

THE IMPACT OF TRADE RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS (TRIPS) ON ACCESS TO ESSENTIAL MEDICINES IN THE DEVELOPING WORLD

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ABSTRACT

Trade Related Aspects of Intellectual Property Rights (TRIPS) is a World Trade Organization (WTO) agreement designed by developed countries to enforce a global minimum standard of Intellectual Property Rights (IPRs). There is strong concern within the international health community of the negative impact the TRIPS standards have on the pharmaceutical industries in the developing world, and in turn the production and affordability of essential medication. Under TRIPS, as of 2005 all countries in the WTO have to protect both product and process patents on pharmaceuticals, which prevents developing countries from making generic versions of essential medications needed to maintain market competition and meet public health demands. In 2001 the Doha declaration granted an extension to least developed countries until 2016 for TRIPS compliance, however Bangladesh is currently the only least developed country with pharmaceutical manufacturing capability. Therefore Bangladesh is the only country in the world that can still produce generic versions of new essential medications, which are needed to prevent a global pharmaceutical monopoly and the inevitable increase of drug prices that would result from the destruction of generic competition as pursued by the pharmaceutical advocates of TRIPS.

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I sincerely thank you all,

Anne St. Martin

EXECUTIVE SUMMARY

Over half of the world's population lives on less than two dollars a day and cannot afford to purchase essential medications. Although the developing world contains eighty percent of the world's population, it has less than two percent of the world's wealth (World Bank), and consumes less than ten percent of the world's pharmaceuticals, most of which are only available to the wealthier residents of those countries. Over 2 billion people, one third of the world's population, do not have access to essential medications (WHO), and every day over 37 000 people die from treatable infectious disease (UNICEF).

Three decades ago, over twenty-five percent of world drug production was accounted for by developing and middle-income countries (Kaplan, 2006). However, over the last few decades, efforts to standardize international intellectual property laws have had a detrimental impact on the pharmaceutical industries in the developing world. This can be observed through the substantial decrease of pharmaceutical production in developing countries, and the centralization of the global drug market within the developed world. As a result, the majority of research and development is focused on diseases that affect the affluent population, while only one percent of pharmaceutical research is aimed at combating tropical illnesses which kill thousands a day in the developing world.

Moreover, there is great concern within the international public health community over the detrimental impact current patent legislation enforced by the World Trade Organization (WTO) has on health in the developing world. The agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) was integrated into WTO legislation after enormous pressure from the Multinational Pharmaceutical corporations. TRIPS was developed to harmonize international intellectual property rights (IPRs) to a standard that is designed for the economic benefit of the developed countries and not appropriate for the developing and least developed world. Advocates of the agreement claim that strengthening IPRs across the globe will serve to aid international development by promoting technological transfer, foreign direct investment (FDI), and increased exportation from developing countries. However, further analysis reveals that stronger IPRs do not aid proper technology transfer, are not considered by

the World Bank (WB) when determining FDI, and actually lead to a greater number of imports to developing countries rather than exportation from.

However, since TRIPS is part of the WTO agreements, developing countries that want access to the global market through the WTO must accept the TRIPS agreement, and integrate its IPR standards into their national legislation. Specifically, the TRIPS agreement requires that countries grant patents on all inventions without discrimination provided the inventions are considered “new” and have “industrial applications”. In addition, TRIPS requires that patents are granted for a period of 20 years, and allows for importation to suffice for proper “working of a patent” within the patenting country, which means that corporations no longer need to manufacture the patented product in every country in which they hold a patent.

The prime concern for health professionals lies with pharmaceutical patents, which may be granted separately for the process, or the method of manufacturing each specific drug, and for the product itself regardless of how it is produced. The countries that today own the majority of the world’s pharmaceutical market, including the US, Japan, and Germany, did not grant product patents on pharmaceuticals until the 60’s and early 70’s when their industries had developed internationally competitive research and development capabilities. Although patents were always issued to protect the product production process, without patent restrictions on products, pharmaceutical companies were still able to use reverse engineering techniques on needed medicines to uncover their molecular structure and thus develop new ways to build the drugs that were needed. These compounds produced through alternate processes were then sold as “generic” versions of the original drug, and drove down the price of the original product through market competition. This generic production not only served to provide much needed medications, but it also greatly strengthened their pharmaceutical knowledge base and research capabilities.

However, now these same countries that refused to grant product patents until well into the 60’s and 70’s are forcing developing countries to recognize and protect pharmaceutical product patents, thereby barring local production and research infrastructure development. Developing countries had until 2005 to implement the TRIPS legislation, and now the world’s primary generic distributors, India and China, are no longer able to produce much needed medicines at affordable prices, depriving millions of people essential medications needed to sustain life.

The TRIPS agreement contains, however, provisions designed to ensure that the agreement does not negatively affect public health, including compulsory licensing and parallel importation, but unfortunately the majority of developing countries lack the legal IP training needed to fully comprehend the TRIPS agreement. Moreover, in order to use the provisions, countries must integrate them into their national legislation, and without proper legal infrastructure and IPR knowledge it is virtually impossible to design TRIPS compliant provisional legislation.

In 2001 as the result of pressure on the WTO from international health activists, the Doha declaration granted least developed countries an extension on TRIPS until 2016. For the majority of least developed countries, the TRIPS waiver has little benefit as they do not have pharmaceutical manufacturing capabilities, and even with freedom from the limits imposed by pharmaceutical patents, they cannot produce medicines their citizens desperately need. Bangladesh, however, is the only least developed country in the world with pharmaceutical manufacturing capabilities, and therefore is currently the only country in the world that is capable of producing much needed drugs at an affordable price to save millions of lives in developing countries across the globe.

The annual general assembly of Health Action International Asia- Pacific (HAIAP) entitled “The Future of Health Services: Who Will Live and Who Will Die”, held April 10th to 14th, 2006, on the campus of Gonoshastaya Kendra, in Savar, Bangladesh, aimed to capture the attention of the Bangladesh media and politicians to convince them of the critical importance of their country with respect to pharmaceutical production and their national patent law. The conference participants, health professionals from the Asia-Pacific region, Africa, and Europe, unanimously recommended that the government of Bangladesh should reform its patent laws to exclude pharmaceutical products from patent protection, as it has every right to do under the WTO TRIPS waiver. This would provide its pharmaceutical industries the freedom needed to produce generic versions of drugs that are under patent in other countries, thereby ensuring affordable prices on essential medications and saving millions of lives worldwide.

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ACRONYMS AND ABBREVIATIONS

AIDS	Acquired Immunodeficiency Syndrome
ARV	Anti-Retroviral
DSB	Dispute Settlement Body
EMRS	Exclusive Marketing Rights
FDI	Foreign Direct Investment
GATT	General Agreement on Tariffs and Trade
GATS	General Agreement on Trade and Services
GDP	Gross Domestic Product
GNI	Gross National Income
HDI	Human Development Index
IBRD	International Bank for Reconstruction and Development
IMF	International Monetary Fund
IPRs	Intellectual Property Rights
ITO	International Trade Organization
LDC	Least Developed Country
MDG	Millennium Development Goals
MNEs	Multinational Enterprises
NCE	New Chemical Entity
NIC	Newly Industrialized Country
PCT	Patent Co-operation Treaty
PPP	Purchasing Power Parity
R&D	Research and Development
TB	Tuberculosis
TNCs	Transnational Corporations
TRIMS	Trade Related Investment Measures
TRIPS	Trade Related Aspects of Intellectual Property Rights
UN	United Nations
UNICEF	United Nations Children's Fund
UNCTAD	United Nations Conference on Trade and Development
WB	World Bank
WHO	World Health Organization
WTO	World Trade Organization

1 INTRODUCTION

The developing world, which contains 80% of the world's population, owns less than 2% of the world's wealth, and consumes less than 10% of the world's pharmaceuticals. Over half of the world's population lives on less than two dollars a day, and one third of the world's population does not have access to essential medications (WHO). Every day over 37 000 people die in the developing world from treatable preventable disease (UNICEF).

Although three decades ago over 25% of the world's pharmaceuticals were produced in developing and middle income countries (Kaplan, 2006), the current pharmaceutical market is centered in the developed world where over 90% of all pharmaceuticals are consumed. This is reflected in the research and development areas pursued by the major pharmaceutical industries, which are focused on diseases that affect the developed world and ignore the needs of developing countries because there is little market incentive to develop drugs for the poor. In addition, pharmaceutical companies claim that they must charge high prices for their products to recoup research and development expenses and fund further research projects. However, analysis reveals that all of the of the nine major US pharmaceutical companies that market top 50 drugs spend on average at least twice as much money on marketing than they do on research and development.

Moreover, developing countries are being forced to follow World Trade Organization (WTO) enforced patent legislation that is not supportive of their emerging pharmaceutical industries, which has lead to the foundering of their research and development capabilities. In contrast, when industrialized countries that currently lead the world pharmaceutical markets were still developing their pharmaceutical industries, they followed the Paris Convention on intellectual property that allowed countries the freedom do decide on the areas of patentability and the duration of patents. With respect to pharmaceutical patents, countries were able to protect process patents and exclude product patents. This provided nations with the freedom to investigate invented medicines through reverse engineering techniques to determine their structure and create new synthetic routes for production. They could then produce "generic" versions of the same drug from this new production process, providing their citizens access to quality drugs at affordable costs, while simultaneously strengthening their national

pharmaceutical industries. These developed countries did not adopt product patents on pharmaceuticals until the late 60's and 70's after their pharmaceutical industries had reached an internationally competitive level.

However, now these same countries that refused to grant product patents until well into the 60's and 70's are forcing developing countries to protect pharmaceutical product patents, thereby barring local production and research infrastructure development. In 1995 the Trade Related Aspects of Intellectual Property Rights (TRIPS) agreement was born with the WTO through pressure from multinational corporations who wanted to harmonize international Intellectual Property Rights (IPRs). As members of the WTO, the TRIPS agreement must be adopted by all countries that want access to the global market, regardless of their stage of development. Although TRIPS advocates argue that the agreement will aid international development, analysis into technology transfer, foreign direct investment (FDI), and exportation from developing countries reveals the fallacy of this claim.

Moreover, health professionals from across the globe are outraged by the impact TRIPS has had on developing pharmaceutical industries. Developing countries had until 2005 to become TRIPS compliant, and now the world's major generic drug producers India and China can no longer produce generics of new medications because they are now obligated to protect product patents under TRIPS. The generic market is extremely important for both the production of needed medications and the maintenance of generic competition that prevents corporations from charging exorbitant prices on medications. It is imperative that generics are produced to prevent a pharmaceutical monopoly from bringing the prices of essential medications further out of reach of the world's suffering poor.

In 2001 as the result of pressure on the WTO from health activists, the Doha Declaration granted a waiver on TRIPS compliance until 2016 for least developed countries. However, Bangladesh is the only least developed country with pharmaceutical manufacturing capability, and is therefore the only country in the world that is capable of producing generic versions of new medications without repercussions from the WTO. If Bangladesh revises its national patent legislation to exclude product patents on pharmaceuticals, then it will save millions of lives through the production of affordable essential medicines, and will in turn provide generic competition to the larger corporations to ensure reasonable prices on pharmaceuticals.

2 DEVELOPING WORLD

The developing and least developed world contains 80% of the world's population, and less than 2% of the world's wealth (World Bank). Developing countries consume less than ten percent of the world's pharmaceuticals, most of which are consumed by the wealthier residents of those countries. WHO estimates that 2 billion people, or one third of the world's population, do not have access to essential medicines, and UNICEF states that every day over 37 000 people die in the developing world from treatable infectious diseases. This section explores the current state of developing countries with specific attention to their lack access to medicines.

2.1 Classification of Developing & Least Developed Countries

The human development index (HDI) is a widely accepted measure of a country's stage of development, and compares among other things measures of poverty, literacy, education, life expectancy, child welfare, and standard of living as measured by gross domestic product (GDP) per capita at purchasing power parity (PPP). Although the United Nations (UN) does not have an official designation for "developed" or "developing countries", the measure of the HDI is widely considered a determinant for this distinction. Developed countries enjoy a high standard of living through a high GDP as the result of their industrialized economy, and countries commonly accepted as developed include Japan (GDP\$ 36,596), Canada (\$31,134), the United States (\$39,935), Australia (\$30,682), New Zealand (\$23,846), and majority of the European countries.

Developing countries on the other hand have a relatively small industrial base, and a low standard of living compared to the industrialized countries as reflected in their HDI represented in Figure 1. Although the GDP per capita of developing countries varies from over \$10,000 to just \$90, there are 59 countries that survive on under \$1000 per capita GDP. In the 1960's the UN recognized that special attention was needed for a number of countries who should not be grouped in with developing nations because they have experienced prolong periods of economic decline. The first resolution on the least developed countries (LDC) was adopted at UNCTAD II in 1968, and the UN created the first list of LDCs in 1971. Least developed countries are determined through the following:

- A “low-income” criterion based on a three-year average estimate of the gross national income (GNI) per capita (under \$750 for inclusion, above \$900 for graduation to the category of “developing nation”).
- A “human resource weakness” criterion based on indicators of nutrition, health, education and adult literacy.
- An “economic vulnerability” criterion based on instability of agricultural production, exports of good and services, merchandise export concentration, handicap of economic smallness, and percentage of population displaced by natural disasters.

Of the LDCs, there is also special classification for countries that are landlocked and countries on small islands, supporting the theory that geographical isolation has a strong impact on a country’s economic development. Currently, there are 50 countries on the LDC list, sixteen of which are landlocked and twelve of which are small islands.

