

Health, Human Rights and the Pharmaceutical Industry by Gerald Montgomery

PARAGRAPH 6 OF THE DOHA DECLARATION ON THE TRIPS AGREEMENT
AND PUBLIC HEALTH, World Trade Organization, 2 September, 2003:

We are committed to helping countries that are experiencing public health crises. We want to find a real solution to problems that prevent Members from being able to address health problems associated with access to pharmaceuticals. We want all Members to be able to use the full flexibility of the TRIPS Agreement to help provide their citizens access to affordable medicines in times of crises.

We note that the Doha TRIPS declaration recognizes that the exclusive rights provided by patents are an important incentive to development of new drugs. Patents provide market incentives for innovators to risk time, energy and resources to develop and bring to market new technology. A system of patent rights and enforcement of those rights for pharmaceuticals provides numerous benefits to society; the availability of exclusive patent rights for pharmaceutical products spurs research and development of new medicines, including those resulting from biotechnology, to treat and cure diseases

The pharmaceutical industry is a crucial touchstone in the discussion of corporate responsibility to promote human rights. This relationship is, however, problematic at best and, at worst work in opposition to each other. At the same time that drug producers are instrumental in promoting a basic level of human welfare, the outlook of major pharmaceutical corporations are mitigated by unfiltered lenses of profit. With hundreds of millions of dollars spent on research and development, patenting, and marketing, they understandably develop strategies for handling reoccurring costs. But should a morally responsible international community redirect these costs to the developing world or ask consumers in the global North to endure “artificially high” prices to offset gross inequalities? Alternatively, is there means to set reasonable prices based on the economic reality of each country?

The broad overriding theme of the selection of texts below will be that TRIPS (Trade-Related Aspects of Intellectual Property Rights) has greatly affected the supply of drugs to the Third World. This is because, among other things, TRIPS is based on the idea that artists, entrepreneurs and inventors have a legal right to protect profits derived from their ideas. An important practical implication of this belief is that it forces competitors to adhere to strict manufacturing guidelines, greatly affecting global drug supply. TRIPS, then, is a legal framework that creates standards that protects these works.

However in the Uruguay round of talks, TRIPS was seen as disproportionately bolstering the legal rights of Northern countries. Characteristic of this, in the Uruguay round of talks Southern states argued that TRIPS promotes the interests of drug manufacturing Northern countries. In an effort to mediate these inequalities other international organizations such as the World Health Organization recommend policies that ensure the availability of drugs at affordable prices in documents like the Doha Declaration. Reflecting the political tenor and policy consequences of these debates, this bibliography organizes itself according to the following categories: pharmaceutical patent issues, company relations with developing countries, research, country cases, TRIPS, general, and laws, initiative, and policy.

Basic Resources

Chien, Colleen. 2003. "Cheap Drugs at What Price to Innovation: does the compulsory licensing of pharmaceuticals hurt innovation?." *Berkeley Technology Law Journal* 18(3): 853-903
<http://papers.ssrn.com/sol3/papers.cfm?abstract_id=486723.>

Abstract: The patent system is built on the premise that patents provide an incentive for innovation by offering a limited monopoly to patentees. The inverse assumption that removing patent protection will hurt innovation has largely prevented the widespread use of compulsory licensing—the practice of allowing third parties to use patented inventions without patentee permission.... The author comments on the use of compulsory licensing to reduce the price of AIDS and other drugs for developing countries. I suggest that, based on past experience, compulsory licenses need not result in a decline in innovation and that this policy option for increasing access to medicines deserves greater exploration.

De Silva, Allenson. 2002. Pharmaceutical Drugs & Health: a Critique. Colombo, Sri Lanka: Centre for Society & Religion.

Granville, Brigitte. 2002. *The Economics of Essential Medicines*. Washington, DC : Royal Institute of International Affairs; distributed worldwide by the Brookings Institution.

Leufkens H.G.M.; F.M. Haaijer-Ruskamp; and A. Bakker. 1995. The Future of Medicines in Health Care: Scenario Report (Commissioned by the Steering Committee on Future Health Scenarios; Scenario Committee on Medicine in Health Care; WHO Collaborating Center for Drugs Policy Studies). Boston: Kluwer Academic Publishers.

McGregor, Alan. 1997. "Counterfeit Drugs Flood Developing World." *Lancet* 350(909): 1690-1694.

