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IN PHARMACEUTICAL PATENTING

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ABSTRACT

This paper revisits the question of whether global welfare is higher under a uniform world-wide system of pharmaceutical product patents or with international rules allowing low-income nations to free-ride on the discoveries of firms in rich nations. Key variables include the extent to which free-riding reduces the discovery of new drugs, the rent potential of rich as compared to poor nations, the ratio of the marginal utility of income in poor as compared to rich nations, and the competitive environment within which R&D decisions are made. Global welfare is found to be higher with free-riding over plausible discovery impairment and income utility combinations, especially when rent-seeking behavior leads to an expansion of R&D outlays exhausting appropriable rents.

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The Uruguay Round TRIPS[1] provisions requiring the extension of first-world patent protection standards to third world nations, including especially the mandate that patents be granted on pharmaceutical products, have been enormously controversial. The ensuing debate led, among other things, to a decision at the Doha WTO conference to delay the requirement that the least-developed nations offer pharmaceutical product patents by at least a decade, to the year 2016.

It is reasonably well established in the economic literature that, especially in a world of AIDS and resistant tuberculosis epidemics, low-income nations enjoy higher economic welfare when they can free-ride on pharmaceutical innovations made and patented in the first world than when they must pay monopolistic prices for the newest and most effective drugs.[2] Less settled is the question of whether total world welfare is higher under uniform pharmaceutical patent standards or with free-riding. This paper provides what I believe are some fresh insights into the global welfare problem.

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1. Trade-related aspects of intellectual property rights.

2. See e.g. Commission on Intellectual Property Rights (2002), Maskus (2000, Chapter 5), and Scherer and Watal (2002).

A foundation is laid by revisiting diagrams used in my 1996 analysis of the pharmaceutical patent question,[3] which in turn was based in part upon an analysis by Alan Deardorff (1990, 1992). Figure 1 views the welfare implications from the perspective of an LDC, whose demand curve for a particular drug is given by D. If the LDC grants patents, the drug is assumed to be sold at the monopoly profit-maximizing price OP_M. In that case, rectangle H measures the producers' surplus realized by the drug's patent holder, presumably, a multinational company, and consumers' surplus triangle B is realized by the citizens of the LDC. If however patents are not granted and the drug is supplied to the LDC's citizens competitively (a strong assumption not questioned here), the citizens of the LDC consume more at the lower price OP_C and gain the much larger consumers' surplus of B + H + A. Given the linearity of demand and cost assumed in my example, B + H + A is four times as large as consumers' surplus B under monopoly. I argue that the LDC is better off only if granting patent rights increases the development and supply of comparable new drugs by at least three times.

Figure 2 asks whether such an increase in the number of new drugs is likely. Extending concepts originally articulated by William Nordhaus (1969), the solid line RD(NCE) shows how the number of new chemical entities developed per year (vertical axis) varies with the amount spent on research and development (horizontal axis). Broken lines Q_1 and Q_2 show how quasi-rents appropriated by innovators (horizontal axis) vary with the number of new chemical entities marketed. Q_2 is shifted to the right by 20 percent relative to Q_1 to reflect my assumption that extending patent protection to LDCs would increase rents by 20 percent, or low-income nations' approximate share of world GDP. Given this and the profit maximization assumptions made by Nordhaus, which I question in my book and will question later but accept tentatively, the equilibrium number of new chemical entities is found by maximizing the horizontal distance between RD(NCE) and a quasi-rent function, leading to the development of 15 new chemical entities if LDCs do not offer patent rights and roughly 18 if they do. The change falls far short of the three-fold increase required to make the LDC whole in granting patents.

Analyzing the global welfare question requires a more complex model. The one presented here is as lean as possible, attempting to focus on three key variables: the relative increase in producer's surplus that can be achieved through patented pharmaceutical sales in the third world, the number of additional pharmaceutical products (each assumed tentatively to have identical demand functions), and -- a key variable that cannot be ignored in comparative welfare analyses -- the average difference in the marginal utility of income for third world as compared to first

3. Scherer (1996, Chapter 9).

world consumers. Another variable will be held constant for the sake of simplicity -- the number of consumers in the third world relative to the number in the first world. The relevant data suggest setting the first- and third-world population shares at $S_1 = S_3 = 0.5$.

