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Patents and Health

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Background

A patent is a property right granted by a sovereign state to the inventor of a novel, non-obvious and useful invention. Because the invention must be novel (meaning that it has not been previously disclosed anywhere in the world) and because it cannot be obvious to one ordinarily skilled in the art, the grant of the property right cannot interfere with the public's access to what already exists.

The benefit of granting an inventor the exclusive property right of a patent for the limited period of 20 years[1] is that he or she is given a powerful incentive to create and for investors to commit the financial resources necessary to support the inventor's research and to develop it to the point where it can be manufactured and made available to the market.

Almost all inventions are patented prior to being made available to the market, regardless of the technology involved. The means by which patent rights are exercised however varies from technology to technology. For example, in the field of consumer electronics patents are widely shared among competitors through cross licenses. Patents on chemical compounds on the other hand are normally not licensed to others and exclusivity is closely guarded.

Whatever patent strategy is employed by the inventor, the aim is always the same – to maximize the profit accruing to the inventor and those who have supplied him or her with the capital necessary to develop and commercialize the invention. For a patent to have any commercial value there must be a market for the invention embodied in the patent, which will support the cost of development of the invention and return a profit.

[1] While not every country currently provides a 20-year patent term, 20 years is becoming the international standard.

Markets are morally neutral. They operate on the principal of scarcity. Scarce products cost more than widely available products. Thus, expensive, high-end electronic gadgets, such as flat liquid crystal television screens are much more expensive to consumers than much bulkier cathode tube television screens. The higher expense is partially justified in the fact that flat panel screens have on-patent technologies embodied within them, while the patents related to the original cathode tube screen inventions have expired. The contrast between flat panel screens and cathode tube screens illustrates that access to the most advanced technologies is limited to only the rich, while the billions of not-so-rich must settle with less sophisticated technologies. This leads to a very important point: A very high percentage of the world's population exists without purchasing any products embodying patents simply because they are too poor to afford innovative technology.

It is a fact that the world's poor can and have lived without making use of the vast majority of inventions available in developed countries. While this has significant implications for the economic gap between wealthy and poor countries, in most cases the lack of access to the most innovative technologies is not a necessity. However, to the extent the poor cannot afford access to necessary inventions, governments normally bear the cost of providing their citizens with such inventions. Thus, in most of the world, governments bear the cost of purchasing inventions that relate directly to sanitation, public health, national defense, public order and security, public transportation and education. For many inventions, the market is primarily a market of governments, not individuals.

The International Context for Patents on Health Care Inventions

Patents on inventions are granted on a territorial basis. In order to receive exclusive rights in an invention, the inventor must petition each nation-state to grant him or her exclusivity. Even where multi-state institutions such as the European Patent Office, the Eurasian Patent Organization or the African Regional Industrial Property Organization exist, these institutions merely attend to the formalities of prior art searching and examination of patent claims. These multi-state patent offices may be endowed with the authority to grant patents, but this is only a delegated authority granted by each member state.

Because inventors must secure rights in each state individually, not all inventions are patented in all countries. Further, many countries have chosen to exempt certain health-related inventions, such as pharmaceuticals, from patent protection entirely. Such subject matter exemptions from patentability are permitted under the Paris Convention on Industrial Property. Examples of countries where pharmaceutical products were not patentable historically are Brazil and India. However, the Agreement on Trade Related Aspects of Intellectual Property (TRIPS Agreement), a covered agreement under the Marrakesh Agreement establishing the World Trade Organization (WTO), requires that signatory countries end patent discrimination against pharmaceutical products. The TRIPS Agreement provides not only that pharmaceuticals be

eligible to be patented,[2] it also requires developing countries to provide non-patent marketing exclusivity to existing pharmaceuticals.[3] Further, the TRIPS agreement limits the broad discretion of countries to require the compulsory licensing of patents as permitted by the Paris Convention.[4]

The TRIPS agreement gave developing countries five years and least developed countries 10 years to begin meeting their obligations.[5] As of 2000, all but the least developed countries were to have TRIPS-compliant patent regimes in place. The recent Doha Declaration of the WTO Council of Ministers has now extended the deadline for TRIPS compliance for least developed countries to 2016.[6] Thus, the world's poorest countries have no immediate obligation to provide patent protection to pharmaceutical inventions.

Patents and the World Health Organization Essential Drugs List

The World Health Organization (WHO) publishes a list of the 308 essential drugs for the treatment of human disease. Of the 308 drugs on the list only five percent are patented in any jurisdiction.[7] Most of these drugs were patented at the time of their discovery, but their patents have long since expired and they are now in the public domain. Therefore, patents play a de minimus role in the global market for essential drugs. Yet, the WHO estimates at least a third of all patients globally lack access to medications on the essential drugs list.[8]

The Patent System is not Incentivizing Development of New Drugs for the Developing World

The global market for pharmaceutical products is estimated to have a value in 2002 of $406 billion.[9] The United States, the European Union and Japan currently account for 80% of this market, while the rest of the world combined, including Africa, Asia, Latin America and the Middle East, represent only 20% of the market.[10] Patents play an integral role in the pharmaceutical research and development occurring in developed countries.

