

Dear Reader:

Intellectual property, international trade and public health. There are a few who argue that there is no compatibility of interest among these three major areas of modern attention. In fact, however, intellectual property is a positive driving force behind both the growth of international trade and for improvements in global public health. The common denominator is innovation bringing new products and new options and choices — new drug therapies and preventive vaccines — to patients, thus ever decreasing the scope of what were once considered as ‘incurable diseases.’

However, there still remain areas of discussion over the nature of the benefits of intellectual property for developing countries — and concerns about ‘access’ to drugs. In reality, developing countries have much to gain from the new global intellectual property system being brought about through the WTO TRIPS agreement. But this does depend to some extent on the adoption of appropriate global financing and infrastructure development policies — as well as national attention to health care priorities.

This paper reflects some of the international discussions over TRIPS and its public health implications. We hope that you will consider this broad overview and refer to some of the other documents IFPMA has produced on related subjects that cover access to healthcare and drugs (including public-private partnerships, e.g., on AIDS, malaria and vaccines), parallel trade, data exclusivity, international price variations and patents. Please consult the IFPMA Website at www.ifpma.org.

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International Federation
of Pharmaceutical
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TRIPS, PHARMACEUTICALS AND DEVELOPING COUNTRIES: IMPLICATIONS FOR HEALTH CARE ACCESS, DRUG QUALITY AND DRUG DEVELOPMENT

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I. The Health Role of Patents and Other Intellectual Property Rights

It has been suggested by some observers of the global health situation that access to health care can be expanded through weakening intellectual property rights. This policy approach is based upon two challengeable views: (1) that all measures to deny intellectual property rights will significantly improve health care or drug access for those who lack it; and (2) that distribution of existing products in the short term is much more important than the development of new products in the long term.

Such a short-sighted perspective is not without its precedents. In 1900, US Patent Commissioner Charles Duell proposed that patents stop being granted because, he said:

“Everything that can be invented has been invented.”

While such a view could be seen as a quaint relic of a century ago, another more recent observation, this time by the chief medical officer of the USA, the Surgeon-General shows that short-sightedness is not the monopoly of our forefathers. In 1967, the Surgeon General, William Stewart, stated simply:

“We can close the book on infectious disease.”

Today, humanity is living with over 25 new infectious diseases that have been identified since 1973, including AIDS, which was identified in the early 1980's. The famous medical research scientist Dr. Joshua Lederberg of Rockefeller University was much closer the mark when he wrote three years ago:

... We are intrinsically more vulnerable than before... We could imaginably adapt in a Darwinian fashion, but the odds are stacked against us... In the race against microbial genes, our best weapon is our wits, not natural selection of our genes.”

The best insight into how to meet this challenge comes from a national leader over 140 years ago – Abraham Lincoln. His view spans the decades on the need for innovation, noting the critical role patents play in increasing consumer welfare. He said in a speech in 1859, a year before he became president:

“The patent system... secured to the inventor, for a limited time, the exclusive use of his invention; and thereby added the ***fuel of interest to the fire of genius*** in the discovery and production of new and useful things.”

This is a firm statement by one of that country's historically great leaders on the importance of full patent protection, guaranteeing the inventor a limited period of "exclusive use". The benefit for the public welfare through this process is clear: public value – through the development of new pharmaceuticals which eventually will come into the public domain – is created in exchange for a limited period of exclusivity for the innovator.

The need for such innovation is even more important today because, as noted previously, more than 25 infectious diseases have been newly recognized since 1973. Some of these diseases are already global in impact, e. g., HIV/AIDS. Others, like cholera, malaria and TB, are re-emerging as global health threats. Factors identified in the emergence and re-emergence of infectious diseases include societal factors (war, urban growth, impoverishment), as well as behavioral (drug use, sexual behavior), environmental (flood, famine), infrastructure (lack of trained health personnel), and health factors (overuse of antibiotics, reduced prevention programs).

New technologies and access to these new technologies will be vital in the fight against communicable and non-communicable disease (e. g., mental health disorders, tobacco addiction). These new technologies, in turn, will depend on strong patent and other intellectual property protection.

The patent system, as recognized by Abraham Lincoln in 1859, represents a compromise between competing short-term and long-term economic and social interests. It also must be noted that a patent is not a simple "monopoly". Due to competition from other products and treatment techniques, products produced under patent protection still face therapeutic competition and thus are subject to market competition. The patent system, along with a well-functioning regulatory structure and marketing system, allows the private pharmaceutical industry to operate and contribute in a socially driven public health sector, providing it with cost-effective new technologies.