Pérez-Casas, Carmen and Emilia Herranz. 2001. "Pricing of Drugs and Donations: options for sustainable equity pricing." *Tropical Medicine & International Health* 6(11): 960-965.

Abstract: Effective medicines exist to treat or alleviate many diseases which predominate in the developing world and cause high mortality and morbidity rates. Price should not be an obstacle preventing access to these medicines. Increasingly, drug donations are required of drug companies, but these are often limited in time, place or use. Measures exist which are more sustainable and will have a greater positive impact on people's health. Principally, these are encouraging generic competition; adopting into national legislation and implementing TRIPS safeguards to gain access to cheaper sources of drugs; differential pricing; creating high volume or high demand through global and regional procurement; and supporting the production of quality generic drugs by developing countries through voluntary licenses if needed, and facilitating technology transfer.

Ratanawijitrasin, Sauwakon; Stephen B. Soumerai; and Krisantha Weerasuriya. 2001. "Do National Medicinal Drug Policies and Essential Drug Programs Improve Drug Use?" *Social Science & Medicine* 53(7): 831-844.

Abstract: Conducts a critical review and synthesis of international literature in an attempt to define the state of knowledge regarding drug policy effects on drug use. Tests whether the development of national policies and regulations by the governments of developing countries increase the affordability, supply safety and rational use of pharmaceuticals.

Stokes, Bruce. 2003. "It's All About the Medicine." *National Journal* 35(29): 2368-2370.

This article presents an effort to dispel myths about the problems developing countries have in accessing low cost drugs. In doing so the article describes why the U.S. is deadlocked with the international community on important parts of the agenda of the upcoming Doha round of talks.

Weissman R. 1999. "AIDS Drugs for Africa." *Multinational Monitor* 20(September): 9-14.

Documents the course of the dispute between the U.S. government and the South African government over providing affordable drugs to the poor. Interestingly, the article argues that South Africa and many other African nations are rendered politically and domestically unstable from high AIDS coupled with unaffordable drug therapies. The conclusion is that the laws and practices of major drug exporting countries such as the U.S. are used by pharmaceutical companies to profit at the expense of developing countries and their populations.

Winestock, Geoff and Helene Cooper. 2001. "Activists Outmaneuver Drug Makers at WTO." *Wall Street Journal - Eastern Edition* (November 14): A2.

World Health Organization. 1999. *Marketing Authorization of Pharmaceutical Products With Special Reference to Multisource (Generic) Products: a Manual for a Drug Regulatory Authority*. Geneva: World Health Organization.

Company Relations With Developing Countries

"Drug Makers Hope to Profit From WTO Decision on Medications." 2003. *Health & Medicine Week* (October 27): 331-334.

Abstract: Reports on the efforts of the Brazil-based drug maker Cristalia Acquisition Corp. to try to profit from the World Trade Organization's agreement allowing impoverished nations to import copied patented medicines to fight killer diseases. Benefits of the agreement for the company; Background of Cristalia; Criticism over the ability of Brazil to produce enough generic drugs for countries that need them.

Global Partnerships: Humanitarian Programs of the Pharmaceutical Industry in Developing Nations. 2003. Washington, D.C.: Pharmaceutical Research and Manufacturers of America. <<http://world.phrma.org/global.partnership.2003.pdf>.>

"Pharmaceutical Company Honored With First Ever Pro Bono Partner Award." 2003. *Biotech Week*: 14.

This article highlights the growing number of U.S. pharmaceutical companies that perform pro bono work fusing the talents of public and private enterprises. Reports on the presentation of CorporateProBono.Org's (CPBO) Pro Bono Partner Award to Abbott Laboratories (ABT) Inc. recognizing its work with Baker and McKenzie and the Midwest Immigrant and Human Rights Center to provide legal counseling to immigrants and career counseling to high school students.

“Pilot Program Launched to Expand Access to Medicines in Poorest Countries.” 2003. *AIDS Weekly* (February 17): 16-18.

Reports on the launch of a pilot program for expanding access to needed medicines for AIDS-infected people in developing countries by Pharmacia Corp. Also highlights the partnership of the company with International Dispensary Association Foundation to grant non-exclusive licenses to generic pharmaceutical companies for AIDS drug Delavirdine.

“Progress Reported in Cutting AIDS Drug Prices for Poor Nations.” 2003. *AIDS Weekly* (February 17): 35-37.

