The Pharmaceutical Industry and the Patent System

Bruce Lehman[1]
President, International Intellectual Property Institute

Executive Summary

Patents are exclusive property rights in intangible creations of the human mind. They exist only as provided in the laws of sovereign states, and can be enforced only to the extent that application has been made and a patent granted covering the territory of an individual state. Patent rights are limited in duration, with the global standard being 20 years from the date of application. The new product, article of manufacture or process described in the patent application must be something that has never been previously disclosed anywhere in the world and something that would not be obvious to a person ordinarily skilled in the field involved. Determinations of whether these requirements have been met are made by comparing the claims of the patent applicant against the body of published literature in the field, including previously issued patents. This process is called examination, and it assures that no one is able to claim patent rights on anything that already is existence.

Patents work differently indifferent industries. In the electronic industry patents are often shared among competitors through pooling or cross licensing. This sharing is necessary because a given product often contains many patented technologies. However, in the pharmaceutical, chemical and biotechnology industries the patent normally equals the product, and protects the extensive investment in research and clinical testing required before placing it on the market. Patent protection for chemical and pharmaceutical products is especially important compared with other industries because the actual manufacturing process is often easy to replicate and can be copied with a fraction of the investment of that required for the research and clinical testing.

The extensive cost required to produce a new pharmaceutical product has meant that private sector investment in pharmaceutical innovation has been disproportionately directed to products meeting the needs of patients in developed countries, particularly in the United States, which combines strong patent protection with a market free of price controls.

Until the TRIPS Agreement in 1994 many developing countries provided no patent protection for pharmaceutical products. And, while countries that have joined the WTO have obligated themselves to provide such protection, least developed countries are not required to meet this obligation until 2016. The continuing lack of patent protection for pharmaceutical products makes it very difficult to establish research-based industries in most developing countries. Most medical research in these countries takes place in the public sector. The lack of any means of patenting these inventions and the related lack of experience in licensing them to the private sector, suppresses the development of commercial enterprises focused on alleviating the disease burdens common to developing countries.

The controversy over availability of patented therapies for the treatment of HIV disease has resulted renewed interest in the compulsory licensing of pharmaceutical products. After two years of discussion, the WTO Council recently affirmed that the TRIPS Agreement permits such compulsory licenses in health emergencies, even in cases where

the compulsory license is for an imported product. However, to date, no compulsory licenses actually have been issued, even though the threat of compulsory licensing has been used as a means of seeking lower prices.

One danger in compulsory licensing is that it will discourage further the commercial R & D necessary to new drugs to fight global epidemics. Another danger is that compulsory licensing can be used to seek price levels below what a given national market is capable of supporting, further concentrating the burden of financing pharmaceutical innovation on developed country consumers and discouraging development of drugs targeted at the disease burdens of countries using compulsory licenses.

There are promising developments in countries such as India and Brazil that are beginning to use patents to develop commercial pharmaceutical industries that produce products directed at local diseases and available at price that patients in those countries can afford. Foundations and nonprofit organizations such as the Bill and Melinda Gates Foundation and OneWorld Health, Inc. are supporting such efforts. These efforts show that developing countries have the capacity to build research-intensive pharmaceutical industries capable of operating profitably in the conditions of the local market. However, for such local industries to take root and grow, effective patent protection must be made available, the commercialization of publicly funded research must be encouraged, and compulsory licensing must be kept to a minimum. Wealthy countries can assist this process by subsidizing local markets for the purchase of drugs through the Global Fund, and by direct programs of assistance such as that recently proposed by President Bush. Consumers in all countries can share the burden of drug development equitably by paying for medicine at a price level consistent with their means, rather than attempting to shift the costs of drug development to others.

What is a Patent?

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 owner of a patent has the right to exclude others from making, using, offering for sale, or selling his or her invention for a period of 20 years from the filing of the patent application. An *invention* is any new or useful process, machine, article of manufacture, or composition of matter. An improvement on any of these items also can be an invention. Patent rights are territorial in nature and exist only in the national jurisdictions in which the patentee has applied for and received recognition of his property rights.

