

Health Care, Intellectual Property and Economics: *Pharmaceuticals and The Developing World*

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Introduction

The contrast in health care provision between populations in the developed and developing world is stark. In 1998, the U.S. spent more than \$4000 per person on health care, while nations in Sub-Sahara Africa spent \$18 per person in the same year.¹ Needing no itemization or detailing, a range of lethal and crippling diseases now afflicts populations that live predominantly or exclusively in developing nations. Malaria and tuberculosis respectively kill 1.5 million and 2 million people per year, while AIDS claims 3 million.²

The implications of resource deficiency in the AIDS tragedy are particularly troubling. Of the 42 million living people who now carry the deadly virus, 95 percent live in the developing world and 70 percent live in sub-Saharan Africa. The virus now infects one of every nine South Africans who live in the continent's largest economy,³ while an estimated 1 in 1000 Africans with contracted HIV now receives treatment.⁴ The disease decimates adult populations now in peak earning potential, leaving a generation of orphans (12 million at present), reducing GDP at a rate of 2 percent per year, and miring Africans in stagnant or retreating economic systems denied the higher standards of living otherwise made possible through economic development.⁵

The issues of health care and economics are very related to the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), which was enacted in 1994 to balance incentives for future invention and accessibility of product.⁶ Provided that owner rights are fairly

¹Amir Attaran and Jeffrey Sachs, "Defining and Refining International Donor Support for Combatting the AIDS Pandemic", *Lancet*, 357:57-61 (2001). Regarding expenditures on pharmaceuticals alone, Japanese and American citizens in a recent year respectively spent \$368 and \$544 per capita for pharmaceuticals, while Indians and Chinese (both of which have significant drug making capacity) respectively spent \$3 and \$5. James Love, "From TRIPS to RIPS: A Better Trade Framework to Support Innovation in Medical Technologies", Workshop on Economic Issues related to Access to HIV/AIDS care in Developing Countries, Marseille, May 27, 2003.

²Sarah Boseley, "Killer Diseases that Target the Poor", *Guardian Unlimited*, August 22, 2002.

³Theresa Agovino, "GlaxoSmithKline lowers prices of AIDS drugs in world's poorest countries", at http://www.immunecentral.com/tempaltes/info_template.cfm/6639/77/11 (visited September 7, 2003).

⁴Report of the World Health Organization International Consultative Meeting on HIV/AIDS Antiretroviral Therapy: May 22-23, 2001; Geneva, Switzerland. At [ww3.who.int/whosis/cmh/cmh_report/e/pdf/177-184.pdf](http://www3.who.int/whosis/cmh/cmh_report/e/pdf/177-184.pdf) (retrieved September 20, 2003)

⁵At <http://www.prcdc.org/summaries/aidsinafrica/aidsinafrica.html> (retrieved September 13, 2003).

⁶WTO members generally have to provide patent protection for any newly invented, nonobvious product or process that bears some industrial applicability; members cannot discriminate

considered, members may enjoy limited exceptions to exclusive rights otherwise conferred by a patent (Article 30). Under Article 31, governments may issue compulsory licenses that allow the unauthorized use of a patented product or process provided, *inter alia*, that any such use should be predominantly for the supply of a domestic market (31(f)) and that rights owners are paid adequate compensation. (31(h))

Per Article 66 of the TRIPS Agreement, least-developed countries have the right to not comply until January 1, 2006, which the subsequent Doha Declaration on the TRIPS Agreement and Public Health (November, 2001) extended to January 1, 2016 in respect of the obligations relating to patents and protection of confidential data for pharmaceutical products.⁷ Recognizing that the compulsory licensing provisions of Article 31(h) offered little potential benefit to LDCs with no or insufficient manufacturing capacity in the pharmaceutical sector, Article 6 of the Doha Declaration also directed the Council for TRIPS to report an expeditious solution to the domestic supply restraint (31(f)) by the end of 2002. After resolving several U.S. concerns, members of the World Trade Organization reached final agreement in Geneva in August, 2003.⁸

There are three general economic issues for the developing world regarding health care, intellectual property, and economics. First, a great number of treatments (such as antibiotics and vaccines) can now be produced competitively at low cost, but cannot reach many populations due to lack of infrastructure and health services. Second, developing countries need new drugs to fight lethal and crippling diseases (such as malaria and tuberculosis) that have been substantively eliminated, or that never existed, in the developed world. Third, developing countries must procure existing patented drugs for diseases that afflict populations in both rich and poor countries.