Figures 3(a) and 3(b), which are conceptually identical to demand curves used by Jayashree Watal and myself to illustrate the benefits of Ramsey-Baumol-Bradford discrimination for the pricing of pharmaceutical products in the first and third worlds,[4] assume that at a zero prices, the same number of prescriptions (13.5 million) would be demanded monthly in the first world and in the third world.[5] However, income effects cause the demand function to be flatter in poor nations than in rich nations. Marginal cost is assumed to be $3 per Rx. As the diagram is drawn, a firm enjoying patent protection in both the rich and poor nations will set a price of about $16.50 per Rx in the rich countries, realizing a contribution to profits and the recoupment of R&D costs (quasi-rent) of roughly $91 million per month there. In the poor nations its price will be $6.50, and its contribution to profits will be approximately $18.4 million, or roughly 20 percent of first-world profits. The 20 percent value mimics the assumption in Figure 2.

To make the numbers simpler and more memorable, we recalibrate the rich-nation producer's surplus to be 100. Using the welfare gain notation of Figure 1, and assuming linearity of demand functions, the tally of surpluses per new product for these two cases, assuming patent protection in both jurisdictions, is as follows:

		Rich Nations	Poor Nations
H	Producer's surplus	100	20
B	Consumers' surplus	50	10

The producer's surplus in poor nations, it should be noted, presumably accrues to rich-nation shareholders of multinational corporations. If on the other hand the poor nations offer no patent protection and receive at competitive prices pharmaceutical products that would be developed in any event in response to rich nation consumers' demand, the welfare gain to poor nation consumers is H + B + A = 40 and producers forego a surplus of 20.

A common assumption in benefit/cost analysis is that one party's surplus is equivalent to another party's surplus. To accept that assumption would be to miss much of what the debate over pharmaceutical product patent rights in the third world is all

4. Watal and Scherer (2002), and Scherer and Watal (forthcoming).

5. The demand equation is P = 30 - 2Q for the rich nations and P = 10 - 0.667 Q for the poor nations.

about. Roughly half of the world's population live in nations where income per capita is only one-tenth that of the United States or western Europe. If one accepts the notion dating back at least to Alfred Marshall that "the richer a man becomes the less is the marginal utility of money to him,"[6] one needs to assign greater weight to the benefits realized by poor nation citizens than to those of rich nation inhabitants. I shall do this through the weighting factor U, which measures the ratio of the marginal utility of income for the median poor nation inhabitant to that of the median rich nation citizen.[7]

We must now tally the appropriately weighted sum of surplus for two different intellectual property regimes: Case 1, in which pharmaceutical products receive full patent protection in all nations, and Case 2, in which patent rights are only conferred in the first world and LDCs free-ride on the inventions made in the first world.[8] Plainly, with larger producer rents in Case 1, there will be more inventions, as implied by Figure 2. How many more successful new chemical entities there are is a key variable. We assume in base Case 1 that with worldwide patent rights, the number of new chemical entities, each assumed to have the same demand characteristics, approved and marketed each year is 25. In Case 2, the number is a variable N whose value is less than 25.

The question is, over what configurations of variables U and N is worldwide welfare higher under Case 1, and when is it higher under Case 2? Disaggregating the accounts so that the benefits in the first world are presented in the first set of brackets, the

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6. Marshall (1948), p. 96. An even older source is the Gospel according to Mark 12: 41-43.

7. When new drug products must be imported in bulk or finished form, U might alternatively or in addition reflect the higher Lagrangian multiplier on foreign exchange budgets in less affluent nations.

8. We ignore welfare increments following the expiration of patents, which are likely to be heavily discounted. Their increase is slightly greater in Case 1 than in Case 2.

producer's surpluses realized by first world firms in third world markets in the second set of brackets, and benefits to third world consumers in the third set of brackets, and using the notation of Figure 1, the accounting is as follows:

Case 1: $[25S_1 (B_1+H_1)] + [25S_3 H_3] + [25S_3 B_3U] = 1875 + 250 + 125U.$

Case 2: $[N S_1 (B_1+H_1)] + [0] + [N S_3 (A_3+B_3+H_3) U] = 75 N + 20 N U.$

When these two equations are set equal, global welfare is identical under either policy; equality identifies the breakeven case. The solid line marked "Nordhaus, Poor = 20%" in Figure 4 shows the breakeven line for the assumptions accepted thus far. Variable pairs above (north of) the solid line show situations in which global welfare is higher under Case 2, i.e., with LDC free-riding. If extending patent protection world-wide leads to a loss of only one NCE per year relative to the base case, global welfare is maximized even if the marginal utility of income is the same for poor as compared to rich nation citizens. But if the sacrifice from eliminating 20 percent of rich-nation rents is 20 percent of the potential or base case NCEs, i.e., five, global welfare is higher if the utility of income in the third world exceeds that of the first world by more than a factor of 2.27. With plausible diminishing returns in the inducement of NCEs as the quasi-rent potential increases (see Figure 2), free-riding becomes globally optimal with utility differentials smaller than 2.27. A key implication is that strong value judgments -- on the magnitude of that differential -- are unavoidable in determining which policy is globally optimal.

