

Pharmaceutical Patents and International Commitments: The Inherent Tensions and Implications for Public Health

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At the beginning of the 21st century, one-third of the world's population still lacks access to the essential drugs it needs for good health. In the poorest parts of Africa and Asia, over 50% of the population do not have access to the most vital drugs.”¹

I. Introduction¹

Pharmaceuticals are critical to health systems, because, if they are readily available, affordable, of good quality, and used appropriately, drugs can provide a cost-effective solution to many health care problems. The availability of essential drugs at a reasonable cost is the basis for reducing childhood infectious diseases, maternal and perinatal conditions and controlling many of the illnesses that plague the poor throughout the world, primarily in developing and least developing countries. The disparity in access to pharmaceuticals between rich and poor is likely to become more pronounced as the wave of new drugs and biopharmaceuticals in development enters the market, the costs of treating formerly untreatable illnesses with new drugs are likely to increase faster than total pharmaceutical procurement budgets in public health systems, and international obligations for pharmaceutical patents are enforced pursuant to the Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement.

In this paper, we put forward some possible resolutions to the issue of improving access of the poor to essential medicines. While intellectual property protection for pharmaceuticals is not the single cause of lack of access of medicines to the poor, for the purpose of this article we focus on this issue exclusively and on the World Bank's potential role in it.² We use the World Bank simply as a model of an international organization that could become more central to the provision of medicines for the poorest.

The paper is organized as follows. First, we provide an overview of the TRIPS Agreement) and its provisions which are relevant for pharmaceutical products and processes. Second, we explain how specific pharmaceutical policy tools can help developing states mitigate the worst effects of the TRIPS Agreement. Third, we provide an overview of the ethical dilemmas intellectual property protection for pharmaceuticals presents. And fourth, we put forward solutions that could be implemented by an international organization, like the Bank, to help overcome the divide between creating private incentives for research and development of innovative medicines and ensuring access of the poor to critical medicines.

¹ This paper is based on a more comprehensive article prepared by the authors “The Dilemma of Intellectual Property Rights for Pharmaceuticals: The Tension between Ensuring Access of the Poor to Medicines and Committing to International Agreements” in *Developing World Bioethics*, Volume 3, Number 1, 2003.

II. Background on the TRIPS Agreement

The TRIPS Agreement was one of the many trade agreements agreed upon during the Uruguay Round, and included in the new international trading system, governed by the World Trade Organization (WTO). The Agreement covers a range of intellectual property issues beyond patents, such as trade- marks, industrial designs, and copyright applicable to any sector. It provides minimum standards for intellectual property law and procedures and remedies so rights holders can enforce their rights effectively. The main rule of TRIPS for patents is that they should be available for any invention, whether product or process, in all fields of technology with discrimination. Inventions covered under the patent law have to meet the criteria of novelty, inventive step and industrial applicability. The minimum obligations for pharmaceuticals are: pharmaceutical products and micro-organisms are patentable for up until twenty years from the date the inventor files for the patent application. Second, there is no discrimination permitted against patent rights for imported products. Third, exclusive marketing rights are granted until patent expiry; and, there are transitional periods for developing countries without pharmaceutical product patents.³

The Agreement does provide a degree of freedom to member states. For example, states can deny patent protection for specific inventions (Articles 27.2 and 27.3), such as “diagnostic, therapeutic and surgical methods for the treatment of humans or animals”; and plants and animals (other than microorganisms) and biological processes (other than microbiological) for their production.⁴ The Agreement also provides governments with the authority to issue a compulsory license for a pharmaceutical license without the permission of the patent owner when it can be justified in the public interest. The latter was strengthened further in the Doha Agreement on TRIPS and Public Health (November 2001). Compulsory license refers to when a judicial or government official is allowed by law to grant a license without permission from the holder on the grounds of general interest (such as public health considerations).⁵ Proponents of the compulsory licensing system stress that consumer price benefits arise from effectively abrogating the patent’s market exclusivity. The TRIPS Agreement also does not prohibit the parallel importing of drug products. Parallel trade refers to the act of purchasing a drug product that is lower priced in another country and importing it to a country for resale where the same product is priced higher.