Reports on the progress made by global business leaders in making cheaper AIDS drugs available in developing countries. Information covered includes a grant announcement by founder of Microsoft Corp. Bill Gates, for funding such medical researches in developing countries; concerns of the U.S. pharmaceutical companies over the protection of drug patents in these nations; reason why charitable institutions have to work really hard in developing countries.

Agrawal, Madhu. 1999. *Global Competitiveness in the Pharmaceutical Industry: the Effect of National Regulatory, Economic, and Market Factors*. New York: Haworth Press.

Bale, Harvey E. “Are International Pharmaceutical Companies Doing Enough to Provide Low-Cost AIDS Drugs to Developing Countries?” *International Debates* 1(4): 108-113.

Presents the author’s views in favor of international pharmaceutical companies’ steps in providing low-cost AIDS drugs in developing countries. Role of pharmaceutical company in developing effective drugs to prevent the disease; Pricing policy followed by pharmaceutical company while subsidizing drugs for AIDS.

Brugha, Ruairi. 2003. “Antiretroviral Treatment in Developing Countries: the Peril of Neglecting Private Providers.” *British Medical Journal*, International Edition 326(7403): 1382.

Abstract: Increased access to antiretroviral drugs is vital to maintain developing countries with high rates of HIV infection. But unless treatment is properly controlled, these drugs could rapidly become useless.

Note: The increasing problem of delivering antiretroviral drugs being handed out in poorer countries is the increased likelihood of the indiscriminate use could lead leading to increased to resistance if drug resistance if the supply and usage s are not regulated. The article includes several case studies from Africa (Uganda and Senegal) and identifies methods (such as working with the private sector) to alleviate this problem.

Carpenter, Dave. 2003. “Do-Good Pharmas?” *Hospitals & Health Networks* 77(10): 48-51.

Provides a discussion of Pfizer as an example of how a company can bridge the gap between profit margins and social responsibility in providing access to health care in developing countries.

Cohen, Jillian Clare. 2001. *Pharmaceutical Napsters?: a Comparative Study of State Response to the Pharmaceutical Imperatives on the agreement on Trade-Related Aspects of Intellectual Property Rights*. Ann Arbor, MI: University of Michigan Press.

Dugger, Celia W. 2001. "A Catch-22 on Drugs for the World's Poor; The Right to make generics, but not the means to do it." *New York Times* (November 16): W1.

A discussion of the inability of poor countries to manufacture low cost drugs, but do not have the means to do so and are not allowed to import them from countries that do so.

Fleck, Fiona. 2003. "No Deal in Sight on Cheap Drugs for Poor Countries." *British Medical Journal; International Edition* 326(7387): 465.

Notes: This article describes trade negotiations held for the purpose of hammering out an agreement on the importation or creation of cheap drugs for the developing world. The United States' blocked agreements to allow third world countries the right to produce low cost drugs because of concern over patent and intellectual property issues.

Ford, Nathan. 2003. "Public Health and Company Wealth: When Public Protest at the Price of AIDS Drugs Reached a Peak, Pharmaceutical Companies Seemed to Take Note, but the Developing World's Health Problems Will Never Really Be Tackled As Long As Remedies for Western Afflictions Remain More Profitable." *British Medical Journal; International Edition* 326(7402): 1296.

This editorial reviews the availability and pricing of drugs in third world countries with those of the developed world. Argues that countries are responsible for ensuring health care and companies supplying drugs need to do take a more responsible role as a partner in the fight against massive epidemics such as aids.

Goodman, Sally. 2003. "Poor Nations Push for Right to Produce Cheap Medicines." *Nature* 411(6841): 982-986.

Reports that developing countries have requested the modification of the global trading rules on the distribution of medicines at the June 20, 2001 meeting of the World Trade Organization in Geneva, Switzerland. Also covers the aim of trade-related aspects of intellectual property rights; reaction of the United States delegates to the request.

Knodro, Wayne. 2003. "Canada Delays Legislation on Cheap Drugs." *Lancet* 362(9397): 1729.