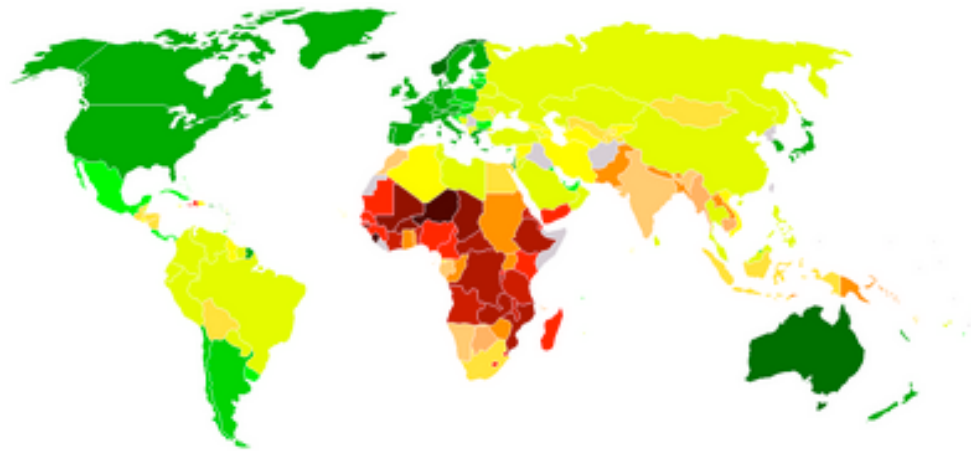
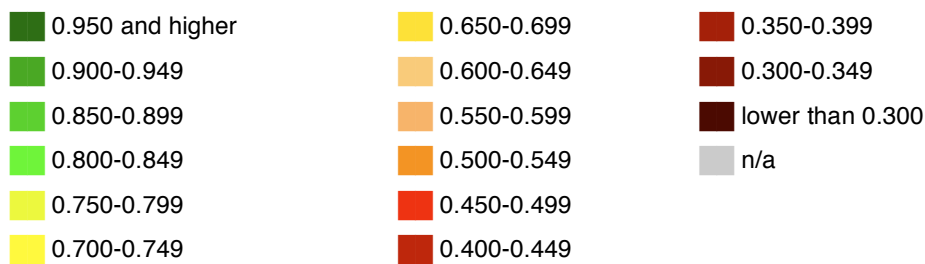


Figure 1: World Map Indicating HDI of UN Member States, 2003



2.2 Distribution of Global Wealth

The wealth of the world's nations can be measured in many ways and varies substantially by level of income across different regions. Current assessments of these variations recognize that the wealth of a nation does not rest solely on the income of its residents, and recent studies have encompassed values for agricultural land, minerals, forests, produced assets, and intangible capital including but not limited to raw labor, human capital, social capital, and quality of institutions. An assessment encompassing so many different sources of wealth was used by the World Bank in a recent publication entitled The Wealth of Nations, which produced the values of global wealth distribution illustrated in Figure 2. While it is very important to assess the full capacity of a country's natural resources and intangible assets for sustainable development policy

approaches, it is important to keep in mind that the resources included in such assessments are often not distributed among the entire populations of developing countries.

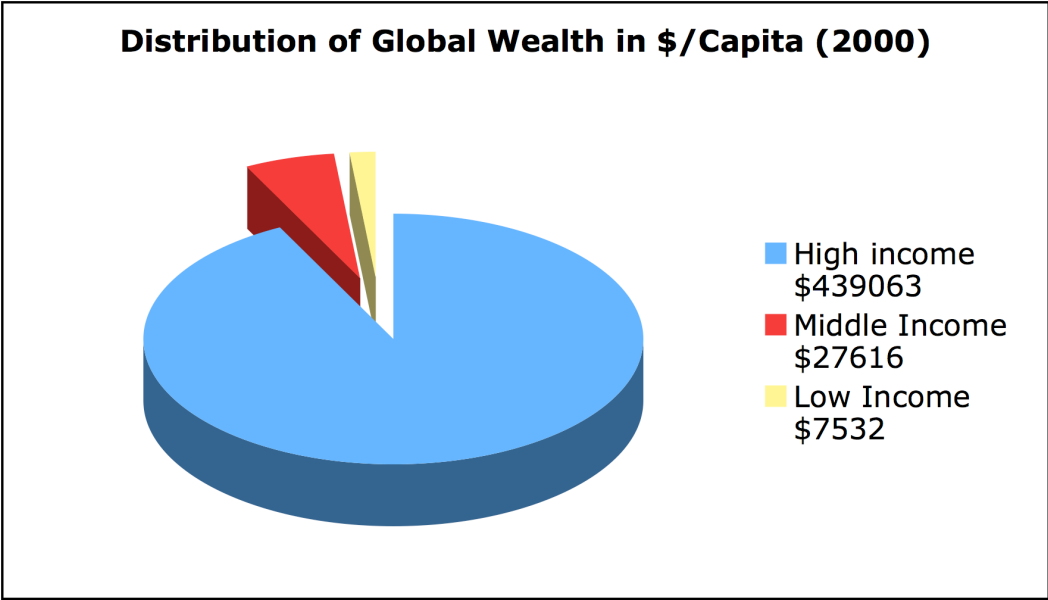
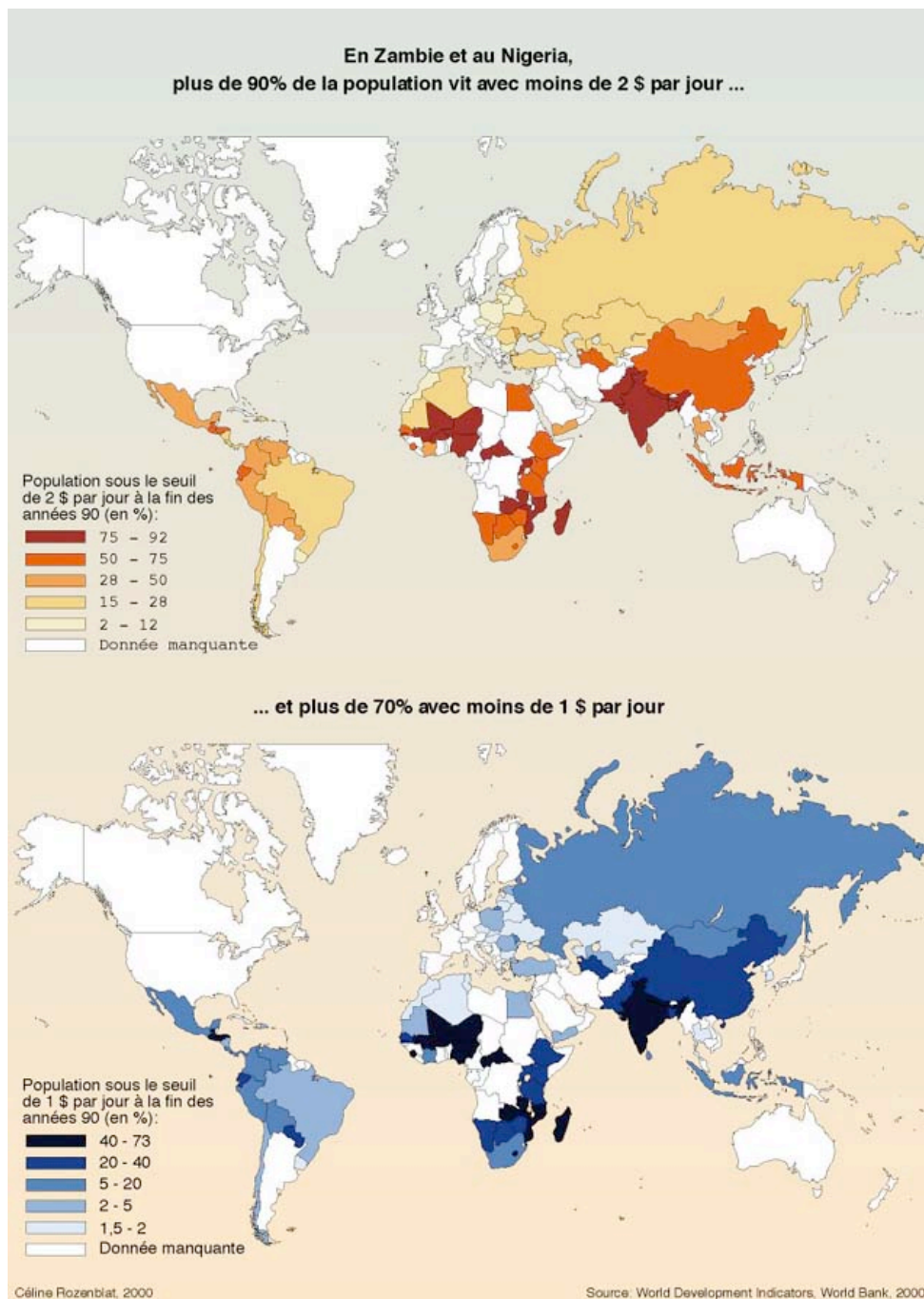


Figure 2: Global Distribution of Wealth (2000)¹

¹ World Bank, Where Is the Wealth of Nations? (2006).



**Figure 3: The Poverty Lines: Population Living with Less than 2 Dollars
and Less than 1 Dollar a Day²**

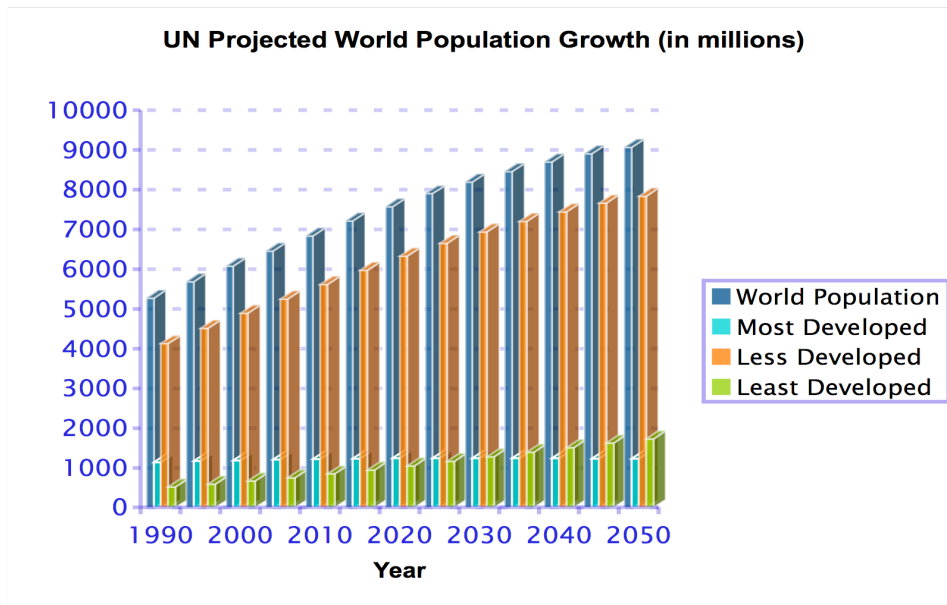
² <http://www.povertymap.net>

Therefore, even though the country might have a significant amount of wealth as calculated by the World Bank (WB), these calculations are not an adequate representation of the wealth of the common citizen who does not have access to such resources and will not feel the benefits of their worth. Moreover, as this measure of wealth is not parallel to the income of the majority of citizens in developing countries, it cannot be used as an estimate of their purchasing power.

This lack of wealth is especially important when considering access to essential medicines, and the ability of the common citizen to afford them. Figure 3 presents a more accurate representation of the ability to purchase medicines in the developing world, as it illustrates the vast numbers of people who live on less than one or two dollars a day, and cannot even afford sufficient daily sustenance. As of the year 2000, 1.3 billion people live on less than one dollar a day; and half of the world, nearly 3 billion people, lives on less than two dollars a day. More than 1.3 billion do not have access to clean water; 3 billion do not have access to sanitation; and 2 billion do not have access to electricity (Wolfenson, 1998). In contrast, a few hundred of the world's millionaires have as much wealth as the world's poorest 2.5 billion people, over one third of the global population. The combined incomes of the population in the 50 least developed countries, where the world's poorest 582 million live, is \$146 billion, or 0.15% of the income of the world's richest 200, which reached \$1 trillion in 1999 (UN, 2000). Moreover, the GDP of the poorest 50 nations, one quarter of the world's countries, is less than the wealth of the three richest people in the world (Ramonet, 1998).

2.3 Population

The current and projected population of developed countries and developing countries as compared to the total world population is illustrated in Figure 4. The least developed and developing countries currently constitute 81% of the world's total population, while the most developed countries constitute less than 19% of the world's population. In addition, while the birth rate of the most developed countries is predicted to remain fairly constant over the next forty years, the birth rate in the developing world is increasing, accounting for the large predicted increase in global population.



**Figure 4: Projected World Population Growth
(Least developed already included in less developed value)³**

This population increase is expected to be concentrated mainly in the Asia Pacific region and Sub-Saharan Africa as illustrated in Figure 5. It is theorized that since developed countries have a high standard of living, they are more conscious of the number of children they have due to the high cost of raising and educating children in the developed world. Furthermore, citizens of developed countries have ready access to contraceptives and are usually able to control their pregnancies. In contrast, contraceptives in the developing world are often unheard of, and it is not uncommon for women to have upward of seven or eight children. The lack of contraceptives and awareness about birth control methods is also a main catalyst for the spread of aids, as very often women in the developing world are uneducated about the threat of the disease.

³ <http://esa.un.org>

FIGURE 12
Rural and urban population in developing regions and high-income countries, 1960-2025

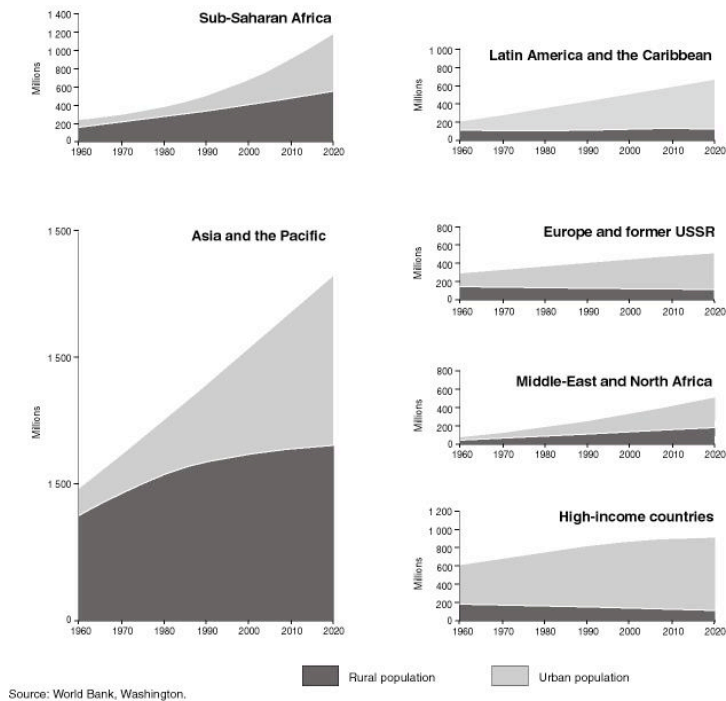


Figure 5: Rural and Urban Predicted World Population Increase (1960-2025)⁴

The estimated world population for 2015 is illustrated on a global map in Figure 6. Overall, the predicted increase in the population of the developing world has serious implications for the state of international public health. Currently the developing world constitutes over 80% of the world population, but owns less than 2% of the world's wealth, and consumes less than 10% of the world's medications. Unless access to and affordability of these medications is improved, then the 1/3 fraction of the world's population that does not have access to essential medicines will only increase, and the current number of 37 000 people that die a day from treatable infectious disease will continue to climb.

