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Speeches

***535** LEGAL STRATEGIES FOR EXPANDING ACCESS TO MEDICINES

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You're not going to get a lot of debate between Leonard and I. [\[FN1\]](#) The Consumer Project on Technology [\[FN2\]](#) and all the groups we work with are deeply committed to the promotion of “the right of everyone to the enjoyment of the highest attainable standard of physical and mental health” that Leonard described. [\[FN3\]](#) Indeed, what I want to talk about is how the Consumer Project on Technology is helping developing countries meet that commitment through legal strategies of legislation and interpretation that promote access to needed medicines. I will draw from some of our work related to the pending case in the South Africa Competition Commission that is considering whether two of the major suppliers of antiretroviral (ARV) medicines used to treat AIDS have abused their dominant market positions ***536** through excessive pricing of their products and refusing to grant patent licenses to lower cost generic producers. [\[FN4\]](#)

This morning we heard the shocking statistics about the toll the AIDS crisis is taking in Africa. [\[FN5\]](#) South Africa has been particularly hard hit by the AIDS epidemic. According to UNAIDS estimates, South Africa has the highest population of people with AIDS of any country in the world. It alone accounts for twelve percent of the world's people living with HIV/AIDS and is the leading cause of death in that country.

The Joint Health and Treasury Task Team charged with examining treatment options in the public sector in South Africa states that there are approximately 4.7 million South Africans infected with the HIV virus and between 400,000 and 500,000 with “clinical AIDS.” [\[FN6\]](#) The estimate of the number with clinical AIDS corresponds to other estimates of the number of people in South Africa with “full blown” or “stage 4” AIDS, meaning that without access to antiretroviral therapy, they will die in twelve to eighteen months. [\[FN7\]](#) The Joint Task Team estimated that 1.2 million ***537** people in South Africa will require ARV treatment by 2010.

AIDS does not affect all segments of the population equally. In South Africa, extensive surveys have shown that those infected with the HIV virus are disproportionately young adults who are poor, female and African.

[FN8] Given the sixty-one percent absolute poverty rate in the African community, the Joint Health and Treasury Task Team appears reasonable in its conclusion that fifty percent of people with AIDS in South Africa “may have inadequate access to food.” [FN9]

We also heard this morning that the majority of AIDS deaths each year, seventy percent of which occur in Africa, over 200,000 a year in South Africa, are avoidable with proper ARV medication. [FN10] Some of the debate in the past was about whether it would work in developing countries, whether there are different strains of AIDS there, and whether ARVs could attack the disease in the same way as in Africa. Those debates are now over. We know from a series of studies by Médecins Sans Frontières (MSF) and others that treatment in Africa and other developing *538 countries can have the same, and even better, success as in the wealthy nations. [FN11]

The problem in South Africa and elsewhere is that people in dire need of medicines that we know will save their lives are not receiving them. [FN12] And there is a raging debate about why this is so.

Perhaps the largest debate that underlies many of the presentations in this conference, and in the larger debate outside this forum, is whether the extension of patents on pharmaceuticals to developing countries is making the access problem worse. [FN13] We've heard several people cite the Attaran-White article that shows that access to medicines is not much better in areas or for specific medicines that lack patent coverage. [FN14] Based on this article, the standard *539 pharmaceutical industry talking point is that patents do not restrain access to medicines--that it is other factors, like ineffective health systems or lack of funding, for which they are not responsible which are to blame. [FN15]

This argument is based on fallacy. No serious contributor to this debate believes that patents are the only barrier to access. The point is that patents are a barrier. If other barriers remain, removing the patent barrier will not miraculously produce access to medicines. There will still be a need for funding for the drugs, for effective health systems, and for wise selection of medicines, to use the factors that Julian Fleet from UNAIDS discussed this morning. [FN16]

The Attaran-White Study is actually useful for showing how patents do block access to needed drugs. When you *540 look at which ARVs are widely patented in developing countries, what you find is that the least expensive medications with the most generic competition are patented, while medicines that are expensive to produce and face little generic competition are rarely patented in Africa, outside of South Africa. Protease inhibitors, for example, are ARVs that have high amounts of active ingredient, making them more expensive to produce, and the presence of patents on these medicines in countries like Brazil and South Africa deters generic entry in the product markets.