Abstract: This article focuses on how developing countries hoping to obtain cheap drugs from Canada to treat AIDS, tuberculosis, malaria, and other diseases will have to wait longer than expected for access to cheap drugs as internal debates have indefinitely delayed passage of the necessary legislation. Although the governing Liberal party tabled legislation on cheap drugs for poor countries on Nov 6—weeks later than promised—it promptly prorogued Parliament, dispatching the bill to death on the order paper, where it will have to be revived by the Prime Minister-in-waiting—Paul Martin—after he assumes office.

Mattias Ganslandt; Keith E. Maskus; and Eina V. Wong. 2001. *Developing and Distributing Essential Medicines to Poor Countries: the DEFEND Proposal*. Stockholm, Sweden: IUI, the Research Institute of Industrial Economics <<http://www.iui.se/wp/wp552/iuiwp552.pdf>>.

Mytelka, Lynn Krieger. 1999. Competition, Innovation and Competitiveness in Developing Countries. Paris: Development Centre, Organisation for Economic Co-operation and Development.

Nullis, Clare. "Agreement on Access to Cheap Medicines Remains Elusive." 2002. *Associated Press* Dec. 12.

Silversides, Ann. 2003. "No Turning Back on Cheap AIDS Drugs for Poor Nations, U.N. Vows." *CMAJ: Canadian Medical Association Journal* 169(10): 1067.

Canada is trying to take the lead in changing drug patents for the purpose of exporting cheaper drugs to developing countries with the hope that other wealthy countries will follow suit.

Thurow, Roger and Scott Miller. 2003. "Empty Shelves: As U.S. Balks on Medicine Deal, African Patients Feel the Pain --- Big Drug Makers, Protecting Their Patents, Seek Limits To a Global Trade Accord --- Searching for Insulin in Chad." *Wall Street Journal - Eastern Edition* (June 2): A1.

Vastag, Brian. 2003. "Alarm Sounded on Fake, Tainted Drugs: Some Wholesalers Are a Weak Link in a Dangerous Chain." *Journal of the American Medical Association* 290(8): 1015-1017.

Weissman, Robert. 1999. "AIDS Drugs for Africa." *Multinational Monitor* 20(9): 9-14.

Documents the course of the dispute between the U.S. government and the South African government over providing affordable drugs to the poor. Interestingly, the article argues that South Africa and many other African nations are rendered politically and domestically unstable from high AIDS coupled with unaffordable drug therapies. The conclusion is that the laws and practices of major drug exporting countries such as the U.S. are used by pharmaceutical companies to profit at the expense of developing countries and their populations.

Country Cases

NA. 2004. "HIV Treatment As a Human Right - Learning From Thailand's Experience." *Biotech Week* (March 3): 157.

Abstract: A new paper discusses the landmark legal case in Thailand where two people with HIV infections successfully challenged a multinational pharmaceutical company for restricting access to a key antiretroviral drug due to its high cost. Nathan Ford and colleagues from the organization Medecins Sans Frontieres, authors of the viewpoint article which appeared in the journal "Lancet" discussed the processes behind this case and the implications for drug access as a human rights issue in other developing countries.

Acharya, Rohini. *The Emergence and Growth of Biotechnology Experiences in Industrialized and Developing Countries*. Cheltenham, UK; Northampton, Mass. E. Elgar, 1999.

Chaudhuri, Shubham; Pinelopi Koujianou Goldberg; and Panle Jia. 2003. *The Effects of Extending Intellectual Property Rights Protection to Developing Countries: a Case Study of the Indian Pharmaceutical Market*. Cambridge, MA: National Bureau of Economic Research.

Patel, Vikram; and Chittaranjan Andrade. 2003. "Pharmacological Treatment of Severe Psychiatric Disorders in the Developing World: Lessons From India." *CNS Drugs* 17(15): 1071-1081.

Discusses the various cultural, biological, and availability issues pertaining to drug treatment in areas of the world that do not have high incidences of mental disorders. Also comments on the costs and treatment options in different regions of the world.

Thomas, L. G., III. 2001. *The Japanese Pharmaceutical Industry: the New Drug Lag and the Failure of Industrial Policy*. Northampton, MA: Edward Elgar.

Laws, Initiative, Policy

"New WTO's Policy to Protect Public Health Interests for Developing Countries." 2003. *Asia-Pacific Biotech News* 7(22): 1452.

"WTO Panel Delays Decision on Cheap Drugs for Poor Countries." 2003. *Drug Week* (September 26): 157-158.