The commercial sector discovers and develops nearly all new drugs and vaccines, and the dependence of pharmaceutical and vaccine discovery and development on adequate and enforceable intellectual property rights is the highest among various industry sectors. It is very expensive and risky to find a new drug compound or vaccine today, and there are several hurdles that must be overcome before it can come to market:

1. The compound must be patentable. It takes a great deal of time, effort and resources to discover and develop new pharmaceutical products which fulfill the requirements of patentability (i. e., being novel and useful inventions);

2. It needs to meet high regulatory standards of safety, effectiveness and quality. The tests required by the major regulatory agencies to meet their standards are very costly and time-consuming; and
3. It must demonstrate the market potential required to achieve a return on the expenditures made in its discovery and development. As pharmaceutical companies are completely self-financed, the return on products in the market needs to pay not only for the products' own R&D and manufacturing costs, but must also cover the costs for developing drugs which do not make it to market (about 999 of every 1000 potential products) and for future research for improved medicines.

Though the patent system cannot address the latter two hurdles, it does provide the incentive necessary to investigate thousands of new compounds and invest an average of several hundred million dollars – the cost of R&D in industrial countries according to US government studies – over more than a decade. (The cost of research and development in developing countries could be much less, however, because the cost of doing clinical trials, including trials that meet international standards, will tend to be less in such countries than in industrialized countries due to lower labor costs.)

The effect of patent protection on research can be measured in terms of the number of drugs and vaccines that are currently in the industry R&D pipeline.

In the United States alone, there are over 100 medicines in development for AIDS, including over 30 anti-retrovirals (such second-generation protease inhibitors), a dozen potential vaccines, over 15 anti-infectives and about a half-dozen gene therapies. Also, there are more than 130 medicines to treat or prevent other infectious diseases, including over 40 vaccines. This number includes the many medicines which industry has developed in the fight against tropical diseases, including malaria, river blindness, sleeping sickness, trachoma, leprosy, lymphatic filariasis, TB, schistosomiasis and helminthiasis, as well as diseases that are prevalent in both developed and developing countries, such as upper respiratory infections which are the largest causes of mortality in developing countries.

II. TRIPS and Investment in Research and Development

To date, research and development have been concentrated in international companies whose home bases are in industrialized countries providing adequate patent protection. In the past a number of developing coun-

tries lacked adequate patent protection for pharmaceutical products. Beginning in the decade of the 1980's, however, the worldwide approach to pharmaceutical patent protection has been changing. As countries develop economically, home-grown, knowledge-based industries grow and grass-roots demands for intellectual property protection develop.

The following developing countries extensively changed or substantially strengthened their patent systems to move towards compliance with their international obligations under the WTO Trade Related Agreement on Intellectual Property Rights (known as TRIPS):

Korea (1987)	Czech and Slovak Republics (1990)
Indonesia, Mexico, Bulgaria, Chile and Belarus, (1991)	Thailand, Taiwan, Romania, Russia and the Ukraine, (1992)
China, Yugoslavia, Poland, Slovenia, Macedonia (1993)	The Andean Pact, Hungary (1994)
Brazil (1996)	Jordan (2000)

Because of the effect of regulatory delays in reducing this 20-year life to below 10 effective years of marketing exclusivity under a patent, the following countries and regions have gone further and have added 4-5 years onto the TRIPS-required standard 20-year nominal patent life for pharmaceutical products:

United States (1984)	Japan (1987)	European Union (1992)	Australia (1998)
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Thus, eighteen members of WHO provide more protection than required by the WTO TRIPS standard of 20 years, and this number is likely to increase in coming years as more countries choose "patent term extension" to promote innovation in pharmaceuticals and as more countries join the European Union, accepting the EU's "*acquis communautaire*" as a condition of joining.

Finally, at least two countries recently eliminated their systematic compulsory licensing of pharmaceutical product patents:

Canada (1987,1992)	New Zealand (1992)
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Under the TRIPS agreement, as of 1 January 2000, many countries are obligated to adopt additional intellectual property rights laws and regulations, including new anti-counterfeiting measures. By 2005, all WTO member countries will have adopted full product patent protection for

pharmaceuticals and biotechnology medicines. (There is a possibility of additional time extensions to be granted for the least-developed countries as defined by the United Nations.)

The particular importance of patent protection to the pharmaceutical sector can be seen in the following chart, showing the degree to which various industries depend on patent protection for the discovery and development of innovative products¹:

Industry	% that would not have been introduced	% that would not have been developed
Pharmaceuticals	65%	60%
Chemicals	30	38
Petroleum	18	25
Machinery	15	17
Fabricated Metal Products	12	12
Primary Metals	8	1
Electrical Equipment	4	11
Instruments	1	1
Office Equipment	0	0
Motor Vehicles	0	0
Rubber	0	0
Textiles	0	0

The same author of this study also published studies for the IFC affiliate of the World Bank showing how developing countries also benefit from strong patent protection, especially in terms of attracting investment.