The ARV drugs that are widely patented in Africa tend to be those for which demand is highest for reasons of both cost and efficacy. For example, the WHO highly recommends using AZT and 3TC together, branded as Combivir by GalxoSmithKline (GSK), for the first two of a standard “first line” three-drug combination in developing countries. According to the Attaran-White paper, this is the most frequently patented ARV medicine in Africa, covered by patents in thirty-seven African countries. For the third drug in the cocktail, the non-nucleoside reverse transcriptase inhibitor (NNRTI) nevirapine (NVP), branded Viramune by Boehringer Ingelheim (BI), is the cheapest in generic form. According to Attaran-White, that key medicine for poor countries is blocked by patents in twenty-five African countries.

In South Africa, a combination of AZT+3TC+NVP costs over \$2,000 a year at private sector wholesale

prices (about \$750 for public sector). Generic versions can be purchased for \$200-\$400, including in three-drug fixed dose combinations (FDCs) with all the medicines in a single pill. Such a three-drug FDC is not available from the brand companies because they do not cross license their products.

South Africa has a gross domestic product per person of about \$3000 a year and an HIV prevalence rate of about 4.7 million people (about ten percent of the population). The *541 median household income is only about \$1000 a year. It is fair to say that the \$2000 price tag for ARVs in South Africa, and the \$750 public sector price, puts the drugs far out of reach of most people in need. [FN17]

According to the analysis of the pharmaceutical industry, these facts do not demonstrate that their use of their patents pose a barrier to accessing ARVs in South Africa. We disagree.

The reason that South Africans are required to pay \$2000 a year for ARVs that can be purchased for about ten percent of that price is because GSK and BI have refused to issue licenses under their patents at reasonable royalties (Cipla Ltd. offered up to five percent per sale). [FN18] The \$2000 price for an ARV cocktail in South Africa is a classic example of the legal realist proposition that “[t]he market value of a property or of a service is merely a measure of the strength of the bargaining power of the person who owns the one or *542 renders the other, under the particular legal rights with which the law endows him, and the legal restrictions which it places on others.” [FN19] The legal realist solution is to alter the rules that produce this unjust and socially harmful outcome.

This is where our project comes in. CPTech's work in this area is based on the premise that access to needed medicines can be expanded by maximizing competition in the places where people cannot presently afford access because of monopoly pricing.

Economic analysis by the Federal Trade Commission on the drug industry reported that “the negative effect of increased competition on prices continues until at least the fifth, and perhaps even the sixth or seventh firm enters” a market and “the extent to which prices approach competitive levels in a market depends upon, among other things, the potential revenues in the market.” [FN20] Patents can allow the holder to raise local and world prices by limiting the number of competitors in the supply side and by limiting the size of markets competitors can supply in the demand side. [FN21] To counter these effects, legal rules can be put in place to increase competition among the maximum number of suppliers and allow each competitor to compete for the opportunity to supply the maximum number of consumers.

There are some illustrations of the dramatic effect on prices that increased competition can have. In 1996, Brazil *543 started purchasing the raw materials for 3TC to make the medicine itself. If you look between 1998 and 2002, prices for the raw materials dropped steadily over time as Brazil became a steady market of demand. The price of a kilo of active ingredients fell from over \$20,000 to under \$500. Not all at once. Over time. [FN22] Similarly, since 1996, the lowest price for a full cocktail of needed ARVs in developing countries has decreased from over \$12,000 to under \$300 as more suppliers have begun producing the products and a (thus far small) additional number of countries have allowed their purchase.

So how do we come in? What can lawyers do?