Reports on the decision of the World Trade Organization (WTO) to delay a measure which will give poor nations access to inexpensive generic drugs. Addresses the impact of the move on poor nations; provides an overview of WTO rules regarding drug importation; and raises concerns of U.S. pharmaceutical industries over drug smuggling.

Jacobzone, Stephane. 2000. Pharmaceutical Policies in OECD Countries: Reconciling Social and Industrial Goals. Paris, France: Organisation for Economic Co-operation and Development.

Kapp, Clare. 2003. "World Trade Organisation Reaches Agreement on Generic Medicines: New Deal Will Make It Easier for Poorer Countries to Import Cut-Price Generic Drugs Made Under Compulsory Licensing." *Lancet* 362(9386): 807.

Reports on an agreement within the World Trade Organization (WTO) which allows developing countries stricken with HIV/AIDS, tuberculosis, and malaria to import cheap generic drugs. The centerpiece of the agreement which concerned the waiver of the normal rule that production of cheap generic drugs without the consent of the patent holder--compulsory licensing--must be primarily for the domestic market; Resolution of the issue which ended a long stalemate; Reactions from representatives of Africa, Brazil and other countries.

Loff, Bebe. 2002. "World Trade Organization Wrestles With Access to Cheap Drugs Solution." *Lancet* 360(9346): 1670.

Reports on the World Trade Organization (WTO) meeting in Sydney, Australia to resolve how poor nations can access cheap drugs. Meeting focusing on the agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) governing domestic patent law and how it influences access to pharmaceuticals; how the WTO softened TRIPS stating that in cases of epidemics it is permissible for governments to grant a compulsory license to manufacture drugs still under patent.

Moran, Alan. 2003. "Trade Laws and Pharmaceuticals." *IPA Review* 53(4): 25-28.

Abstract: Focuses on trade aspects of intellectual property rights and provides a history of property rights. Also addresses manufacturing and administrative costs for a vaccine as well as features of modern commerce and law that prevent goods from being supplied more cheaply to developing countries.

Moran, Mary and Nathan Ford. 2003. "The G8 and Access to Medicines: No More Broken Promises." *Lancet* 361(9369): 1578.

Provides a detailed timeline of the previous conferences held by the G8 and their focus on the affordable drugs to developing countries while looking forward to the upcoming G8 conference in France.

Oxfam GB. 2001. *Cut the Cost: Patent Injustice: How World Trade Rules Threaten the Health of Poor People*. Oxford: Oxfam.

http://www.oxfam.org.uk/what_we_do/issues/health/downloads/patentinjustice.pdf

Pfizer Inc. 2003. "Bringing Treatments, Developing Cures." *The Pfizer Journal: Perspectives on Health Care and Biomedical Research*. New York: Impact Communications.

Pollock, Allyson M. and David Price. 2003. "New Deal From the World Trade Organization May Not Provide Essential Medicines for Poor Countries." *British Medical Journal; International Edition* 327 (7415): 571-573.

Winestock, Geoff; and Helene Cooper. 2001. "Activists Outmaneuver Drug Makers at WTO." *Wall Street Journal - Eastern Edition* 238(96): A2.

World Health Organization. 1999. Marketing Authorization of Pharmaceutical Products With Special Reference to Multisource (Generic) Products: a Manual for a Drug Regulatory Authority. Geneva: World Health Organization. <<http://www.who.int/medicines/library/qsm/manual-on-marketing/multisource-contents.html>>.

Pharmaceutical Patent Issues

"Institute for Oneworld Health Licenses Potent Therapy." 2003. *Drug Week* (August 1).

This article reports that the pharmaceutical company Oneworld Health has licensed a novel class of high-potency chemical compounds that may result in medicines for developing countries.

"Patents and HIV/AIDS Drugs." *International Debates* 1(4): 104.

Abstract: Presents information about patent rights of manufacturing drugs to prevent HIV infection and AIDS disease. Gives criteria of granting patent to a particular pharmaceutical company; factors determining the access to essential drugs including drugs to treat HIV and other infections; and risk of HIV infection and AIDS in developing countries.

Correa, Carlos María. 2000. Integrating Public Health Concerns into Patent Legislation in Developing Countries. Geneva: South Centre.

Cullet, Phillipe. 2003. "Patents and Medicines: the Relationship Between TRIPS and the Human Right to Health." *International Affairs* 79(1): 139-60.