In some developing countries, a fundamental change is already occurring which promises to improve the supply of effective new drugs and vaccines and to improve access to medicines for patients worldwide. In developing countries, drug R&D has been rising in countries that are experiencing strong economic growth and which have adopted more effective patent protection in recent years. For example, most new patent applications in Korea are coming from local companies, and Korea is becoming a technology exporter.

Even in countries such as India, which seek to take advantage of the TRIPS transition period, local companies see the future changing from one

¹ Source for this chart is: E. Mansfield. "Patents and Innovation: An Empirical Study". *Management Science*. February 1986.

in which molecule copying or “piracy” is condoned to a situation where intellectual property rights are respected and protected. As a result, Indian companies are adopting several strategies to meet the TRIPS challenge. One senior Indian executive recently described them as follows:

1. Shift from reverse engineering to product development
2. Commencement of basic R&D activities
3. Pooling of resources
4. Upgrading facilities (i. e., to global GMP standards)
5. Developing strategic ties to international companies

As described by important Indian pharmaceutical executives, the opportunities for developing countries are to do:

1. R&D activities on diseases which are particular to developing countries
2. Clinical trial and other development activities
3. Development of the global marketing of the domestic pharmaceutical industry

The benefits foreseen for developing countries in raising the level of intellectual property rights protection for pharmaceuticals are seen as

Social and Economic:

1. Improved healthcare through access to newer medicines
2. Access to modern technology and information and technology transfer
3. Stimulation of indigenous R&D aimed at unmet medical needs
4. Job creation for skilled labor
5. Raised profile as country to host high technology investment
6. Robust economic growth
7. Increased joint ventures
8. Limit on “brain drain”

Political:

1. Improved international credibility
2. Contribution to global technological advance
3. Creation of image as a visionary rather than reactionary political regime²

The main conclusions to be drawn from a serious look at the role of TRIPS-style protection of intellectual property rights in health and econom-

² Dr. P. V. Venugopal, “Industrial Property and the Pharmaceutical Industry – Opportunities and Challenges for Developing Countries,” WIPO Conference on Intellectual Property and Economic Development, Geneva, June 3, 1999.

ic development is that it stimulates a true globalization of the effort to find cures for disease, spreading the effort to countries that have core scientific skills but previously lacked the incentives that, as US President Abraham Lincoln once said, fuel the fire of genius. Local companies, with or without the help of international firms, have the advantage of being close to disease patterns that can be of greater importance to their locales than to countries where large international companies are based. Thus, TRIPS increases the probability that better treatments will be found for diseases, such as malaria and TB that have been “neglected” in drug development.

Protection of trademarks, as under TRIPS, also helps to clean up counterfeit products from the marketplace. TRIPS requires countries to implement strict and strong measures to reduce counterfeiting. Counterfeit and substandard pharmaceuticals pose serious risks to public health and safety, as well as burdening perhaps under-resourced regulatory and customs authorities. Essential antibiotics are the most counterfeited types of products in developing countries, leading to increases in lives lost and morbidity from bacterial diseases and antibiotic resistance. Thus, effective intellectual property protection leads to improved public safety through helping eliminate counterfeit and substandard drugs from the marketplace and improving the quality of the drug supply for the population. The strength of patent incentives will only be as great as there is the absence of loopholes that benefit copycat firms or international traders.

III. Misconceptions About Compulsory Licensing (CL)

“Compulsory licensing” has been touted as an elixir or magic policy potion to improve conditions of access to medicines in developing countries. Compulsory (or “forced”) licensing of a patent to a competitor, provided for in some way in most countries, is normally limited in application to extraordinary circumstances, often related to technology issues in industry mergers, particularly in the US and European Union.

Proponents of an activist compulsory licensing system see the issue in terms of consumer price benefits arising from effectively abrogating the patent’s marketing exclusivity. They ignore many of the problems with this approach, which was last used extensively in Canada and repealed in 1992.

First, advocates of such a policy assume that there is a licensee that can duplicate the originator’s skills in manufacturing an equally safe and effective product. This issue is complex and deserves more consideration than

any activist compulsory licensing proponent has given it. “Know-how is critical to supplying patients safe and effective products.

Second, there is an assumption that governments will use this “tool” as a pro-consumer tool – creating a very large difference in prices between the originator compound’s price and the copiers’ product prices. However, recent history suggests that governments tend to use compulsory licensing measures as industrial policy. In Canada, under the compulsory licensing system existing for a number of years, generic versions received prices that were approximately 75 % of the originator’s price – without having to pay any R&D costs and less than 5 % in royalties to the patent holder. Experience thus shows that under a CL scheme, in most instances, the major beneficiary will be the copier, not the patient or social insurance system, arising from an interaction between the government and local producers. (The same result occurs in a system of parallel trading – the major beneficiaries of parallel trade are the traders, at the expense of the patient in the low price country and the originator/inventor.)³

Finally, if a country adopts CL measures or a disease area (e. g., HIV/AIDS) is subject to CL policies, then a natural consequence is that fewer research funds will be allocated either to that country or disease area due to the resulting disincentives for research in these areas. If AIDS drugs and vaccines were subject to CL measures, then one has to expect fewer improvements in the level of “pharmatechnology” in AIDS. The development of the new range of drugs available will be restricted, at the expense of AIDS patients and society.