⁴ Rekaewicz, P. World Bank. (2001).

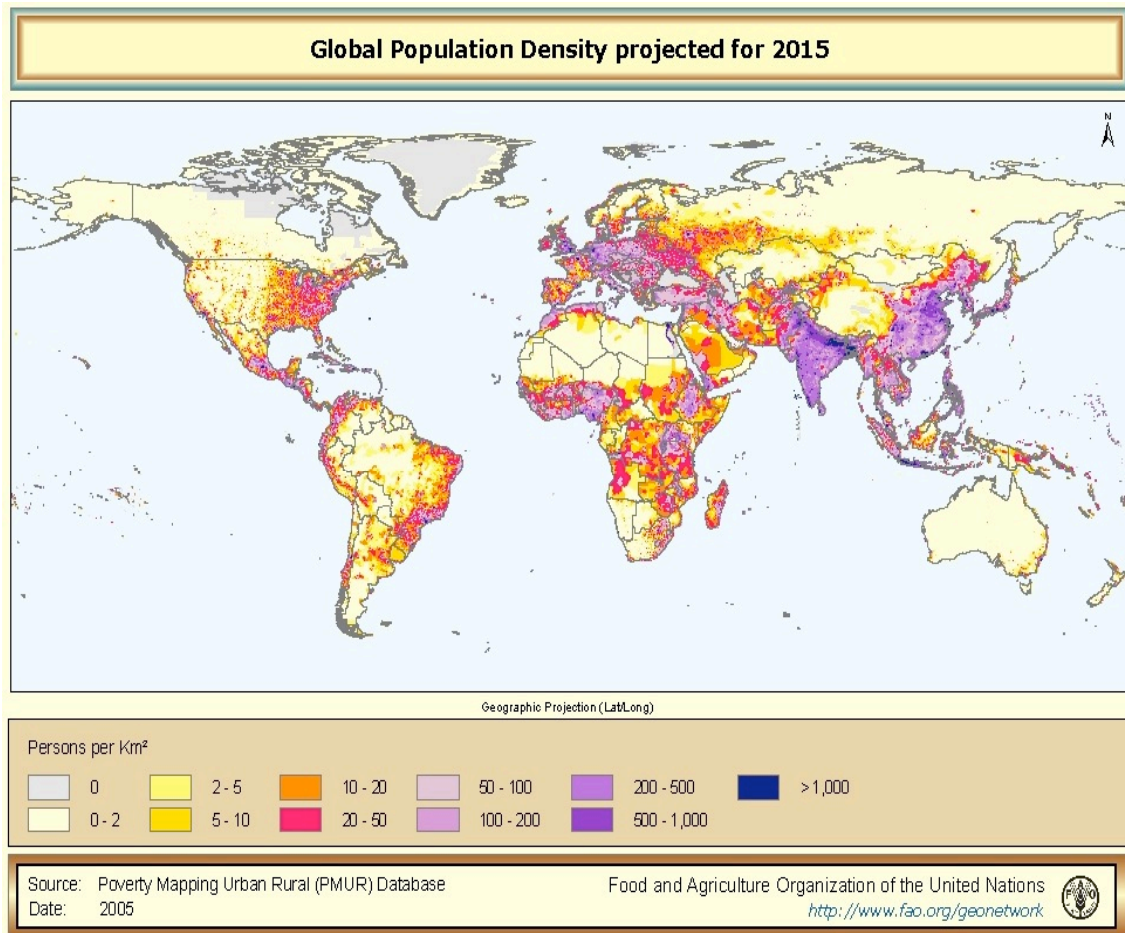


Figure 6: Global Population Densities 2005⁵

2.4 Public Health

Although this paper focuses specifically on access to essential medicines in the developing world, it is necessary to mention the complex nature of international public health, and the numerous barriers to public health that must also be addressed. These include but are far from limited to proper nutrition, access to clean potable water, and access to sanitation. While medical treatment is necessary, working to provide these basic health necessities will greatly reduce the level of disease and sickness in the developing world, and greatly reduce the number

⁵ Poverty Mapping Urban Rural (PMUR) Database, www.povertymap.net.

of deaths from preventable diseases. The UN Millennium Development Goals were created to inspire global cooperation to fight these barriers and to improve the basic health and standard of living in the world's developing and least developed countries.

Within the developing world where countries are indebted and struggle to provide health services to their populations, even in best case scenarios, upwards of 25-70% of overall health care expenditure is spent on the purchase of medications, compared with 15% in developed countries (WHO, 2004). Even with this high expenditure, medicines still do not reach large numbers of the populations. Moreover, in countries with inadequate health care financing systems, it is up to the individual households to purchase their own medications. As illustrated previously, for the 3 billion people who live on less than two dollars a day and cannot afford basic sustenance, the current cost of medicines is extremely impossible to meet. In such cases when there is no government or international support, it is the poor and sick that suffers the most, and have no voice in global affairs to defend their right to medicines readily available in the developed world. WHO estimates that in some countries half the people living in poor households, some 1.7 billion people receive none of the essential medicines needed to treat acute illnesses. The result, as deserves repeating, is over 37 000 people die a day from treatable infectious disease (UNICEF).

A main measure of the development of a country lies in the welfare of its children. The total number of children in the world is 2.2 billion, and one billion of these, or every second child is born into poverty. Across the globe, 1.4 million children die each year from lack of access to safe drinking water and proper sanitation. Of the 1.9 billion children in the developing world (86% of the world's children), one third do not have adequate shelter (640 million, 29% of world's children), one fifth do not have access to safe drinking water (400 million, 18% of world's children), and one seventh do not have access to health services (270 million, 12% of world's children). In 2002 at least 3.5% of the world's children died from preventable disease because they were born into this overwhelming poverty and were not provided with life-saving medicines. In that year one million children died from malaria, another 2 million child deaths were caused by perinatal diseases, and 4 million more from pneumonia, measles, and diarrhoea (WHO). That results in a bare minimum count of 7 million child deaths in developing countries in 2002 from mostly preventable diseases that are no longer a threat to the developed world where medicine for treatment and prevention is readily available. In 2003, it is estimated that in

the developing world, 10.6 million children died before the age of 5, which equals the total child population of France, Germany, Greece, and Italy (UNICEF, 2005).

In the year 2002 alone, there were over 6 million deaths from malaria, TB, and AIDS. In addition, millions of people, especially children, lose their lives to completely preventable diseases like pneumonia, measles, and diarrhoea. Other major causes of death common to high and middle income countries that are now becoming an increasing problem in low income countries include heart disease, stroke, and cancer. A major turning point in the field of international public health was brought about by the huge impact of AIDS on the global population. The aids virus spread from 6.3 million people in 1988 to over 40 million people in 2003, and it is estimated that 2.5 million of the infected are children. Furthermore, Sub-Saharan Africa is home to 30% of the aids cases, even though it only holds 2% of the world's population. The epidemic threat of the AIDS virus has shed light within the international community upon many problems in medicine policy. Namely, since AIDS is a disease that affects developed countries, there is a huge demand for and substantial amount of research being done to find cures for the virus. The anti-retro viral therapies (ARVs) that have been developed by the major pharmaceutical corporations are desperately needed by people in the developing world, and NGOs have been insistently pleading their concerns over the high prices and inaccessibility of the ARV treatments. While the problems of accessibility and affordability have always existed with pharmaceuticals, AIDS holds a stronger pull on the international community because it is not an isolated disease seen only in the poorest countries, but it is also on the front door of many of the wealthiest neighborhoods in the developed world. Unfortunately, at the same time that AIDS was getting the attention of the global community, the pharmaceutical community was simultaneously pressuring developing countries, through the World Trade Organization, to sign legislation protecting pharmaceutical patent rights to remove their freedom to make generics of the newly developed ARVs and other essential medicines.

3 PHARMACEUTICAL INDUSTRIES AND DEVELOPMENT

Pharmaceutical markets are concentrated in the developed world, which consumes 90% of the world's pharmaceuticals. The research and development of these markets are centered on illnesses that are common in affluent countries, ignoring the needs of the majority of the world's population who suffer from neglected tropical disease. In addition, while there are treatments available for diseases that kill over 37 000 a day in the developing world, the high prices of these therapies are unaffordable for more than one half of the global population living on less than 2 USD a day. Pharmaceutical companies claim that the prices are needed to recoup costs for past and future research and development, however an analysis of the revenue allocation of the ten top pharmaceutical corporations reveals the fallacy of this claim as the majority of revenue is spent on marketing and advertising or harbored as net profit.

3.1 Major Pharmaceutical Markets

The global pharmaceutical market is concentrated in a select number of developed nations as illustrated in Figure 7. The pharmaceutical industry is centered in North America with 40% of the market, and Europe and Japan constituting together about 40% of the market. Latin America contributes about 6%, China less than 2%, and South Korea, Australia, and India

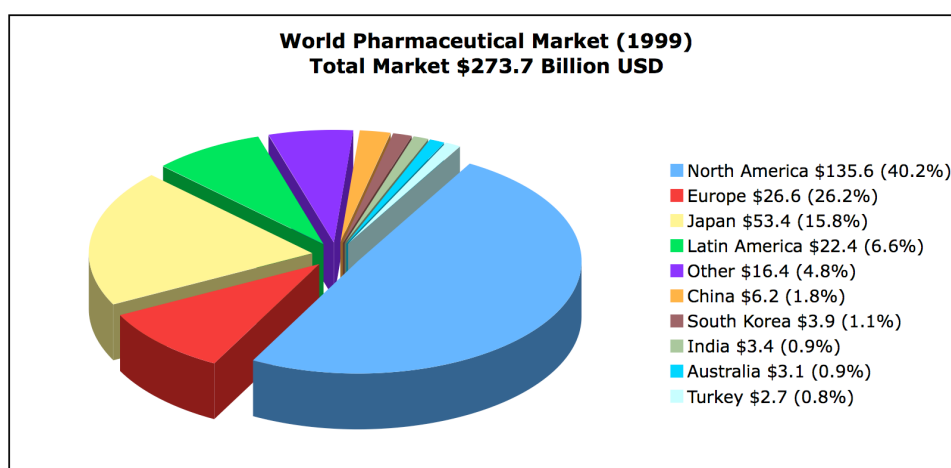


Figure 7: World-Wide Pharmaceutical Market (1999) USD in billions⁶

⁶ IMS World Review (2000).

each approximately 1%. It can easily be observed from the chart that developing countries, which aside from India are classified as “other”, constitute less than 5% of the pharmaceutical market, even though they constitute more than half of the global population. A more recent analysis covering the years 2001 and 2005 is provided in Figure 8, which illustrates the world’s largest pharmaceutical markets, constituting 79.1% of the industry. There is an obvious shift in the control of the market, with the United States alone controlling over 51% of the world’s major pharmaceutical sales. An estimate of the WHO states that over 90% of the world’s pharmaceuticals are consumed by just 15% of the population.

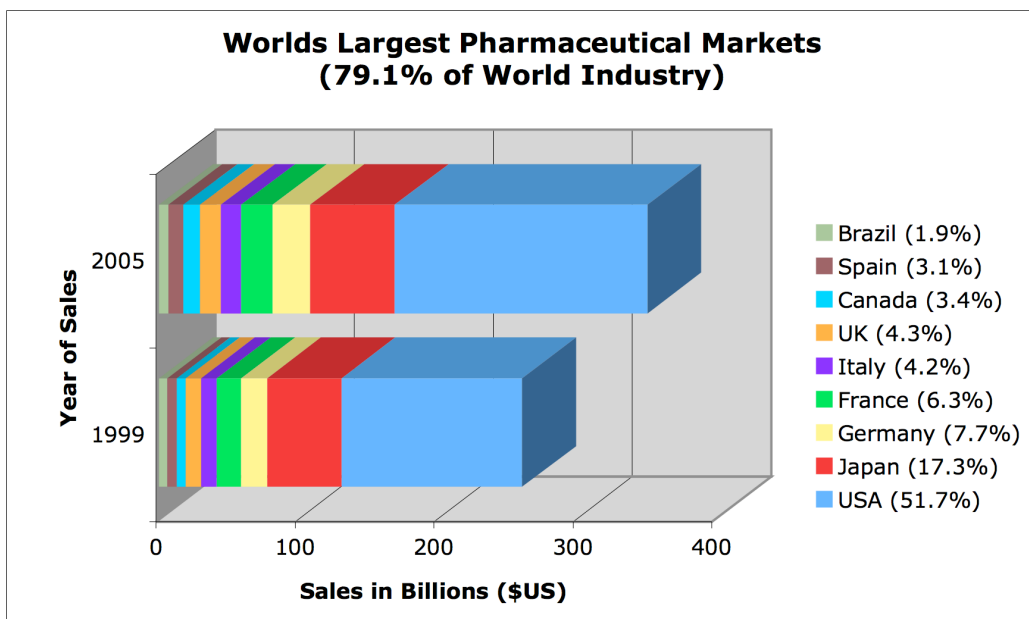


Figure 8: World’s Largest Pharmaceutical Markets (79.1% of Total Market)

In stark contrast, over two decades ago 25% of world drug production was accounted for by developing and middle-income countries as illustrated in Table 1 (Kaplan, 2006). In 1992, multinational drug companies in 10 industrialized countries had a substantial research and development base capable of supporting innovation of new chemical entities, while Argentina, China, India, Korea, and Mexico had innovative capabilities to manufacture new drugs and develop generic copies of existing drugs.