The Problem of Infrastructure for Health Care

As a primary determinant of health care difficulties, developing nations lack access to the physical and social infrastructure needed for drug delivery and implementation of programs for disease prevention and treatment. These problems complicate the delivery of even the least expensive drugs.

between different fields of technology or the place of invention (Article 27.1). The minimal length of patent protection is 20 years from the date of file (Article 33). Governments can refuse to grant patents for some inventions related to public health. (Articles 27.2, 27.3a, 27.3b).

⁷At <http://www.cptech.org/ip/wto/p6/wto12162002.html> (retrieved September 20, 2003)

⁸At http://www.wto.org/english/news_e/pres03_e/pr350_e.html (retrieved September 20, 2003).

In contrast to Europe (3.9 physicians per thousand) and the U.S. (2.7 physicians per thousand), LDCs have 0.1 physicians per thousand people to fight a considerably higher disease burden. . The World Health Organization found that up to 75 percent of antibiotics are prescribed inappropriately, only 50 percent of patients take medicines correctly, and 10 to 20% of sampled drugs fail quality control tests in many developing countries.⁹ Although salaries of professionals are often prioritized, work attendance is spotty and administration corrupt. Private practitioners are often untrained, medications often unnecessary, direct administration no more helpful than self-administration, and procedures for self-administration often not properly implemented.¹⁰

The deficiency of infrastructure now curtails and damages far more human life than the high of drugs. Of the 325 medicines on the World Health Organization's 12th Model List of Essential Medicines in 62 poor countries, only 19 are patented anywhere in the world.¹¹ However, despite the fact that nearly 94 percent of essential medicines are not patented, over one-third of the world's population in the poorest parts of Africa and Asia still lacks access to essential drugs¹² About half of the children in developing nations now fail to receive vaccines that cost pennies per day to produce and that do not require any diagnosis; three million lives are lost annually as a result.¹³ The inoculation rate for vaccines against influenza and hepatitis (which are both inexpensive to produce) is worse.¹⁴ India, which has no patents and ten companies that produce anti-retrovirals (ARVs), now provides ARV treatment to 3,000 of 500,000 AIDS victims.¹⁵

Up until recently, monetary assistance from developed countries has been meager.¹⁶ In the year 2000, the World Bank, U.K., and U.S. respectively donated \$149 million, \$147 million, and \$112 million for AIDS assistance to developing nations. The other five G-7 members - Canada, France, Italy, Japan, and

⁹At <http://www.who.int/medicines/organization/par/edl/expertcomm.shtml> (retrieved September 19, 2003).

¹⁰World Bank, World Development Indicators, Washington D.C. (2001)

¹¹Amir Attaran, "A Quantitative Analysis of Patents and Access to Essential Medicines in Developing Countries, The 2nd IAS Conference on HIV Pathogenesis and Treatment.

¹²Supra note 9.

¹³World Bank, Immunization at a Glance, Washington, D.C. (2001).

¹⁴Michael Kremer, "Pharmaceuticals and the Developing World", 16(4) Journal of Economic Perspectives, 67, 68 (2002)

¹⁵David Rosenberg, "Access to Medicines: The Background to the Doha Debate", Presentation at the Fordham University Intellectual Property, Media, and Entertainment Law Journal Symposium (April, 2002).

¹⁶Amir Attaran, "Why AIDS Treatment for the Poor is Not Happening, and How to Change It", Presentation at Fordham University School of Law, Tenth Annual Conference on International Intellectual Property Law and Policy (April 5, 2002).

Germany -- respectively donated \$10, 5, 4, 4 and 3 million. Recent efforts have stepped up worldwide assistance considerably.