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[2] Agreement on Trade Related Aspects of Intellectual Property Rights [hereinafter "TRIPS Agreement"], Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization [hereinafter "WTO"], Annex 1C, 33 I.L.M. 81 (1994), art. 27:1.
[3] *Id* at art. 39.
[4] *Id* at art. 31.
[5] *Id* at arts. 65 & 66.
[6] WTO Doha Ministerial, *Declaration on the TRIPS Agreement and Public Health* [hereinafter "Doha Declaration"], WT/MIN(01)/DEC/2 (Nov. 14, 2001).
[7] International Federation of Pharmaceutical Manufacturers Association, News Release: TRIPS Council Special Session (Sept. 21, 2001) http://www.ifpma.org/pdfifpma/tripscouncil.pdf.
[8] World Health Organization [hereinafter "WHO"], *The Impact of Essential Drugs* http://www.who.int/medicines/strategy/whozip16e/ch04.htm (last visited Apr. 15, 2002).
[9] IMS Health, *Market Report* (August 2001) http://www.ims-global.com/insight/report/global/report.htm.
[10] *Id*.

Research and development expenditures by American pharmaceutical companies alone reached $30.5 billion in 2001.[11] In the United States the National Institutes of Health (NIH) (the primary government source of medical research funding) spent $20.4 billion on research of all types, including pharmaceuticals.[12] The policy of the United States government is to vest patent rights in government-funded research in the non-governmental institutions performing the research. In the case of patented technology developed directly in government laboratories, the policy is to transfer exclusive patent rights to private sector entities prepared to commercialize the inventions. Thus, U.S. public investment is heavily weighted toward basic research, leaving it to the private sector to expend the additional resources necessary to develop the research to the point of approved therapies, which can be marketed to patients. In recent years the United States has overtaken the European Union in expenditures on pharmaceutical research and development. As of 1997, total U.S. expenditures exceeded those in Europe by 11 percent.[13] According to a 2001 report of the European Federation of Pharmaceutical Industries, "the European pharmaceutical industry is losing competitiveness as compared with U.S. industry and there is a process of concentration of R&D into North America …. Between 1990 and 1999, R&D investment in Europe doubled while in the United States it grew by 3.5 times."[14]

One possible reason for the shift in investment from Europe to the United States is the difference in profitability for patented products in each market. As observed in the 1998 European Commission Communication on the Single Market in Pharmaceuticals, there is widespread use of price controls on pharmaceuticals in Europe. This results in lower prices – and therefore lower profits – for research-based pharmaceutical companies in Europe. The importance of the unregulated price structure of pharmaceuticals in the United States has been recognized among the leaders of the research based, patent dependent pharmaceutical industry. In an industry conference in 2001 Fred Hassan, CEO of Pharmacia Corporation, stated, "the United States has become the must-win market for every pharmaceutical company. In addition, there are just 6 or 7 other critical markets, including Japan and key countries in Europe."[15]

Clearly, commercial pharmaceutical research and development is being overwhelmingly directed to produce patented drugs which will meet patient needs in a handful of countries in the developed world, most notably in the market with the strongest patent protection and without price controls – The United States of America.

This conclusion is consistent with economic research that has compared the relationship between gross profit margins of pharmaceutical companies with research and development outlays. Research by economists F. Michael Scherer and J.D. Kleinke shows a direct correlation

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[11] Pharmaceutical Research and Manufacturers Association of America [hereinafter "PhRMA"], *2001 Industry Profile*, at v.

[12] National Institutes of Health, *Press Release for Fiscal Year 2003 President's Budget* (Feb. 4, 2002) http://www.nih.gov/news/budgetfy2003/2003NIHpresbudget.htm.

[13] The European Commission, *Commission Communication on the Single Market in Pharmaceuticals* (1998).

[14] European Federation of Pharmaceutical Industries and Associations [hereinafter "EFPIA"], *The Pharmaceutical Industry in Figures Key Data- 2001 Update* (2001) at 14.

[15] Fred Hassan, *Being a Modern Pharmaceutical Company; New Paradigms for the Pharmaceutical Industry*, as reported in Clinical Pharmacology and Therapeutics, 69 (May 2001) 281.

between the gross profit margins of pharmaceutical companies and their investment in research and development.[16]

Where does all of this leave the developing world?

Only 10% of global health research is devoted to conditions that account for 90% of the global disease burden.[17] The global disease burden is heaviest in the poorest countries. Those living in absolute poverty are five times more likely to die before reaching age five, and two and a half times more likely to die between the ages of 15 and 59.[18] Infectious and parasitic diseases account for 25% of the disease burden in low and middle-income counties compared to only three percent in high-income countries.[19] Yet, over the last 25 years, only 15 new drugs were indicated for tropical diseases and tuberculosis, which account for 12% of the global disease burden, while 179 new drugs were developed for cardiovascular disease, which represents 11% of the global disease burden.[20] Between 1975 and 1999, only 1% of 1,191 new drugs approved for marketing were specifically indicated for a tropical disease.[21] Even this statistic however overstates the direction of research, since the development of some new drugs indicated for tropical diseases were supported by research for treatments of diseases more common in developed world markets.

Responses to a 2001 survey of 15 patent-dependent pharmaceutical companies conducted by the Drugs for Neglected Disease Working Group and Harvard Medical School indicated that less than 25% of research spending was directed at infectious disease with no spending on sleeping sickness, leishmaniaisis and Chagas disease, diseases of the developing world. Only two companies devoted research to malaria.[22]

Patents are tools for generating inventions that will be exploited in markets. If there are no markets for an invention, it is unlikely that the requisite investment leading to the commercial exploitation of a patent will be made. Clearly, the problem faced by poor countries is that they do not constitute a market capable of inducing patent-driven investment.