III. The Costs and Benefits of Intellectual Property Protection

The potential costs and benefits of intellectual property protection are well known and have been discussed at length elsewhere. Thus, in this section, we highlight a selection of the arguments on both sides of the debate to serve as requisite background for our ensuing discussion. The application of intellectual property rights is viewed by some as a

beneficial government intervention insofar as it can possibly prevent free-riding behavior and the attendant “congestion problem” that is particularly acute when intellectual assets are easy to copy. (This applies to the pharmaceutical sector, as the reverse engineering of patented drugs is not technically demanding.) New knowledge potentially may suffer from overuse in the absence of intellectual property because access to it would not be costly. The overuse of knowledge could minimize the economic value of an innovation and limit incentives for others to pursue advances in knowledge.⁶ Intellectual property rights thus mitigate the tendency toward free-riding behavior by limiting who has the rights to an intellectual asset.

They, furthermore, provide an inventor with some degree of certainty that he can capture a sufficient amount of rent for his innovation effort by preventing congestion behavior and thus encourage the pursuit of new knowledge. This argument assumes that pharmaceutical patents provide incentives for firms to invest resources in the research and development of new drug therapies. New drug therapies are desirable if we assume that they can help cure or prevent diseases and improve the health of the population, which in turn, can lead to economic growth.⁷ Pharmaceutical patent protection should, thus, encourage firms to invest in the research and development of new drug therapies specific to the disease burden of developing states that had previously not protected pharmaceutical patents. This, we deem is highly unlikely given existing trends in the research and development of pharmaceuticals.

The TRIPS Agreement imposes minimum standards for pharmaceutical patents for member states of the WTO. Compliance for most developed states, including those with relatively mature production and innovation systems, did not demand significant changes in existing standards and institutions.⁸ For developing states, the pharmaceutical patent regime, for the most part, was considerably below the minimum criteria of the TRIPS Agreement. From the standpoint of innovating drug firms in the advanced economies, the TRIPS Agreement corrects deficiencies in the latter regimes that lead to copying of products and ultimately loss of rent for innovating firms. These include the absence of patents for pharmaceutical products, the issuing of compulsory licenses for products without adequately compensating the firm of an innovating product, and a weak or poorly defined system of rules to protect trade secrets, therefore facilitating the imitation and copying of products.⁹

From a public health perspective, particularly for the poorest, intellectual property protection for pharmaceuticals may maintain the uneven direction of product research and development, by limiting the type of drug therapies available to treat disease of the poor. Here’s the reason why. Patents impede progress in technology by precluding other firms from cross learning and building on the original innovation. Patents produce a loss or “deadweight burden” insofar as the benefits of the new knowledge to society would have been greater in the absence of a patent regime, and reduces the capacity for other firms to exploit the knowledge on a competitive basis.¹⁰ Additionally, the application of

pharmaceutical patents could result in the further concentration of production of pharmaceutical in advanced economies. International drug firms will be free to export finished or semi-finished products, instead of transferring technology. Foreign direct investment may, as a result of this, be lessened.¹¹

A much anticipated cost of the TRIPS Agreement is that it gives pharmaceutical firms greater scope for price discrimination, a rational move for profit-maximizing firms but exploitative to persons in developing countries.¹² If drug prices increase, in addition to the obvious implications this has for public health, this consequence could be potentially politically disastrous for many politicians in developing states that are already under pressure from their constituents to improve access to medicines and lower pharmaceutical prices.

Although the innovating pharmaceutical industry emphasizes the importance of patents as an incentive for research and development, there are also powerful economic arguments that counter them. Arrow (1962) argued that the entrenched patent monopolist has weaker incentives than a “would-be” entry firm to initiate an R&D program that would produce substitutes, even superior quality ones, than for goods, which were already, profit generating.¹³ This, in turn, results in sub-optimal outcomes for social welfare.

Prior to the TRIPS Agreement, many governments in developing countries had adopted an explicit policy preference not to honor intellectual property protection for pharmaceuticals in an effort to promote self-sufficiency in the production of basic medicines, and as in the case of India, develop a competitive local industry. Domestic producers, both private and public, could, then, supply their populations with basic medicines, at prices often considerably lower than those of the research-based pharmaceutical industry and learn by doing.