Stage of Development	Number of Countries		
	Industrial	Developing	Total
Sophisticated pharmaceutical industry with a significant research base	10 ^a	0	10
Countries with innovative capabilities	12	5 ^b	17
i) Those producing both therapeutic ingredients and finished products	6	8	14 ^c
ii) Those producing finished products only	2	87	89
No pharmaceutical industry	1	59 ^d	60
Totals	31	159	190

Table 1: International Pharmaceutical Manufacturing Capabilities in 1992⁷

- a. (United States, Japan, 8 countries in Western Europe)
- b. Argentina, China, India and Mexico
- c. European and higher income Latin American (e.g. Brazil) and Asian countries
- d. Primarily African countries and small islands

In addition, there were national drug companies in eight developing countries within Latin America and Asia that were capable of producing both therapeutic ingredients and finished products, and there were national drug companies in 90 developing countries capable of producing finished products only (Balance, 1992). Finally, there were 59 developing countries that had no pharmaceutical manufacturing capabilities. In 1995 with the creation of the World Trade Organization (WTO) and the introduction of the Agreement of Trade Related Aspects of Intellectual Property Rights (TRIPS), pharmaceutical manufacturing capabilities in the developing country were greatly damaged by the introduction of product patents. The broad impact that the TRIPS agreement has had on developing countries and their pharmaceutical markets is explored further on in the paper.

⁷ Balance, The World's Pharmaceutical Industries: An International Perspective on Innovation, Competition, and Policy, (1992) quoted in Kaplan, W. Laing, R., Is Local Production of Pharmaceuticals A Way to Improve Pharmaceutical Access in Developing and Transitional Countries? (2006).

3.2 Research and Development

As the world's pharmaceutical market is centered in the developed world, the research and development pursued by the major companies is focused on disease and illness that affects the affluent and not on the diseases that affect the largest portion of the world's population. Pharmaceutical companies work for profit, and they develop medications that are demanded in the developed world for which they will be able to recoup R&D costs and additional profits. Table 2 illustrates the current focus of the pharmaceutical industries, and as can be observed the ten leading medicines account for 31% of global sales. In the listed therapies, there are six major therapeutic areas that account for 85% of medicinal sales - cardiovascular, central nervous system, metabolic, infectious, respiratory, and musculo-skeletal disease - which together account for the burden of disease in the developed world.

Rank	Audited World Therapy Class	2000 Sales (US\$Bn)	% Global Sales	% Growth Year-Over-Year
1	Antiulcerants	17.4	5.5%	13%
2	Cholest & Triglyceride Reducers	15.9	5.0	21
3	Antidepressants	13.4	4.2	18
4	Calcium Antagonists	9.8	3.1	2
5	Antirheumatic Non-Steroidials	9.5	3.0	26
6	ACE Inhibitors, Plain	7.3	2.3	3
7	Cephalosporins & Combinations	6.9	2.2	-5
8	Antipsychotics	6.0	1.9	22
9	Non-Narcotic Analgesics	6.0	1.9	3
10	Oral Antidiabetics	5.9	1.9	26
	Total Leading 10 ATC's	\$98.2	31.0%	+13%

Table 2: Analyses of U.S. Research and Development Areas (2000)⁸

Meanwhile, in the developing world infectious and parasitic diseases rage, and there is extremely limited research aimed at combating such diseases. Within the past 25 years only 1% of pharmaceutical research and development was aimed at Tropical Diseases and Tuberculosis, which account for over 11% of global disease (WHO, 2004). Neglected diseases including

⁸ Families USA, Off The Charts: Pay, Profits and Spending by Drug Companies (2001).

trypanosomiasis (sleeping sickness), Buruli ulcer, and Chagas disease cause great suffering and death in the developing world and have no suitable treatments. Although there are hundreds of millions at risk for these diseases, and some threaten to return to levels not seen for 75 years, the populations who are suffering have no purchasing power, and therefore there is little incentive from pharmaceutical markets for companies to pursue research and development for these neglected diseases.

3.3 Revenue Allocation

Pharmaceutical companies claim to charge high prices on their manufactured drugs to recoup research and development costs and support future research endeavors. An analysis by Families USA of the profits and spending of Drug Companies reveals the fallacy of this claim as illustrated in Table 3. All of the nine major US pharmaceutical companies that market top 50

Company	Revenue (Net Sales in Millions \$US)	Percent of Revenue Allocated		
		Marketing/ Advertising/ Administration	R&D	Profit (Net Income)
Merck and Co., Inc	40,363	15%	6%	17%
Pfizer Inc.	29,574	39%	15%	13%
Bristol-Myers Squibb Company	18,144	30%	11%	26%
Pharmacia Corporation	13,746	37%	15%	4%
Abbott Laboratories	13,263	21%	10%	20%
American Home Products Corporation	10,862	38%	13%	-18%
Eli Lilly and Co.	9,815	30%	19%	28%
Schering-Plough Corporation	1,563	36%	14%	25%
Allergan, Inc.	1,563	42%	13%	14%

Table 3 Analysis of U.S. Pharmaceutical Revenue Allocation (2000)⁹

drugs spend on average at least twice as much money on marketing and advertising then they do on research and development. In addition, six of the nine made more in net profits then they spent on R&D, and three, Merck, Bristol-Myers Squibb, and Abbott Laboratories received twice as much in net profit as they spent on R&D. In addition, as can be viewed in Table 4, the average and median compensation for the highest paid executive in each of the nine major

⁹ Families USA, Off The Charts: Pay, Profits and Spending by Drug Companies (2001).

Company	Executive	Total Compensation
Abbott Laboratories	Robert L. Parkinson, Jr. Retired President and C.O.	\$ 6,484,284
Allergan, Inc.	Lester Kaplan, Corporate VP and Pres. R&D	\$ 13,271,881
American home Products Corporation	John R. Stafford, Chairman and CEO	\$ 27,008,927
Bristol-Myers Squibb Company	M.F. Mee, Executive VP & CEO	\$ 6,924,102
Eli Lilly and Co.	Sidney Taurel, Chairman, President and CEO	\$ 18,788,703
Merck and Co. Inc.	Edward M. Scolnick, Executive VP	\$ 26,454,600
Pfizer Inc,	William C. Steere, Jr., Chairman	\$ 40,191,845
Pharmacia Corporation	Phillip Needleman, Senior Exec, V.P.	\$ 9,305,888
Schering-Plough Corporation	Richard Jay Kogan, Chairman and CEO	\$ 21,444,020

**Table 4 Highest Compensation Package by Company,
Exclusive of Unexercised Stock Options¹⁰**

pharmaceutical companies, exclusive of unexercised stock, was almost \$19 million USD in the year 2000. These figures plainly refute the argument that high prices must be charged on all medications to support research and development costs, as the majority of revenue is not put towards research and development, but marketing, advertising, compensation packages, and stock.

¹⁰ Families USA, Off The Charts: Pay, Profits and Spending by Drug Companies (2001).

4 INTELLECTUAL PROPERTY RIGHTS (IPRs)

Since the industrial revolution, Intellectual Property Rights (IPRs) have played a dominant role in the development of industrialized economies. By protecting the rights to inventions, IPRs stimulate more innovation from individuals and corporations, in turn improving the development of industrialized society. However, outside of the industrialized nations, IPRs do not serve the same role. During the development of modern industrialized countries, international IPR legislation through the Paris Convention was flexible, allowing countries to exclude certain technologies from protection and determine on their own the length of protection afforded. This gave countries the freedom to adapt their own national legislation to suit their specific development needs at various time periods, especially with respect to pharmaceutical patents. In parallel, developing countries of today who lack indigenous technological capability need the freedom to adapt their own legislation to encourage transfer of technology, increase foreign investment, and in turn support the development of their own industries. However, major global corporations fear loss of revenue from weak IPR regulations around the world, and during the Uruguay Rounds put pressure on the rest of the international community to adopt IPRs into world trade agreements. This pressure resulted in the implementation of the agreement of Trade Related Aspects of Intellectual Property Rights (TRIPS), which must be adopted by any country wishing to join the World Trade Organization and have access to the global market. Under TRIPS, developing countries are required to meet developed country standards on IPRs, severely damaging their own industrial growth, most notably that of their pharmaceutical industries.

4.1 Role of IPRs: Patents

IPRs cover many areas of creative works, including inventions, literary and artistic works, symbols, names, images, and designs as used in commerce. A major branch of IPRs involve patent rights, which are awarded by society to individuals or organizations for creative works and knowledge, and provide the right to prevent others from making, selling, distributing, importing, or using their invention without authorization for a limited period of time. The inventor must then in return disclose the invention to society so that others can put it into practice, increasing the wealth of knowledge for further research. In order to qualify for patent

protection, an invention must be novel, non-obvious, and have utility (as in US) or industrial applicability (as in Britain).

Protecting the rights of inventions under patents provides incentives for individuals and organizations to invest in innovation and development. When an invention is copied and produced at a fraction of the cost taken to develop it, then the inventor loses on his return, and will no longer invest time in new inventions, which is referred to as *market failure* and would in turn impeded the development of society as a whole.

4.2 Intellectual Property and Development

The development of economies in developing countries is primarily a reflection of their indigenous technological capability and their research and innovation capability. In order to build technological capacity, developing countries require substantial transfer of basic technologies, which they may dissect and absorb into their own technological capacity. In addition, they require increased foreign direct investment and greater exports to stimulate research and development within their industries. It is theorized by developed countries that increased IPR will serve to increase technology transfer, FDI, and exports, thereby strengthening indigenous technological capability in developing countries and improving their respective economies. However, with patent protection also comes major restrictions on the ability of developing countries to use the same reverse engineering techniques used by today's developed countries during their industrial developments limiting developing countries' ability to build their industries in the same manner as today's developed countries. Moreover, patent protection is designed fundamentally to protect and stimulate innovation, and the majority of today's developing countries do not currently possess innovative capabilities worth protecting. Therefore, the application of international IPRs in developing countries must be evaluated with respect to the development of their technological capacity, especially with respect to pharmaceutical research, development, and manufacturing capabilities. This theme will be explored further throughout the paper.

4.3 The Evolution of International Intellectual Property Legislation

While the world's current industrialized nations were developing, the Paris Convention was the governing international legislation on IPRs. The Paris Convention allowed room for individual countries to adapt their own legislation to meet their individual development needs by allowing nations to exclude certain technologies from patent protection, and to determine the length of protection afforded to them. Namely, with respect to pharmaceutical patents, countries were able to only protect process patents and not product patents, allowing their developing industries to take products from other countries and use reverse engineering techniques to find new synthetic routes to product development. This not only allowed the developing industries to manufacture needed medicines, it also helped them build their research infrastructure and synthetic knowledge base. Those same countries, which now have the strongest pharmaceutical industries, refused to grant product patents in their countries until their industries reached an internationally competitive level. However, with the introduction of TRIPS, developed countries are forcing the developing countries to protect product patents, which developed countries themselves refused to do until the late sixties and seventies. This is not only causing great damage to the pharmaceutical industries in developing countries, but it is also destroying the generics markets, thereby raising the price of needed pharmaceuticals and putting essential medicines even further out of reach in the developing world and killing tens of thousands daily.

4.3.1 International Trade Organization (ITO)

Although the United States has always participated in international trade, it did not adopt an active role within global trade policy until after the Great Depression. While Congress had always been responsible for promoting and regulating commerce as outlined in the constitution, foreign policy negotiations had been the exclusive responsibility of the executive branch. This division of powers has resulted in a constant governmental battle over the compromises needed to promote trade and protect industry (Aaronson, 2001). To remedy this situation, in 1934 the Reciprocal Trade Agreement Act was passed. This law provided the US government the authority to enter into bilateral agreements for reciprocal tariff reductions.

After the great depression and the economic hardship of the Second World War, many industrialized nations recognized the value of negotiating an order to govern monetary relations between independent nation states. The United States at the time was the world economic

powerhouse, and took the lead role in organizing the conference and spear-heading the agenda. From July 1st to 22nd, 1944, over 730 delegates from 45 Allied nations gathered in Bretton Woods, New Hampshire at the Mount Washington Hotel for the United Nations Monetary and Financial Conference. This conference resulted in the signing of agreements to construct the International Monetary Fund (IMF), and the International Bank for Reconstruction and Development (IBRD), which is now part of the World Bank (WB). In addition, the Bretton Woods Conference proposed the creation of an International Trade Organization (ITO) that would establish rules and regulations for trade between countries, and act as “the third pillar of the post war liberal international economic order.” (Sneyd, 2005)

The ITO was originally designed with the main goal of supporting development, and was greatly influenced by the theories of John Maynard Keynes. It “represented an internalization of the view that governments could play a positive role in encouraging international economic growth” (Aaronson, 2001), and was drafted with loopholes and freedoms for developing countries to maintain legislation that would be supportive of their individual countries needs. Specifically, the Charter’s “most distinctive feature was the integration of an ambitious and successful program to reduce traditional trade barriers, with a wide-angled agreement that addressed investment, employment standards, development. . . . [I]t pioneered the idea that trade disputes had to be settled by consultation and mediation rather than legal clout” (Drache, 2000). The preparatory committee formed at Bretton Woods worked four years drafting the ITO Charter, which was signed in March 1948 by fifty-three nations.

4.3.2 General Agreement on Trade and Tariffs (GATT)

Through the years of the ITO Charter development, export-oriented nations were simultaneously negotiating tariff concessions in a separate process. These negotiations resulted in the General Agreement on Tariffs and Trade (GATT), which is based on the “unconditional most favored nation principle”: that is, the conditions that apply to the least restrictive trading nation also apply to all other trading nations. The GATT agreement was signed by twenty-three nations in January 1948, just months before the ITO Charter. Many developing nations assumed that GATT was going to be incorporated into the more comprehensive ITO Charter, and they feared that if they did not sign the GATT agreement then the more powerful nations would not support the ITO. However, although the ITO Charter was signed in 1950, President Truman

stated that he was not going to bring the Charter in front of Congress, claiming that the Charter was not supported by the Senate or export-oriented corporations. Many critics believe that the block was prompted by fears within the American business community that the International Trade Organization could be used to regulate, rather than liberate, big business (Wilkins, 1997). The US was the global leader for international trade agreements at the time, and without US ratification the Charter, was essentially nullified for the international community. Therefore, by not seeking ratification of the Charter President Truman simultaneously blocked the birth of the ITO (Sneyd, 2005), leaving in its place the GATT agreement as the governor of world trade. The fight of developing nations to adapt international trade policy to accommodate their need for development has been raging ever since.