It might be asserted that less-developed nations have more than 20 percent of wealthy nations' pharmaceutical rent potential.[9] Suppose the rent potential is 40 percent rather than 20 percent -- e.g., because the poor nation demand curve's vertical intercept is raised to 15 instead of 10. Then holding the rich nation quasi-rent potential constant at 100, consumers' surplus in Case 1 rises to 20 for the poor nation and so also does avoided deadweight loss triangle A in Figure 1. The higher surpluses in LDCs shift the breakeven curve downward (dotted line in Figure 2), increasing the likelihood that free-riding is globally optimal for any given retardation of new chemical entity development. To be sure, sacrifice of larger potential quasi-rents due to free-riding makes it likely that the number of new chemical entities will also be smaller than in the 20 percent scenario. But again, there are likely to be diminishing marginal returns, as shown in Figure 2. With a 28 percent diminution to 18 NCEs, breakeven occurs when the

9. This criticism of my 1996 assumptions is advanced in Sykes (2002).

income utility ratio is 1.77. With a 36 percent diminution to N = 16, breakeven occurs with an income utility ratio of 2.38.

In addition to the customary reluctance of economists to make the kind of income utility comparisons I have advanced, there are two likely criticisms of this model.

One questions whether the producer's surplus rectangles H in my model are in fact clear-cut welfare gains. Those surpluses are a stimulus to investment in research, development, and testing. For a complete welfare accounting, the costs of R&D must be subtracted from the quasi-rents, assumed to be discounted to present value at the same benchmark date. My service as chair of the U.S. Office of Technology Assessment advisory committee for its study of pharmaceutical profits and R&D in the early 1990s led me to wonder how quasi-rent margins in the pharmaceutical industry can be so high, stimulating R&D spending, while correctly computed returns on industry investment exceed risk-adjusted norms by only one or two percentage points on average.[10] I have gradually come to the realization that the best characterization of the industry's behavior is a full rent-seeking model. That is, rising quasi-rent potentials are almost fully exhausted by the competitive escalation of costs -- for R&D, marketing, and implicit returns on R&D investment -- leaving only a small pure surplus for the stockholders of pharmaceutical companies.[11] One implication of this alternative behavioral model is that industry equilibrium occurs at points R_1 and R_2 rather than W and Y in Figure 2, and so, depending upon the strength of the diminishing returns phenomenon, there are far more new products forthcoming in a given year. Another implication follows from the largely forgotten insights advanced in a debate two decades ago, showing that when innovators are competing rent-seekers rather than secure Nordhaus-type profit maximizers, the welfare-maximizing life of invention patents is drastically shortened.[12]

In the model presented here, the implication is that the H rectangles cannot be counted as social welfare gains. Thus, the comparison of gains when LDC quasi-rent potential is 20 percent of

10. See U.S. Office of Technology Assessment (1993).

11. For empirical support, see Scherer (2001).

12. McFetridge and Rafiquzzaman (1986), with a comment by Roger Beck.

the rich nation potential is altered to:

Case 1: $[25\ S_1\ (B_1)] + [0] + [25\ S_3\ B_3\ U] = 625 + 125\ U.$

Case 2: $[N\ \ S_1\ (B_1)] + [0] + [N\ S_3\ (A_3+B_3+H_3)\ U] = 25\ N + 20\ N\ U.$

With this change of assumptions, the breakeven curves (labeled "Rent-Seeking" in Figure 4) are shifted dramatically toward the origin. If the loss of LDC quasi-rent potential amounting to 20 percent of rich-nation rents in Case 2 implies a 40 percent reduction in the number of new products to 15 per year, global welfare (with breakeven given by the dot-dash line) is higher under free-riding if the ratio of LDC to rich nation income utility exceeds 1.43. If the reduction in the number of new products is only eight out of 25 (i.e., 32 percent), global welfare is higher under free-riding if the ratio of LDC to rich nation income utility exceeds 0.93! With 40 percent LDC rent potentials relative to those of the high-income nations, the downward shift of the breakeven curve (dashed line) is even greater, so that global welfare is maximized under free-riding even if the number of NCEs falls by half and no distinction is made between the income utility of rich and poor consumers. And these rent-seeking assumptions, I am convinced, are more realistic than the assumption that producer's surplus is a pure social gain, accepted in my initial model. If one believes that competitive rent seeking dissipates producers' surpluses, free-riding policies become all the more attractive, even from a global standpoint.