One thing we can do is help developing country governments use the right they have under the TRIPS Agreement to issue compulsory licenses for patented medicines. [FN23] The TRIPS Agreement does not limit the grounds countries can select for these licenses. They can use licenses to serve any public purpose, and in-

creasing access to affordable medicines is a public purpose recognized by the World Health Organization, [FN24] the United Nations, [FN25] international human rights law [FN26] and in the *544 authoritative interpretation of the TRIPS Agreement by a WTO Ministerial Committee. [FN27]

Specifically, we propose that developing countries adopt an “access gap theory” for issuing compulsory licenses for needed medicines, including thorough interpretation of general patent and competition law concepts of when a patent holder is abusing its dominant position in the relevant market. [FN28] Under the access gap theory, you create legal triggers or presumptions that a compulsory license should issue for any patented medicine that is needed to address an important public health problem and for which there is lack of access in society at least in part because it is priced significantly higher than would be the case in a competitive market with reasonable royalties paid to the patent holder. Where these factors are present, the burden should be on the patent holder to prove that it has promoted the lowest price possible consistent with receiving due reward for use of its invention; for example, by instituting an open licensing program that issue licenses as of right at reasonable royalties to any potential competitor. [FN29]

*545 It is important to note that the access gap theory recognizes a right of patent holders to reasonable royalty payments. The theory does not force patent holders to forfeit their patents, as was the common remedy for failing to serve a market on reasonable terms in the original Paris Convention. [FN30] Rather, it converts the patent right from a property rule (right to exclude) to a liability rule (right to be paid) in the specific situation where competition is needed to increase access to medicines. [FN31]

There are terrific examples of government interventions converting intellectual property rules into liability rules when necessary to further public interests. For example, in 1917, in the beginning of World War I, the Wright Brothers and a few other companies held patents that prevented broad competition in the production of airplanes needed to fight the war. The response of the U.S. government was to create a manufacturing patent pool with automatic royalties to lower the royalties on each plane and do away with the need for individual negotiations. Royalties started at \$1000 a plane and dropped over time, as the patent holder received adequate compensation, to \$25 a plane. One might add that our side won that war.

*546 We can win the war against AIDS and the debilitating effects of lack of access to needed medicines too. But we need to use the tools at our disposal to do so. These tools include legal tools, and lawyers can help governments use them.

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[FN1]. Leonard Rubenstein, The Evolution of the Right to Health, Speech at The NEXUS Symposium: An Interdisciplinary Forum on the Impact of International Patent & Trade Agreements in the Global Fight against HIV & AIDS (Apr. 3, 2003), in [17 Emory Int'l L. Rev. 525 \(2003\)](#).

[FN2]. Home Page of Consumer Project on Technology, at www.CPTech.org (last visited Sept. 25, 2003).

[FN3]. International Covenant on Economic, Social and Cultural Rights, G.A. Res. 2200 (XXI), U.N. GAOR, 21st Sess., Supp. No. 16, at 49, U.N. Doc A/6316 (1966), 993 U.N.T.S. 3, art. 12(1) [hereinafter ICESCR]

[FN4]. Statement of Complaint in Terms of Section 49B(2)(b) of the Competition Act 89 of 1998, *Tau v. Glaxo-SmithKline South Africa, Ltd.* (South African Competition Comm'n) (filed Sept. 17, 2002), available at <http://www.tac.org.za/Documents/DrugCompaniesCC/HazelTauAndOthersVGlaxoSmithKlineAndOthe> (last visited Sept. 25, 2002).

[FN5]. Julian Fleet, U.N. Approach to Access to Essential AIDS Medications, Speech at The NEXUS Symposium: An Interdisciplinary Forum on the Impact of International Patent & Trade Agreements in the Global Fight against HIV & AIDS (Apr. 3, 2003), in [17 Emory Int'l L. Rev. 451 \(2003\)](#).

[FN6]. Summary Report of the Joint Health and Treasury Task Team Charged with Examining Treatment Options to Supplement Comprehensive Care for HIV/AIDS in the Public Health Sector 5-6 (2003), available at www.gov.za/reports/2003/ttr010803sum.pdf (last visited Sept. 25, 2003) [hereinafter Summary Report]; see also Dep't of Health, S. Afr., National HIV and Syphilis Sero-prevalence Survey in South Africa, Summary Report (2001) (estimating that there are approximately 4.74 million South Africans living with HIV/AIDS), at <http://196.36.153.56/doh/aids/docs/sum-report.html> (last visited Sept. 25, 2003).