In short, the TRIPS Agreement requires developing states to reform drug policy and thereby limit the drug portfolios of local firms. The potential impacts of this are more costly pharmaceuticals and/or limited access of the population to essential medicines. Developed states, by comparison, have tended to support pharmaceutical patent protection in order to protect revenue streams from their established innovative pharmaceutical industry and to promote investment in technological innovation.¹⁴

IV. Recommended Solutions to Lessen the Tension between Local and International Imperatives

Specific pharmaceutical policy tools, such as parallel importing, compulsory licensing, and price controls, could potentially mitigate the worst effects of the TRIPS Agreement on drug supplies in developing states. We do not claim that these mechanisms solve the issue of improving access of the poor to essential medicines. However, they are policy

tools for governments to use in order to adjust the terms of the treaty to local economic and public health realities.

At the international level, however, possible policy options exist that could help ease the tension between ensuring access of the poorest to essential medicines and intellectual property rights. Our proceeding suggestions do not purport to be original but we offer new thinking by assigning responsibility for the realization of these suggestions to an international global policy maker and use the World Bank as an example here. Each one of the ensuing recommendations is imperfect; entailing trade-offs, either for the local and international pharmaceutical industry or for developing states but they present possible resolutions to the increasingly complex problem of providing incentives for the development of new drug therapies and ensuring equity access of the population to these new therapies.

These are: (1) intensified loans or grants to client states for the purchase of patented medicines; (2) the cancellation of debt relief and the use of these “extra” financial resources for pharmaceuticals currently under patent; (3) the purchase of patents from the research-based pharmaceutical industry and the licensing of production of the patented drugs to generic drug firms in client states (a split-TRIPS model); (4) the promotion of a tiered pharmaceutical pricing (equity pricing) system.

Resolution One: Intensified Pharmaceutical Loans for Patented Drugs

An international organization, such as the World Bank, could assume an important role in resolving the conflict surrounding the TRIPS Agreement by providing specific loans and grants to developing countries that could enable them to have the financing they need for the purchase of essential medicines that are protected under the patent treaty. To achieve this, the Bank would need to allocate more financing for pharmaceutical procurement and for the monitoring of the types of drugs that client states purchase through these special loans to ensure that they are in compliance with intellectual property laws and that the drugs are distributed effectively to those in need.

Alternatively, the Bank could provide its client states with loans to purchase drug patents from pharmaceutical firms and license the production of specific drugs to local firms. This solution would enable public financing to reduce the prices of medicines to their marginal costs of production and permit the research and development firms to recoup their sunk costs of research and development by ensuring that they receive payment for their products. This Resolution presents potential disadvantages to developing states as well as to the international research-based pharmaceutical industry. Unfortunately, some countries, as noted earlier, may not even have the capacity to manufacture these products. For the international research-based pharmaceutical industry, the disadvantage is clearly the reduction of rents in developing markets.

Resolution Two: Debt Cancellation to Purchase Critical Pharmaceuticals

Another possible mechanism that could contribute to abating the conflict surrounding the TRIPS Agreement is for international institutions, like the Bank, to forgive the debt of the poorest countries and demand as conditions attached to the forgiveness of debt, that the “surplus” money is spent on priority medicines under patent for those in need.¹⁵ This Resolution builds on the Highly-Indebted Poor Countries Initiative (HIPC I) in 1996 and HIPC II in 1999, which the Bank initiated along with the International Monetary Fund (IMF). The HIPC Trust Fund has obtained \$2.5 billion in bilateral contributions and pledges from about 20 countries. To date, the Bank has transferred more than \$1.3 billion to the Bank component of the Trust Fund.¹⁶

To ensure that the states honor their commitment to purchase patented medicines, the debt relief assigned to drug purchases could be transferred directly to the Bank. The Bank would then be responsible for managing the procurement of essential drugs under patent and monitoring their delivery in the targeted client state. This Resolution could benefit both developing states and the pharmaceutical industry. Developing states make gains by having their debts cancelled and likely improve the access of their population to pharmaceuticals. It does not guarantee that increases in drug spending will result in measurable gains in health outcomes. Nor does this Resolution offer a long-term solution to the dilemma of ensuring rents to the research-based pharmaceutical industry and access to patented drugs to the most vulnerable. Finally, it assumes that the Bank will have sufficient human resources to take on these expanded responsibilities.

