

PHARMACEUTICALS AND COMPULSORY LICENSING: EPIDEMICS IN THE DEVELOPING WORLD

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1. 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-Saharan Africa spent a bit more than \$18 per person.¹ Needing no itemizing or detailing, a range of lethal or crippling diseases now afflicts populations that live predominantly 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

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¹Amir Attaran and Jeffrey Sachs, "Defining and Refining International Donor Support for Combating the AIDS Pandemic", *Lancet*, 357 (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, Marseilles, May 27, 2003.

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

developing world and 70 percent live in sub-Saharan Africa. The virus now infects one of every nine South Africans -- the continent's largest economy,³ while an estimated 1 in 1000 Africans with contracted HIV currently 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. As a result, Africans in stagnant or retreating economic systems are denied the higher standards of living otherwise made possible through economic development.⁵

The issues of health care and economics are intrinsically 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 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

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 (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 between different fields of technology or the place of invention (Article 27.1). The minimal length of patent protection is 20 years

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))

Article 66 of the TRIPS Agreement affords least-developed countries the right to not comply with the provisions of the Agreement until January 1, 2006, and this date was extended by the Doha Declaration on the TRIPS Agreement and Public Health (August 2003) until January 1, 2016.⁷ 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 2002.⁸

There are three general economic issues for the developing world regarding health care and intellectual property. 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 funding and the health services infrastructure necessary for

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)

delivery. Second, developing countries need new drugs to fight 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.

2. The Problem of Infrastructure for Health Care

A comprehensive health policy must acknowledge the critical deficiency of the care infrastructure that would enable physical delivery and medical services. Prevention – economic development, improved sewage treatment, clean water access, proper nutrition, cautionary sexual practices – is the first order on the agenda.

The general numbers are sobering. 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. With a deficient penetration of physicians, 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 administrations are corrupt. Private practitioners are often untrained, medications are often unnecessary, direct administration are no more helpful than self-administration, and procedures for self-administration are often not properly implemented.¹⁰

Comment [TWG1]: Source – it isn't generally true that work attendance is spotty and administrations corrupt. If this assertion is going to be made, as specific example must be provided.

The deficiency of training and infrastructure for medical delivery now curtails and damages *far more human life* than the high price 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 lack access to essential drugs¹² About half of the children in developing nations now fail to receive vaccines that may cost pennies per day to produce and do not require any diagnosis before administration; three million lives

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

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.

are lost annually as a result.¹³ The inoculation rate for vaccines against influenza and hepatitis (both inexpensive to produce) is worse.¹⁴ India -- which has only just recently passed a patent law amendment to include a provision for the patenting of pharmaceutical products -- has to date patented no pharmaceuticals, has ten companies that produce generic anti-retrovirals (ARVs), and provides ARV treatment to 3,000 of its 500,000 AIDS patients.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 Germany -- respectively donated \$10, 5, 4, 4, and 3 million.

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

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

¹⁵Daniel 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).

Recent efforts have considerably stepped up worldwide assistance. If supported by developed countries, relief programs and other forms of collective action can have real economic logic if they facilitate general advances that no individual nation may have the resources to pursue.¹⁷ From a collective perspective, advances in world health enhance economic growth, widen markets, and limit the harm from disease contagion.¹⁸ As long-run benefits may indeed redound to the donor nations, the question remains is who will apportion the financial responsibilities among the donor nations.

3. The Economics of Pharmaceutical Products

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 pharma industry.¹⁹ Moreover, an additional 40 percent of total expenses account for marketing,

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 (1991).

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 costs up to \$800 million to develop, while the corresponding generic costs less than 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 Less than 1 percent of the compounds that are examined in the pre-clinical period actually wind up in 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

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 (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 (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 (2000).

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

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 collateralize their investments in R&D by charging higher prices for the successful ones that actually make it to market. That is, some portion of the price of a newly marketed drug *pays for the costs of the many commercial 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 aims to safeguard new product from economic competition that would otherwise reduce prices and eliminate profit margins and the incentive for new research. Most scholarly studies concur; of any surveyed industrial group, pharmaceutical managers now place the highest priority on patent protection. Indeed, economist Z.A. Silberston concluded that pharmaceutical companies were in a

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

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

class of their own with respect to the need for patent protection;²⁶ Prof. Edwin Mansfield of the University of Pennsylvania concluded that 60 percent of drug inventions in a representative time period would not have been developed without patent protection.²⁷ The correlation between patent protection and R&D is also confirmed in studies involving cross-sectional analysis between different countries.²⁸

Some part of the health care problem in the developing world now results because private companies, which now undertake 50 percent of expenditure on drug research, rarely research new drugs specific to the needs of developing countries.²⁹ A rough rule of thumb in the industry is that a \$250 million annual market is needed to motivate the substantial investment required beforehand; this is beyond economic possibility for less developed nations without foreign assistance.³⁰ Indeed, less than 5 percent of research in private pharmaceutical companies goes toward diseases that are specifically related to the epidemiological needs of developing countries. Moreover, of the 1233 new drugs that

²⁶Z. A. Silberston, "The Economic Importance of Patents", London: The Common Law Institute of Intellectual Property, (1987).