4.3.3 Paris Convention

The first international agreement on Intellectual Property Rights was signed in Paris, France on March 20th, 1883 and is known as the Paris Convention for the Protection of Industrial Property. This agreement held the guiding principle that public interests must take precedence over commercial interests, and therefore allowed for flexibility within national Intellectual Property Rights legislation to allow each country to cater their policy to meet their individual development needs. The developed countries of today were still developing at the time and took full advantage of the Paris Convention provisions to allow their developing industries access to needed technologies, most notably pharmaceuticals.

Primarily, the Paris convention provided the freedom for countries to decide on the areas of patentability and duration of patents. Many countries decided not to provide patent protection for pharmaceutical products or medicines, but rather only grant patents for the processes, or the method of manufacturing each specific drug. These process patents were granted for a period of seven to ten years, but did not impede the transfer of pharmaceutical knowledge and technologies because of reverse engineering strategies used in the developing world. Granting process and not product patents allowed other nations to investigate newly invented medicines to determine their chemical structure, then work backwards and deduce step-by-step possible synthetic routes for production. Other nations could then produce a generic version of the same drug through a different synthetic route, providing their citizens access to quality drugs at an

affordable costs, while simultaneously strengthening national pharmaceutical industries by the mere investigation of foreign medicines.

In addition, article 5b of the Paris Convention obliged the patent owner to work the patent in the country that grants process patent protection, that is, the product had to be manufactured in every country to which patent protection was granted. Importing of the product does not qualify as “working the product”; therefore patenting a product in a particular nation was a serious commitment to ensure the manufacturing of that product.

Finally, the Paris convention also allowed governments to issue compulsory licensing if the protected patent was not being worked in the named country and the drug was not regularly available. Under these circumstances the government that required the drug could authorize a domestic drug company to manufacture the drug after paying a compensation fee to the patent holder. However, “a compulsory license may not be applied for on the ground of failure to work or insufficient working before the expiration of a period of four years from the date of filing of the patent application or three years from the date of the grant of the patent, whichever period expires last.” (Paris Convention, 5A4)

Many researchers note that a patent free environment was essential for the growth of pharmaceutical industries, which is reflected in the fact that the countries with today’s most successful pharmaceutical industries refused to grant patent protection on medicines until they had reached a certain standard of development. Most notably, France was the first country to introduce product patents in 1960, followed by Germany in 1968, Japan 1976, Switzerland 1977, Italy and Sweden in 1978. (K. Balasubramaniam, 1996) The United States specifically stated that it was freely entitled to foreign works to further its social & economic development, despite British retaliation (US Congress, 1986).

4.3.4 World Trade Organization (WTO)

The GATT national memberships increased substantially from 1948 until 1993. Within that time eight different rounds of trade negotiations were held between member nations. During these negotiations while the developed countries had “hundreds of trained specialists in all fields available to discuss all issues, underdeveloped countries usually were only able to send one trade counselor who was shuffled from meeting to meeting with no real understanding of issues

against all specialists” (Balasubramaniam, 1996). The working groups were arranged by the presiding officer with no attempt to balance the groups with representation from developed and developing countries. Furthermore, in the negotiation rounds developing country representatives were not included in the important sessions and were left in the dark on the major decisions, only to be consoled into negotiation when their votes were required. Moreover, the rounds were withheld from the public and respective ministries of all involved countries, and there were no recordings made of the negotiations so it is impossible to fully analyze their evolution. With the developing countries extremely over faced and ill prepared to fight against the developed countries, the rounds resulted in industrialized-favored agreements that left the needs of the developing countries in the dust. Specifically, these negotiations resulted in reduced tariffs, special-case treatments of individual products, and certain special exceptions and modifications for each country.

The final round of negotiations, known as the Uruguay Round, lasted eight years, from September 1986 until April 1994, and resulted in the “Final Act” and the creation of the World Trade Organization (WTO). This new institutional organization was aimed at increasing international trade by lowering trade barriers, and allowing maximum freedom for corporate decision making, minimizing the role of national governments in the economy (Balasubramaniam, 1996). The Final Act involved the integration of international trade issues with legislation designed to increase the accessibility of Trans National Corporations (TNCs) to national economies. While GATT had always ensured that member nations had the freedom to determine their own rules governing domestic agriculture, intellectual property rights, foreign investment, infrastructural services, professional services, and health and safety standards, the new international agreement incorporated rules governing these national interests into the previous GATT Legislation.

4.4 Trade Related Aspects of Intellectual Property Rights (TRIPS)

The main result of the final negotiations was the creation of the agreement on Trade Related Aspects on Intellectual Property Rights (TRIPS), which was integrated into WTO regulation. The agreement created a global standard for IPRs, and any nation wishing to be part of the WTO must adapt their laws to meet these standards. As a part of the WTO Agreements, TRIPS is subject to WTO’s dispute mechanism, which allows member states to apply trade

sanctions against non-compliant countries. This has placed unnecessary pressure on the developing countries to adopt IPR legislation that is not at all suitable to their developing economies or the health and needs of their people. Developing countries fear that if they do not follow the TRIPS agreement and choose instead to alternately design legislation in support their own development needs, then they will be sanctioned by developed countries, a nightmarish possibility.

4.4.1 TRIPS and Pharmaceuticals

With respect to pharmaceuticals, there are provisions of TRIPS that are particularly detrimental to the pharmaceutical industries of developing countries, greatly impeding access to essential medicines in the developing world. These provisions include the following:

- All countries have to accept patents on all inventions provided they are “non-obvious” and have “industrial applicability” without discrimination to the place of invention, the field of technology or whether the protected product is locally produced or imported.
- Developing countries have to provide 20-years patent protection to pharmaceutical products and processes.
- Patent holders will not be obliged to work the patent by setting up production facilities to manufacture product in the product granting country, rather they can force the country to import the product and still hold the monopoly.

The first provision is “ a clear expression of the search by industrialized countries for a legal system that facilitates international trade rather than local workings of inventions” (Correa, 2006). Developing countries need the freedom to decide upon patent regulation to meet their individual stage of development, and forcing them to protect all patents greatly impedes the growth of their own industries. As stated previously, the developed countries of today with the strongest pharmaceutical industries did not protect product patents of pharmaceuticals until the late 60’s and 70’s, allowing their companies to find alternate routes to manufacture needed drugs. This control over their own productive development served to strengthen research capabilities while simultaneously providing access to needed medications for their citizens. However, now under TRIPs, developing countries are not free to make this decision, and their

pharmaceutical industries as well as the majority of their populations are suffering greatly as a result.

Unfortunately, a 20-years patent protection greatly limits access to a majority of medications the majority of medications that are needed immediately, and they might be useless to the population after 20-years of further R&D and or mutations of viruses and evolution of diseases. Further, holding 20-years of patent protection is excessive as the return of investment is usually achieved within the first five years, and any additional revenue is funneled into net profit and marketing. This 20-year patent provision means that countries cannot begin to produce generic versions of a drug until after 20-years, which gives the patent holder a monopoly over the drug and the ability to charge the maximum the market can bear. This greatly limits the affordability and availability of many essential medications, and in turn results in the unnecessary death of millions a year.

Moreover, before the TRIPs agreement a patent was considered null if it was not produced in the country holding the patent. In other words, if Pfizer held a patent on a specific drug in South Africa, the company was required to produce the drug in South Africa to maintain the patent rights, and if it failed to do so then South Africa could produce generic versions on its own. Under TRIPs however, companies are not required to manufacture their drugs in all countries where it has obtained patents, rather importation of the drug to each country will suffice for proper “working of the patent”.

5 IMPACT OF TRIPS ON THE DEVELOPING WORLD

The impact of IPRs on developing countries is extremely difficult to assess due to the wide variety of economic and institutional factors contributing to development at all levels of the developing world. However, although it is difficult to isolate the impact of IPR, it is possible to analyze various areas of development in which IPR plays a crucial role and explore changes in these areas since the introduction of the TRIPS agreement. Specifically, in order to achieve economic development it is necessary to develop indigenous technological capability, and many multinationals claim that increased IPR protection in developing countries will serve to increase technology transfer, foreign direct investment (FDI), and exports, which are debatably believed to be the roots of technological development. However, further analysis reveals the fallacy of this claim. With specific regard to pharmaceutical industries, the effect of IPRs through TRIPS has been detrimental to the development of pharmaceutical manufacturing and research capabilities in developing countries, and has lead to the collapse of many of the developing world's leading affordable medicine manufacturers.

5.1 Indigenous Technological Capability

In order to improve the economy of developing countries and reduce poverty, it is imperative that these countries develop indigenous technological capacity like the developed countries before them. As explored in 2002 by the UK Commission on Intellectual Property Rights, the development of this indigenous technological capacity determines the ability of these countries to assimilate and apply foreign technology and is therefore the key factor in achieving successful technology transfer. In order to achieve successful economic development, developing countries need technology transfer from more developed countries so they can imitate the technology and build their own technological capacity. However developing countries have different levels of quality and capacity in their technological and scientific infrastructures. Therefore, the question is not so much whether IPR increases trade or foreign investment in developing countries, but rather the effect it has on their ability to obtain and assimilate technologies necessary for their development.

In order to assess the indigenous technological capability of developing countries, one can assess the patenting activity in the US and internationally through the Patent Cooperation Treaty (PCT). A country with decent indigenous technological capability should also have a substantial innovative research base, and therefore should have a number of international patent applications. In 2001, less than 1% of US Patents were granted to developing countries, and nearly 60% of those were granted to seven of the more technologically advanced developing countries. From 1999-2001, within the PCT fewer than 2% of all patent applications were from developing countries, and 95% of those were from the more technologically developed China, India, South Africa, Brazil, and Mexico (UK Commission, 2002). As can be observed, the technological capacity of most developing countries is very limited, a point that is also reflected in the pharmaceutical research and development markets as discussed previously. Research and Development expenditure is very concentrated in developed countries and a handful of stronger developing countries, proving the lack of sufficient capacity within the developing world to obtain and assimilate technology from developed countries for further development of their own indigenous capacity.

5.1.1 Transfer of Technology

As explored by the UK Commission on IPR, the transfer of technology needed to develop indigenous technological capacity in developing countries must be sustainable. The Commission identifies “ the crucial issue in respect of IP is not whether it promotes trade or foreign investment, but how it helps or hinders developing countries to gain access to technologies that are required for their development”. As an example, licensing a foreign technology to a domestic firm in a developing country will serve to enrich the local economy by building technological understanding and infrastructure. In contrast, importing high technology goods will not necessarily help the underdeveloped economy, as it will not have the technological ability to dissect the new technology for understanding and promotion of new innovation. In the past, low levels of IPR were used by today’s technological leaders to allow them access to foreign technology that they then developed through reverse engineering to build indigenous technological capabilities.

5.1.2 Foreign Investment

Although developed countries and their affiliates claim that stronger IPRs will result in greater FDI to developing countries, many studies have shown that there is little correlation between IPRs and FDI (Noges, 1991). The World Bank Zedillo Report on financing for development makes no mention of IPRs, and the majority of industries likewise omit IPRs when determining factors important for foreign investment. As examples, East Asia and Latin American economies with high growth rates have received the bulk of FDI even though they have weak IPRs. Specifically, China, Singapore, Malaysia, Hong Kong, and Indonesia in 1991 accounted for 90% of FDI flows in the Asia Pacific Region even with considerably weak IPR legislation that did not come close to the currently minimum standards under TRIPS (Correa, 2000). Overall, the “foreign direct investment by US firms is largely devoted to sales and distribution outlets and rudimentary production and assembly facilities, a country’s intellectual property rights protection will have little effect on the total amount invested by US firms” (Mansfield, 1994).

5.1.3 Export Increase

Developed countries also claim that stronger IPR protection will result in greater investment with respect to more sophisticated technologies if a country has the scientific capacity and a sufficient market needed to justify cost of patents. However, even under those circumstances, IPR has led to greater imports instead of the anticipated investment and boost in local production. According to a statement issued by the UN in 1993, innovative companies in the developed world are more apt to directly sell products or services rather than transfer technology through FDI or licensing agreements, which results in an increase in exports to developing countries from developed countries, and a decrease in needed technology transfer. This is observed in a study done by Helpman and Krugman at the University of Delaware that found a correlation between an increase in exports from the US in 1992 and the strengthening of IPRs in importing countries (Smith, 1995). Furthermore, another study done by Maskus in 2000 reveals “that if an average developing country were to strengthen its patent index by one unit, local sales on US affiliates would rise by about 2% of average annual sales... and a one-unit increase in the patent index of the average developing economy would raise the asset stock on US multinational affiliates by... about 16% of average annual stock.” (Maskus, 2000) In

addition, “the value of exports from high income countries after the introduction of TRIPS in 1995 grew from 20 billion to over 80 billion in 1999.” (Balasubramaniam, 2002)

With specific respect to the pharmaceutical industry, FDI in Brazil’s pharmaceutical industry surpassed all other FDI once protection for medicines was abolished. In addition, FDI in Turkey’s pharmaceutical manufacturing industry was the largest of all other manufacturing industries after Turkey eliminated patent protection for pharmaceutical products in 1961 (UN, 1993). In contrast, a study by WB economist Nogueira in 1990 reveals that as a result of increased patent protection, the welfare loss to six developing countries (Argentina, Brazil, India, Mexico, Korea, Taiwan) was at minimum US \$3.5 billion and maximum US \$10.8 billion, while the gain to foreign patent holders was from US \$2.1 billion to US \$14.4 billion. The disparity between the growth of pharmaceutical sales in developed countries and that of the developing world has only increased since this study, as can be observed in Figure 9 where data gathered from the IMS Pharmaceutical consultation documents was used to assess the growth of the world’s pharmaceutical industries. The total global pharmaceutical market has grown from approximately \$300 billion in 1998 to over \$600 billion in 2006, and over 50% of the current market is controlled by North America (IMS, 2006). It is obvious from this data that as a result of stronger IPR protection the exports and sales of the developed countries’ pharmaceutical products have grown substantially while the markets of the developing countries have remained stagnant.