Whether a claimed invention meets the tests of novelty and non-obviousness is determined by comparing it to the body of previously disclosed information in the same field. This information is usually called "prior art." The most commonly used prior art consists of published patents that have already been issued or published by the world's patent offices.

While all countries require that the tests of novelty and non-obviousness be met before patent rights can be enforced against infringers, many countries do not determine whether these tests have been met though a substantive examination as in the United States, Japan, the U.K. and Germany. In counties, such as France, claims to patent rights are registered with the state but not actually tested for their validity until or unless they are asserted in a judicial proceeding. At that time the responsible judicial authorities engage in the fact-finding process necessary to determine whether the tests of patentability have been met.

The benefit of granting an inventor the exclusive property right of a patent for the limited period of 20 years is that he or she is given a powerful incentive to create. The inventor is assured that investors will be given the incentive 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.

Patents Work Differently in Different Industries

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.

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 plasma television screens are much more expensive to consumers than much bulkier cathode ray television screens. The higher expense is a reflection of the market power given to manufacturers of the plasma screens by virtue of the patents in the technologies embodied in them, while the lower cost of the cathode ray television screens is partly a function of the fact that patents have long ago expired on the technologies embodied in them. The market exclusivity and higher prices made possible by the patent rights function as a reward for the risk undertaken by those who financed the research and development leading to the new technologies. Thus, prices of plasma television screens exceed the purchasing power of poor consumers and they must be satisfied with older cathode ray screens or no television at all. This example illustrates 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 live 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 these inventions, the market is primarily a market of governments, not individuals.

The Global Institutions Responsible for Administering the Patent System

National Patent Offices

Every country with a patent system has a national patent office where claims of inventors may be made a matter of public record. As mentioned above, in many countries there is an examination before an inventor is given any substantive rights. In other countries patent clams are registered but detailed examination is delayed until a dispute over infringement arises. However, even in these countries a search of the prior art is often conducted as a part of the registration process, and the search results are published so that members of the public can assess the claims made by the registrant.

The World Intellectual Property Organization (WIPO)

Headquartered in Geneva, WIPO is the specialized United Nations Agency that serves as the secretariat for administration of most of the global intellectual property treaties. It is the principal forum for negotiation of new patent treaties and the leading provider of technical assistance to developing countries in the field of intellectual property rights. WIPO was created in 1967 as the successor organization to the International Bureau for the Protection of Intellectual Property, which had been in existence since the 19th Century. WIPO Currently has 179 member states.

The World Trade Organization (WTO)

The World Trade Organization was established in 1994 in Marrakech following the successful conclusion of the Uruguay Round of Trade Negotiations. The predecessor to the WTO was the General Agreement on Tariffs and Trade (GATT). A key reform of the Uruguay Round was the Agreement on Trade Related Aspects of Intellectual Property Rights, known as TRIPS, codified as an annex to the treaty establishing the WTO.

It is important to recognize that the TRIPS Agreement was intended to create a more equitable system of international trade. Wealthy countries agreed to reduce barriers to imports of price competitive imports from abroad while developing countries agreed to open their markets to the high value added exports of the developed nations. These high value added exports disproportionately consist of technology in which much of the value is intangible and must be protected by strong intellectual property regimes to be effectively exploited. Pharmaceutical products constitute one of the most important categories of high technology products.

Among the major requirements of the TRIPS agreement are the following:

- WTO Member States must provide a level of rights equal to those provided in the major global intellectual property treaties administered by WIPO, including the Paris Convention on Industrial Property.

- WTO member states may not discriminate among technologies in providing patent protection, meaning that exceptions to patent protection in many countries for pharmaceutical products must be eliminated.

- WTO member states must provide patent protection for at least 20 years from the date of filing a patent application

- WTO Member States must provide effective judicial enforcement of intellectual property rights.

- A TRIPS Council was created to coordinate WTO policy in the area of intellectual property rights and to manage the resolution of disputes among states on implementation of TRIPS obligations.

