by paying less than the marginal cost of production.

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