Interrogates the dilemma of the human right to health versus the idea of intellectual property rights defined in TRIPS. It addresses the problem of how patents stand in the way of access to drugs and gives solutions on what can be done to alleviate the disparity.

Cunningham, Ralph. 2003. "Health Crises Undermine Patent Rules." *Managing Intellectual Property* 130: 43-50.

Abstract: Global patent issue -- ability of sick in developing countries to obtain patented medicines -- rights under threat -- any relaxing of rules by WTO or TRIPs could result in fewer patents -- new legislation in Asian countries -- new court takes over -- legislative tweaking -- effect of new laws in Pakistan unknown -- PCT possibilities.

Vass, Alex. "WTO Relaxes Rule on Drug Patents." *British Medical Journal International Edition* 323(7322):1146.

Abstract: International trade rules amount to institutional fraud and are preventing development in poor countries, says a report published this week by a leading charity. Whereas trade has been one of the most powerful driving forces in increasing prosperity for much of the world, millions of the world's poor are being left behind, and there is a widening of inequalities between the rich and poor. International trade rules, says the Oxfam report, are "rigged in favour of the rich." When developing countries export to rich country markets, they face tariff barriers that are four times higher than those faced by rich countries. These barriers cost them \$100bn (£70bn; 113bn) a year, twice as much as they receive in aid. The report calls for an end to the universal application of the intellectual property blueprint, and argues for the right of developing countries to retain shorter and more flexible systems of patent protection.

Drug Research

"Phase II Trial With PRO 2000 to Prevent HIV Transmission Begins in Africa." 2003. *Biotech Week* (July 16): 7.

Abstract: Indevus Pharmaceuticals, Inc., (IDEV) announced the initiation of a phase II clinical trial in Africa assessing the safety of PRO 2000, a topically administered, vaginal microbicide designed to prevent infection by the human immunodeficiency virus (HIV) that causes AIDS. This trial will provide safety data for PRO 2000 in a sexually active, developing country population, and PRO 2000 may be investigated in such African populations in expanded phase III testing in the future," said Dr. Bobby Sandage, executive vice president, research and development at Indevus. Findings will build upon the growing clinical database for the drug.

"Study: Generic Drugs Helping AIDS Fight." 2003. *Health & Medicine Week* (October 13): 627-628.

Presents a report released by Doctors Without Borders on the use of generic drugs to treat AIDS patients in developing countries. Citation of competition between generic and branded

retroviral drugs; failure of most countries in meeting the goal of fighting and reversing the epidemics; problem of discrimination of HIV-positive persons.

Bourinbaiar, Aldar S. and Vichai Jirathitikal. 2003. "Low-Cost Anti-HIV Compounds: Potential Application for AIDS Therapy in Developing Countries." *Current Pharmaceutical Design* 9(18): 1419-1432.

Abstract: Considerable progress has been made in recent years in the field of drug development against HIV. However, the current cost of AIDS drugs is the main obstacle preventing their use in developing countries, where 95% of HIV infected patients reside. The average yearly price of AIDS therapy and related health care of affected patients in the USA runs as high as \$22,000...Even in the USA, patients without medical insurance cannot afford the costly therapy. ...This review summarizes the development and discovery of affordable and potentially promising AIDS drugs.

Kettler, Hannah and Adrian Towse. 2002. *Public Private Partnerships for Research and Development: Medicines and Vaccines for Diseases of Poverty*. London: OHE.

Lang, Trudie and Brian Greenwood. 2003. "The Development of Lapdap, an Affordable New Treatment for Malaria." *Lancet Infectious Diseases* 3(3): 162-168.

Abstract: There is much discussion on how new drugs can be developed for use in developing countries at a price that makes them accessible to those who need them most... The partnership comprised between GlaxoSmithKline (formerly SmithKline Beecham), the World Health Organization (WHO), and the UK's Department for International Development.

TRIPS

Abbott, Frederick M. 2002. *WTO TRIPS Agreement and Its Implications for Access to Medicines in Developing Countries*. London: Commission on Intellectual Property Rights. <http://www.iprcommission.org/papers/pdfs/study_papers/sp2a_abbott_study.pdf>.

Bale, H.E. 2000. *TRIPS, Pharmaceuticals, and Developing Countries: Implications for Drug Access and Drug Development*. Geneva, Switzerland: International Federation of Pharmaceutical Manufacturers Association.