Resolution Three: Purchase of Patents by the Bank and Licensing of Patented Drugs to Generic Drug Manufacturers

The Bank could purchase patents from the research-based pharmaceutical industry and make licensing agreements with generic drug firms, that may or may not, be located in developing states. Using financing provided by donors, the Bank could purchase patents from the research-based pharmaceutical industry and then provide licenses to generic drug manufactures in developing states to produce the requisite medicines and distribute them widely.¹⁷

This Resolution is a modification of compulsory licensing, which the TRIPS Agreement permits, whereby a government can compel a patent holder to grant licenses to domestic firms. These firms then pay the patent holder a royalty for the license. The benefit of having the Bank purchase the patent from the pharmaceutical firm is that the firm may have more trust that the Bank will deliver a sufficient level of rent. Furthermore, the Bank could exercise some measure of quality control by only agreeing to license out the patented drug to generic drug firms that meet international standards, such as Good Manufacturing Practices (GMPs).

Resolution Four: Equity Pricing

The pharmaceutical industry currently prices its pharmaceuticals by using a tiered pricing system. This type of pricing refers to market segmentation on the basis of the economic profile of a state. We propose, like others before us, that the research-based pharmaceutical industry offer countries an equity-pricing scheme, based on the economic profile of the poorest consumer of a state. This is based on the concept of price discrimination whereby a pharmaceutical firm sells the same product to different consumers at different prices. Prices are not based on the costs of production but what the consumer will and can pay. The Bank, ideally, could assist the pharmaceutical industry and developing states in this type of initiative by acting as a broker between them.

Pharmaceuticals under patent could be subject to different pricing schemes depending on the purchasing power of the poorest consumer and health needs. Consumers in developed states would then find themselves subsidizing the pharmaceutical needs of consumers in developing states. For developing states, equity pricing is potentially beneficial because it takes into account social and economic conditions but does not guarantee universal access. For the research-based pharmaceutical industry, equity pricing poses the risk of more intensified parallel imports between states. Parallel importing occurs when drugs are imported from a state where pharmaceutical product is placed on the market with patent holder consent to another state, without the patent holders consent. The use of parallel importing is permissible under the TRIPS Agreement and employed by many countries such as those of the European Union.

V. Some Moral Considerations

Whether to implement one or more of these Resolutions should be made in light of ethical considerations. Although each of the Resolutions is beneficial in so far as it aims to facilitate access to needed medicines to people living in developing countries, we argue that an equity pricing system is morally preferable. This is not to say that we do not support each Resolution, for the problems that face developing countries are of such a magnitude that all of the Resolutions may need to be implemented. Prior to developing our argument in favor of Resolution Four, equity pricing, we will look at some of the moral problems raised by Resolutions One, Two, and Three.

Our argument is made against the background of two assumptions about the World Bank: that (1) its resources are limited in light of its mission to fight poverty in the developing world and to “...establish economic growth that is stable, sustainable and equitable” and (2) that this mission is morally important.¹⁸ This is only to say that the demand for World Bank resources far exceeds the available resources and that some priority setting is necessary. Although we also assume that pharmaceutical organizations have limited resources, we do not *assume* that their mission is *necessarily* morally

important. Nonetheless, our argument will show that once pharmaceutical organizations are acknowledged to have a de facto social and morally important mission, then arguably they ought to shoulder greater moral responsibility for ensuring access to essential drugs.

We are concerned that Resolution One's proposal to offer additional loans to already heavily indebted countries for the purpose of purchasing essential drugs, will not significantly improve access to drugs and, in turn, reduce the suffering in developing countries. Resolution One ensures that pharmaceutical firms will receive rent on their products, and arguably in this way encourages innovation of medicines that may help people, including those living in developing countries, although for the latter current trends do not suggest this will be the case. However, the prospect of such debt, often in addition to longstanding debt, may have a chilling effect on the willingness and ability of developing countries, especially the least developed, to secure loans for essential drugs for their communities. Our fear then is that Resolution One will do little in the end to relieve the suffering in developing countries.