Another vulnerable point in the model presented here is the assumption that each product has the same demand curve and hence the same constellation of surpluses. This is at odds with reality in pharmaceuticals and indeed in virtually every field of technological innovation. The distribution of returns to innovation is highly skew. Blockbuster innovations always capture a share of quasi-rents or profits disproportionate to their numbers.[13]

It might be argued that consumers in less-developed countries will benefit because there are vast numbers of them, they suffer from diseases not prevalent in the rich nations, and (arguably) the granting of patent rights will induce pharmaceutical companies (presumably, multinational pharmaceutical companies) to do research they would otherwise not undertake on diseases found mainly in poor nations, discovering new drugs with blockbuster potential. This is indeed the strongest argument for extending pharmaceutical product patent rights throughout the world. But it is not conclusive for four reasons.

13. See Scherer, Harhoff, and Kukies (2000).

First, in the nations where the so-called "tropical diseases" abound, most potential consumers are very poor, with annual incomes measured in the low hundreds of dollars. Those nations also tend to have at best primitive public health systems, and most drugs must be purchased with consumers' own funds, for which a myriad of life-sustaining uses compete. In other words, demand functions are pressed even closer to marginal cost functions than implied in Figure 3(b). Even when they are aggregated over hundreds of millions of consumers, it is not clear that there are quasi-rent potentials anywhere near those associated with medicines targeted toward coronary problems, common cancers, gastritis, depression, and inadequate sexual function in rich nations. If the quasi-rent potential is weak, not much rent-seeking research and testing will be induced.

Second, uncertainty abounds in predicting during R&D phases how large the market for a particular therapeutic molecule will be. Molecules often turn out to have therapeutic uses quite different from those initially contemplated. Viagra is an example of such serendipitous discovery, as was the discovery that Bayer's praziquantil is effective against schistosomiasis. And at the clinical testing stage, it remains uncertain what fraction of a target audience will respond favorably to the drug's use. Even as simple a matter as the way the drug is introduced into the body -- e.g., injection, three-per-day oral delivery, or once-per-week time release delivery -- can significantly affect the extent of use in less-developed nations, where systematic care by nurses or physicians is the exception rather than the rule. Ex ante, therefore, the expected distribution of returns from innovation entails more uniformity of quasi-rents than it does after full technological and marketing experience has been accumulated.[14]

Third, interest in developing new tropical disease cures may be keener en situ than in pharmaceutical laboratories thousands of miles away from the disease locus. But in the nations most afflicted by tropical diseases, the technological capabilities needed to do state-of-the-art research and product development are scarce. Advancing from incentive to innovation is not automatic. Research by Sandy Weisburst and mentored by me showed, for example, that Italy, with a vibrant generic drug industry, did not achieve any significant increase in the discovery of innovative drugs during the first decade after the Italian Supreme Court mandated

14. This is shown in simulations by Scherer, Harhoff, and Kukies (2000).

the issue of pharmaceutical product patents.[15]

If there are exceptions to the Italian experience, India, having replaced Italy as the world's leading generic drug source, is the most likely candidate. But this raises my fourth caveat. Jean O. Lanjouw (1997) has conducted preliminary interviews on the probable response of Indian pharmaceutical firms to a new regime in which pharmaceutical product patents can be received in India. The first results suggest that the Indian firms are more interested in developing new drugs that will be blockbusters in the first world than in targeting tropical disease remedies. This may change. But one has reason to doubt whether the extension of patent protection will elicit large investments in third world diseases.

It is nevertheless possible that multinational pharmaceutical companies will reorient their R&D portfolios to place more emphasis on third world diseases. The Uruguay Round intellectual property agreements have now been a reality for eight years, but during this period, I have seen little evidence of such changes. I confess that I have not made a systematic search into the question. One should certainly be undertaken.