Cullet, Phillipe. 2003. "Patents and Medicines: the Relationship Between TRIPS and the Human Right to Health." *International Affairs* 79(1): 139-60.

Abstract: Interrogates the dilemma of the human right to health versus the idea of intellectual property rights defined in TRIPS. It addresses the problem of how patents stand in the way of access to drugs and gives solutions on what can be done to alleviate the disparity. Access to drugs in developing countries is at present largely influenced by the TRIPS Agreement. TRIPS compliance in the field of health requires substantial changes to existing patent laws in some countries. These changes must be analyzed in the context of the spread of epidemics like HIV/AIDS and in relation to other international obligations that states have, for instance, with regard to the human right to health. Intellectual property rights treaties today have significant impacts on the realization of some human rights like the right to health. Also examined are these issues from the point of view of human rights

considering, in particular, the ways in which the relationship between human rights and intellectual property can be improved in international law.

Lanoszka, Anna. 2003. "The Global Politics of Intellectual Property Rights and Pharmaceutical Drug Policies in Developing Countries." *International Political Science Review* 24: 181-198.

Abstract: One of the major characteristics of the emerging international economic order is the treatment of intellectual property rights (IPRS). Developing country members are very concerned about the impact that the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) will have on their economies. TRIPS emphasizes a property rights approach whereby private "owners" of the inventions can restrict access on the basis of commercial considerations. As a consequence, higher prices for pharmaceuticals and other healthcare inventions can prevent low-income consumers in developing countries from obtaining life-saving medications and equipment. Many developing countries, however, lack the necessary financial resources and have not yet developed appropriate competition rules to deal effectively with the challenges presented by the TRIPS Agreement.

Lybecker, Kristina Marie. 2000. *Counterfeit Pharmaceuticals: Product Piracy and the Transition to Stronger Intellectual Property*. <<http://www.lebow.drexel.edu/lybecker/piracy.doc>>.

Macklin, Ruth. 2003. "Bioethics, Vulnerability, and Protection." *Bioethics* 17(5-6): 472-487.

Abstract: ...Vulnerable individuals and groups are subject to exploitation, and exploitation is morally wrong. Multinational research invests in situations in which vulnerable people can be exploited even if they are not harmed, and harmed even if they are not exploited. The types of multinational research likely to raise the most ethical concerns are those in which the investigators or sponsors are from a powerful industrialized country or a giant pharmaceutical company and the research is conducted in a developing country. In such a scenario, women are particularly vulnerable. ...On the positive side, recent developments reveal a new awareness of exploitation and efforts to enhance the ability of developing countries to protect themselves and their citizens from exploitation at the hands of powerful sponsors of research. In addition, human rights principles are increasingly being used to monitor the actions (or inaction) of governments regarding women's reproductive rights and vulnerability with respect to HIV/AIDS, and to take remedial actions.

Scherer, Frederic M.; and Watal Jayashree. 2001. *Post-Trips Options for Access to Patented Medicines in Developing Countries*. CMH Working Paper Series. Commission on Macroeconomics and Health. http://www.cmhealth.org/docs/wg4_paper1.pdf.

Subramanian, Arvind. 1995. "Putting Some Numbers on the TRIPS Pharmaceutical Debate." *International Journal of Technology Management* 10(2/3): 252-269.

Abstract: Estimates the changes in prices, profits and social welfare arising from increased patent protection for pharmaceuticals in a number of developing countries

Sykes, A. O. 2002. *TRIPS, pharmaceuticals, developing countries, and the Doha 'solution'*. <http://papers.ssrn.com/paper.taf?abstract%5Fid=300834>.

Abstract: The WTO ministerial meeting in Doha produced a declaration that will encourage developing nations to use compulsory licensing and parallel importation to reduce the prices of patented pharmaceuticals in their markets. Developing nations have long had little intellectual property protection for pharmaceuticals, which may have resulted at least in part from an acute collective action problem—developing nations reap the full benefits from lower prices when they do not create pharmaceutical patents, yet the costs in terms of diminished research

incentives are largely externalized to the rest of the developing world. The WTO TRIPS agreement held out some promise of overcoming part of this problem, but just as the obligations of developing nations under TRIPS were beginning to take hold, the Doha ministerial declaration casts great doubt on the future credibility of patent rights for pharmaceuticals in the developing nations.