From a justice perspective, it is also worth asking whether given the health and welfare crisis in developing countries and the economic robustness of the pharmaceutical industry, it is just for developing countries, to be further burdened with additional debt when pharmaceutical companies might well assume greater economic responsibility. This is a concern about who ought to shoulder the burden. World Bank funds that are not directed at paying for patented drugs could be directed toward meeting other urgent social needs in the developing world. The pharmaceutical industry argues that they need to charge high prices on their patented property in order ultimately to effectively undertake R & D. But a recent article in the Economist reports that the cost of R & D in the pharmaceutical industry is on the decline.¹⁹ Moreover, as Resnik and later Schuklenk and Ashcroft point out, the developing world is not the primary source of pharmaceutical profits.²⁰ From a justice-based perspective increasing the burden on developing countries, even indirectly through the World Bank, when there is another alternative is morally problematic.

Naturally, we are also concerned that measures, such as loans, will place developing countries in the morally undesirable position of depending on others for additional loans that they may never be able to pay back and will not contribute to the development of sustainable pharmaceutical systems. We assume that this will encourage a cycle in which loan repayment figures importantly, and sound economic development becomes impossible. In the end, Resolution One may do little to alter the burden of disease in developing countries.

Resolution Two, which proposes to forgive debt contingent upon using the forgiven amount for the purchase of needed medicines, also raises moral concerns. First, although the World Bank could offer to forgive debt contingent on the beneficiary using the forgiven amount to purchase critical drugs, many developing countries cannot now afford to repay their debts because they simply do not have the economic wherewithal to

do so. If funds are unavailable to repay loans, they may likewise be unavailable to pay the high cost of patented drugs for the millions of people who need them. If so, then developing countries would ultimately be unable to make use of the opportunity afforded by Resolution Two. Thus, as with Resolution One, we assume that Resolution Two will not result in benefits for developing countries.

Second, given the wide ranging economic and social problems that many developing countries face, it is far from clear that they ought to devote the “surplus” to pay the high prices of patented pharmaceuticals and, in this way ultimately subsidize the pharmaceutical preferences of the developed world.²¹ Using loan forgiveness as an incentive to fashion a developing countries’ health policy may be paternalistic.

Third, Resolution Two may also be coercive in so far as the original agreement was not made between free and equal parties. Consider the following. The fairness of a given agreement is determined in part by whether the parties to the agreement are free and equal at the time of the agreement.²² It is not clear that any agreement between developed and developing countries or NGOs for the purpose of providing necessities to developing countries is fully voluntary.²³ The pull of poverty, sickness, and death place the bargainers under duress. Even if, strictly speaking, the agreements are valid, they can certainly be challenged under the moral principles that ground the notion of an agreement made freely and without duress. When necessities, such as food, shelter and medicine are at issue, it is not clear that repayment ought to be demanded in any case. If the initial loan agreement were morally compromised because one of the parties was under great duress, neither equal nor free at the time of the agreement, then the original wrong would only be compounded were the forgiveness of the loan made contingent upon purchasing drugs. In other words, the loan should be forgiven outright.

It might be argued that Resolution Two has the merit of benefiting both the research-based pharmaceutical industry and developing countries by increasing demand for pharmaceuticals, creating incentives and ensuring that developing countries get the drugs they need. But again as with Resolution One, we are not convinced that the resources of the World Bank (and indirectly the developing countries) should pay for patented drugs.

Although Resolution Three, like One and Two, has the potential to make critical medicines more accessible to those in need in developing countries, it does so at a high cost since it also requires the payment of “market” price for these patents. Thus, it shares some of the same moral weakness as Resolutions One and Two.

Resolution Four proposes that an international broker, like the World Bank, negotiate an equity pricing system with pharmaceutical firms and that the pharmaceutical industry implement such a policy. Because this Resolution prices medicine according to morally relevant factors, such as what countries are able to pay, it has distinct moral advantage. It ensures that the principle of charging what the market will bear will not impede access of the poor to needed medicines. It promises to reduce suffering in a way that Resolution

One, Two, and Three do not. Presumably most people would share the view that ability to pay for medicine should not determine whether someone enhances the quality of his or her life or even lives or dies, recalling the extraordinary properties of medicines. Moreover it shifts the burden of helping improve access of the poor to medicines to the pharmaceutical industry. We propose this with the understanding that pharmaceutical corporations have obligations to their shareholders. We argue, however, that this obligation should not be viewed as an obstacle to implementing Resolution Four – an equity pricing system.