A comprehensive health policy must acknowledge the primary role of infrastructure development. Supported by developed countries, relief programs and other forms of collective action have economic logic if they facilitate general advances that no individual nation may choose to pursue.¹⁷ From a collective perspective, advances in world health enhance economic growth, widen markets, and limit the harm from disease contagion.¹⁸

The Economics of Pharmaceutical Markets

A distinguishing characteristic of production in the pharmaceutical industry is the considerable upfront expenditure necessary to research the molecule and construct new production plant. Including the opportunity costs of foregone capital payments, R&D now accounts for 30 percent of the costs of a new product in the research-based pharmaceutical industry.¹⁹ Moreover, an additional 40 percent of total expenses accounts for marketing, administration, and inventory costs. In the end, only 25 percent of total production costs are actually related to the direct manufacture and distribution of pharmaceutical product.²⁰

The research process for new drugs is daunting. The average new drug entails up to \$800 million to develop, while the corresponding generic costs under two million.²¹ Development time for a new drug averages over 15 years. This long development time gives less opportunity during patent life to collateralize investment, and most efforts at innovation fail.²² Fewer than 1 percent of the compounds that are examined in the pre-clinical period actually wind up in

¹⁷Mancur Olson, *The Logic of Collective Action*, (Cambridge: Harvard University Press) (1972).

¹⁸Regarding the concept of health externalities, see David M. Cutler and Mark McClellan, "Is Technological Change in Medicine Worth It?" *20 Health Affairs* (Sept./Oct. 2001), 21.

¹⁹Joseph DiMasi, et al., "The Cost of Innovation in the Pharmaceutical Industry", *10 Journal of Health Economics*, 107-42 (1991).

²⁰Patricia M. Danzon, "Price Discrimination for Pharmaceuticals, Welfare Effects in the U.S. and the EU", *4 International Journal of the Economics of Business* 301, 305 (1997).

²¹Joseph A. DiMasi, Ronald W. Hansen, and Henry G. Grabowski, "The Price of Innovation: New Estimates of Drug Development Costs" (Boston: Tufts University Center for the Study of Drug Development, 2002); for generics, U.S. Congressional Budget Office, "How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry", (Washington, D.C.: U.S. Government Printing Office, 1998), Theodore Goldberg et al., "Generic Drug Laws: A Decade of Trial: A Prescription for Progress (Washington, D.C.: NCHSR, 1986).

²²Joseph A. DiMasi, "Trends in Drug Development Costs, Times, and Risks", *29 Drug Information Journal*, 375-84 (1995); Kenneth I. Kaitin and Joseph A. DiMasi, "Measuring the Pace of New Drug Development in the User Fee Era", *34 Drug Information Journal*, 673-80 (2000).

human testing, and only 20 percent of these gain FDA approval.²³ Nor is patent protection so protective of price; a study of 148 new drugs in the U.S. found that only 13 had no close substitutes.²⁴ Indeed, most new chemical entities in the 1980s and 1990s generated insufficient revenues to cover development cost.²⁵

Faced with a portfolio of occasional winners, drug companies must collateralize their investments in R&D by charging higher prices for the market. That is, some portion of the price of a newly marketed drug pays for the costs of the many failures. Given the nature of the research lottery, it is simplistic to suggest that a particular drug is priced too high simply because its revenues exceed related costs by some considerable margin.

The patent system, which attempts to provide incentives by restricting competitive imitation for some period, then safeguards new product from economic competition that may otherwise drive prices down to marginal cost and therefore eliminate the incentive for new research. Most scholarly studies concur - of any industrial group, pharmaceutical managers now place the highest priority on patent protection.²⁶ Indeed, economist Z.A. Silberston concluded that pharmaceutical companies were in a class by themselves with respect to the need for patent protection;²⁷ Edwin Mansfield concluded that 60 percent of drug inventions in a representative time period would not have been developed without patent protection.²⁸ The correlation between patent protection and R&D is also confirmed in studies involving cross-sectional analysis between different countries.²⁹

Some part of the health care problem now results because private companies, which now undertake 50 percent of expenditure on drug research, rarely

²³Joseph A. DiMasi, "Success Rates for New Drugs Entering Clinical Testing in the United States", 58 *Clinical Pharmacology and Therapeutics* 1-14 (1995).

²⁴J.L. Lu and W.S. Comanor, "Strategic Pricing of New Pharmaceuticals", 80 *Review of Economics and Statistics*, 108-18 (1998).

²⁵H.G. Grabowski and J.H. Vernon, "Brand Loyalty, Entry, and Price Competition in Pharmaceuticals after the 1984 Act", 35 (2) *Journal of Law and Economics* 331-50 (1992)

²⁶Richard Levin, et al., "Appropriating the Returns from Industrial Research and Development", *Brookings Papers on Economic Activity*, 793-820 (1987); Wesley Cohen et al., "Appropriability Conditions and Why Firms Patent and Why They Do not in the American Manufacturing Sector", Working Paper, Carnegie Mellon University, (1997).