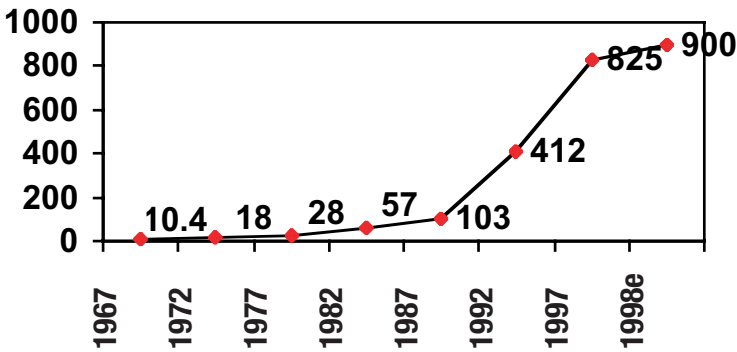
Evidence of the effect of CL on investment in a country is presented by the case of Canada. Canada repealed its 20-year compulsory licensing regime because it simply was inconsistent with drug R&D progress in Canada and it did not bring great consumer benefits, as noted above. Canada was helped along by a provision to which it was a party in negotiating the TRIPS agreement – i. e., Article 27 that does not permit governments to discriminate unfavorably against patent holders according to their “field of technology.”

But the more substantive reason that Canada’s policy changed in 1992 is that the Canadian society suffered from a lack of R&D with no offsetting benefit except that which was conferred narrowly on a few local copying firms.

³ Please see H. Bale, “The Conflicts Between Parallel Trade and Product Access and Innovation: The Case of Pharmaceuticals,” *Journal of International Economic Law*, Vol. 2, No. 1 (Oxford University Press, 1999) pp. 637-653. Also: C.E. Barfield and M.A. Groombridge, “Parallel Trade in the Pharmaceutical Industry; Implications for Innovation, Consumer Welfare and Health Policy”, *Fordham Intellectual Property, Media & Entertainment Law Journal*. Vol. X, No.1. Autumn 1999.

The chart below shows the evolution of overall Canadian pharmaceutical R&D from 1967 to 1998. The Canadian CL policy was in its most severe phase from 1969 until 1987, when it was relaxed somewhat. It was repealed in 1992, and the subsequent increases in investments in R&D in Canada have been dramatic -- as shown by the following chart. Canada has shifted from being an earlier “free-rider” on research and development performed abroad to becoming an important location of R&D into new, including biotechnology, medicines.

Canadian Pharmaceutical R&D Spending
(C\$ millions)



Sources:

1997, 1998 as compiled by Deloitte and Touche

1984-1987 as compiled by Peat Marwick, 1988-1995 as compiled by the Canadian PMPRB

IV. Problems Beyond Patents That Need to Be Addressed: Access to Quality Health Care

The Director-General of the World Health Organization has said that a third of the world’s population and far too many patients in developing countries have inadequate or no access to existing quality essential medicines, and that there are no “quick fixes” to this problem; also, the WHO correctly notes that many diseases prevailing in the poorest of the developing world lack effective new therapies or vaccines (e. g., malaria).

Thus, there are two major gaps identified here: 1) a “discovery/development” gap between the morbidity and mortality in developing (as well as, developed) countries and available remedies; and 2) an “access” imbalance between consumption of medicines in the developing world and the

developed world. The exposure of poorer countries to the discovery/development gap is particularly acute because of poverty, poor infrastructure and urbanization. It should be added that there are a number of other health and pharmaceutical-related gaps that should also be highlighted that contrast the health situation in the 'North vs. South' context:

- *The Quality/Counterfeit Medicines Gap*: Patients in developed countries can be assured that the medicines that they consume are genuine and quality products; on the other hand, very many patients in developing countries are exposed to substandard products, either lacking in GMP standards or being outright counterfeits; this is related to the relatively large gap in regulatory capability and training between developed and developing countries as well as the differences in enforceability and penalties for counterfeiting activities;
- *The R&D Imbalance*: While the relative incidence of infectious diseases is higher in developing countries, up until now little pharmaceutical or vaccine research and practically no drug and vaccine development has gone on outside of the laboratories on international companies, including R&D on malaria and TB;
- *The Urban/Rural Gap*: In the poorer developing countries, a small minority of the population live in towns; but they receive three-quarters or more of medical services and products; this geographical variance in access to health care is, to a certain extent a global phenomenon, but bears most heavily on poorer populations in developing countries.