In the meantime, I believe, an opportunity has been lost. The debate over drug patent rights under TRIPS would have provided an ideal opportunity for someone like Kofi Annan to say to the multinational pharmaceutical companies, "We will support your demand for strong patent rights throughout the world if you will commit 20 percent of your research and development budgets to diseases specific to less-developed nations." The multinational pharmaceutical companies made an analogous commitment in persuading Canada to abandon its vigorously enforced drug patent compulsory licensing laws. As a quid pro quo, the pharmaceutical companies agreed to locate in Canada R&D activities proportional to Canada's share of the companies' drug sales. If such a commitment were forthcoming, my fourth caveat would be less persuasive.

15. Weisburst and Scherer (1995). See also Challu (1995).

To sum up, my analysis reveals that global welfare is maximized by letting low-income nations free-ride on the patented inventions of first-world nations over a wide range of negative new product development impacts if one accepts the reasonable premise that the marginal utility of income is appreciably higher in poor nations than in rich nations. The Doha round of negotiations appears to have gravitated toward a proper solution, deferring implementation of the TRIPS provisions on pharmaceuticals in the least-developed nations for a considerable period.[16] In the interim, we will be able to observe the response of pharmaceutical companies to the limited grants of exclusivity already implemented under the Treaty of Marrakech. And there will be time for commitments to be extracted that could change the conditions under which tropical medicines are supplied and increase the relative welfare gains from world-wide uniformity of pharmaceutical patent policies.

16. The U.K. Commission on Intellectual Property Rights (2002, p. 162) recommended extension of this delay for all aspects of TRIPS along with flexible interpretation of its provisions after the year 2016.

