THE TRIPS AGREEMENT: BALANCING INNOVATION INCENTIVES AND ACCESS

The contribution of strong intellectual property protection to human progress goes beyond economics. By providing incentives for the development of new medicines, patent protection improves health and reduces both the economic and human toll of disease.

Policies are urgently needed to turn the advances in the new technologies into advances for all humankind.

At the conclusion of the Uruguay Round in 1994, the founding member of the new World Trade Organization (WTO) signed the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), the most comprehensive global agreement on intellectual property rights (IPR). For the first time, a multilateral agreement imposing minimum standards on patents, copyright, trademarks and trade secrets on innovations was put into place in all member countries. Included in this landmark agreement was a requirement for strong global pharmaceutical patents. It obliged countries to offer a patent term of at least 20 years on all products and processes, including lifesaving pharmaceuticals.1

The TRIPS Agreement has been the subject of much controversy since its inception. Namely, the decision sparked fierce debate regarding international patent rules and public health. The debate is rooted in the fundamental tension between pricing and incentives. A strong patent system is believed to provide incentives for corporate research and development (R&D) investment to create pharmaceutical drugs. However, patent protection often increases the prices


Cecilia Hyunjung Mo prepared this case under the supervision of Professor Condoleezza Rice and Professor William Barnett as the basis for class discussion rather than to illustrate either effective or ineffective handling of an administrative situation.
of pharmaceutical drugs paid by governments and consumers in poor countries, depriving millions of sick people access to medicine. The TRIPS Agreement sought to harmonize the need for innovation incentives with the need for public access to innovations, especially lifesaving drugs. Is the TRIPS Agreement the best the world can do?

**What is TRIPS?**

**Understanding TRIPS**

The WTO was established at the end of the Uruguay Round of the General Agreement on Tariffs and Trade (GATT) in 1994 to act as the international body dealing with the rules of trade between nations. The goal of the organization is “to help producers of goods and services, exporters, and importers conduct their business” by “reducing obstacles to international trade and ensuring a level playing field for all.” As of July 2008, 153 countries, ranging from more affluent Organization for Economic Co-operation and Development (OECD) countries to the least developed, were members of the WTO, accounting for over 97 percent of world trade (See Exhibit 1 for an introduction to the WTO).

The TRIPS Agreement, negotiated in the 1986-1994 Uruguay Round, is one key obligatory agreement between WTO members, and is the most far-reaching multilateral agreement on IPR regulations. The IPR agreement was drafted in response to a fast-growing knowledge economy, in which a company’s chief assets are bright ideas rather than physical capital coupled with inconsistent regulations between countries. Although each country implements IPR law at the national level, the TRIPS Agreement introduced global minimum standards for protecting all forms of IPR: (1) copyright and related rights; (2) trademarks, including service marks; (3) geographical indications; (4) industrial designs; (5) patents; (6) layout-designs (topographies) of integrated circuits; and (7) undisclosed information, including trade secrets. These standards are enforced through WTO’s integrated dispute settlement system, which means that if a country does not fulfill its baseline IPR obligations, trade sanctions can be applied against it.

**Motivating TRIPS**

At the time TRIPS was negotiated, the extent of protection and enforcement of these rights varied widely around the world. As intellectual property became more important in trade coupled

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4 Compiled from WTO websites: http://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm and http://www.wto.org/english/thewto_e/whatis_e/inbrief_e/inbr02_e.htm. Note that, as of July 2008, 30 more countries are currently negotiating membership.
with increasing globalization, these differences became a source of tension between countries. The WTO’s TRIPS Agreement was conceived as an attempt to narrow the gaps in the way intellectual property rights are protected around the world. For instance, at the time that negotiations began, over 40 countries did not grant patent protection for pharmaceutical products, making generic production possible. The TRIPS Agreement achieved an internationally-agreed upon set of trade rules for IPR, to introduce order and predictability, as well as a systematic method for resolving trade disagreements with respect to intellectual property.\(^8\)

Beyond the fact that a common set of international rules facilitates trade between countries, uniform rules across countries ensure that there is trade without discrimination. As in other WTO agreements, the TRIPS Agreement is rooted in a principle of non-discrimination. In protecting IPR, countries are mandated to meet the requirements of the TRIPS Agreement abiding by the principle of national treatment (treating one’s own nationals and foreigners equally), and the principle of most-favored-nations treatment (equal treatment for nationals of all trading partners in the WTO). As such, the TRIPS Agreement is, in principle, established to promote non-discriminatory practices globally.\(^9\)