The problem of the gap in access to drugs is related to issues involving access to adequate *health care* generally. The access issue concerns the accessibility to existing therapies, whether they are pharmaceutical, primary care or hospital care.

In most developed and some newly industrialized countries, access to health care depends on whether the health care system in a country applies universally, which is the principle that basic health services should be available to all by right, according to need, and not restricted by individual ability to pay. It is consistent with the World Health Organization (WHO) "Health-for-All" objective. For the poorest developing countries, however, the question of universality may not arise due to the lack of resources to provide even rudimentary health care to many citizens. Indeed, even if universal access to health care is mandated by a country's constitution, as in Brazil, misallocation of resources and poor infrastructure make delivery of quality health-care very uneven across the population.

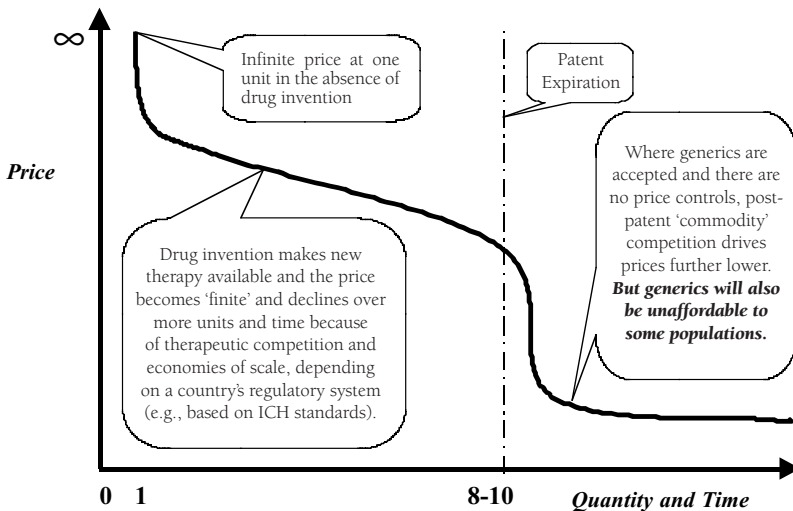
Therefore, understanding the causes of access problems for the poorer developing countries is an important and complex exercise. It would be incorrect to suggest that access to health care and pharmaceuticals is a problem that should be examined solely in terms of one variable, such as pharmaceuticals – particularly with a focus on their costs and prices.

V. “Costs” and Access to Medicines

One needs to carefully consider what “costs” are. Is the cost of a drug the issue looked at in terms of its absolute price – or should costs be considered from the point of view of the costs of disease to the health system and society as well as the savings, well-being and economic growth gains that can be had through therapeutic and vaccine innovation?

It is worthwhile to devote some thought to the subject of costs and prices of innovative medicines. Indeed, what is the price of a cure or vaccine that does not exist for a disease? In reality, it cannot be bought at any price. Regardless of anyone’s willingness to pay, neither rich nor poor can buy a medicine which does not already exist. Therefore, its price is, in a real sense, infinite. The following diagram illustrates this concept:

**Affordability – Is the Problem the Drug or the Disease?
Drug Life-Cycle (circa 2000)**



While the “price” of a treatment, cure or vaccine is infinite in the absence of a new drug, innovation makes therapeutic options available. Further, therapeutic competition among alternative drugs drives market prices lower, with post-patent conditions making the product a generic ‘commodity’ subject to even greater competitive pricing pressures.

However, certain people will not be able to afford the treatment at any time during the product’s life cycle. A drug, or any other health intervention, cannot be “affordable” to everyone as long as incomes are unequally distributed, as they are everywhere. Special means must be developed to improve access to the poorest populations.

Improving conditions for access correctly means focusing on a wide number of factors affecting access to health care and medicines. Indeed, access to health care is restricted in many ways. For example, where some developed countries impose tight restrictions on spending on health care, rationing arises and lengthy waiting times have evolved, for example, for heart surgery, reducing the quality of life and increasing pain and general discomfort to patients. Patients in the United Kingdom are among those experiencing such decreased quality of care due to an over-emphasis focus on monetary cost of treatment while discounting the physical and economic costs borne by the patients and society.

In developing countries, insufficient funding often exists to provide even the most basic healthcare services and products to the majority of the population, while the elites within these countries have access to international standards of care. Within developing and developed countries, people working in the gray labor market are often not allowed to enter the social security health care system. These examples are just a few that illustrate barriers that exist to restrict access to health care. The problems of access to health care can be generally classified into the following areas:

- Conflict, Social and Political Issues
- Financial Hurdles
- Physical Barriers
- Damaging Economic Policies
- Informational Gaps
- Cost and Price Issues

Conflict, Social and Political Issues

- **Conflict and political problems:** The existence of cross-border and civil conflicts in many developing countries prevents healthy people from being vaccinated and sick people from being treated.