The problem of market failure in the development of pharmaceuticals for poor countries with high disease burdens led to the creation, in 1998, of the Global Forum for Health Research, headquartered in Geneva. The Global Forum is an attempt to bring together government policy makers, multilateral organizations, bilateral aid donors, international foundations, national and

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[16] F. Michael Scherer, Ph.D. and J.D. Kleinke, *Measuring the Value of Health Innovation: The Policy Implications of New Medical Technology*, Congressional Briefing organized by the Alliance for Health Reform and the National Pharmaceutical Council, September 7, 2001.
[17] Medecins Sans Frontieres Access to Essential Medicines Campaign, *Fatal Imbalance, The Crisis in Research and Development for Drugs for Neglected Dis*eases [hereinafter "MSF"] (September 2001), at 1.
[18] World Health Organization, *The World Health Report1999* (Geneva 2000).
[19] *Id*.
[20] MSF, *supra* note 17, at 1.
[21] Patrice Trouillier et. al., *Neglected Diseases and Pharmaceuticals Between Deficient Market and Public Health Failure*, (2001), cited in MSF, *supra* note 17, at 2.
[22] Dyann F. Wirth, *Survey for the Drugs of Neglected Diseases Working Group*, Switzerland (May 2001) http://www.accessmed-msf.org.

international Non-Governmental Organizations (NGOs), women's organizations, research-oriented bodies and universities, private-sector companies and the media. It is managed by a Foundation Council of 20 members and has a small secretariat housed in the offices of the WHO. The Global Forum provides financial support for studies on the burden of disease, serves as a network linking key institutions in health research, acts as a catalyst for efforts to be undertaken by its partners and seeks to promote equality among partners by providing a neutral ground for discussion.

Two of the activities of the Global Forum are directed at the market failure problem discussed above. The first is to direct attention of policy makers to the insufficient investment in publicly-funded health research for specific diseases disproportionately affecting poor countries. A finding of the Global Forum is that, "decision-makers take mostly local considerations into account and not a world view of needs for health and health research. As a result, opportunities to provide important benefits for all are forgone."[23]

The second activity directed at market failure is to "strengthen the research capacity in developing countries [as] a powerful, cost effective and sustainable means of advancing health and development." The Global Forum's 2000 report notes that, "although substantial [research] capacity exists, efforts must be focused on the identified needs of the countries concerned and on measurement of results."[24]

However, more focused and expanded public sector investments in health research alone will not address the imbalance in the pharmaceutical market between investment in therapies directed at diseases in rich countries versus those investment directed to diseases of poor countries. The lack of mechanisms to develop basic research into clinically tested drugs capable of meeting international regulatory standards for safety and efficacy is a systemic problem of great importance to developing countries.

The identification of promising compounds in laboratory tests and animal studies is merely the first stage in the long process of producing useful therapies for human beings. In the United States and other developed countries, governments and foundations sponsor research primarily directed at this first stage of drug development. It is the profit making pharmaceutical industry, which supplies the enormous capital and clinical resources to actually produce an approved, medically useful product. Where the initial research by a foundation, government laboratory or university has identified promising chemical compounds, patents are usually obtained on these compounds by the foundation, government or university involved. As mentioned above, these patents are normally licensed to pharmaceutical companies, which will make the investments necessary to turn the initial research into an approved drug. Without the transfer of the patent rights, the pharmaceutical company would have no incentive to spend the capital necessary to finance this critical and costly stage of drug development.

According to the National Institutes of Health, government funding in the United States has contributed substantially to general advances in the health sciences. However, 75% of government-licensed patents amounted to no more than proof of concepts – which required

[23] The Global Forum for Health Research, *The 10/90 Report on Health Research 2000,* at 5.
[24] *Id* at 11–12.

vastly more research to develop. In a report to Congress, the NIH found that only four of 47 new drugs with U.S. sales of $500 million per year had been developed out of NIH-funded research.[25]

New drug development is a very expensive process. A recent study by The Tufts University Center for Drug Development found that the average cost of developing a new drug to the point of regulatory approval is now $802 million.[26] This enormous cost reflects the fact that for every five to ten thousand compounds screened by researchers, 250 enter pre-clinical testing, five enter clinical testing involving human subjects, and only 1 is approved by regulatory authorities as safe and efficacious.[27] The lion's share of costs of drug development is born by profit-making pharmaceutical companies seeking to respond to market demand. Patents are the principal mechanism by which companies recover these large development costs and make a profit. As noted above, research demonstrates a direct relationship between profitability and investment in new drug development.