[FN7]. See Rob Dorrington et al., HIV/AIDS Profile in the Provinces of South Africa: Indicators for 2002 6 (2002) (estimating that 407,000 people in South Africa are in stage four). Stage four is the final stage of AIDS. In stages one and two, patients test positive for HIV virus but are relatively asymptomatic. In stage three, patients suffer from weight loss and increased episodes of opportunistic infections as the immune system weakens. Many people in stage three are recommended for ARV treatment based. In stage four, HIV infection is considered 'full-blown' AIDS disease. Patients in stage four are frequently bed ridden, have severely diminished immune systems, experience frequent opportunistic infections and are highly likely to die from an AIDS-related complication within one year.

[FN8]. See Nelson Mandela/HSRC Report on HIV/AIDS in South Africa (2002); Dorrington, *supra* note 7, at 4. These surveys show that among youth aged fifteen to twenty-four years, there are approximately four infected young women for every infected young man (21.6% and 5.8%, respectively) and Africans have approximately twice the HIV prevalence rates of Caucasians and Blacks and eight times that of Indians/Asians.

[FN9]. Summary Report, *supra* note 6, at 14.

[FN10]. See generally Centers for Disease Control and Prevention, Dep't of Health & Human Servs., HIV/AIDS Surveillance Report, Dec. 2001, available at <http://www.cdc.gov/hiv/stats/hasr1302.htm> (last visited Sept. 25, 2003); UNAIDS, Report on the Global HIV/AIDS Epidemic 10 (2002), available at http://www.unaids.org/EN/resources/publications/corporate+publications/report+on+the+global+hi_aids+epidemic+200+.asp (last visited Sept. 25, 2003).

[FN11]. See World Health Organization, *Scaling Up Antiretroviral Therapy in Resource-Limited Settings: Guidelines for a Public Health Approach* 24 (2002) (“The reductions in morbidity and mortality resulting from the introduction of [HAART] have been confirmed in all settings in which it has been used, including developing countries, e.g. Brazil, Senegal, Thailand, and Uganda.”) [hereinafter *Scaling Up*], available at http://www.who.int/hiv/pub/prev_care/en/ScalingUp_E.pdf (last visited Sept. 25, 2003).

[FN12]. I do not think there are exact statistics for how many people are taking ARVs in Africa. In his 2003 State of the Union Address, President Bush stated an estimate that 50,000 Africans are receiving ARV therapy. President George W. Bush, *State of the Union Address* (Jan. 28, 2003), available at <http://www.whitehouse.gov/news/releases/2003/01/20030128-19.html> (last visited Sept. 25, 2003). It is widely recognized that over four million people in Africa need ARV treatment or they will die in less than eighteen months.

[FN13]. Recognition of patent rights on pharmaceutical products and processes is required by the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property (TRIPS). See Robert Weissman, *A Long, Strange Trips: The Pharmaceutical Industry Drive to Harmonize Global Intellectual Property Rules, and the Remaining WTO Alternatives Available to Third World Countries*, 17 *U. Pa. J. Int'l Econ. L.* 1069, 1075 (1996). Prior to TRIPS, fifty countries did not provide patent protection for pharmaceutical products, and forty countries did not patent pharmaceutical processes or products. France did not provide patent protection for medicines until 1960, Germany until 1968, Japan until 1976, and Italy, Sweden, and Switzerland until 1978. UNDP, *Human Development Report 2001: Making New Technologies Work for Human Development* 106 (2001) [hereinafter *UNDP Report*], available at <http://hdr.undp.org/reports/global/2001/en/> (last visited Sept. 25, 2003).

[FN14]. Amir Attaran & Lee Gillespie-White, *Do Patents for Antiretroviral Drugs Constrain Access to AIDS Treatment in Africa?*, 286 *JAMA* 1886-1892 (2001). Attaran and Gillespie-White base their study on self-reporting by the pharmaceutical industry and therefore is not the best source of data for determining the actual number of patents in Africa as reflected in country-specific patent records. Cf. MSF, *Drug Patents Under the Spotlight: Sharing Practical Knowledge About Pharmaceutical Patents* passim (2003), available at http://www.accessmedmsf.org/documents/patents_2003.pdf (last visited Sept. 25, 2003).