²⁷Edwin Mansfield, "Patent and Innovation: An Empirical Study", 32 *Management Science* 175 (1986).

²⁸ Robert E. Evanson and Sunil Kanwar "Does Intellectual Property Protection Spur Technological Change", (New Haven: Yale Economic Growth Center) (2001).

²⁹Generally, see Jean O. Lanjouw and Iain Cockburn "New Pills for Poor People: Empirical Evidence After GATT", *World Development* (2001).

³⁰Kremer, *infra* note 51, Part II

were licensed worldwide in 1975-1997, 13 were for tropical diseases, and only four of these were new products developed by commercial pharma firms for the specific gain of populations in developing countries.³¹ The problem here is not one of high prices that restrict buyer demand so much as low rewards that restrict producer supply.

4. Dual Market Procurement

A remaining 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.

If a new drug can recover substantial amounts of revenues in more developed countries, pharmaceutical companies may actually have the opportunity to reduce prices for developing countries.³² For example, TB drugs are now priced to developing nations at a

³¹Bernard 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.

³²While 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 *Rand Journal of Economics* 253 (1988).

97 percent discount compared with developed nations,³³ and market leader Glaxo now sells ARV drugs at comparable percent reductions.³⁴ As a consequence of differential pricing, access in the developing world has increased by a factor of 4-7 times.³⁵ Accordingly, stronger patent protection for dual markets can be twice beneficial; it generates in developed nations high profit margins and the resulting incentives for research, and simultaneously allows drug producers who earn such profits to market product in the developing world at selective discounts.³⁶

However, preferential pricing to poor countries depends on an important commitment; beneficiary nations must be stopped from diverting donated product back into developed markets. Seemingly nondiscriminatory, and purportedly “fair”, re-export of discounted pharmaceuticals actually permits circumvention of the *very price differentials that enable preferential pricing in the first place*.³⁷ To accommodate the concern, IP owners

³³R.O. Laing, K.M. McGoldrick, Tuberculosis Drug Issues: Prices, Fixed Dose Combination Products and Second Line Drugs, Int. J. Tuberc. Lung Dis., S194 (2000).

³⁴For the 63 poorest countries, Glaxo reduced the prices of its AIDS medicines five times since 1997. The price per year is now somewhere around \$350. The corresponding price in the U.S. is \$10,000 Agovino, supra note 3.

³⁵J. Dumoulin, “Global Pricing Strategies for Innovative Essential Drugs”, 3 Int. J. Biotechnology 338 (2001)

³⁶see generally European Commission, Proposal for a Council Regulation to Avoid Trade Diversion into the European Union of Certain Key Medicines (2002)

³⁷David 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 Word

and developing nations must then eliminate trade diversion (or parallel importing), at least into developed countries.³⁸ Reference pricing, a process whereby buyers and observers in developed nations attempt to adjust their prices to track those in the developing world is similarly problematic.

Besides discounting prices, pharmaceutical companies may assist developing countries through direct donations of product. Here too, wealthier nations must not demand similar largesse. Merck made history in 1987, when it donated for unlimited duration a drug treatment to eliminate river blindness; the program benefitted over 100 million people in the next ten years. The huge success of the program 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.³⁹

Intellectual Property Organization. At www.wipo.org/about-ip/en/studies/pdf/ssa_maskus_pi.pdf (retrieved September 20, 2003)

³⁸Poor 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.pdf (retrieved September 14, 2003)

³⁹Id., 54

The U.S. tax code accommodates this. American corporations 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 for the care of the ill, the needy, or infants.”⁴⁰ 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.⁴¹

5. Compulsory Licensing for Developing Countries

Since the domestic supply constraint of TRIPS (Article 31(f)) has been loosened and broader terms of compulsory licensing enabled by Article 31(h), poor countries presumably may procure drugs at lower prices by importing product from more efficient foreign facilities where trade agreements would otherwise disallow export.