²⁷Z. A. Silberston, *The Economic Importance of Patents* (London: The Common Law Institute of Intellectual Property, (1987).

²⁸Edwin Mansfield, "Patent and Innovation: An Empirical Study", 32 *Management Science* 175 (1986).

²⁹ Robert E. Evanson and Sunil Kanwar "Does Intellectual Property Protection Spur Technological Change", (New Haven: Yale Economic Growth Center) (2001).

research new drugs specific to the needs of developing countries.³⁰ A rough rule of thumb in the industry is that a \$250 million annual market is needed to motivate substantial research, and this is beyond economic possibility without foreign assistance.³¹ Indeed, less than 5 percent of private research goes toward diseases that are specifically related to developing countries. Moreover, of the 1233 new drugs that were licensed worldwide in 1975-1997, 13 were for tropical diseases, and only four of these were new products developed by commercial firms for the specific gain of populations in developing countries.³²

The problem here is not one of high prices so much as low rewards – developing countries do not have the financial wherewithal to pay for either drugs or infrastructure.

Dual Market Procurement

A third concern for developing economies is the procurement of dual market pharmaceuticals that are now available for fighting diseases, such as cancer and AIDS, that may afflict populations in both affluent and poorer countries. The problem requires careful economic context.

With substantial amounts of revenues that could be collected in developed countries, research-based pharmaceutical companies now reduce prices for developing countries and may, in so doing, promote economic efficiency.³³ For example, TB drugs are now priced to developing nations at a 97 percent discount,³⁴ and market leader Glaxo now sells ARV drugs at comparable percent reductions.³⁵ (Please see attached press release detailing GSK's latest price

³⁰Generally, see Jean O. Lanjouw and Iain Cockburn "New Pills for Poor People: Empirical Evidence After GATT", World Development, (2001).

³¹Kremer, *infra* note 56, Part II

³²Bernard Pecoul, et al, "Access to Essential Drugs in Developing Countries: A Lost Battle?", 281 *Journal of the American Medical Association*, 361-67 (1999). Of the remainder, two were modifications of existing medicines, two were produced for the military, and five came from veterinary research.

³³While price discrimination is often economically efficient under static circumstances, it can be more so when new innovation can be introduced. Jerry A. Hausman and Jeffrey K. MacKie-Mason, "Price Discrimination and Patent Policy", 19(2) *Rand Journal of Economics*, 253-65 (1988).

³⁴R.O. Laing, K.M. McGoldrick, Tuberculosis Drug Issues: Prices, Fixed Dose Combination Products and Second Line Drugs, *Int. J. Tuberc. Lung Dis.*, S194-S207 (2000).

³⁵For the 63 poorest countries, GlaxoSmithKline (GSK) reduced the prices of its AIDS medicines five times since 1997. Backbone drug Combivir is now priced at \$0.65 per day, or \$235 per year. The corresponding price in the U.S. is \$10,000 per year Agovino, *supra* note 3. In non-profitable pricing, GSK also sells Eпивir at \$0.19 per day and Retrovir at \$0.58 per day. see Press Release, GlaxoSmithKline, "GlaxoSmithKline takes Further Action to help the World's Poorest Fight HIV/AIDS", at <http://www.gsk.com/media/archive.htm> (visited November 18, 2003).

reductions announced on 16 October 2003.) As a consequence of differential pricing, access in the developing world has increased by a factor of 4-7 times.³⁶ Accordingly, stronger patent protection for dual markets can be twice beneficial; it provides incentives for pharmaceutical research and helps finance such investments.³⁷

However, preferential pricing to poor countries depends on an important commitment; beneficiaries must avoid diverting donated product back into developed markets. Seemingly nondiscriminatory and therefore “fair”, re-export nonetheless permits circumvention of the very price differentials that enable preferential pricing in the first place.³⁸ To accommodate the concern, IP owners and developing nations must then eliminate trade diversion (or parallel importing), at least into developed countries.³⁹ Reference pricing, a process whereby buyers and observers in developed nations attempt to use prices in the developing world as reasonable benchmarks for their own terms, is similarly problematic.