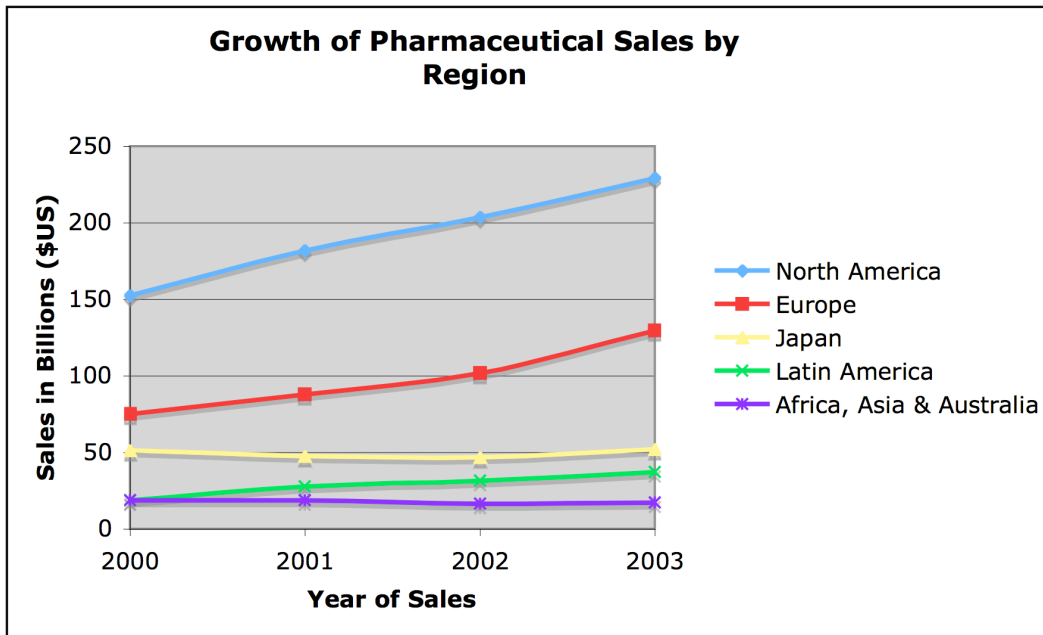


Figure 9: Growth of Pharmaceutical Sales by Region¹¹

5.2 Impact on Pharmaceutical Prices

Universal IPR legislation creates a monopoly on pharmaceuticals through patent protection that removes generic competition. This results in high prices which reflect the maximum the market can bear to maximize profits; a common practice in the developed world. An uncontested set of studies done within developed and developing countries by the WB & IMF clearly indicate price increases on pharmaceuticals as a result of increased IPR. “The existence of a patent allows, by the very nature of the rights conferred, isolation of a product from price based competition, and the question at stake is the quantum rather than the existence of that increase” (Correa, 2000).

To illustrate the disparity between pharmaceutical prices in different countries with different IPR regulations, Figure 10 Compares the prices on top medicines in 1997, and Table 5 the price ratios of drugs under different patent status in developing and developed countries. Both figures reveal the substantial difference in drug prices between countries with various levels of IPR legislation.

¹¹ IMS World Review (2000).

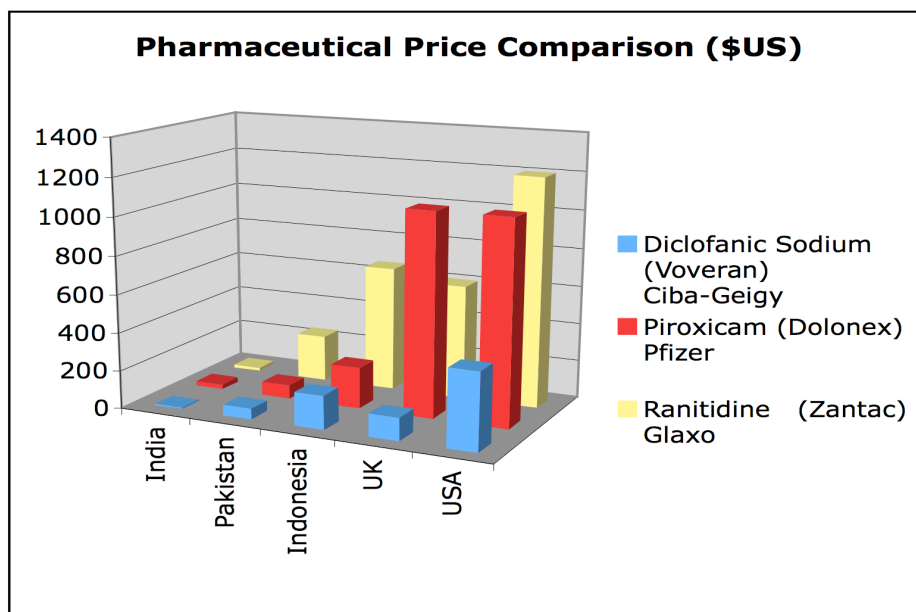


Figure 10 Comparisons of Prices on Top Medicines (1997)¹²

Patent Status	Range of Ratios Between Lowest and Highest Retail Prices of 100 Units of Selected Drugs			
	OECD		Developing Countries	
	No of Dosage Forms	Range of Ratios	No of Dosage Forms	Range of Ratios
Drugs Protected by Patents	8	1:1.7 – 1:1.2	6	1:1.2 - 1:4
Multi-source Drugs	13	1.2 - 1:11.5	17	1:1.7 – 1:59

Table 5 Price Ratios of Drugs Under Different Patent Status in Developed and Developing Countries¹³

¹² B.K. Keayla. TRIPS Agreement on Patent Laws: Impact on Pharmaceuticals and Health for All (1997).

¹³ K Bala, K Sagoo, Patents and Prices. HAINNEWS No 112, April/May (2000).

5.3 Case Studies

An investigation into the impact of IPR on pharmaceutical production in developing countries can be observed through the industries of South Africa and India. While the IPR legislation in South Africa practically destroyed its manufacturing capability, the decision in India to not protect product patents on pharmaceuticals has led to a substantial growth of pharmaceutical industries, and after two decades has produced the lowest price of pharmaceuticals in the world.

5.3.1 South Africa: 39 Manufacturers vs. the SA Government

In the late 1990's there was over eighty pharmaceutical manufacturers in Sub-Saharan Africa. In 1997 South Africa amended its patent legislation to comply with TRIPS, and the manufacturers fought back with a court case against the government, which the latter dropped in 2001 after great pressures. After numerous mergers and great restrictions on manufacturing following adoption of TRIPS, many manufacturing companies were forced to close. There are currently only 14 pharmaceutical manufacturers remaining to produce ARV treatments in South Africa (Intellectual Property Watch, 2006).

5.3.2 India: No Product Protection Needed for Pharmaceutical Growth

As a former British colony, India's patent law in the 1950's and 60's reflected UK legislation that protected product patents on pharmaceuticals, and as a result India had some of the highest drug prices in the world. In the 60's India realized that patent laws were blocking the growth of its pharmaceutical industry, and the former British colony adapted its patent law to mirror German legislation. Specifically, they decided to grant process patents for 7-10 years, they excluded pharmaceutical products from protection, they obliged the title-holder to work the patent, and they made provisions for compulsory licenses. India quickly developed itself as a world leader in generic manufacturing, and simultaneously developed its research and innovative base with a growth of over 200 000 pharmaceutical companies. Within 2 years, drug prices in India became the lowest in the world, sometimes up to 41 percent cheaper than the multinational price.

6 CONCLUSION: WHAT CAN BE DONE

Global IP systems must be reviewed and restructured to aid in the development of poor countries through the stimulation of technology transfer and innovation while simultaneously providing products at affordable prices, most notably medicines. With the current TRIPS legislation, public health in the developing world faces a gigantic barrier that will not be easy for countries just beginning industrial growth to overcome. While the removal of TRIPS from the WTO would be the best solution, it is not likely to happen as long as the developed countries control the WTO. Therefore, developing countries must take advantage of the safeguards currently available under TRIPS, and it is imperative that they develop their own legislations to create as many opportunities possible to pursue development interests and meet public health needs.

6.1 Legislation in Developing World

Although it is established that health within the developing world is being severely damaged by the TRIPs agreement, there are some provisions within the agreement that may be used to obtain medications needed to treat at least a fraction of the millions worldwide that are in desperate need of such products. These provisions include the principle of exhaustion of rights (otherwise referred to as parallel importation), compulsory licensing, and the “bolar provision”. However, a major problem in developing countries is the lack of adequate intellectual property legal force, and when the knowledge of IPR issues and legislation is lacking in a country, it is virtually impossible to navigate to around the congested TRIPs agreement. Therefore, it is necessary for developing countries to strengthen their knowledge of IP Law, and their legal infrastructure and legislative process to deal with IPR issues.

6.1.1 Parallel Imports

Primarily, the principal of exhaustion of rights refers to the termination of rights given to an inventor with the granting of a patent. The provision states that an inventor relinquishes his right to the given product as soon as he sells the product to another. In other words, once a patented product is sold, it can then be re-sold without royalty paid to or consent from the original patent holder. Exhaustion of rights can also be extended to parallel importation, where a product sold for a low price by country X to country Y may be bought by country Z for the same

low price paid by Y, preventing country X from charging country Z full market price for the product. This is especially important with pharmaceuticals, as some developing countries pay considerably lower prices for certain medications than other countries, and therefore if this provision is properly instituted, other developing nations can legally import the needed medications at the lowest offered price without consulting the original manufacturer.

6.1.2 Compulsory Licensing

When a country is able to prove an imperative need for a product, there is a provision for compulsory licenses which may be instituted that allows the country to bypass the IPRs on that product and produce a generic version of the needed drug. A compulsory license is granted by the country in need, provided its national legislation accounts for the provision, and does not need to be approved by outside parties. However, due to the limited IPR council in developing countries, it is difficult for most countries to sort their way through the legal jargon and adapt their legislation to provide for these compulsory licenses. To date the provision has been used more as a bargaining tool with pharmaceutical companies than a method to gain access to needed medications.

For any of the following reasons a country may issue compulsory licenses:

- Dependency of patents, that is, another invention requires the use of the patent in question to exercise the right of the new invention
- Government or non-governmental use
- Cases of national emergency
- Remedy against anti-competitive practices
- Reasons of public health
- Protection of environment

Further, the following conditions must be met before a license may be granted:

- Must be non-exclusive
- Case-by-case consideration
- Possibility for revocation of compulsory license if circumstances that motivated granting of license disappears

- Refusal by the title holder of a prior offer by the prospective user made on reasonable commercial terms
- Adequate remuneration paid to the title holder

When granting compulsory licenses, it is entirely up to the country using the compulsory license to define the scope of “reasonable commercial terms” and “adequate remuneration” for patent holder approval, however those terms must be approved by the title holder.

Included within that list is a provision for “reasons of public health”, which was designed to ensure that TRIPS does not have the negative effect on public health, as widely feared. It is meant to encompass all threats to public health and should therefore theoretically be used by all countries to gain access to needed medications. In addition, *the government and non-governmental* use provision should theoretically be easy for governments to justify given the current state of the world’s poor. However, to repeat an important consideration, as the legal know-how needed to empower these provisions is quite complicated and has been designed by experts in the field from industrialized countries, it is extremely difficult for developing countries to work towards these provisions for fear that if they make a legal mistake they will incur the reprimand of the WTO and/or hurt their bilateral trade agreements with the developed world. If these provisions were truly designed to ease the state of the world’s suffering, they would be used often all over the world, and the necessary infrastructural support needed by developing countries would be more easily acquired from the more industrialized nations. The simple fact that they are rarely used proves their insufficient nature.

6.1.3 Bolar Provision

The “bolar provision” was established in Canada and allows for the testing and regulatory approval of a generic version of a drug before the patent of that drug expires. This allows the necessary development and registration of generic versions of the drug to be completed before the end of the patent allowing the generic manufacturer to begin sale of the drug as soon as its patent expires. This greatly facilitates generic competition, and provides more immediate access to needed medications at affordable prices (WHO, 2006).

6.1.2 Infrastructure

The majority of developing countries do not have a proper patent application revision processes, and a large number of patents that pass through their systems should in actuality not be accepted. Many applications received claim trivial or generically determined processes, second uses of known products, or formulations of products already in the market. Although TRIPS states that “all patents shall be granted to protect inventions that are *new, involve an inventive step, and are capable of industrial application*”, these specific requirements are not defined, and each country is allowed to determine the scope of each definition. While the term “invention” generally refers to a developed solution to a problem through the use of technological application, it would be beneficial for developing countries to cater their individual legislation to their special circumstances, thus allowing more freedom for local innovations. For example, when it comes to biological related patents, in order to protect traditional medicines and biodiversity it is possible to follow a definition of invention that broadly excludes material pre-existing in nature (Correa, 2000).

6.2 The Prospect of Bangladesh

In 2001, after substantial pressure and lobbying by public health activists, the Doha Declaration was enacted to ensure that TRIPS would not act as a barrier to access to medicines in the developing world. The Doha Declaration provided an extension to 2005 for Developing Countries to meet the minimum TRIPS requirements, and an extension to 2016 for the Least Developed Countries. However, now in 2006 the world’s major generic drug manufacturers for the developing world, India and China are following TRIPS regulation and can no longer produce generic versions of new foreign drugs. As the main suppliers of essential medications to the developing world, this new restriction on pharmaceutical production will be detrimental to the health of the world’s population. Although LDC’s were granted an extension until 2016 to meet TRIPS compliance, the only LDC with pharmaceutical manufacturing capability is Bangladesh, which is currently under pressure from trade agreements to adopt TRIPS compliant IPR legislation. If Bangladesh resists the trade pressures and chooses to revise its patent legislation to exclude product patents on pharmaceuticals, it can potentially become the major generic manufacturer for the developing world. This would not only serve to boost its economy, but it would also serve to strengthen its research base and innovative capability while

simultaneously providing essential medications at affordable prices to the world's most desperate citizens.