Market demand is not uniform throughout the world. As noted above there is a general market failure in poor countries. The U.S., Europe and Japan account for 80% of current market demand.[28] However, even among highly developed countries, market demand varies greatly. Recent studies have shown that Americans value new medical discoveries much more than Europeans. Survey data show that 66% of Americans are "very interested in" new medical technologies, while only 44% of Europeans are very interested in such technologies.[29] These attitudes affect the desire of American consumers for new, patented medicines. As much 34% of Americans believe that modern medicine can cure almost any illness for people who have access to the most advanced technology and treatment whereas only 11% of Germans hold such beliefs. When asked whether being able to get the most advanced tests, drugs and medical procedures and equipment is "absolutely essential," 35% of Americans said yes compared to 21% of Germans.[30]

The difference in perceived value of pharmaceutical innovations between Americans and Europeans may account, in part, for the fact that Europe's drug market is far more subject to price controls – and therefore less profitable – than the U.S. market. Governmental regulation of drug prices is a subject of concern for the European pharmaceutical industry. A recent report of the European Federation of Pharmaceutical Industries ("EFPMI") complained that, "constraints on the industry have tightened in recent years…. In contrast with the U.S., the pharmaceutical industry in Europe is faced with a patchwork of pricing and reimbursement regulations.[31]

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[25] National Institutes of Health, *A Plan to Ensure Taxpayers Interests are Protected*, (July 2001).
[26] Tufts Center for the Study of Drug Development, News Release, *Tufts Center for the Study of Drug Development Pegs Cost of a New Prescription Medicine at $802 Million* (Nov. 30, 2001).
[27] PhRMA, *Pharmaceutical Industry Profile 2002*, at 20.
[28] Robert J. Blendon, Ph.D. *Measuring the Value of Health Innovation: the Policy Implications of New Medical Technology*, presented in a Congressional Briefing sponsored by the Alliance for Health Care Reform and the National Pharmaceutical Council (Sept. 7, 2001).
[29] *Id*.
[30] *Id*.
[31] EFPIA, *supra* note 14, at 6.

EFPMI has linked these regulatory "constraints" with the declining European share of the world market. Its report noted:

> According to IMS data, 57% of sales of new medicines marketed since 1995 are generated on the U.S. market, compared with 25% on the European market…. The world pharmaceutical market was worth an estimated 392,640 million Euros (at ex-factory prices) in 2000. The North American Market (USA & Canada) grew fastest and remained the world's largest market with a 43% share, well ahead of Europe and Japan.[32]

European industry's concern about unfavorable market conditions and the resulting loss of competitiveness echo an earlier analysis by the European Commission which observed in a 1998 report that:

> The competitiveness of the European Industry appears to be weakening: 20 years ago Europe led the way in pharmaceutical research and development; more recently, to judge from patent filings at least, Europe has been overtaken by the U.S. The trend … is confirmed by the latest data. Of the 47 new active substances launched on the World market in 1997, 19 (or 40%) had been discovered and developed in Europe; 30 years ago Europe's share of pharmaceutical discoveries was 65%."[33]

The existence of a more favorable market in the United States was confirmed by an analysis of the Canadian Government's Patent Medicine Prices Review Board. In a report issued in 2000 by the Board found that "prices in the U.S. appear to be higher than in Europe and Canada."[34] According to the report, U.S. prices for patented drugs were 61% higher than in the price-regulated Canadian market. The price differential was even greater between the U.S. and France and the U.S. and Italy.[35]

Given the strong relationship between profitability and investment in new drug development identified by Scherer and Kleinke and described earlier in this paper, it is not surprising that global pharmaceutical research and development today is focused increasingly on the needs of American patients. The combination of strong patent protection and weak price regulation create in the United States the most profitable market in the world for new drugs.

The disease burden of European States, Canada and other developed countries is not significantly affected by the dominant role of the U.S, market because the diseases most common in those countries are the same as in the United States. However, the consequences of this market imbalance are severe for developing countries because their disease burden is characterized by diseases not common in the United States.

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[32] *Id*.
[33] The European Commission, *supra* note 13, at 3.
[34] Patented Medicines Review Board, *Trends in Drug Prices and Expenditures Annual Report* (2000).
[35] *Id*.

Patents, HIV and Developing Countries

In recent years the disease burden of many developing countries has increased exponentially as a result of the rapid spread of Human Immunodeficiency Virus ("HIV"). The disease was first identified in the United States in the early 1980s as a malady primarily affecting homosexual men. Originally termed Auto Immune Deficiency Syndrome ("AIDS"), the cause was, at first, unknown. However, research soon revealed that the disease was caused by a virus that was transmitted by, among other means, sexual intercourse.