Special Problems of Pharmaceutical Patents

The pharmaceutical industry is one of three technology-based industries in which the patent virtually equals the product. The others are the chemical industry (including agricultural chemicals) and the biotechnology industry, whose innovations span the spectrum from engineered plant varieties to human pharmaceutical therapies. These three industries are much different than other patenting industries such as computers and electronics. While responsible for many patent filings the computer and electronics industries are characterized by extensive use of other techniques for managing inventions, including the use of trade secrecy and the pooling of patents with those of competitors to accommodate government and industry technical standards. Most importantly, unlike industries which produce products requiring expensive and complex manufacturing infrastructures, the patented products of pharmaceutical companies can be easily and cheaply replicated by copiers with little capital investment. Since capital investment in the pharmaceutical industry disproportionately is directed to laboratory research and clinical trials rather than the manufacture of the final product, patent exclusivity is the only effective way to protect and receive a return on that investment.

The pharmaceutical industry has an important characteristic that sets it apart from other industries that rely on patent protection. In many technology-based industries it is possible to keep inventions a secret until the moment they are marketed. This enables inventors to delay patent filings until the last possible moment and, therefore, to maximize the effect of the 20 year patent term which runs from filing of the patent application. The culture of medical research, however, emphasizes very early disclosure of inventions, usually long before a resulting product can be placed on the market. This is because scientists working in the field of human pathology have an obligation to share their findings as soon as possible with their peers so that those peers will be able to benefit from the new knowledge in their own research. And, unlike industries such as computers and software, the pharmaceutical industry is heavily regulated by government agencies to assure the safety and efficacy of products which will be sold to consumers. In the United States the Food and Drug Administration performs this function. Much of the investment in new drugs is in the clinical trials which are necessary to satisfy safety and efficacy regulators. The tolerance for a “buyer beware” philosophy in the pharmaceutical industry is extremely low compared to other industries.

The lengthy time period between patent filing and placing a product on the market means that pharmaceutical manufacturers receive far shorter periods of patent exclusivity than is the case for other patent dependent industries. This problem has been addressed in legislation in the United States and elsewhere which permits a patent applicant to apply for extensions of patent term to compensate for the inability to market inventions due to safety and efficacy regulation. However, the time periods permitted for such extensions do not equal the time lost in ability to market. In the United States patents can be

extended only for half the time period consumed by the regulatory approval process, and for a maximum effective patent term of fourteen years.[2] Further, the legislation restricts the exclusive right of use which normally accompanies the patent grant by permitting generic competitors to use the product for testing and developing the generic alternative while the patent is still in effect. This permits a generic product to be marketed virtually the moment the patent expires.

Nowhere has the patent incentive been more successful in attracting investment in technology that in the commercial pharmaceutical industry in the United States. A strong patent system – combined with a market without price controls – caused a massive flow of investment into the American industry. Expenditures on research increased from $1.7 billion in 1977 to $26.4 billion in 2002.[3] Much of this increase represented a shift investment from Europe, where increasingly onerous price controls have threatened investors' return on capital. This shift is represented in the fact that in the year 2002, 82% of the investment by global pharmaceutical companies was spent in the United States, versus 18% elsewhere, including Europe. The result for the United States economy is that since 1990 the patent-driven pharmaceutical industry grew twice as fast as the economy at large. And, pharmaceutical companies now employ over 223,000 workers in the United States.[4]

While the contribution of the patent-based pharmaceutical business to job creation and the economy is impressive, the inventions of pharmaceutical researchers have a dimension difficult to quantify in economic terms – their impact in extending life and alleviating human suffering. In 2001 the pharmaceutical industry pipeline contained 402 new cancer medicines, 123 new treatments for heart disease and stroke, 83 new AIDS treatments and 176 new medicines for neurological diseases.[5] These statistics are particularly sobering in light of the current debate over whether patents covering HIV drugs should be respected. None of the new drugs in the pipeline, much less the 74 medicines that already have caused deaths from AIDS to plummet in the United States, would have come into existence without the patent incentive and the prospect of a return on investment provided by that incentive.