6.3 Pharmaceutical Industry Development

In order to meet the health needs of the developing world it is imperative that pharmaceutical capability is established within their borders. Eleven years after TRIPS, it is obvious that the developed world is not going to invest in research and development on diseases that affect the world's poor because there would be little financial return. In addition, TRIPS has had a detrimental impact on the pharmaceutical capabilities of the developing world and will continue to curb innovation and development of industries there until it is abolished, or at least revised to exclude pharmaceutical products. If this is not done, then the pharmaceutical industries of the world's developing countries will continue to founder under TRIPS, and they will never be able to establish their own research and innovation capabilities to meet their desperate health needs.

Pharmaceutical companies within developing countries, namely India and China, can no longer produce generics of new foreign drugs and threaten to follow the same deteriorating path of those in South Africa at the end of the 90's. In order to stay afloat, the governments of these countries should encourage and support these companies to pursue the manufacturing of chemical intermediates that may be marketed to other countries, including Bangladesh, which will serve to maintain the survival of the pharmaceutical infrastructure until the TRIPS issue is resolved. Although not a long term solution, shifting focus from generic production to the production of chemical intermediates will help boost the research base and innovative capacity of the stagnant industries, and might tide the industries over long enough until more drugs come off patent and become available to the generic market.

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Appendix A: Intellectual Property Legislation

A.1. Paris Convention

<http://beta.austlii.edu.au/au/other/dfat/treaties/1972/12.html>

PARIS CONVENTION FOR THE PROTECTION OF INDUSTRIAL PROPERTY OF 20 MARCH 1883, AS REVISED AT BRUSSELS ON 14 DECEMBER 1900, AT WASHINGTON ON 2 JUNE 1911, AT THE HAGUE ON 6 NOVEMBER 1925, AT LONDON ON 2 JUNE 1934, AT LISBON ON 31 OCTOBER 1958, AND AT STOCKHOLM ON 14 JULY 1967

Article 1

[Establishment of the Union; scope of industrial property]

- (1) The countries to which this Convention applies constitute a Union for the protection of industrial property.
- (2) The protection of industrial property has as its object patents, utility models, industrial designs, trademarks, service marks, trade names, indications of source or appellations of origin, and the repression of unfair competition.
- (3) Industrial property shall be understood in the broadest sense and shall apply not only to industry and commerce proper, but likewise to agricultural and extractive industries and to all manufactured or natural products, for example, wines, grain, tobacco leaf, fruit, cattle, minerals, mineral waters, beer, flowers, and flour.
- (4) Patents shall include the various kinds of industrial patents recognized by the laws of the countries of the Union, such as patents of importation, patents of improvement, patents and certificates of addition, etc.

Article 2

[National treatment for nationals of countries of the Union]

- (1) Nationals of any country of the Union shall, as regards the protection of industrial property, enjoy in all the other countries of the Union the advantages that their respective laws now grant, or may hereafter grant, to nationals; all without prejudice to the rights specially provided for by this Convention. Consequently, they shall have the same protection as the latter, and the same legal remedy against any infringement of their rights, provided that the conditions and formalities imposed upon nationals are complied with.
- (2) However, no requirement as to domicile or establishment in the country where protection is claimed may be imposed upon nationals of countries of the Union for the enjoyment of any industrial property rights.
- (3) The provisions of the laws of each of the countries of the Union relating to judicial and administrative procedure and to jurisdiction, and to the designation of an address for service or the appointment of an agent, which may be required by the laws on industrial property be expressly reserved.

Article 3

[Same treatment for certain categories of persons as for nationals of countries of the Union]

Nationals of countries outside the Union who are domiciled or who have real and effective industrial or commercial establishments in the territory of one of the countries of the Union shall be treated in the same manner as nationals of the countries of the Union.

Article 4

[A to I. Patents, utility models, industrial designs, marks, inventors' certificates: right of priority. - G. Patents: division of the application]

- A. (1) Any person who has duly filed an application for a patent, or for the registration of a utility model, or of an industrial design, or of a trademark, in one of the countries of the Union, or his successor in title, shall enjoy, for the purpose of filing in the other countries, a right of priority during the periods hereinafter fixed.
- (2) Any filing that is equivalent to a regular national filing under the domestic legislation of any country of the Union or under bilateral or multilateral treaties concluded between countries of the Union shall be recognized as giving rise to the right of priority.**
- (3) By a regular national filing is meant any filing that is adequate to establish the date on which the application was filed in the country concerned, whatever may be the subsequent fate of the application.
- B. Consequently, any subsequent filing in any of the other countries of the Union before the expiration of the periods referred to above shall not be invalidated by reason of any acts accomplished in the interval, in particular, another filing, the publication or exploitation of the invention, the putting on sale of copies of the design, or the use of the mark, and such acts cannot give rise to any third-party right or any right of personal possession. Rights acquired by third parties before the date of the first application that serves as the basis for the right of priority are reserved in accordance with the domestic legislation of each country of the Union.
- C. (1) The periods of priority referred to above shall be twelve months for patents and utility models, and six months for industrial designs and trademarks.
- (2) These periods shall start from the date of filing of the first application; the day of filing shall not be included in the period.**
- (3) If the last day of the period is an official holiday, or a day when the Office is not open for the filing of applications in the country where protection is claimed, the period shall be extended until the first following working day.
- (4) A subsequent application concerning the same subject as a previous first application within the meaning of paragraph (2), above, filed in the same country of the Union, shall be considered as the first application, of which the filing date shall be the starting point of the period of priority, if, at the time of filing the subsequent application, the said previous application has been withdrawn, abandoned, or refused, without having been laid open to

public inspection and without leaving any rights outstanding, and if it has not yet served as a basis for claiming a right of priority. The previous application may not thereafter serve as a basis for claiming a right of priority.

D. (1) Any person desiring to take advantage of the priority of a previous filing shall be required to make a declaration indicating the date of such filing and the country in which it was made. Each country shall determine the latest date on which such declaration must be made.

(2) These particulars shall be mentioned in the publications issued by the competent authority, and in particular in the patents and the specifications relating thereto.

(3) The countries of the Union may require any person making a declaration of priority to produce a copy of the application (description, drawings, etc.) previously filed. The copy, certified as correct by the authority which received such application, shall not require any authentication, and may in any case be filed, without fee, at any time within three months of the filing of the subsequent application. They may require it to be accompanied by a certificate from the same authority showing the date of filing, and by a translation.

(4) No other formalities may be required for the declaration of priority at the time of filing the application. Each country of the Union shall determine the consequences of failure to comply with the formalities prescribed by this Article, but such consequences shall in no case go beyond the loss of the right of priority.

(5) Subsequently, further proof may be required.

Any person who avails himself of the priority of a previous application shall be required to specify the number of that application; this number shall be published as provided for by paragraph (2), above.

E. (1) Where an industrial design is filed in a country by virtue of a right of priority based on the filing of a utility model, the period of priority shall be the same as that fixed for industrial designs.

(2) Furthermore, it is permissible to file a utility model in a country by virtue of a right of priority based on the filing of a patent application, and vice versa.

F. No country of the Union may refuse a priority or a patent application on the ground that the applicant claims multiple priorities, even if they originate in different countries, or on the ground that an application claiming one or more priorities contains one or more elements that were not included in the application or applications whose priority is claimed, provided that, in both cases, there is unity of invention within the meaning of the law of the country.

With respect to the elements not included in the application or applications whose priority is claimed, the filing of the subsequent application shall give rise to a right of priority under ordinary conditions.

G. (1) If the examination reveals that an application for a patent contains more than one invention, the applicant may divide the application into a certain number of divisional

applications and preserve as the date of each the date of the initial application and the benefit of the right of priority, if any.

(2) The applicant may also, on his own initiative, divide a patent application and preserve as the date of each divisional application the date of the initial application and the benefit of the right of priority, if any. Each country of the Union shall have the right to determine the conditions under which such division shall be authorized.

- H. Priority may not be refused on the ground that certain elements of the invention for which priority is claimed do not appear among the claims formulated in the application in the country of origin, provided that the application documents as a whole specifically disclose such elements.
- I. (1) Applications for inventors' certificates filed in a country in which applicants have the right to apply at their own option either for a patent or for an inventor's certificate shall give rise to the right of priority provided for by this Article, under the same conditions and with the same effects as applications for patents.

(2) In a country in which applicants have the right to apply at their own option either for a patent or for an inventor's certificate, an applicant for an inventor's certificate shall, in accordance with the provisions of this Article relating to patent applications, enjoy a right of priority based on an application for a patent, a utility model, or an inventor's certificate.

Article 4bis

[Patents: independence of patents obtained for the same invention in different countries]

- (1) Patents applied for in the various countries of the Union by nationals of countries of the Union shall be independent of patents obtained for the same invention in other countries, whether members of the Union or not.
- (2) The foregoing provision is to be understood in an unrestricted sense, in particular, in the sense that patents applied for during the period of priority are independent, both as regards the grounds for nullity and forfeiture, and as regards their normal duration.
- (3) The provision shall apply to all patents existing at the time when it comes into effect.
- (4) Similarly, it shall apply, in the case of the accession of new countries, to patents in existence on either side at the time of accession.
- (5) Patents obtained with the benefit of priority shall, in the various countries of the Union, have a duration equal to that which they would have, had they been applied for or granted without the benefit of priority.

Article 4ter

[Patents: Mention of the inventor in the patent]

The inventor shall have the right to be mentioned as such in the patent.

Article 4^{quater}

[Patents: patentability in case of restrictions of sale by law]

The grant of a patent shall not be refused and a patent shall not be invalidated on the ground that the sale of the patented product or of a product obtained by means of a patented process is subject to restrictions or limitations resulting from the domestic law.

Article 5

[A. Patents: importation of articles; failure to work or insufficient working; compulsory licenses. B. Industrial designs: failure to work; importation of articles. C. Marks: failure to use; different forms; use by co-proprietors. D. Patents, utility models, marks, industrial designs: marking]

- A. (1) Importation by the patentee into the country where the patent has been granted of articles manufactured in any of the countries of the Union shall not entail forfeiture of the patent.
- (2) Each country of the Union shall have the right to take legislative measures providing for the grant of compulsory licenses to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work.
- (3) Forfeiture of the patent shall not be provided for except in cases where the grant of compulsory licenses would not have been sufficient to prevent the said abuses. No proceedings for the forfeiture or revocation of a patent may be instituted before the expiration of two years from the grant of the first compulsory license.
- (4) A compulsory license may not be applied for on the ground of failure to work or insufficient working before the expiration of a period of four years from the date of filing of the patent application or three years from the date of the grant of the patent, whichever period expires last; it shall be refused if the patentee justifies his inaction by legitimate reasons. Such a compulsory licence shall be non-exclusive and shall not be transferable, even in the form of the grant of a sub-license, except with that part of the enterprise or goodwill which exploits such license.
- (5) The foregoing provisions shall be applicable, *mutatis mutandis*, to utility models.
- B. The protection of industrial designs shall not, under any circumstance, be subject to any forfeiture, either by reason of failure to work or by reason of the importation of articles corresponding to those which are protected.
- C. (1) If, in any country, use of the registered mark is compulsory, the registration may be cancelled only after a reasonable period, and then only if the person concerned does not justify his inaction.
- (2) Use of a trademark by the proprietor in a form differing in elements which do not alter the distinctive character of the mark in the form in which it was registered in one of the countries of the Union shall not entail invalidation of the registration and shall not diminish the protection granted to the mark.
- (3) Concurrent use of the same mark on identical or similar goods by industrial or commercial establishments considered as co-proprietors of the mark according to the provisions of the domestic law of the country where protection is claimed shall not prevent registration or diminish in any way the protection granted to the said mark in any

country of the Union, provided that such use does not result in misleading the public and is not contrary to the public interest.

- D. No indication or mention of the patent, of the utility model, of the registration of the trademark, or of the deposit of the industrial design, shall be required upon the goods as a condition of recognition of the right to protection.

Article 5bis

[All industrial property rights: period of grace for the payment of fees for the maintenance of rights; patents: restoration]

- (1) A period of grace of not less than six months shall be allowed for the payment of the fees prescribed for the maintenance of industrial property rights, subject, if the domestic legislation so provides, to the payment of a surcharge.
- (2) The countries of the Union shall have the right to provide for the restoration of patents which have lapsed by reason of non-payment of fees.

Article 5ter

[Patents: patented devices forming part of vessels, aircraft, or land vehicles]

In any country of the Union the following shall not be considered as infringements of the rights of a patentee:

1. the use on board vessels of other countries of the Union of devices forming the subject of his patent in the body of the vessel, in the machinery, tackle, gear and other accessories, when such vessel temporarily or accidentally enter the waters of the said country, provided that such devices are used there exclusively for the needs of the vessel;
2. the use of devices forming the subject of the patent in the construction or operation of aircraft or land vehicles of other countries of the Union, or of accessories of such aircraft or land vehicles, when those aircraft or land vehicles temporarily or accidentally enter the said country.

Article 5quater

[Patents: importation of products manufactured by a process patented in the importing country]

When a product is imported into a country of the Union where there exists a patent protecting a process of manufacture of the said product, the patentee shall have all the rights, with regard to the imported product, that are accorded to him by the legislation of the country of importation, on the basis of the process patent with respect to products manufactured in that country.

Article 5quinquies

[Industrial designs]

Industrial designs shall be protected in all the countries of the Union.

Article 6

[Marks: conditions of registration; independence of protection of same mark in different countries]

- (1) The conditions for the filing and registration of trademarks shall be determined in each country of the Union by its domestic legislation.
- (2) However, an application for the registration of a mark filed by a national of a country of the Union in any country of the Union may not be refused, nor may a registration be invalidated, on the ground that filing, registration, or renewal, has not been effected in the country of origin.
- (3) A mark duly registered in a country of the Union shall be regarded as independent of marks registered in the other countries of the Union, including the country of origin.

Article 10

[False indications: seizure, on importation, etc, of goods bearing false indications as to their source or the identity of the producer]

- (1) The provisions of the preceding Article shall apply in cases of direct or indirect use of a false indication of the source of the goods or the identity of the producer, manufacturer, or merchant.
- (2) Any producer, manufacturer, or merchant, whether a natural person or a legal entity, engaged in the production or manufacture of or trade in such goods and established either in the locality falsely indicated as the source, or in the region where such locality is situated, or in the country falsely indicated, or in the country where the false indication of source is used, shall in any case be deemed an interested party.