Besides discounting prices, pharmaceutical companies may assist developing countries through direct donations of product. Merck made history in 1987, when it donated for unlimited duration a drug treatment to eliminate river blindness, to the benefit of over 100 million people in the next ten years. The huge success and Merck’s subsequent partnerships with the World Bank, World Health Organization, and Carter Foundation inspired others to follow. In similar programs, Glaxo Wellcome, Pfizer, and Smith Kline respectively donated anti-malaria Malarone, antibiotic Zithromax, and anti-elephantiasis Albendazole.⁴⁰

American corporations also may deduct charitable expenses from operating income. Section 170(e)(3) of the U.S. Internal Revenue Code now allows further step up in tax deductions in instances when the donated property is used “solely

³⁶J. Dumoulin, “Global Pricing Strategies for Innovative Essential Drugs”, 3 Int. J. Biotechnology 3-4, 338-49 (2001)

³⁷see generally European Commission, Proposal for a Council Regulation to avoid trade diversion into the European Union of certain key medicines (2002)

³⁸David A. Malueg and Marius Schwartz, “Parallel Imports, Demand Dispersion, and International Price Discrimination”, 37 Journal of International Economics 167 (1994); K. E. Maskus, “Parallel Imports to Pharmaceuticals: Implications for Competition and Prices in Developing Countries”, Final Report to World Intellectual Property Organization. At www.wipo.org/about-ip/en/studies/pdf/ssa_maskus_pi.pdf (retrieved September 20, 2003)

³⁹Poor countries may reasonably be allowed to parallel import to one another. Frederick M. Scherer and Jayashree Watal, Post-TRIPS Options for Access to Patented Medicines for Developing Countries, WHO Commission on Macroeconomics and Health (2001). At www.cmhealth.org/docs/wg4_paper1.pdj (retrieved September 14, 2003)

⁴⁰Id., 54

for the care of the ill, the needy, or infants.”⁴¹ In the Vaccines for the New Millennium Act, the U.S. government provided a 30% tax credit on qualified research and development expenditures on microbicides for diseases that kill 1 million or more people annually.⁴²

Compulsory Licensing for Developing Countries

If the domestic supply constraint (Article 31(f)) of TRIPS is loosened and broader terms of compulsory licensing are enabled by Article 31(h) poor countries may presumably procure drugs less expensively by importing product from more efficient foreign facilities where trade agreements would otherwise disallow export.

The matter of compulsory licensing now generally implicates treatments for AIDS. As mentioned above, of the 19 existing drugs in the world that are now under patent in at least one country, 12 are used in the treatment of HIV.⁴³ Patents for at least 1 drug was issued in the 29 African countries that accounted for 72 percent of the HIV-infected population. Furthermore, the eleven countries that had six or more patents included 46 percent of the infected population.⁴⁴

Since national investments would require the construction of separate production plant in each country, such plant may lack the capacity to scale efficiently. Accordingly, proponents suggest that compulsory licensing may improve scale efficiencies at the manufacturing stage. As a second consideration, possible gains from trade are made possible by low-cost manufacture and competitive pricing.⁴⁵

However, neither scaling nor trading efficiencies by themselves present an unambiguous reason why exclusive IP rights must be relaxed. Generally speaking, a patent-owning company in a free market has the economic incentive to assign production rights to the most efficient manufacturer (including its own

⁴¹Amir Attaran et al., “A Tax Credit for Sales of HIV, Tuberculosis, and Malaria Vaccines”, at <http://www.cid.harvard.edu> (retrieved September 10, 2003). With current accounting procedures, Scherer and Watal show that donating companies may actually save money by introducing a creative donation arrangement Id., 56

⁴²At www.sfaf.org/policy/hivpolicywatch/0009pw.html (retrieved September 19, 2003)

⁴³Supra note 13.

⁴⁴James Love, E-drugs: Attaran/Gillespie-White and PhRMA patent surveys, at <http://www.essentialdrugs.org/edrug/archive/200110/msg00050.php> (retrieved September 20, 2003); see also Amir Attaran and Lee Gillespie-White, “Do Patents for Antiretrovirals Drugs Constrain Access to AIDS Treatment in Africa”, 286 Journal of the American Medical Association, No. 15.

⁴⁵Cost differences may arise due to available location, the availability of skilled chemists, low cost labor, relaxed environmental rules, government subsidy, and easier capital treatment.

facilities), so long as equal royalties are paid for any sale.⁴⁶ Indeed, the semiconductor industry has pursued economic efficiency through disintegration; i.e., chip design and fabrication occur in different plants now located in different countries.⁴⁷ However, such vertical disintegration occurs with IP only if the patent owner is secure that its ownership cannot be trumped or circumvented somewhere down the line.