This is not to dismiss the fact that many patients in the world cannot pay for these drugs and do not have access to them. However, this is not the result of the patent system. It is the result of lack of a source of funding for the purchase of drugs for those currently too poor to buy them themselves. While in the United States Medicaid provides a safety net for those without health insurance or other means to pay for drugs, in many parts of the world there is no similar source of public financing. However, the Bush Administration has recognized this, and Congress currently is in the process of appropriating U.S. tax money for the 2004 fiscal year to subsidize purchases of HIV medicines by public health authorities in poor countries.

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[2] 35 USC Sec. 156
Phamaceutical Industry Profile 2003 at 10.
[4] *Id* at 17
[5] *Id* at 16

Effective use of the patent system in the 20th Century gave rise to commercial enterprises that advanced the progress of medical science beyond anything known in prior history. While public funding of the training of scientists and basic research vastly expanded the understanding of human pathology as the century progressed, it was the profit incentive operating through pharmaceutical companies accountable to investor shareholders, which provided desperately needed new therapies to patients. By the decade of the 1980s patent dependent pharmaceutical companies developed more than 92% of all new drugs.

Patents and Research and Development in Developing Countries

Few developing countries have private sector industries characterized by investment in research and development. Economies in these countries are based on agricultural commodities, extraction of minerals or low-tech, low wage manufacturing. And, in most developing countries the scientists and engineers most likely to invent are employed in the public sector, either in state-run laboratories or universities. These countries historically have lacked the institutions and policies that encourage and make possible the patenting and commercialization of inventions of public sector employees. This is in contrast to developed countries, such as the United States, which have sophisticated systems in place to commercialize publicly funded research. This is shown in patent filing statistics published by WIPO. Over 95% of all patent filings in the world are by nationals of OECD member countries.[6]

Yet the capacity to invent in exists in developing countries. Many poor countries have universities and government-run laboratories where research takes place, particularly in the fields of medicine and agriculture. However, the patent incentive is not available to many developing country inventors in these fields because there still is no effective patent protection for health related technologies. The TRIPS Agreement gave to least developed countries a long grace period before they were required to provide patent protection for pharmaceutical products. And, in December 2001, the WTO Council agreed to extend this grace period until 2016.

Since, medicine is the focus of much of the public sector research that takes place in the developing world, this means a large proportion of developing country inventors continue to be shut out of the patent system.

Further, the national patent offices of many developing countries are under-funded and under-staffed, making it difficult for them to provide services to local inventors.

And, the cumbersome and expensive formalities of global filing make it difficult, if not impossible, for developing country inventors to obtain patent protection in the world's big markets, such as Europe, The United States, and Japan.

The lack of Patent protection for pharmaceutical products in many developing countries also is a product of import substitution policies that were popular among development economists in the later half of the 20th Century. These policies led to national

[6] WIPO, *Industrial Property Statistics, Publication A: 2001*

pharmaceutical markets being dominated entirely by local companies copying the drugs of developed country inventors. In some countries, such as Argentina, these local companies have formed a strong national lobby in opposition to the introduction of patents for pharmaceuticals. While such lobbying may result in maintaining market dominance for domestic copiers of foreign pharmaceuticals, it precludes the development of a local research-based commercial pharmaceutical industry. This kind of lobbying activity extends to international providers of pharmaceuticals. Recently, non-patent pharmaceutical industries in countries like Thailand and India have attempted to capture the market for antiretroviral drugs for the treatment of AIDS purchased under grants from the Global Fund for AIDS, Tuberculosis and Malaria, by requesting the Fund's Board of Directors to establish a preference for the use of drugs supplied by such companies, and to guarantee a profit to such companies as a part of the preference. Thus far the Global Fund has not yet established such a preference.[7]

The Controversy Over Aids Medications and the Doha Declaration

The HIV/AIDS epidemic has caused many to question whether a stronger global patent regime creates new obstacles to meeting public health emergencies.