To this end, it will be helpful to evaluate the theoretical model that has been used to justify the corporate practice of charging what the market will bear. Although we shall call this the “primacy of the shareholder” view, it has been referred to in a number of ways.²⁴ According to this principle, the primary duty of organizations is to maximize shareholder profits. Managers who sacrifice profit may be interpreted to be in breach of their legal Duty of Care to shareholders.²⁵

Our discussion of shareholder primacy will be framed around the dialogue that took place between David Resnik and Dan Brock in which they discussed the concept of corporate social responsibility as it applied to pharmaceutical companies.²⁶ Although a number of related matters were discussed in that dialogue, we will focus only on their discussion of corporate responsibility. Resnik argued that pharmaceutical companies have social responsibilities to the developing world because they like other moral agents “...have obligations to avoid causing harm and to promote social welfare.”²⁷ Brock argued that corporations are unlike moral agents in so far as their responsibilities are to their shareholders.²⁸ Brock seems to be invoking an argument in support of role differentiation. That is, he appears to be arguing that corporations do not have the same moral obligations as individuals because they serve a different social role—one that requires shareholder primacy.

The American firm seems to be responding to other imperatives than simply shareholder primacy. If this is so, it is a mistake to shield pharmaceutical companies from increased moral responsibility for ensuring access to essential drugs for those in developing countries on the basis of shareholder primacy. Moreover, pharmaceutical companies may at least in theory embrace the social entity view. Merck, for example, says in its first statement of values “Our business is preserving and improving human life.” Second, Merck claims, “we are committed to the highest standards of ethics and integrity.”²⁹

If we move away from the belief that corporations are obligated only to shareholders, we can better evaluate Resolution Four. In effect our strategy has been to show that the *role* that was invoked to exempt pharmaceutical companies from assuming greater social responsibility to render aid, namely their duty to shareholders, is a fiction.

Pharmaceuticals for Social Justice: Equity Pricing

It is arguable that the pharmaceutical industry could assume a greater role in providing medicines to the neediest. Such action can be justified on the basis of a number of principles, including consequentialism, the principle of beneficence and its social and legal correlate, Good Samaritan laws.³⁰ In what follows, we will focus on the principle that Peter Singer articulates in his paper “Famine, Affluence and Morality.” The principle goes as follows: “if it is in our power to prevent something bad from happening, without thereby sacrificing anything of comparable moral importance, we ought morally to do it”.³¹ The application of this principle to the issue at hand is obvious, but it will be helpful to go through the analysis. Relieving pain, suffering, loss and unnecessary death are moral goods by many moral barometers—including consequentialism and the principle of beneficence. Equity pricing can relieve the suffering of many of those in developing countries who need essential drugs by making those drugs affordable. So clearly pharmaceuticals can satisfy the first part of Singer’s principle—that is, they can prevent something bad from happening, death and suffering.

We examine briefly if an equity pricing scheme could be accomplished without losing something of comparable moral value. The only loss of comparable value would be the loss of other lives. Would the lives saved through equity pricing cause the loss of other lives? We can speculate confidently that the answer is “no.” It is worth noting that the pharmaceutical industry is the most profitable industry in the U.S.³² Moreover, many of the drugs it manufactures are “me too” drugs, requiring little innovation but rendering high profits. And the industry spends much more on marketing than on R & D.³³ Many of the drugs that the industry spends money on have little to do with saving lives and much more to do with improving quality of life (e.g. Viagra, Paxil, Ritalin). When we apply Singer’s Principle, we find that pharmaceutical companies ought to respond more appropriately to the health needs of the poor in developing countries, such as through an equity pricing system.

VI. Penultimate Thoughts

A study conducted by MIT in 1995 found that of the 14 drugs the pharmaceutical company had identified as the most medically important in the last 25 years, 11 were partially supported by government funds. Publicly funded science is, thus, an important component of the pharmaceutical industry’s R&D.³⁴ Thus, the view that profits belong solely to the pharmaceutical industry because it has only invested in R&D is not always the case. The industry does invest large amounts into R&D for innovative medicines, but public entities, such as the National Institute for Health, also contribute. This is a large issue, which cannot be sufficiently addressed here but we raise it for consideration.