Article 10bis

[Unfair competition]

- (1) The countries of the Union are bound to assure to nationals of such countries effective protection against unfair competition.
- (2) Any act of competition contrary to honest practices in industrial or commercial matters constitutes an act of unfair competition.
- (3) The following in particular shall be prohibited:
 1. all acts of such a nature as to create confusion by any means whatever with the establishment, the goods or the industrial or commercial activities, of a competitor;
 2. false allegations in the course of trade of such a nature as to discredit the establishment, the goods, or the industrial or commercial activities, of a competitor;
 3. indications or allegations the use of which in the course of trade is liable to mislead the public as to the nature, the manufacturing process, the characteristics, the suitability for their purpose, or the quantity, of the goods.

Article 10ter

[Marks, trade names, false indications, Unfair competition: remedies, right to sue]

- (1) The countries of the Union undertake to assure to nationals of the other countries of the Union appropriate legal remedies effectively to repress all the acts referred to in Articles 9, 10, and 10bis.
- (2) They undertake, further, to provide measures to permit federations and associations representing interested industrialists, producers, or merchants, provided that the existence of such federations and associations is not contrary to the laws of their countries, to take action in the courts or before the administrative authorities, with a view to the repression of the acts referred to in Articles 9, 10, and 10bis, in so far as the law of the country in which protection is claimed allows such action by federations and associations of that country.

Article 11

[Inventions, utility models, industrial designs, marks: temporary protection at certain international exhibitions]

- (1) The countries of the Union shall, in conformity with their domestic legislation, grant temporary protection to patentable inventions, utility models, industrial designs, and trademarks, in respect of goods exhibited at official or officially recognized international exhibitions held in the territory of any of them.
- (2) Such temporary protection shall not extend the periods provided by Article 4. If, later, the right of priority is invoked, the authorities of any country may provide that the period shall start from the date of introduction of the goods into the exhibition.
- (3) Each country may require, as proof of the identity of the article exhibited and of the date of its introduction, such documentary evidence as it considers necessary.

Article 12

[Special national industrial property services]

- (1) Each country of the Union undertakes to establish a special industrial property service and a central office for the communication to the public of patents, utility models, industrial designs, and trademarks.
- (2) This service shall publish an official periodical journal. It shall publish regularly:
 - (a) the names of the proprietors of patents granted, with a brief designation of the inventions patented;
 - (b) the reproductions of registered trademarks.

A.2. Trade Related Aspects of Intellectual Property Rights (TRIPS)

http://www.wto.org/english/tratop_e/trips_e/t_agm3c_e.htm#5

ANNEX 1C OF THE MARRAKESH AGREEMENT ESTABLISHING THE WORLD TRADE ORGANIZATION, SIGNED IN MARRAKESH, MOROCCO ON 15TH APRIL 1994

PART II — STANDARDS CONCERNING THE AVAILABILITY, SCOPE AND USE OF INTELLECTUAL PROPERTY RIGHTS

Article 27 [Patentable Subject Matter]

1. Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. (1) Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.

2. Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.

3. Members may also exclude from patentability:

(a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;

(b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.

Article 28 [Rights Conferred]

1. A patent shall confer on its owner the following exclusive rights:

(a) where the subject matter of a patent is a product, to prevent third parties not having the owner's consent from the acts of: making, using, offering for sale, selling, or importing (2) for these purposes that product;

(b) where the subject matter of a patent is a process, to prevent third parties not having the owner's consent from the act of using the process, and from the acts of: using, offering for sale, selling, or importing for these purposes at least the product obtained directly by that process.

2. Patent owners shall also have the right to assign, or transfer by succession, the patent and to conclude licensing contracts.

Article 29 [Conditions on Patent Applicants]

1. Members shall require that an applicant for a patent shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art and may require the applicant to indicate the best mode for carrying out the invention known to the inventor at the filing date or, where priority is claimed, at the priority date of the application.

2. Members may require an applicant for a patent to provide information concerning the applicant's corresponding foreign applications and grants.

Article 30 [Exceptions to Rights Conferred]

Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

Article 31 [Other Use Without Authorization of the Right Holder]

Where the law of a Member allows for other use (3) of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected:

(a) authorization of such use shall be considered on its individual merits;

(b) such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly;

(c) the scope and duration of such use shall be limited to the purpose for which it was authorized, and in the case of semi-conductor technology shall only be for public non-

commercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive;

(d) such use shall be non-exclusive;

(e) such use shall be non-assignable, except with that part of the enterprise or goodwill which enjoys such use;

(f) any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use;

(g) authorization for such use shall be liable, subject to adequate protection of the legitimate interests of the persons so authorized, to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur. The competent authority shall have the authority to review, upon motivated request, the continued existence of these circumstances;

(h) the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization;

(i) the legal validity of any decision relating to the authorization of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;

(j) any decision relating to the remuneration provided in respect of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;

(k) Members are not obliged to apply the conditions set forth in subparagraphs (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive. The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases. Competent authorities shall have the authority to refuse termination of authorization if and when the conditions which led to such authorization are likely to recur;

(l) where such use is authorized to permit the exploitation of a patent (“the second patent”) which cannot be exploited without infringing another patent (“the first patent”), the following additional conditions shall apply:

(i) the invention claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent;

(ii) the owner of the first patent shall be entitled to a cross-licence on reasonable terms to use the invention claimed in the second patent; and

(iii) the use authorized in respect of the first patent shall be non-assignable except with the assignment of the second patent.

Article 32 [Revocation/Forfeiture]

An opportunity for judicial review of any decision to revoke or forfeit a patent shall be available.

Article 33 [Term of Protection]

The term of protection available shall not end before the expiration of a period of twenty years counted from the filing date (4)

Article 34 [Process Patents: Burden of Proof]

1. For the purposes of civil proceedings in respect of the infringement of the rights of the owner referred to in paragraph 1(b) of Article 28, if the subject matter of a patent is a process for obtaining a product, the judicial authorities shall have the authority to order the defendant to prove that the process to obtain an identical product is different from the patented process. Therefore, Members shall provide, in at least one of the following circumstances, that any identical product when produced without the consent of the patent owner shall, in the absence of proof to the contrary, be deemed to have been obtained by the patented process:

(a) if the product obtained by the patented process is new;

(b) if there is a substantial likelihood that the identical product was made by the process and the owner of the patent has been unable through reasonable efforts to determine the process actually used.

2. Any Member shall be free to provide that the burden of proof indicated in paragraph 1 shall be on the alleged infringer only if the condition referred to in subparagraph (a) is fulfilled or only if the condition referred to in subparagraph (b) is fulfilled.

3. In the adduction of proof to the contrary, the legitimate interests of defendants in protecting their manufacturing and business secrets shall be taken into account.

Notes:

(1) For the purposes of this Article, the terms “inventive step” and “capable of industrial application” may be deemed by a Member to be synonymous with the terms “non-obvious” and “useful” respectively.

(2) This right, like all other rights conferred under this Agreement in respect of the use, sale, importation or other distribution of goods, is subject to the provisions of Article 6.

(3) “Other use” refers to use other than that allowed under Article 30

(4) It is understood that those Members which do not have a system of original grant may provide that the term of protection shall be computed from the filing date in the system of original grant.

http://www.wto.org/english/tratop_e/trips_e/t_agm3c_e.htm#5

A.3. Doha WTO Ministerial 2001: Declaration on the TRIPS Agreement and Public Health, Nov 20th, 2001

http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm

1. We recognize 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.
2. We stress the need for the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) to be part of the wider national and international action to address these problems.
3. We recognize that intellectual property protection is important for the development of new medicines. We also recognize the concerns about its effects on prices.
4. We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all.

In this connection, we reaffirm the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.

5. Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include:
 - . In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.
 - 1. Each member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.
 - 1. Each member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, 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.
 - 1. The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4.
6. We recognize that WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002.

7. We reaffirm the commitment of developed-country members to provide incentives to their enterprises and institutions to promote and encourage technology transfer to least-developed country members pursuant to Article 66.2. We also agree that the least-developed country members will not be obliged, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement or to enforce rights provided for under these Sections until 1 January 2016, without prejudice to the right of least-developed country members to seek other extensions of the transition periods as provided for in Article 66.1 of the TRIPS Agreement. We instruct the Council for TRIPS to take the necessary action to give effect to this pursuant to Article 66.1 of the TRIPS Agreement.

http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm

Appendix B: Data

B.1. Population in Thousands

<http://esa.un.org>

World	Medium	High	Low	constant
1	5 279 519	5 279 519	5 279 519	5 279 519
2	5 692 353	5 692 353	5 692 353	5 692 353
3	6 085 572	6 085 572	6 085 572	6 085 572
4	6 464 750	6 464 750	6 464 750	6 464 750
5	6 842 923	6 903 276	6 781 431	6 881 529
6	7 219 431	7 382 434	7 054 584	7 337 041
7	7 577 889	7 873 172	7 280 148	7 819 287
8	7 905 239	8 336 867	7 471 426	8 321 838
9	8 199 104	8 784 155	7 618 083	8 855 299
0	8 463 265	9 237 907	7 712 423	9 439 779
11	8 701 319	9 709 446	7 753 745	10 092 723
12	8 907 417	10 184 739	7 741 810	10 827 058
13	9 075 903	10 646 311	7 679 714	11 657 999

More developed

1990	1 148 572	1 148 572	1 148 572	1 148 572
1995	1 173 983	1 173 983	1 173 983	1 173 983
2000	1 193 354	1 193 354	1 193 354	1 193 354
2005	1 211 265	1 211 265	1 211 265	1 211 265
2010	1 225 678	1 236 012	1 215 277	1 224 603
2015	1 236 561	1 262 834	1 210 085	1 233 679
2020	1 244 413	1 289 550	1 198 800	1 238 658
2025	1 248 954	1 312 272	1 185 003	1 239 736
2030	1 250 658	1 333 175	1 168 279	1 237 269
2035	1 249 903	1 355 347	1 147 542	1 231 312
2040	1 247 071	1 381 006	1 121 890	1 221 875
2045	1 242 398	1 409 776	1 091 378	1 209 441
2050	1 236 200	1 439 850	1 057 485	1 195 081

Less developed

1990	4 130 947	4 130 947	4 130 947	4 130 947
1995	4 518 369	4 518 369	4 518 369	4 518 369

2000	4 892 218	4 892 218	4 892 218	4 892 218
2005	5 253 484	5 253 484	5 253 484	5 253 484
2010	5 617 246	5 667 265	5 566 154	5 656 926
2015	5 982 871	6 119 600	5 844 499	6 103 363
2020	6 333 475	6 583 622	6 081 348	6 580 629
2025	6 656 285	7 024 595	6 286 423	7 082 103
2030	6 948 446	7 450 980	6 449 804	7 618 030
2035	7 213 362	7 882 561	6 564 881	8 208 467
2040	7 454 248	8 328 440	6 631 856	8 870 848
2045	7 665 019	8 774 963	6 650 432	9 617 618
2050	7 839 702	9 206 461	6 622 229	10 462 918

Year	World population	Most Developed	Less Developed	Least Developed
1990	5279519	1148572	4130947	521816
1995	5692353	1173983	4518369	596962
2000	6085572	1193345	4892218	673524
2005	6464750	1211265	5253484	759389
2010	6842923	1225678	5617246	852025
2015	7219431	1236561	5982871	951610
2020	7577889	1244413	6333475	1057086
2025	7905239	1248954	6656285	1167461
2030	8199104	1250658	6948446	1281335
2035	8463265	1249903	7213362	1397057
2040	8701319	1247071	7454248	1512643
2045	8907417	1242398	7665019	1626025
2050	9075903	1236200	7839702	1735368

Year	(in millions)			
	World Population	Most Developed	Less Developed	Least Developed
1990	5279.519	1148.572	4130.947	521.816
1995	5692.353	1173.983	4518.369	596.962
2000	6085.572	1193.345	4892.218	673.524
2005	6464.75	1211.265	5253.484	759.389
2010	6842.923	1225.678	5617.246	852.025
2015	7219.431	1236.561	5982.871	951.61
2020	7577.889	1244.413	6333.475	1057.086
2025	7905.239	1248.954	6656.285	1167.461
2030	8199.104	1250.658	6948.446	1281.335
2035	8463.265	1249.903	7213.362	1397.057
2040	8701.319	1247.071	7454.248	1512.643
2045	8907.417	1242.398	7665.019	1626.025
2050	9075.903	1236.2	7839.702	1735.368

B.2 World's Largest Pharmaceutical Markets (1999-2005): Sales in Billions of 79.1% of World's Industry

	1999	2005
USA (51.7%)	130.1	181.8
Japan (17.3%)	53.5	61
Germany (7.7%)	18.5	27
France (6.3%)	17.8	22.5
Italy (4.2%)	11.3	14.6
UK (4.3%)	11	15.2
Spain (3.1%)	6.6	10.9
Brazil (1.9%)	6.2	6.8
Canada (3.4%)	6.5	11.9
		351.7
Canada	6.5	11.9
Brazil	6.2	6.8
Spain	6.6	10.9
UK	11	15.2
Italy	11.3	14.6
France	17.8	22.5
Germany	18.5	27
Japan	53.5	61
USA	130.1	181.8

IMS World Review

B.3. Drug Price Comparison of Diclofanic Sodium (Voveran), Piroxicam (Dolonex) and Ranitidine (Zantac) in India, Pakistan, Indonesia, UK, and USA (in USD)

	India	Pakistan	Indonesia	UK	USA
Diclofanic Sodium (Voveran)					
Ciba-Geigy	6.49	55.62	177.18	120.12	402.8
Piroxicam (Dolonex)					
Pfizer	24.64	72.5	218.45	1064.8	1064.8
Ranitidine (Zantac)					
Glaxo	17.39	241.44	658.36	603.36	1200.8

B.K. Keayla. TRIPS Agreement on Patent Laws: Impact on Pharmaceuticals and Health for All (1997)

B.4. Growth of Pharmaceutical Sales by Region in Billions (2000-2003)

World Market	North America	Europe	Japan	Latin america	Asia, Africa & Australia
2000	152.8	75.3	51.5	18.9	18.7
2001	181.8	88	47.6	27.9	18.9
2002	203.6	101.9	46.9	31.6	16.5
2003	229.5	129.7	52.4	37.3	17.4

IMS World Review