First, it is essential to understand that the matter of compulsory licensing now primarily implicates treatments for exactly one disease – i.e., AIDS. To review, as mentioned above, there are nineteen existing drugs in the world that are now under patent in at least

⁴⁰Amir 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

one country and therefore implicated immediately by the Doha Agreement; twelve are used in the treatment of HIV.⁴² Patents for at least one AIDS drug were issued in the 29 African countries that accounted for 72 percent of the HIV-infected population. Furthermore, the eleven countries that needed six or more patented drugs included 46 percent of the infected population.⁴³

However, since national investments would require the construction of separate production plant in each country, individual national plants may lack the ability to scale efficiently. For this reason, proponents suggest that compulsory licensing may improve scale efficiencies at the manufacturing stage. As a second consideration, gains from trade purportedly are made possible by strategic location, low-cost manufacture, and competitive pricing.⁴⁴

However, neither plant scaling nor trading efficiencies by themselves present a compelling reason why compulsory licensing must be instituted. Generally speaking, a

⁴¹At www.sfaf.org/policy/hivpolicywatch/0009pw.html (retrieved September 19, 2003)

⁴²Supra note 13.

⁴³James 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.

patent-owning company has the economic incentive to assign exclusive or non-exclusive production rights to the most efficient manufacturer(s) (including its own facilities), so long as equal royalties are paid for any sale of the product.⁴⁵ Indeed, a great number of companies have efficiently outsourced production to independent producers located throughout the world. However, efficient assignment and plant specialization can occur with an IP product only if the patent owner is secure that its ownership cannot be circumvented somewhere down the line.

An admittedly stronger case for compulsory licensing of HIV applications in developing nations can be made if such licensing can enable some transactional economies between complementary products used in the treatment of advanced disease.⁴⁶ As a therapeutic intervention, the combined use of different drugs in a cocktail can be an effective procedure to maximize availability and reduce delivery costs; since no one combination is ideal in all instances, the widest menu of competitive choices is best. Here, the fragmentation of owner rights to complementary elements used in particular cocktails may involve transactional difficulties that lead to haggling and holdup in a multi-stage

⁴⁴Cost differences may arise due to available location, the availability of skilled chemists, low cost labor, relaxed environmental rules, government subsidy, and easier capital treatment.

⁴⁵Robert Bork, *The Antitrust Paradox: A Policy at War with Itself*, 376 (New York: Basic Books) (1978).

⁴⁶see generally Oliver Williamson, "Transaction Cost Economics", in R. Schmalensee and R. Willig, eds., *Handbook of Industrial Organization* 1989, vol. 1, 136 (Amsterdam: North Holland Elsevier)

licensing process. Compulsory licensing here may reduce the danger of such holdup,⁴⁷ and generic producers do cite some examples of lower prices.⁴⁸ However, the bearing of the argument is also compromised by the fact that some generic drugs used in a compulsory cocktail (such as Cipla's Triomune) have not been completely tested or pre-qualified by the World Health Organization.

6. Compulsory Licensing and Economic Incentives

The Doha Agreement went well beyond any properly specified policy target and instrument. The Agreement widely extended the *domain of compulsory licensing to all patented drugs*, and well beyond consideration of complementary drugs used specifically in cocktails to treat AIDS. Subject to appeal process, developing nations under present terms may apparently make unauthorized takings in all drugs, including those *that have*

⁴⁷Indeed, the U.S. Department of Justice recognized the danger of transactional holdup in the advance of new technology when it quickly approved 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)

⁴⁸Generic producers cite some events to substantiate their claim. Apparently, manufacturer Cipla makes a generic d4T/3TC/Nevearpine 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

yet to be invented, with compensation to patent owners based on methodologies *that have yet to be designed*. This global reform is a significant overkill that goes way beyond the immediate treatment of AIDS.

This combination of taking and regulation will weaken or destroy incentives of pharmaceutical researchers to produce new product. A scholarly 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*.”⁴⁹ [emphasis mine] As Prof. Lanjouw recognizes,⁵⁰ *compulsory licensing only functions when there are drugs to license*.

A reasonable means of increasing the incentive for the production and manufacture of needed drugs entails “market making”.⁵¹ That is, centralized procurement agents would

year. Expert Declaration, James Love, para. 22, at <http://lists.essential.org/pipermail/random-bits/2003-February/001022.html> (retrieved September 10, 2003).

⁴⁹Jean 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).

⁵⁰Id., and surrounding text.

⁵¹Mathias 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,

concentrate national demands and solicit bids from would-be competitors,⁵² as is now sometimes done for some vaccines.⁵³ The process of market making may work as follows. Supported by an international fund of donated revenues, a procurement agency may specify design characteristics for use and safety of a specific needed drug. The winning bidder would be the company that comes up with a satisfactory design for a needed 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.