Public funds are directed to research that will, ideally, result in helpful medicines that contribute to the public good. This is so for many reasons including the moral qualities

of medicine. Medicines play a foundational role in supporting other community values, such as liberty, equal opportunity, and human flourishing and are critical for the good functioning of health systems. In view of this, they cannot be considered as equivalent to other consumer goods. A similar intuition underlies Dodd's view that public utilities have unique social obligations.³⁵ In short, we believe that of the four Resolutions, Resolution Four, which advocates equity pricing, has distinct moral advantage and is likely the most practical Resolution to apply.

VII. Conclusions

The TRIPS Agreement and pharmaceutical pricing policies present complex ethical dilemmas about ensuring access of the poor to critical medicines. The Treaty may impede efforts to improve access of the poor to medicines under patent, unless creative public policies are put forward. We have argued that there is space for a global policy maker – such as the World Bank – to assume a central and active role. We put forward four potential Resolutions: (1) Intensified Pharmaceutical Loans and Grants for Patented Drugs; (2) Debt Cancellation to Purchase Critical Pharmaceuticals; (3) Equity Pricing; and, the (4) Purchase of Patents by the Bank and the Licensing of Patented Drugs to Generic Drug Manufacturers. These Resolutions are not novel. Some are even well in progress. Indeed, there is a trend toward equity pricing. Because of considerable pressure from public health activists, pharmaceutical companies, such as Merck & Co. and GlaxoSmithKline PLC are beginning to provide drugs at marginal production costs or less in developing countries.³⁶ While prices are still out of reach for the poor, they at least demonstrate that equity pricing can be put in practice.

¹ G. H. Brundland. Speech to the WHO/Public Interest NGO Pharmaceuticals Roundtable, Third Meeting, Geneva, Switzerland, May 1, 2000.

² For example, poor infrastructure, mismanagement, and sometimes corruption, are all variables, which can potentially limit the access of the poor to essential medicines.

³ H. Redwood. 1995. *Brazil: The Future Impact of Pharmaceutical Patents*. Felixstowe, Suffolk, England. Oldwicks Press.

⁴ Jeffery J. Schott (ed.). *The WTO After Seattle*, Washington DC: Institute for International Economics, 5, 118.

⁵ Schott, *op. cit.* 5, 41.

⁶ K.E. Maskus. *The International Regulation of Intellectual Property*, paper prepared for the IESG Conference on International Trade and Investment, Nottingham, September 12–14, 1997, p. 3.

⁷ The Bank health sector strategy paper notes, “no country can secure sustainable economic growth or poverty reduction without a healthy, well nourished, and educated population.” Bank. 1997. *Health, Nutrition, and Population Sector Strategy Paper*. Washington, D.C. Bank Group: 10.

⁸ C. R. Frischtak. 1993. Harmonization Versus Differentiation in Intellectual Property Rights Regimes. In *The Global Dimensions of Intellectual Property Rights in Science and Technology: A Conference*. M.B. Wallerstein, M.E. Moguee, and R.A. Schoen, eds. Washington, D.C. National Academy Press: 99.

⁹ Maskus, op.cit. 10.

¹⁰ Maskus, op. cit. 10, 34.

¹¹ WHO. March 2001. Globalization, TRIPS and Access to Pharmaceuticals. In *WHO Policy Perspectives on Medicines*. Geneva. WHO.

¹² J. Stiglitz. *Two Principles for the Next Round: Or How to Bring Developing Countries in From the Cold*. Paper prepared for the ‘WTO/Bank Conference on Developing Countries in a Millennium Round’, WTO Secretariat, Geneva, 20–21 September 1999. p. 34. (Stiglitz argues further that in the next round of trade negotiations, efforts should be made to explore ways to ensure that developing countries achieve “most favored pricing” status).