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Figure 1

Impact of Patent Policy on LDC Welfare

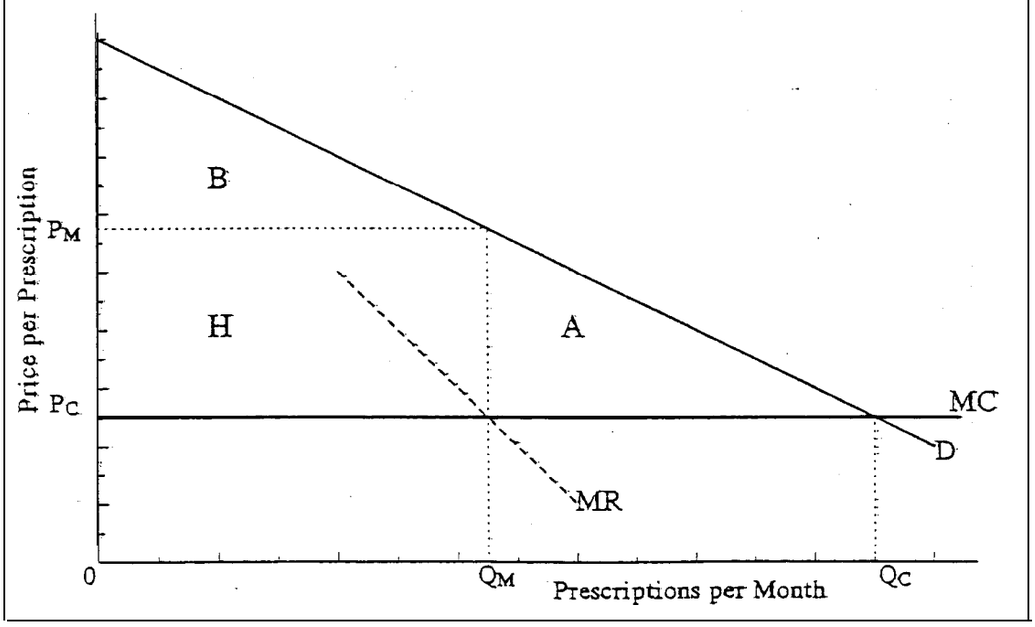

Figure 2

Impact of Quasi-Rent Volume on NCE Development

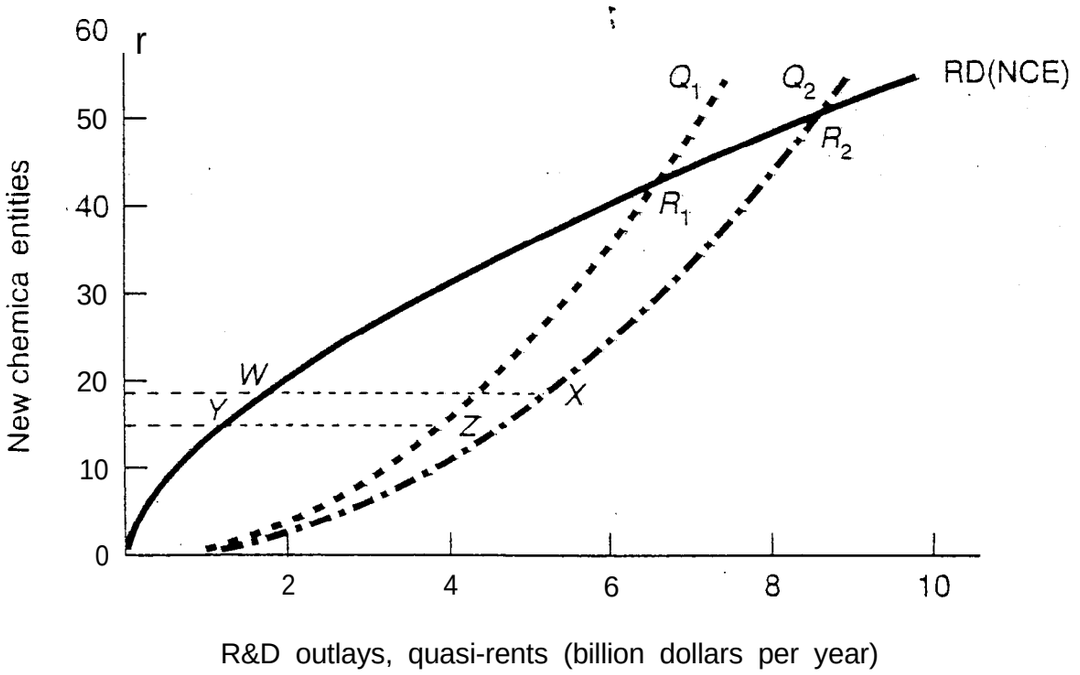

Figure 3(a)

Demand Conditions in Rich Nations

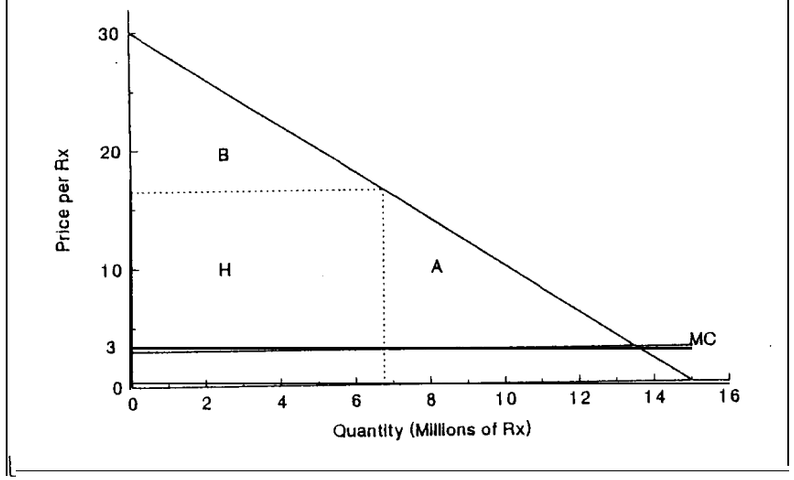

Figure 3(b)

Demand Conditions in Poor Nations

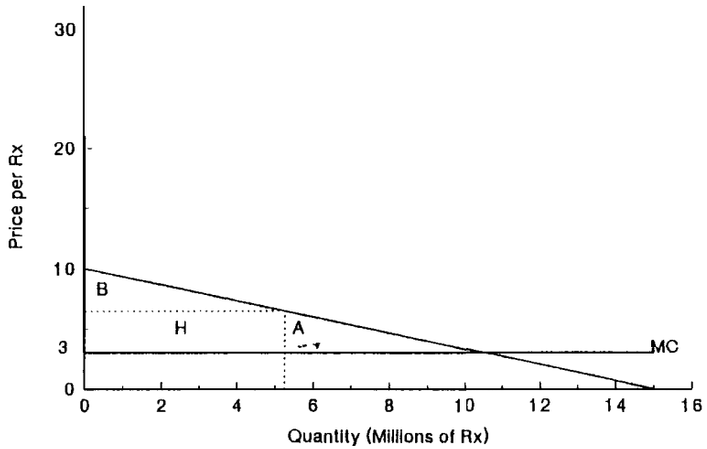

Figure 4

Total Welfare Tradeoff for NCE Productivity and Marginal Utility

Base Case = 25 NCEs with Full World Patent Rights