If the offered compensation does not attract enough research within a specified period of time, the “market maker” may appropriately increase prizes.⁵⁴ Second, intermediate payments can also be made to a producer who clears certain hurdles in a specified amount of time’ agencies may negotiate that intermediary rights might be transferable to

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).

⁵²For a detailed discussion, see Kremer, Id.

⁵³McKinsey 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)

a second-source producer once the contracted award is paid. Third, particular drugs may be awarded special patent protection, such as that in the U.S. Orphan Drug Act,⁵⁵ for a longer period.

Programs can be complemented with grants or loans to individual nations that facilitate the purchase of other drugs or *the buildout of health care infrastructure*. As a result, the system could actually be made yet more complementary, and therefore more rewarding, to the research sector. 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.

If market-making can be implemented in specific applications, infrastructure financing might be better facilitated if an additional percent surcharge is established on each implicated drug in an administratively transparent manner. Such a system should be non-distorting; i.e., a percent surcharge would raise each price by an equal percentage and therefore create no price distortion between different treatments. Collected surcharge

⁵⁴Kremer, *supra* note 51.

⁵⁵Designed 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.

amounts for infrastructure funding can be matched equitably by contributions from developed nations.. Outside support for relief efforts can also be collected from direct donations or a dedicated fund of tax credits.

7. Conclusion

This economic discussion regarding appropriate policy-making that involves intellectual property and health care delivery requires pragmatism and non-ideological thinking. At least in their better moments, professional economists do not write or speak in order to assure ideologues otherwise. The policy matter at hand is quite complex, the tradeoffs between conflicting goals are many, and the consequences in human life for bad decisions are somber indeed. A careful balancing is required if we are to put things in order.

ABOUT THE AUTHORS

Bruce A. Lehman (<http://iipi.org/2010/07/iipi-personnel>) advises clients on all aspects of intellectual property law, including prosecution, litigation and policy, both domestically and internationally. He is the chairman of the International Intellectual Property Institute (IIPi), a nonpartisan, nonprofit organization, based in Washington, D.C. The Institute promotes the creation of modern intellectual property systems and the use of intellectual property rights as a mechanism for investment, technology transfer and the creation of wealth in all countries of the world. From January 1999 to May 2004 he also served as the chief executive officer of IIPi.

From August 1993 through December 1998 Mr. Lehman served as assistant secretary of commerce and U.S. commissioner of patents and trademarks. As the Clinton administration's primary representative for intellectual property rights protection, he was a key player on these issues, both domestically and internationally. At the request of the president, he served concurrently in the fall of 1997 as acting chairman of the National Endowment for the Humanities, which fosters and recognizes the work of America's artistic and creative community.

In 1994 *The National Law Journal* named Mr. Lehman its "Lawyer of the Year." In 1997 public-policy magazine *National Journal* named him as one of the 100 most influential men and women in Washington, noting, "In today's Information Age, the issue of intellectual property rights is no longer an arcane concern, but a vital part of U.S. trade policy. Since taking over his current posts in 1993, Lehman has been the Clinton Administration's outspoken voice on such matters here and abroad."

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In the technology sector, Dr. Einhorn worked at Bell Laboratories and the U.S. Department of Justice (Antitrust Division) and consulted to General Electric, AT&T, Argonne Labs, Telcordia, Pacific Gas and Electric, and the Federal Energy Regulatory Commission. He has advised parties and supported litigation in matters involving [patent damages](#) and related valuations in semiconductors, medical technologies, search engines, e-commerce, and proprietary and open source software.

Litigation support involving media economics and [copyright damages](#) has involved [music](#), movies, television, advertising, branding, apparel, architecture, fine arts, video games, and photography. Matters have involved Universal Music, BMG, Sony Music Holdings, Disney Music, NBCUniversal, Paramount Pictures, DreamWorks, Burnett Productions, Rascal Flatts, P. Diddy, Nelly Furtado, Usher, 50 Cent, Madonna, and U2.

Matters involving trademark damages have included the Kardashians/BOLDFACE Licensing, Oprah Winfrey/Harpo Productions, Madonna/Material Girl, CompUSA, Steve Madden Shoes, Kohl's Department Stores, *The New York Observer*, and Avon Cosmetics. Matters in publicity right damages have involved Zooey Deschanel, Arnold Schwarzenegger, Rosa Parks, Diane Keaton, Michelle Pfeiffer, Yogi Berra, Melina Kanakaredes, Woody Allen, and Sandra Bullock.

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