Article 31 of the TRIPS Agreement permits WTO member states to limit the exclusive rights of patent owners where a national government needs to use the patent itself or where it is necessary to issue a compulsory license to a third party, such as in a health emergency. While 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 only if "efforts to obtain a voluntary license on reasonable terms and conditions" are first made. And, the scope and duration of the use must be limited and the compulsory license or government use must be non-exclusive. Article 31 limits these exceptions, to "the supply of the domestic market of the member [state] authorizing the use." It also requires that "the patent owner must be paid adequate remuneration taking into account the economic value of the authorization."

These Article 31 provisions became the subject of a contentious debate at a meeting of trade ministers in Doha in November 2001. The debate resulted in a ministerial "Declaration on the TRIPS Agreement and Public Health" that acknowledged, "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."[8]

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[7] Interview with observers at recent Global Fund Board meetings.

[8] The Ministerial declaration stated: "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."

While the ministers agreed that there were "WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector…" they were not able to agree on waiving the limitation of compulsory licenses to the domestic market only. The TRIPS Council was requested to resolve this issue before the end of 2002. It was not, in fact, resolved until August 30, 2003 when WTO's General Council agreed that compulsory licenses could be issued for imports from another country where "needed to address the public health problems" referenced in November 2002 Declaration, namely situations involving "HIV/AIDS, tuberculosis, malaria and other epidemics." Further, the decision required that the importing country establish "that it has insufficient or no manufacturing capabilities…for the product(s) in question…" and that "only the amount necessary to meet the needs of the eligible importing" country could "be manufactured under the license…" With regard to the question of royalties to be paid to the patent holder, the decision reaffirmed that the exporting country was responsible to see that "adequate remuneration" is paid *"taking into account the economic value to the importing Member…."* (Emphasis supplied.) These limitations contained in the decision itself were supplemented with a statement of the Council Chairman noting that the system "established by the Decision should be used in good faith to protect public health and … not be an instrument to pursue industrial or commercial policy objectives."

As of this writing no compulsory licenses under Article 31 of the TRIPS Agreement have been issued, including compulsory licenses involving importation under August 30, 2003 decision. However, Brazil is in the process of enacting legislation authorizing the use of such compulsory licenses. Also, the author has been informed that the government of Brazil has demanded that patent owners reduce already discounted prices for HIV/AIDS therapies used in that country to a level equivalent to those charged in the least developed countries, or face compulsory licensing. Such a demand clearly violates the Article 31 provisions in the TRIPS Agreement, reaffirmed in the recent WTO Council decision, that the "right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization." The "economic value" of a license in Brazil – a middle-income country – is clearly higher than in a least developed country.

Threats to use the compulsory licensing provisions of TRIPS article 31 to depress pharmaceutical prices to a level below what national markets can afford violate the fundamental trade-off of the Uruguay Round negotiations which gave rise to the TRIPS Agreement – that rich countries would lower barriers to manufacturing imports from developing countries in return for effective market access to their technology-based products, including pharmaceuticals, in developing country markets. However, a greater concern is that attempts to use Article 31 to unfairly deprive pharmaceutical innovators of a return on investment may have the result of discouraging the developing of better drugs that can effectively bring an end to health crises such as the AIDS epidemic.

Inadequate Patent Protection Discourages the Development of a Market for Pharmaceuticals Addressed to the Disease Burden of Developing Countries

The global market for pharmaceutical products was 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 pharmaceutical research and development occurring in these developed countries. And, the presence of strong patent protection combined with the concurrent ability to assure a profitable return on investment means that commercial pharmaceutical research and development is being overwhelmingly directed at producing drugs which will meet patient needs in these developed countries, especially the needs of patients in the United States of America. This is confirmed by economic research that has compared the relationship between gross profit margins of pharmaceutical companies with research and development outlays.[11]

The power of these economic forces to focus pharmaceutical research and development on the disease burden of richer countries with strong patent systems is seen in the fact that of the 308 essential drugs listed by WHO in 2002 as essential to developing country public health systems, only five percent were patented in any jurisdiction.[12] And, by WHO estimates at least a third of all patients globally lacked access even to these mainly off-patent medications.[13]

Much of the research and development that occurs in developing countries is financed by the public sector rather than private pharmaceutical companies, which in these countries overwhelmingly manufacture generic versions of drugs developed elsewhere.