- **Language barriers:** If the patient is illiterate or does not understand the language used by the health care providers, then they will have difficulty in accessing care.
- **Minority (including ethnic or gender)** groups may experience discriminatory access barriers.
- **Problems of corruption:** In countries where corruption is prevalent, health care access is impeded through diversion of products and services from official channels into black markets.

Financial Hurdles

- **The shortage of financial resources** in the poorer developing countries is the most important barrier to access to health care, including medicines, in these countries.
- **Lack of adequate public funding:** Not even rudimentary health care is provided by many countries due to insufficient resources and/or from governments not setting health care services as a high enough priority in determining the use of national resources.
- **Inadequate purchasing power** for medicines and a lack of an adequate number of medical professionals and hospital facilities to deliver health care result from this lack of adequate financial resources.

Physical Infrastructure Barriers

- **Inadequate health care facilities** to meet the needs of a growing population due to insufficient public and private resources.
- **Insufficient transportation infrastructure** to permit access to medical care providers for much of the population.
- **Unequal distribution of health care facilities**, which may be, concentrated in densely populated urban areas, leaving wider, rural areas without adequate coverage.
- **Inadequate nutrition and water supply**, which weakens the general health of the population. Furthermore, resources which could be used for health care are instead devoted to the additional efforts needed for procuring food and water in poor-infrastructure environments.

Damaging Economic Policies

- **Protectionism:** Many governments protect their local insurance and pharmaceutical companies from foreign competition through tariffs and other trade barriers, making local insurance and pharmaceutical costs higher than they should be.

- **Non-competitive distribution networks:** Protected wholesalers and other distributors can artificially raise distribution margins, making drug costs in developing countries high – perhaps even higher than in some developed countries.
- **Poor Intellectual Property Protection:** The lack of adequate and effectively enforceable intellectual property rights hurts access to health care and pharmaceuticals by eliminating incentives for research and development of new products.
- **Price Controls:** Price controls tend to reduce supply and damage incentives for the research and development-based industry, as well as negatively affecting the development of a GMP-based local generics industry, as can be seen in looking at the experience in countries in Europe with the tightest controls.

Informational Gaps

- People may fail to access health care due to a **lack of information about the need to treat diseases** such as tuberculosis, hepatitis, or hypertension.
- Patients may not know how or where to access health care (particularly in the cases of minorities or immigrants).
- Self-medication by poorly informed patients may lead to **ineffective drug utilization**.
- **Poorly-informed physicians** in developing countries often treat illnesses such as diarrhea inappropriately or not cost-effectively.
- **Uncertainty about the quality of generic products:** In most developing countries, providers and patients prefer brand name products because they are unsure of the origin, safety and reliability of generic products.
- **Lack of adequate training for inspectors and regulators** allows substandard and counterfeit drugs to enter national markets and endanger the population's health.

Cost and Price Issues

- Regarding the price impact in the market from the introduction of patents, the evidence suggests that the linkage is weak or, in many cases, non-existent due to price levels being determined by many factors – distribution conditions and markups, price controls, foreign exchange fluctuations, inflation, taxes, measurement techniques, differing treatment modalities and others. In a 1995 study, countries with intellectual prop-

erty protection did not have higher prices than countries without such protection. Indeed, countries such as Argentina, Egypt and Jordan (which did not have protection at the time) often had higher prices than Korea, Mexico and Taiwan, depending on the product. In looking at manufacturers' price and sales data over a period of 11 years, the authors confirmed that "improving intellectual property protection does not cause prices of existing branded or licensed pharmaceutical products to increase."⁴ The Children's Vaccine Initiative, in its 1999 publication: "Intellectual Property Protection: Its Role and Benefits", noted that while patents and royalties do not raise the price of vaccines "dramatically", "... countries which do not recognize IP... may actually inadvertently hinder access to vaccines... by discouraging legal vaccine technology transfer and by failing to encourage domestic vaccine research and development."⁵ Patient groups and decision-makers are increasingly recognizing this reality. As the "European Coalition of Positive People" recently noted with regard to HIV/AIDS drugs, focusing on patent protection and pricing is "simplistic and fails to take into account the serious practical problems that need to be addressed...."

- Patents do not, in fact, have a significant influence on access to the drugs which most of the population in developing countries actually consumes, which are primarily off-patent drugs. Furthermore, many developing countries do not currently have TRIPS-compliant intellectual property legislation and the poorest of these countries will not be required to implement such legislation until 2005.
- Countries without effective patent protection could already start producing their own versions of patented products. In fact, India already produces generic copies of patented AIDS drugs. If patents were indeed the problem, large populations within India and similar countries should have easy access to these copied, generic versions of AZT and other medications; but in India and parts of Africa this is demonstrably not the case. Access is poor in some countries regardless of the status of patents.