¹³ K. J. Arrow. 1993. Economic Welfare and the Allocation of Resources for Invention. In *The Rate and Direction of Inventive Activity: Economic and Social Factors*. Princeton, N.J. National Bureau of Economic Research: 609–25, as quoted in Paul A. David. Intellectual Property Institutions. In *The Global Dimensions of Intellectual Property Rights in Science and Technology: A Conference*. M.B. Wallerstein, M.E. Moguee, and R.A. Schoen, eds. Washington, D.C. National Academy Press: 4.

¹⁴ C. Correa, op.cit. 22.

¹⁵ J. Sachs. Submission to the Senate Subcommittee on African Affairs, Washington, February 24, 2000.

¹⁶ For more information, see <http://www.worldbank.org.hipc>.

¹⁷ R. Weissman. AIDS and Developing Countries: Facilitating Access to Essential Medicines. *Foreign Policy in Focus* 2001; 6, no. 6.

¹⁸ <http://www.worldbank.org/about/whatwedo>.

¹⁹ G. Carr. Survey: The Pharmaceutical Industry: Beyond the Behemoths. *The Economist* February 21, 1998: 16-18.

²⁰ D. Resnik. Developing Drugs for the Developing World: An Economic, Legal, Moral, and Political Dilemma. *Developing World Bioethics* 2001; 1, no.1: 11-22.; U. Schuklenk and R. Ashcroft. Affordable Access to Essential Medication in Developing Countries: Conflicts Between Ethical and Economic Imperatives. *Journal of Medicine and Philosophy* 2002; 27, 2: 179-195.

²¹ D.J. Ncayiyana. Antiretroviral Therapy Cannot Be South Africa's First Priority. *CMAJ JAMC* 2001; 164, no. 13: 1857-1858.

²² This is implicit in the kinds of considerations that are used to negate contracts (e.g. infancy, insanity, undue influence, and duress). See A.L. Corbin. 1950. St. Paul. West Publishing Company. *Corbin on Contracts*.

²³ see *Henningsen v. Bloomfield Motors* Supreme Court of New Jersey, 32 N.J. 358; 161 A.2d 69 (a good case on necessities).

²⁴ It has been referred to by a number of terms, including fiduciary duty and classical view. We choose this term because it is most perspicuous for an interdisciplinary audience.

²⁵ M. Friedman. 1997. The Social Responsibility of Business is to Increase Profits. In *Ethical Theory and Business*. T. L. Beauchamp and N.E. Bowie, eds. Upper Saddle River, NJ. Prentice Hall: 30, 56; Revised Model Business Code 8: 30 (a), 1992.

²⁶ D. Resnik. Developing Drugs for the Developing World: An Economic, Legal, Moral, and Political Dilemma. *Developing World Bioethics* 2001; 1, no. 1: 18.; D.W. Brock. Some Questions about the Moral Responsibilities of Drug Companies in Developing Countries. *Developing World Bioethics* 2001; 1, no. 1: 33-37.

²⁷ Ibid.

²⁸ D.W. Brock. Some Questions about the Moral Responsibilities of Drug Companies in Developing Countries. *Developing World Bioethics* 2001; 1, no. 1: 34.

²⁹ Merck & Co., Inc. "Mission Statement: Our Values," at www.merck.com.overview/philosophy.

³⁰ See for example, The Bill Emerson Food Donation Act. Public Law 104-210 (October 1, 1996), which protects donors (typically grocery stores) who donate food to non-profit organizations from liability for harm caused by the product. Although not typical of Good Samaritan laws, this Act shows that as a community we encourage organizations to render aid that they are uniquely suited to render, especially with respect to necessities.

³¹ P. Singer. 2001. Famine, Affluence and Morality. In *Writings on an Ethical Life*. New York. Harper Collins: 107.

³² Angell, op. cit. 34, 1902-1904.

³³ Angell, op. cit. 34, 1902-1904.

³⁴ J. Gerth and S.G. Stolberg. Medicine Merchants: Birth of a Blockbuster; Drug Makers Reap Profits On Tax-Backed Research. *New York Times*, April 23, 2000.

³⁵ Dodd, op. cit. 41, 1162.

³⁶ M. Ganslandt, K.E. Maskus and E.V. Wong. Developing and Distributing Essential Medicines to Poor Countries: the DEFEND Proposal, IUI Working Paper Series 552, The Research Institute of Industrial Economics.