Compulsory licensing for HIV applications in developing nations may yet enable transactional economies.⁴⁸ As a therapeutic intervention, the combined use of different drugs can be an effective procedure to maximize availability and reduce delivery costs; no one combination is ideal in all instances, and the widest menu of competitive choices is best. This said, patent owners often have conflicting interests with regard to the licensing of complementary products that should be efficiently combined.⁴⁹ Here, the fragmentation of rights may involve transactional difficulties that lead to haggling and holdup. Compulsory licensing may expedite the transactional process and reduce the danger of such holdup,⁵⁰ and generic producers do cite some examples of lower prices.⁵¹ These lower

⁴⁶Robert Bork, *The Antitrust Paradox: A Policy at War with Itself*, 376 (New York: Basic Books) (1978).

⁴⁷Bronwyn H. Hall and Rosemary H. Ziedonis, "The Patent Paradox Revisited: An Empirical Study of Patenting in the U.S. Semiconductor Industry: 1979-1995", 32 (1) *Rand Journal of Economics* 101 (2001).

⁴⁸see generally Oliver Williamson, "Transaction Cost Economics", in R. Schmalensee and R. Willig, eds., *Handbook of Industrial Organization* 1989, vol. 1, 136-82 (Amsterdam: North Holland Elsevier)

⁴⁹Regarding HIV treatment, three companies -- Bristol Myers Squibb, Glaxo, and Boehringer Ingelheim -- now control separate component rights in the least expensive drug cocktail (d4T/3TC/nevirapine), a good substitute (d4T/AZT/nevirapine), and the combination (d4T/Abacavir/nevirapine) that now receives the highest ratings for adherence and long term toxicity in the U.K.'s ARV guidelines. Each producer now controls exclusive rights to its drug. As a complicating issue, Glaxo controls the rights for all the drugs in the Trizivir substitute (AZT/3TC/abacavir) and is then positioned to block any one component.

⁵⁰Indeed, the U.S. Department of Justice recognized the danger of transactional holdup in the advance of new technology when it quickly approved a two different patent-pool arrangements that allowed owners of complementary rights to DVDs to license their patents as one group. At www.usdoj.gov/opa/pr/1999/June/238at.htm (retrieved September 19, 2003) By contrast, the Federal Trade Commission blocked a licensing combination that involved two processes that were competitive substitutes. At www.ftc.gov/opa/1998/08/sumvisx.htm (retrieved September 19, 2003)

⁵¹Generic producers cite some events to substantiate their claim. Apparently, manufacturer Cipla makes a generic d4T/3TC/Neveirapine available for \$350 year to medical activists Medecins Sans Frontieres, down from the prevailing market price of \$1100. More specifically, Glaxo's Combivir (which combines AZT and 3TC) is now priced at its manufacturing cost of 97 cents per day. By contrast, Cipla's generic version of the same drug -- preapproved by the World Health Organization -- now sells for 56 cents a day, or \$204 per year. Expert Declaration, James Love, para. 22, at <http://lists.essential.org/pipermail/random-bits/2003-February/001022.html> (retrieved September 10, 2003).

prices are admittedly compromised by the fact that some generics (such as Cipla's Triomune) have not been completely tested or pre-qualified by the World Health Organization.

As envisioned, compulsory licensing would apparently be implemented through a two-tiered system, depending on whether there was a patent in the exporting country or not.⁵² If there is no patent in the exporting country, the importing country can set the license fee unilaterally. Presumably, subject to compliance with Article 31(h) TRIPs, this could be based on production costs, estimated value of life, or a reasonable benchmark derived from similar uses. However, if there is a patent in the exporting country, both the exporting and importing country may set license fees, and resolve differences through negotiation. Remuneration for a compulsory licence will only be paid in the exporting country, but must then be calculated on the basis of its economic value in the importing country.