[FN15]. See Ellen 't Hoen, *TRIPS, Pharmaceutical Patents, and Access to Essential Medicines: A Long Way from Seattle to Doha*, 3 *Chi. J. Int'l L.* 27, 43 (2002) (describing use of the Attaran-White study by pharmaceutical company representatives).

[FN16]. See generally World Trade Organization, Council for Trade-Related Aspects of Intellectual Property Rights, *Technical Cooperation Activities: Information from Other Intergovernmental Organizations*, IP/C/W/305/Add.3 (Sept.25, 2001) (submission by the World Health Organization stating that access to medicines is dependent on multiple factors including: (1) affordable medications, (2) effective health systems, (3) appropriate selection and adequate supplies of medicines and (4) sustainable financing), available at <http://docsonline.wto.org> (last visited Sept. 25, 2003); accord Globalization, *TRIPS and Access to Pharmaceuticals*, WHO Policy Perspectives on Medicines (World Health Organization, Geneva, Switz.), Mar. 2001, at 5, available at http://www.who.int/medicines/library/edm_general/6paggers/PPM03ENG.pdf (last visited Sept. 25, 2003); see also Hoen, *supra* note 15, at 28 (“Many factors contribute to the problem of limited access to essential medicines. Unavailability can be caused by logistical supply and storage problems, substandard drug quality, inappropriate selection of drugs, wasteful prescription and inappropriate use, inadequate production, and prohibitive

prices.”).

[FN17]. At the public sector price, it would cost South Africa 0.8% of its GDP to provide everyone in need with a first line treatment. That is nearly equivalent to the percentage of GDP that South Africa now spends on all medicines through the public and private sector, and much higher than the 0.6% of GDP that Organisation for Economic Co-operation and Development (OECD) countries spent on medicines in 1990, according to the WHO. See Henry Dummett, *An Overview of Supply and Demand in South Africa's Pharmaceutical Industry-- Opportunity or Risk*, Bus. Briefing: Pharmatech, 2002, at 49-54, available at <http://www.bbriefings.com/businessbriefing/pdf/pharmatech2002/book/dummett.pdf> (last visited Sept. 25, 2003); Sarah Bennett et al., *Public-Private Roles in the Pharmaceutical Sector: Implications for Equitable Access and Rational Drug Use* 32 (1997), available at <http://www.who.int/medicines/library/dap/who-dap-97-12/who-dap-97-12.htm> (last visited Sept. 25, 2003).

[FN18]. Analysis by James Love at the Consumer Project on Technology, recently submitted to the South African Competition Commission, has demonstrated that a royalty rate of between two to eight percent of annual sales is a reasonable compensation term for foreign production of a patented pharmaceutical product, and that royalties of approximately five percent are average for the industry. See Statement of Information, Consumer Project on Technology, Statement of Complaint in Terms of Section 49B(2)(b) of the Competition Act 89 of 1998, *Tau v. GlaxoSmithKline South Africa, Ltd.*, at 17,40-41 (South African Competition Comm'n) [hereinafter CP Tech Statement of Information], available at www.cptech.org/ip/health/cl/cl-cases/rsa-tac/cptech-statement.doc (last visited Sept. 25, 2002).

[FN19]. Robert Hale, quoted in Duncan Kennedy, *The Stakes of Law, or Hale and Foucault!* 15 *Legal Studies Forum* 327, 328 (1991).

[FN20]. David Reiffen & Michael R. Ward, *Federal Trade Commission, No. 248, Generic Drug Industry Dynamics* 35-36 (2002), available at <http://www.ftc.gov/be/econwork.htm> (last visited Sept. 25, 2003).

[FN21]. Cf. F.M. Scherer & Jayashree Watal, *Commission on Macroeconomics & Health, Paper No. WG4:1, Post Trips Options for Access to Patented Medicines in Developing Countries* 11 (2001), available at www.cmhealth.org/docs/wg4_paper1.pdf (reporting on studies finding mean price increase of over 200% with introduction of product patents).