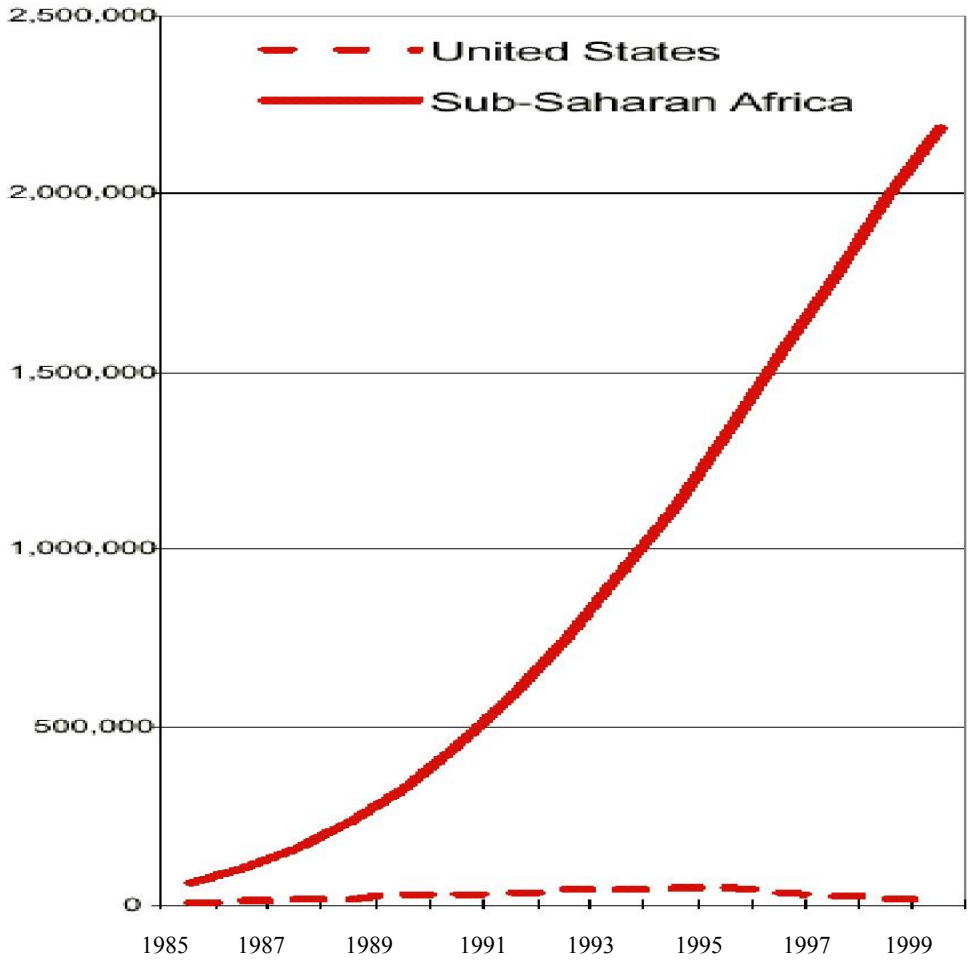
After the disease was identified in the United States it began to be diagnosed in patients in many other countries. While the disease in the developed world remained primarily one affecting male homosexuals, in the developing world it soon began spreading rapidly among the heterosexual population. In certain parts of the world, particularly in sub-Saharan Africa, the spread of the virus reached epidemic proportions unknown in modern history. At the present time there is no known cure for the disease. Initially, the disease proved fatal with the exception of a very small percentage of individuals who seem to have natural defenses which are still not understood. However, shortly after its initial diagnosis in the United States, drug therapies were identified which could treat symptoms of the disease and prolong the life of patients. Eventually, more powerful drugs were developed which can suppress – although not eliminate – the virus in patients to the point that it is no longer life threatening. These therapies are known as antiretroviral drugs.

The drugs which effectively suppress HIV were developed by U.S. and European, research-intensive pharmaceutical companies. All of these therapies currently enjoy patent protection in many countries. Purchased at retail prices in developed country pharmacies, antiretroviral drugs are extremely expensive. The annual course of treatment for a patient in the United States can run up to as much as $12,000.[36] However, because of the high price and lack of medical infrastructure in many of the developing countries most affected, these life-saving therapies were not initially available. And, in many countries – particularly in Africa – they remain unavailable to the general population. Of the 34.3 million people in the world infected with HIV, 24.5 million are in Sub-Saharan Africa where anti-HIV therapies are available only to a tiny percentage of the population.[37] This disparity in access to life-saving drugs has created a moral and political crisis that has caused policy makers in forums such as WHO and in the WTO to question whether patents operate as a barrier to access to effective treatment.

There is no question that effective treatment for HIV disease is not available in many countries and that this is having a catastrophic effect on those societies. The following graph illustrates the difference in mortality from AIDS between the United States, where treatment is widely available and sub-Saharan Africa where it is not.

[36] Robert Pear, *Clinton to Seek More Money to Pay for AIDS Drugs*, N.Y. Times (Jan. 30, 1997), at A14.
[37] UNAIDS, *Report on the Global HIV/AIDS Epidemic* (June 2000), at 8.

Comparison Between Death Rates in the United States and Sub-Saharan Africa from HIV Disease[38]



The gravity of the crisis is illustrated in Botswana where, unless treated, 80% of adults will die before 2020, leaving a population largely consisting of orphans.[39] Organized society in Botswana will not be sustainable in such a situation.

There has been a vigorous debate about the solution to the impending HIV catastrophe. Much of the debate has centered on the role of the patents protecting antiretroviral therapies and the requirement of the TRIPS Agreement that all WTO member countries provide patent protection for pharmaceutical products.

A leading voice in arguing for generic production of patented HIV treatments for use in developing countries is the U.S.-based Consumer Project on Technology (CPT). In an October

[38] Source, Amir Attaran, *Why AIDS Treatment for the Poor is Not Happening and How to Change It*, Presentation at the Fordham University School of Law Tenth Annual Conference on International Intellectual Property Law and Policy (Apr. 5, 2002).
[39] *Id*.