Although remuneration must now be set by country authorities, administration might arguably be improved if an international regulatory agent could affix a percent surcharge on each drug. If established by an international panel, percent surcharges can be administratively transparent and may reduce administrative costs associated with bilateral negotiation. Second, such a system is non-distorting; i.e., a percent surcharge would raise each price by an equal percentage and therefore create no price distortion between different treatments. Third, collected royalty amounts can be easily matched quid pro quo by contributions from developed nations that can support lower prices, infrastructure, or professional services. Outside support for relief efforts can be collected from direct donations or a dedicated fund of tax credits. Finally, as a political matter, percent surcharges have reasonable precedent as an instrument for compensating patent owners.⁵³

Compulsory Licensing and Economic Incentives

As implemented, the present Doha Agreement goes well beyond the treatment of AIDS. Subject to appeal processes, developing nations may apparently make

⁵²Frederick M. Abbott, Compulsory Licensing for Public Health Needs: The TRIPs Agenda at the WTO after the Doha Declaration on Public Health, Section IX(a).

⁵³Supra note 51, at 19. Canada implemented a four percent-of-revenue approach to compulsory licensing in the 1970s and 1980s. Pharmacia established a voluntary royalty rate of 5 percent of generic sale value for poor countries. The Pharmaceutical Research and Manufacturers Association and the U.S. Internal Revenue Service have submitted documents that consider a royalty of 5 percent to be average in the U.S. The United Nations Development Program offered 4 percent as a central guideline.

takings in all drugs, including those that have yet to be invented, with compensation to patent owners based on methodologies that have yet to be designed.

This combination of taking and regulation will not provide much incentive to pharmaceutical researchers. A researcher in pharmaceutical development and a careful advocate for developing countries, Professor Jean Lanjouw, is even less charitable: "It seems certain that compulsory licensing or stringent price control regimes that limit the returns to discovering new products specifically designed to treat poor country health problems would prevent any beneficial redirection of research."⁵⁴

As Prof. Lanjouw recognizes,⁵⁵ compulsory licensing only functions when there are drugs to license. The agreement implemented in Geneva does not appear to recognize the attending danger of failed incentive. In this regard, compulsory licensing must be supplemented with rules to safeguard procurement and protect intellectual property.

A reasonable means of increasing the incentive for new drugs entails "market making".⁵⁶ That is, centralized procurement agents would concentrate national demands and solicit bids from would-be competitors,⁵⁷ as is now sometimes done for vaccines.⁵⁸ The process may work as follows. Supported by an international fund of donated revenues, a procurement agency specifies design

⁵⁴Jean O. Lanjouw, "A Patent Policy Proposal for Global Diseases", Section 8, (Brookings Institution: Washington, D.C.) (2001), at <http://www.brook.edu/views/papers/lanjouw/20010611.html> (retrieved September 10, 2003)

⁵⁵Id., and surrounding text.

⁵⁶Mathias Ganslandt, et al., "Developing and Distributing Essential Medicines to Poor Countries: The DEFEND proposal", Working Paper No. 552, Section 2, Research Institute of Industrial Economics, Stockholm (2001); Michael Kremer, "Creating Markets for New Vaccines", Parts I and II, in A.B Jaffe, J. Lerner, and S. Stern, eds., *Innovation Policy and the Economy* (Cambridge: MIT Press) (2001).

⁵⁷For a detailed discussion, see Kremer, Id.

⁵⁸McKinsey and Company, *Evaluation of the Global TB Facility*. 35 (2003), at <http://www.stoptb.org/GDF/default.asp> (retrieved September 14, 2003). The World Health Organization in 2001 put into place its highly successful Global TB Drug Facility that reduced drug prices some thirty percent in the following two years. Supported by a McKinsey study of the TB Facility, the World Health Organization recently announced plans for concentrated procurement of HIV treatments that will be implemented in December, 2003. Smaller projects for pooled procurement are already in place at UNICEF, the Generic Antiretroviral Procurement Project (South Africa), and the International Dispensary Association (Netherlands). At Daniel Raymond, *Learning from Tuberculosis: Applying Pooled Procurement to HIV*, August, 2003, at <http://www.amfar.org/cgi-bin/iowa/td/feature/record.html?record=104> (retrieved September 14, 2003); R. Gupta, et al., "Responding to Market Failures in Tuberculosis Control, *Science*, 293: 1049-51. (2001)

characteristics for use and safety. The winning bidder would be the company that comes up with a satisfactory drug in the shortest time. For its efforts, the winning bidder would receive a patent and specified lump sum prize, as well as a running royalty based on sale units or revenues.