⁴ See Rozek and Berkowitz, "The Effects of Patent Protection on the Prices of Pharmaceutical Products." *The Journal of World Intellectual Property*, March 1998, pp. 179-243, particularly Table 21 of that study; Children's Vaccine Initiative (CVI), *Intellectual Property Protection: Its Role and Benefits*, Geneva, April 1999, p. 3. The Rozek and Berkowitz study has been attacked, but not answered by critics of patent protection, except by the argument that "It's common sense!" that prices rise when patents are introduced. Thus, according to this argument – an argument reminiscent of the view of proponents that it is self-evident that the sun revolves around the earth -- no analysis is required. The CVI paper suggests minor pressures on the price of newer, patentable vaccines

⁵ CVI, *Intellectual Property Protection*. p. 6.

- It must also be remembered that patented products also face competition from off-patent products for the same conditions as well as with other therapeutic alternatives. Indeed, the time gaps between the introduction of innovative drugs and therapeutically similar products have lessened dramatically over time. About 30 years ago, it took ten years between the introduction of the first beta-blocker and the second one. Today, the time gap between innovator and follower products has been reduced to generally (plus or minus) one year.⁶
- Generic production is not an automatic answer to access, the evidence shows otherwise: generic producers in developing countries may charge lower prices than the original innovator (although there are cases where the generic competitor charges higher prices than the originator), but prices are still above levels which the majority of the population in developing countries can pay.

VI. Recommendations for Action

The following global actions are among those that might be considered to improve access and innovation for the benefit of developing countries in areas of the medicines and vaccines component of health care:

First, consider public-private partnerships for the development and distribution of medicines and vaccines where newer therapies are needed and where vaccines are not getting adequately distributed. Recent examples include:

The IFPMA/WHO/World Bank partnership – the recently-formed Medicines for Malaria Venture (MMV) – is designed to stimulate new therapeutic compounds, and eventually a vaccine, for malaria treatment.

The Global Alliance for Vaccines and Immunization (GAVI) has been established as a public-private partnership in order to increase national and multilateral aid financing for the distribution of vaccines that are emerging as valuable contributions to disease prevention in children. Lack of such financing in the past has hindered the access to older vaccines (e. g., smallpox, Hepatitis B) and will continue to be a serious problem if international agencies, do not give this matter higher priority;

⁶ Harvey E. Bale, Jr. "Patent Protection and Pharmaceutical Innovation". New York Journal of International Law and Politics. Volume 29 Number 1-2, Fall 1996-Winter 1997

Second, governments can foster local industry investment in R&D and transfer of know-how into developing countries through timely adoption of WTO TRIPS standards of intellectual property rights.

Local companies must shift their activities from copying drugs to developing new ones of importance in the fight against priority diseases (see the discussion of developments in India above). A corollary benefit of instituting incentives that stimulate technology transfer is the improvement of drug quality locally. It must be recognized that it is the weakening of patent protection that ultimately harms consumers and the local economy. In a recent editorial, an important Indian newspaper raised the question: “Who’s Afraid of Patents?” The editorial noted that local industry could really take advantage of TRIPS to both upgrade research and develop a global generics base. It noted: “Clearly, the Cassandras who proclaimed the death of the Indian pharmaceutical industry after 2005 were wrong.... In general, Indian companies have no reason to be frightened of stronger intellectual property regimes; indeed these might be a blessing in disguise.” (*Mumbai Business Standard*, April 19, 2000). As a corollary, counter-productive, ‘quick-fix’ schemes such as parallel trade and compulsory licensing need to be discouraged as they have the effect of discouraging technology-owners from supplying newer products and technology to local markets;

Third, governments can encourage local innovation by avoiding price controls, either directly or indirectly. Price controls tend to reduce the supply of newer innovative therapies and can have a distinctly dampening effect on innovation in pharmaceuticals, a trend which has been observed in Europe as well as in Japan. The vast majority of new products are discovered by industry and all products on the market were brought there through industry’s investing in developing, testing, and undertaking the very strict requirements needed to allow a product to be marketed, a long and complex process taking many years and costing into the hundreds of millions of dollars. Pharmaceutical research and development has a very high failure rate, however; and all further research for future products must be paid for by the pharmaceutical companies themselves from the revenues generated by products on the market. Thus, price controls are a very short-sighted policy: while they may make current medicines cheaper, in the long run they will make developing new drugs more difficult. Furthermore, as price controls often go from being “price ceilings” to “price floors,” they can lead to higher prices in the medium- to long run, compared to permitting competitive pricing in the post patent period.

Fourth, governments can stimulate the supply of affordable and high-quality generics in developing countries by working to inculcate the importance of good manufacturing practice among local producers.