7, 2001 memorandum to Gro Harlen Brundtland, Secretary General of WHO, the Director of CPT, James Love, requested that WHO seek compulsory licenses for five antiretroviral drugs for use in sub-Saharan Africa.[40]

While there is universal agreement that most patients in Africa are not now receiving antiretroviral treatments, there is some disagreement about the role that patents play in the lack of drug availability in the region. A recent study by Amir Attaran of Harvard University and Lee Gillespie-White of the International Intellectual Property Institute (IIPI), found that patents for antiretroviral treatments have not been obtained in many African countries.[41] The study found that overall, only 21.6% of possible patents had been obtained in Africa. South Africa is an exception, however, as most antiretroviral drugs have been patented there.[42] The Attaran / Gillespie-White study was a follow-up to an earlier study by IIPI under the sponsorship of WIPO.[43]

The current status of patent protection for antiretroviral drugs in Africa is confused. As demonstrated in the Attaran / Gillespie-White study, the relevant drugs do not enjoy patent protection in many African countries. Further, patent owners in some cases have offered to make their drugs available either at no cost or significantly reduced prices. James Love has observed that d4T, the least expensive antiretroviral to manufacture, is off patent outside South Africa and that the patent owner, Bristol Meyers Squibb, has offered to make it available in South Africa at $0.15 per day for some purchasers as opposed to the normal price of $7 per day.[44] The same company has offered discounted prices at $0.85 per day for ddI.[45] Mr. Love notes that Baxter International has offered to make available Neverapine for free to mother-to-child-transmission programs in Africa. However, as of Mr. Love's October 7, 2001 memorandum, Glaxo Smith Kline had not offered discount licenses for use of their 3TC and AZT patents for use in combination pills.[46]

Patent critics such as Mr. Love maintain that effective treatment in African countries requires simple-to-take prescriptions that combine three patented drugs in one pill and can be taken twice per day. The confused patent status of the drugs necessary for this combination and the conflicting licensing policies of patent holders make it difficult if not impossible to manufacture and distribute cheaply the large quantity of medications necessary to arrest the death rate for HIV disease in Africa.

However, others have argued that patents and confused licensing options are not the primary reason that easy-to-use pharmaceuticals are not available to African patients. In his introduction to the 2000 IIPI/WIPO study on patents and HIV drug availability in sub-Saharan

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[40] James Love, *Request that WHO seek compulsory licenses for 5 essential antiretrovial products in Sub-Saharan Africa* (Oct. 7, 2001) [http://lists.essential.org/pipermail/ip-health/2001-October/002012.html].
[41] Amir Attaran & Lee Gillespie-White, *Do Patents for Antiretroviral Drugs Constrain Access to AIDS Treatment in Africa?*, Journal of the American Medical Association Vol. 286 (Oct. 17, 2001) 1886.
[42] *Id* at 1887.
[43] International Intellectual Property Institute [hereinafter "IIPI"], *Patent Protection and Access to HIV/AIDS Pharmaceuticals in Sub-Saharan Africa* (2000) http://www.wipo.int/about-ip/en/pdf/iipi_hiv.pdf.
[44] Love, *supra* Note 40.
[45] *Id*.
[46] *Id*.

Africa, the author of this paper, Bruce Lehman, observed that "the issue of access to affordable drugs involves numerous and complex issues, including health care infrastructure, international pricing mechanisms, financing, debt, and tariffs…" as well as patents. He states that:

> Perhaps the most important conclusion of this report is that the TRIPS Agreement is not an impediment to the distribution of HIV/AIDS pharmaceuticals. It does not yet apply to the majority of sub-Saharan African countries, and where it does, it permits sufficient flexibility for countries to avoid the negative effects. Similarly, patents are not an issue in access to drugs in sub-Saharan African countries, since most drug companies have not obtained patients widely in Africa. The real issue…is that of adequate financing of the overall health system and the development of health care infrastructures.[47]

Bruce Lehman's view is shared by Dr. Amir Attaran of Harvard, who argues that the primary impediment to solving the problem of AIDS treatment in poor countries is lack of money to set up a treatment infrastructure and to purchase and distribute antiretroviral therapies. He notes that financial assistance from the nine leading industrialized countries and the World Bank totaled only $459 million in 2000. The following chart lists the contribution of each entity.[48]

AIDS ASSISTANCE IN THE YEAR 2000

World Bank	$149 Million
United Kingdom	$147 Million
United States	$112 Million
Norway	$10 Million
Canada	$10 Million
Australia	$9 Million
France	$5 Million
Netherlands	$5 Million
Italy	$4 Million
Japan	$4 Million
Germany	$3 Million

Dr. Attaran attributes the crisis in funding AIDS treatment to a policy breakdown in which those countries with the capability to supply the resources to solve the problem have not chosen to do so.

That patents alone are not the principal impediment to supplying patients with daily antiretroviral therapy is evident by examining the situation in India. India has a large

[47] IIPI, *supra* note 43, at 3.
[48] *See* Attaran, *supra* note 38.

pharmaceutical manufacturing capability with at least 22,000 pharmaceutical manufacturing facilities. Ten Indian companies produce antiretroviral drugs. There are no patents on antiretroviral drugs in India. There are an estimated 500,000 AIDS cases in India. Yet, only 3,000 patients are receiving daily observed antiretroviral treatment—less than one percent of the infected population.[49]

Yet, other countries have established effective programs for treatment of AIDS patients regardless of ability to pay. One of the best examples is Brazil where, since 1997, approximately 85,000 patients have received daily antiretroviral therapy free of charge. This program has been credited with reversing the rate of infection in Brazil. Brazilian health authorities estimate that without the program at least 1.2 million Brazilians would have become infected by 2000.[50] While Brazilian health authorities have threatened to use drugs produced without license from patent owners, the Brazilian program at present relies on the use of licensed products.[51]

Certainly the aggressive position of Brazilian authorities, including threats of compulsory licensing, has had a big impact on the pricing policies of patent owners in that market.[52] However, the costs of drugs is only one part of the larger infrastructure of treatment created by public health authorities in Brazil. The total cost of the Brazilian program – paid by government – is about $4,000 per patient per year.[53] The HIV disease burden in Brazil is sufficiently small compared to the GDP of the nation that such a sophisticated program is within the capability of the country's public health system. This is not the case in many, far less wealthy African countries with much larger disease burdens.