The upfront payment and running unit/revenue royalty that are paid for a new drug together compose incentives for R&D, and there is an evident tradeoff between the two. From a short-run pricing perspective, the upfront prize should be maximized to allow agents to minimize the associated running royalty; this would drive market prices to levels closer to marginal cost. Such a strategy would maximize allocative efficiency and simultaneously shelters drug developers from the risk of unanticipated market shortfalls.

However, if a sequence of drugs is designed in time, the procuring agent may be committed to a string of upfront payments for drugs that may have relatively short lifetimes in the market. As new drugs come to market, the procuring agent must then phase down upfront prizes and increase the running royalty. As the market sufficiently deepens, no upfront payment will be needed and the unit royalty can be determined by the market itself.

As mentioned above, there is no reason why the developer must necessarily be the subsequent manufacturer. If so specified, the procurement agency may itself reserve the right to assign production to a competitive source, so long as contracted royalties are paid to the owner. Depending on its knowledge of manufacturing process, its previous experiences, and general concerns over product quality and waste disposal, the designated producer may be sole source (e.g., the winning bidder or one selected competitive alternative) or multiple source (some combination of two or more firms).⁵⁹

With multiple sourcing, the procurement agency may attempt to develop a sector of competing producers. However, an industrial policy that aims to design a competitive market can be problematic. First, a "split award" process necessarily increases the number of transactions that the procuring agent and its production sector must incur, expectedly raising costs for all concerned.⁶⁰ Second, shared

⁵⁹ The dual source option represents a strategy attempted by the U.S. Department of Defense, where competitive outsourcing grew from 15 to 80 percent of the procurement budget Andy Pasztor, *When the Pentagon was for Sale: America's Biggest Defense Scandal*, 123-5 (New York: Scribner), 1995

⁶⁰ Transactions cost for the procurement agent may include designing projects, arranging financing, selecting advisers, conducting studies, prequalifying bidders, and evaluating bids. Bidders' transaction costs entail initial feasibility studies, learning the procurement process, conducting engineering and economic studies to identify costs, and entering into possible consortia to prepare a joint bid. Michael Klein, Jae So, and Ben Shin, "Transaction Costs in Private Infrastructure Projects--Are They Too High?" *Private Sector* 8, September 1996, 21-24

markets may reduce the ability of any one producer to achieve scale efficiencies by concentrating production. Accordingly, it may then be most efficient to require production rivals to engage in “winner take all” competition.⁶¹

A number of interesting modifications may be beneficial. At whatever starting point, if the offered compensation does not attract enough research, the “market maker” may appropriately increase the prize (or the running royalty) until a reasonable amount of competition results.⁶² Second, the procurement agent may commit to intermediate lump sum payments that could be made to a producer who clears certain hurdles in a specified amount of time. Third, particular drugs may be awarded special patent protection, such as that in the U.S. Orphan Drug Act,⁶³ for a longer period, or even indefinitely until a superior product is invented.

As a final point, programs can be complemented with grant or loans to individual nations that facilitate the purchase of other drugs or the buildout of infrastructure. As a result, the system could actually be made yet more profitable to the research sector. For if drugs and services become more easily deliverable over a wide population, the financial incentive for new research grows. In so doing, a wider health effort could then widen the incentive for research into other diseases.

Conclusion

This economic discussion over appropriate policy involving IP and health care purposely counsels pragmatism and non-ideological thinking. Indeed, economists generally do not write or speak in order to assure ideologues that their pronouncements and visions are correct. Replete with contingencies, the policy matter is quite complex, and the tradeoffs between conflicting goals are many. A careful balancing is required if we are to put things in order.

⁶¹Harold Demsetz, “Why Regulate Utilities?”, 11 *Journal of Law and Economics* 55-66 (1968).
Eduardo Engel, Ronald Fischer, Alexander Galetovic “ Competition in or for the field: Which is better”, NBER Working Paper No. w8869 (April 2002)

⁶²Kremer, *supra* note 56.

⁶³Designed to stimulate more pharmaceutical R&D, the U.S. Congress passed the Orphan Drug Act of 1983 (at <http://www.fda.gov/orphan/oda.htm>, retrieved September 20, 2003) An orphan drug is a product (affecting less than 200,000 patients) that presumably provides less incentive to researchers. Under the Act, additional economic incentives include R&D tax credits, research grants, accelerated reviews, and extended market exclusivity. With special protection, the development of new orphan drugs in decades immediately prior and posterior to implementation of the Act jumped from 10 to 200.