An example of a country with significant public sector investments in life sciences research is Brazil. The State of Sao Paulo directs 1% of its annual tax collections to the support of public sector research and development through a foundation established by the state. Sao Paulo state generates 70% of the GDP in the 10th largest economy in the world. Yet, this investment has not resulted in commercial pharmaceutical products. This should not be surprising in that until very recently Brazil provided no patent protection for the health related inventions flowing from these public investments. And, few government and university laboratories in Brazil have a mechanism in place for patenting and licensing to the commercial sector the work of their scientists. Most patents on

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[9] IMS Health, *Market Report* (August 2001) http://www.ims-global.com/insight/report/global/report.htm.
[10] *Id.*
[11] 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.
[12] International Federation of Pharmaceutical Manufacturers Association, News Release: TRIPS Council Special Session (Sept. 21, 2001) http://www.ifpma.org/pdfifpma/tripscouncil.pdf.
[13] World Health Organization [hereinafter "WHO"], *The Impact of Essential Drugs* http://www.who.int/medicines/strategy/whozip16e/ch04.htm (last visited Apr. 15, 2002).

pharmaceuticals granted in Brazil today are issued to foreign nationals and protect work done abroad, not research results of Brazilian scientists.

Brazil's experience is similar to many countries in the developing world, such as India and Argentina. This means that countries with ecosystems rich in the genetic starting material of possible new drugs – and traditions of folk medicine providing clues to the potential of this starting material – lack policies most likely to encourage commercialization of these resources. Yet, this is the kind of pharmaceutical innovation most likely to address local and regional disease burdens.

Promising Developments

There are signs of change in some developing countries. One example is India. The Indian Council for Scientific and Industrial Research (CSIR) has established an aggressive program to commercialize the research of the scientists working in its laboratories. This program involves identifying useful inventions and patenting them not only in India, but in big markets like the United States as well. In 1991 CISR received 6 patents from the United States Patent & Trademark Office. In 2002 the number of U.S. patents granted to CISR had risen to 145. Many of these patents involve pharmaceutical products arising out of research based on traditional knowledge and the local ecosystem of India. One of the most successful examples is Asmon, a polyherbal medication for the relief of bronchial asthma, which blocks the leukotriene and lymphokine pathways that cause asthma. The product is now on the market in India and is available to asthma sufferers in that country at a price they can afford.[14] Similar commercialization activities involving new therapies for leprosy, HIV and cancer are in development as a result of partnerships between CISR and private Indian pharmaceutical companies such as Cadila Pharmaceuticals, Ltd. [15]

University research in Brazil is leading to spin-off biotechnology companies specializing products based on the rich genetic resources of the Amazon region. [16]And, organizations such as the Gates Foundation and the Global Malaria Initiative are funding efforts to viable create pharmaceutical industries in developing countries that can address the disease burdens of those countries. The innovative efforts of One World, Health, Inc. of San Francisco to transfer patent rights and technology to such companies is an example of these efforts.[17]

Conclusion

Many developing countries have the capacity to build research-intensive pharmaceutical industries capable of operating profitably by providing products directed to the diseases

[14]Information supplied by R.K. Gupta, Head, Intellectual Property Management Division, CISR, India. September, 2003.
[15]Information supplied by Prabuddha Ganguli, Ph.D., Mumbai, India, September 2003.
[16] Information supplied by Antonia Paes de Carvalho, President, Extracta Molecules Naturais, Rio de Janeiro, Brazil, September 2003.
[17] *See* http://www.oneworldhealth.com for a description of this program.

common to their own nationals that can be supported by the economics of the local market. However, for such local industries to take root and grow, effective patent protection must be made available, the commercialization of publicly funded research must be encouraged, and compulsory licensing must be kept to a minimum. Wealthy countries can assist this process by subsidizing local markets for the purchase of drugs through the Global Fund, and by direct programs of assistance such as that recently proposed by President Bush. Consumers in all countries can share the burden of drug development equitably by paying for medicine at a price level consistent with their means, rather than attempting to shift the costs of drug development to others.