TRIPS, Doha and the Continuing Debate

Prior to the TRIPS Agreement nothing in international law required a country to have a patent system. Countries adhering to the Paris Convention were required to recognize certain principals of industrial property, but they had considerable discretion with regard to the fields of technology for which they chose to permit patent protection. As a result, many countries excluded inventions relating to public health from patent protection. Further, countries were given wide discretion to single out certain fields of technology for compulsory licensing. Under a compulsory license the exclusive rights of a patentee can be assigned without his or her permission to another party.

Countries adhering to the WTO Treaty, however, have agreed to limit their discretion over the patent system and the conditions on which compulsory licenses can be granted. The

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[49] David Rosenberg, *Access to Medicines: The Background to the Doha Debate*, Presentation at the Fordham Intellectual Property, Media and Entertainment Law Journal Symposium (April 2002).
[50] Stephen Buckley, *Brazil Becomes Model in the Fight Against AIDS*, The Washington Post (Sep. 17, 2000).
[51] Interview with Jose Gracia Aharana, President, Brazil's Instituto Nacional da Propriedade Industrial in New York, NY. (Jan. 15, 2002).
[52] Brazil is not the only country to use the threat of compulsory licensing to encourage a lower price for a pharmaceuticals needed in an emergency situation. Last year U.S. Secretary of Health & Human Services Tommy Thompson threatened to use the government's powers of eminent domain to manufacture without permission an antibacterial medicine effective against anthrax infection.
[53] UNAIDS, *Report on the Global HIVAIDS Epidemic* (2000) at 8-11.

limitations on denying patent protection to certain fields of technology are found in Article 27 of the TRIPS Agreement which provides that, "patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether the products are imported or locally produced."

This prohibition of discrimination against "fields of technology" is what requires WTO member states to include pharmaceutical and other health –related technologies within the scope of patent protection.

However, WTO member states continue to have discretion under Article 8 of the TRIPS Agreement "in formulating their laws and regulations, [to] adopt measures necessary to protect public health and nutrition…" Such measures, however, are to be "consistent with the provisions of this [TRIPS] Agreement."[54]

Article 31 of the TRIPS Agreement permits WTO member states to continue to use patented inventions without the permission of the patent owner, either by the government itself ("government use") or by third parties ("compulsory licensing"). However, the discretion of member states to use inventions without authorization is far more limited than the exceptions to patent protection previously common in many countries. While unauthorized use by government is permitted merely upon notice to the patent owner provided it is "considered on its individual merits," compulsory licenses may be granted to third parties only if "efforts to obtain a voluntary license on reasonable terms and conditions" are first made.[55] Further, the scope and duration of the use must be limited and the compulsory license or government use must be non-exclusive.[56]

The most restrictive provision of the Article 31 exceptions, is that limiting government use or a compulsory license to "the supply of the domestic market of the member authorizing the use."[57] Also, in all cases, "the patent owner must be paid adequate remuneration taking into account the economic value of the authorization."[58]

As noted earlier, the provisions of the TRIPS Agreement did not require immediate changes in laws and practices in the developing world and as a result of the phase-in periods for developing countries, TRIPS had no effect on pharmaceutical use in any developing country until 2000.

The rise of the HIV/AIDS epidemic subsequent to the Diplomatic Conference creating the WTO and the TRIPS Agreement has caused many to question whether a stronger global patent regime creates new obstacles to meeting public health emergencies. NGOs began to criticize the pricing policies of pharmaceutical companies manufacturing HIV therapies and questioned whether patent protection prevented low-cost, widespread distribution of essential pharmaceuticals to patients most in need. The WHO became a forum for this debate at a meeting of Health Ministers in early 1999.

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[54] TRIPS Agreement, *supra* note 2, at art. 8:1.
[55] *Id* at art. 31(b).
[56] *Id* at art. 31(d).
[57] *Id* at art. 31(f).
[58] *Id* at art. 31(h).

The debate on the relationship of the TRIPS Agreement to health care found its way into discussions leading to a further round of negotiations on liberalization of the international trade regime. This debate culminated in action by the Fourth Session of the Ministerial Conference of WTO in Doha November 9-14, 2001. On November 14, 2001 the Ministers issued a "Declaration on the TRIPS Agreement and Public Health."

The Doha Declaration acknowledged that "intellectual property protection is important for the development of new medicines" but expressed "concerns about its effect on prices." The ministers recognized "the gravity of the public health problems afflicting many developing and least developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics" and affirmed "that the [TRIPS] Agreement does not and should not prevent Members from taking measures to protect public health."