International organizations and industry can help organize training seminars for local regulatory officials using industrial nations' R&D and industry expertise. Officials in developing countries might consider establishing regional centers for the promotion of good manufacturing standards. On the other hand, negative approaches such as attempting to withdraw the right of a producer to market its trademarked medicine, should be avoided. Trademarks are a sign of the origin of a medicine, and trademark owners must therefore stand behind the quality of the product. This promotes the quality of the products with concurrent improvements in public health and safety. If consumers, particularly in developing countries, avoid unbranded generics it is not because of trademarks, but rather because consumers lack confidence in their quality. Thus the answer is to focus on quality. To deny trademarks rights would be to soften the competitive and pressure on generics producers to produce high standard medicines.

Fifth, governments can ensure the supply of needed drugs in developing countries by working to prevent parallel trade.

Parallel trade is product diversion, which may seem seductive if a country's officials believe that they will be receiving relatively low-priced imports. However, for officials of the low-price country, parallel traders would be buying up supplies of essential drugs for resale in higher-priced markets, thus diverting them from the population who needs them. *When parallel trade is discussed it is always assumed by proponents that there are only parallel imports, and that there is no diversion of key products via parallel exporters. However, if it is assumed that parallel imports can make a significant difference in lowering the price domestically, then someone else abroad must be paying more through this diversion.*

Furthermore, even for importing countries, the alleged benefits of parallel trade tend to be less than expected. While the European Union has parallel trade within its borders consistent with its commitment to establishing a common market allowing the free movement of goods, services, capital and labor, the EU's experience shows that the benefits of parallel trade accrue mainly to the parallel traders, not consumers. This is because the former capture most of the "rents" arising from the differences in ex-manufacturer prices across countries and do not pass them on to consumers.

In addition, parallel trade distorts distribution channels and thus increases opportunities for counterfeit and substandard products to enter

the market, creating increased health and safety risks for consumers, as well as increasing the burden on inadequately resourced regulatory staff in developing countries. In fact, the experience of Kenya with parallel trade was so negative that the Director of the National Quality Control Laboratory even wrote to her counterpart in South Africa strongly warning South Africa to avoid using parallel trade. Re-importation of US-manufactured pharmaceuticals back into the US is forbidden for the same health and safety reasons, a position that has been supported by former FDA Commissioners who were directly responsible for US drug safety.

Sixth, governments might consider creating publicly-financed, regional research centers in the developing world to foster medical research, pooling the scientific expertise and related resources of many countries and providing a greater capacity to do research into disease areas of regional interest. While industry does its own drug discovery and drug development research, it also has worked with public agencies, such as the National Institutes of Health (NIH), to build on basic research to bring new compounds to patients. Perhaps developing countries and local and international industry together could, through such a mechanism, develop effective treatments for malaria, TB, HIV/AIDS, cancer and depression over the next decade.

Seventh, judicial authorities, the police and industry professionals in developing regions must work together to implement model anti-counterfeiting legislation to reduce the influence of organized crime in the distribution of medicines in both developing and developed countries. Severe penalties should be imposed for counterfeit drug traffickers, which make essential antibiotics and pain-relievers targets of their criminal acts;

Eighth, policy-makers should adopt global drug review standards to speed up the approval of new drugs. Improved access to medications can be helped through reducing unnecessary tasks and duplication in the review of drugs internationally. One major effort, conducted in partnership between the public and private sectors, is the International Conference on Harmonization (ICH), which has been in existence since 1990. Its mission is to improve the efficiency of the development and registration process of new pharmaceutical products, specifically in Europe, Japan and the USA. IFPMA has held two conferences in Southeast Asia on the subject of regulatory standards, and another conference will be held in Bangkok in March 2001; and

Ninth, consumers need to be empowered to choose well. Another vital aspect of effective access to medicines relates to information about these medicines and their proper use. Patients and consumers around the world are increasingly seeking more information about medicines and medical treatments to empower themselves in their own medical care. In particular, patients in remote areas, the elderly and the incapacitated are seeking better access to information about medicines. The Internet, as a truly global medium, therefore has the potential to be a vital and positive resource for society, as it can inform and educate global audiences and serve as a source of information on health care and medicinal products. Industry is concerned and joins in concerted efforts to meet the challenges and dangers posed by the use of the Internet to distribute medicines. In light of consumers' need for information, the focus of control measures by regulators should be on the physical movement of goods. In the area of globalization of information and trade, governments and international institutions need to consider appropriate policies regarding this new health care medium.

VII. Conclusions

The benefits of the new system of intellectual property rules embodied by the TRIPS accord far outweigh possible costs. The problem of access to health care and pharmaceuticals is serious and may get worse as conditions of poverty remain and are aggravated by continuing regional warfare. However, the problem of access to healthcare and medicines in developing countries is multifaceted. Therefore, it is important that the relative significance of the various barriers discussed in this paper is better understood, so that priority can be given to removing the most serious barriers – not through, what WHO Director-General Brundtland appropriately describes as counterproductive “quick fixes” -- but rationally and for the benefit of all.