[FN22]. Analysis by James Love, Consumer Project on Technology.

[FN23]. A compulsory license is a government authorization to use the patent without the permission of the patent holder, authorized by Article 31 of the Agreement on the Trade-Related Aspects of Intellectual Property. *Agreement on Trade-Related Aspects of Intellectual Property Rights*, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, *Legal Instruments--Results of the Uruguay Round* vol. 31, 33 *I.L.M.* 81, art. 31 (1994), available at http://www.wto.org/english/docs_e/legal_e/27-trips.pdf (last visited Sept. 25, 2003).

[FN24]. Germán Velásquez & Pascale Boulet, *Globalization and Access to Drugs: Implications of the WTO/TRIPS Agreement* 9-15 (1999 ed.), available at <http://www.who.int/medicines/library/dap/who-dap-98-9-rev/who-dap-98-9-rev.pdf> (last visited Sept. 25, 2003).

[FN25]. See Declaration of Commitment on HIV/AIDS, U.N. GAOR, 26th Special Sess., Agenda Item 8, at

para. 15, U.N. Doc. A/RES/S-26/2 (2001); UNDP Report, *supra* note 13, at 8; U.N. ESCOR, 27th Sess., Agenda Item 3, at para. 15, U.N. Doc. E/C.12/2001/15 (2001).

[FN26]. See U.N. ESCOR, 22d Sess., Agenda Item 3, at para. 15, U.N. Doc. E/C.12/2000/4, CESCR (2000).

[FN27]. See Declaration on the TRIPS Agreement and Public Health, Nov. 14, 2001, 4th Session, Doha Ministerial Conference, WT/MIN(01)EC/2 (recognizing that TRIPS “can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all” and stating: “Each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted”).[hereinafter Doha Declaration], available at http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.pdf (last visited Sept. 25, 2003).

[FN28]. See CP Tech Statement of Information, *supra* note 18.

[FN29]. Section 41(4) of Canada's 1969 Patent Act, in place until 1992, created a presumptive right to a compulsory license for any pharmaceutical product and instructed that “in settling the terms of the licence and fixing the amount of royalty or other consideration payable, the Commissioner shall have regard to the desirability of making the medicine available to the public at the lowest possible price consistent with giving to the patentee due reward for the research leading to the invention and for such other factors as may be prescribed.” Jerome H. Reichman & Catherine Hasenzahl, *Non-Voluntary Licensing of Patented Inventions: The Canadian Experience* 34 n.236 (UNCTAD/ICTSD Project on Intellectual Prop. Rights & Sustainable Development, 2002), available at <http://www.iprsonline.org/unctadicstd/projectoutputs.htm> (last visited Sept. 25, 2003); see also Section 41 of the UK Patent Act of 1949 (creating a rebuttable presumption in favor of compulsory licensing to ensure that food, medicine and surgical devices were available to the public at the lowest prices consistent with the patentees' deriving reasonable advantage from their patent rights).

[FN30]. See Jerome H. Reichman & Catherine Hasenzahl, *Non-Voluntary Licensing of Patented Inventions: Historical Perspective, Legal Framework under TRIPS, and an Overview of the Practice in Canada and the USA* 4-6 (UNCTAD/ICTSD Project on Intellectual Property & Sustainable Development, Issue Paper No. 5, 2002) (describing global shift in policy and practice from using forfeiture to compulsory licensing to remedy failure to work and other abuses of patent rights), available at <http://www.iprsonline.org/unctadicstd/projectoutputs.htm> (last visited Sept. 25, 2003).

[FN31]. Cf. Robert P. Merges, *Contracting into Liability Rules: Intellectual Property Rights and Collective Rights Organizations*, 84 Cal. L. Rev. 1293 passim (1996); J. H. Reichman, *Of Green Tulips and Legal Kudzu: Repackaging Rights in Subpatentable Innovation*, 53 Vand. L. Rev. 1743 passim (2000); Guido Calabresi & A. Douglas Melamed, *Property Rules, Liability Rules, and Inalienability: One View of the Cathedral*, 85 Harv. L. Rev. 1089, 1092 (1972).

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