In recognition of their concerns, the Doha Declaration focused on the flexibility supplied by Article 31 of TRIPS and stated that:

> Each Member has the right to grant compulsory licenses and the freedom to determine the grounds on which such licenses are granted…. [and] the right to determine what constitutes a national emergency…it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.

The Doha Declaration concluded with two action items. The ministers extended to January 1, 2016 the obligation of least-developed countries to implement TRIPS with respect to pharmaceutical products, and they instructed the TRIPS Council "to find an expeditious solution" to the problem of the Article 31 limitation of compulsory licenses to the domestic market only. This was in recognition of the fact that there are "WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector…" to make "effective use of compulsory licensing under the TRIPS Agreement." The TRIPS Council is to report its "solution" to the General Council of WTO before the end of 2002.

NGOs have been encouraging the TRIPS Council to interpret TRIPS Article 30 "to permit countries to export medicines and other inventions to address health needs."[59] Specifically, they have proposed adoption of the following statement by the TRIPS Council.

Under Article 30 of the TRIPS Agreement, Members may provide an exception to the exclusive rights conferred by a relevant patent to permit all acts associated with the production for export to a third country of a patented product produced by a patented process; where the export addresses health needs in the third country; and the product and/or process is either (a) not patented; or (b) a compulsory license has been granted or government use made of the relevant patent in the third country.[60]

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[59] Joint Letter from Consumer Project on Technology, Essential Action, Medicines Sans Frontieres, Oxfam International, Health GAP Coalition, and the Third World Network to the World Trade Organization's TRIPS Council (Jan. 28, 2002) http://www.cptech.org/ip/health/art30exports.html.

[60] *Id*.

As of this writing the TRIPS Council has not yet made its recommendations.

Conclusions and Recommendations for Discussion

Most of the medicines essential to the control of disease were created in the past and the term of their patents has expired. There are many places in the world in which they were never patented. The patent system is the primary economic mechanism by which investment in health care inventions is induced. As a mechanism of the free market, the patent system focuses investment on health care solutions most likely to return the maximum profit. The United States of America is the only large market in which health care products, in particular pharmaceuticals, are not subject to some form of price regulation. Therefore, the United States is the most profitable market for providers of health care inventions.

The disease burden of the United States differs greatly from the disease burden of the majority of developing countries. Therefore, the patent incentive in the United States does not induce health care inventions most needed by developing countries.

Many developing countries, particularly the least developed, lack the health care infrastructure necessary to meet the needs of their populations. This health care infrastructure consists of many elements other than pharmaceuticals. Physicians, clinics, hospitals, equipment and preventative care also are in short supply in the least developed countries. Essential off-patent pharmaceuticals are often not available to those who need them.

The lack of adequate health care infrastructures and the lack of inducements to create new pharmaceutical inventions for diseases affecting developing countries have led to a disproportionate disease burden in many developing countries. This disproportionate disease burden has been greatly exacerbated by the rapid rise in HIV infection in many developing countries, most particularly in sub-Saharan Africa. HIV disease differs from many other diseases common in developing countries in that all of the therapies currently available to prevent death and prolong life are recent inventions under patent in the countries where they were created and in many of the countries of the world.

The TRIPS Agreement has required countries previously without patents covering pharmaceuticals and other health care inventions to begin providing patent protection to these inventions. For countries fully subject to the TRIPS Agreement, the ability to exclude health-related inventions from patent protection has been greatly restricted. Similarly, the ability to grant compulsory licenses to pharmaceuticals has been limited. The impact of the TRIPS Agreement is mixed because least developed countries have until 2016 to comply.

By the end of the current year the TRIPS Council will propose a mechanism by which countries subject to the Agreement may invoke emergency, TRIPS-consistent procedures to obtain supplies of essential patented medicines where they are not otherwise available at a price or in a quantity necessary to meet the needs of a population in a health care crisis.

Given the current international debate on the relationship of patents to the health needs of developing countries, it is appropriate that WIPO contemplate its role. WIPO is not in a position to amend the TRIPS agreement. However, WIPO can be a forum for providing a better understanding of the relationship of patents to innovation, of patents to health care, and of patents to health crises.

Among questions which the WIPO Policy Advisory Commission may wish to address are the following:

1. What can policy makers do to correct the dysfunction in the current market which addresses the disease burden of rich countries and leaves unaddressed the disease burden of poor countries?

2. What can policy makers do to create a more attractive market for patent-induced inventions addressed to the disease burden of developing countries?

3. What can policy makers do to more effectively harness the research and development potential of developing countries, in particular to encourage their use of the patent incentive to induce local investment in new drug research and development?

4. Is there a relationship between traditional knowledge, biodiversity and the health needs of developing countries?

5. Can traditional knowledge and the unique ecosystems of some developing countries be used more effectively to spur development of local pharmaceutical industries that target the local disease burden?

6. What can policy makers do to encourage developed countries to provide the financial assistance necessary to create a market for new drugs aimed at the disease burden of developing countries?

7. Can developing countries create micro markets for pharmaceutical innovation that can exist profitably along side the giant markets in countries like the United States and member states of the European Union?

8. What relationship will patents play to the proposed global fund for HIV/AIDS?

9. Can WIPO offer technical assistance to the global fund?

10. Can WIPO offer technical assistance to states negotiating licenses to HIV and other needed pharmaceutical inventions, including expertise on business models and implementation of TRIPS Article 31 compulsory licenses where their use is found necessary?

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