At the core of the agreement, however, is the belief that there is a strong relationship between knowledge ownership and innovation: “intellectual property protection contributes to technical innovation and the transfer of technology,” and as such “economic and social welfare should be enhanced.”\(^10\) This belief is based on the fact that knowledge is a public good leading to a public goods problem (for a primer on the public goods problem, see Exhibit 2). As such, without IP protection, there is no market incentive to fund the costs of discovery and development of valuable information (e.g., the cure for HIV/AIDS). Country-by-country solutions (country specific patent systems) addressed the public goods problem (with varying degrees of success) in the past, but with increasing globalization country-specific solutions were found to be insufficient. A binding multilateral agreement on to increase the supply of knowledge, one class of public goods, became necessary.

According to Gerald J. Mossinghoff, a former U.S. Assistant Secretary of Commerce and Commissioner of Patents and Trademarks, “without international respect for pharmaceutical patents, medical innovation would suffer.”\(^11\) Pharmaceutical research (PhRMA) companies argue that the pharmaceutical industry is characterized by high fixed costs (US$ 230-500 million per drug over 12-15 years) and low variable costs.\(^12\) Moreover, successful drugs must generate additional revenue to cover all the failed drugs. With limited barriers of entry, the first mover incurs all research costs (including that of failed projects), while subsequent movers, such as

\(^8\) Ibid, p.39.
\(^9\) Ibid.
\(^10\) Ibid, p.40.
generic drug companies) can free ride. A 1988 study by Edwin Mansfield of the University of Pennsylvania estimated that 65 percent of pharmaceutical products would not have been introduced had there not been adequate patent protection.

There are competing values at play. Intellectual property (IP) laws attempt to harmonize the need for innovation incentives with public interest in the development and availability of new products and technologies.

**KEY PROVISIONS OF TRIPS**

Fierce debate regarding TRIPS has ensued as the global minimum standards formalized in the agreement are far tighter than existing legislation in most developing countries and are viewed by some as detrimental to the national interests and needs of least developed countries (LDCs). Key provisions related to the pharmaceutical industry and access are as follows.

**Patent Protection:** The TRIPS Agreement requires WTO members to provide patent protection for at least 20 years, in contrast to 5 to 7 year terms in several developing countries, from the filing date of a patent application for any invention. The agreement also requires countries to provide patent protection for both processes and products. Before TRIPS, many countries provided only process patents. Product patents provide for absolute protection of the product, whereas process patents provide protection for the method of manufacturing. Protection for process patents absent product patents would not preclude the manufacture of patented products by an alternative method from that which has been invented (and patented), which enables manufacturers to create and sell generic versions of patented medicines at much more affordable prices. The price difference is clear when contrasting drug prices in Pakistan, where there are patents, to its neighboring India, where there are none (see Exhibit 3).

**Protection of Data Submitted for the Registration of Pharmaceuticals:** Drug regulatory authorities require pharmaceutical companies to submit data demonstrating the safety, quality and efficacy of the product before selling their product. TRIPS requires that WTO members protect submitted data against unfair commercial use. With this data exclusivity approach, once a company has submitted original test data, no competing manufacturer is allowed to rely on these data as proof of a similar product for a period of time. Prior to this requirement, generic manufacturer could rely on this test data to register substitutes. The public interest in limiting

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14 Ibid.


Data protection is to promote competition and ensure that data protection does not become the means to block timely entrance of affordable generic medicines of public health importance.\(^{20}\)

**Transition Periods:** The TRIPS Agreement provides for transition periods, permitting developing countries additional time to bring national legislation and practices into conformity with TRIPS provisions. The dates of application of the TRIPS Agreement are as follows: (1) for industrialized countries, 1996; (2) for developing countries that issued patent before TRIPS Agreement, 2000; (3) for developing countries with no patent protection, 2005; and (4) for least developed countries: 2006 originally, but the 2001 Doha Declaration extended the deadline for LDCs (49 of the poorest countries) to 2016.\(^{21}\)

**DISPUTES OVER PHARMACEUTICAL PATENTS**

**Flexibility Provisions**

While stringent, the TRIPS Agreement contains provisions that allow countries a degree of flexibility to accommodate their own IPR systems and development needs. However, developing countries have faced obstacles when using its discretion to seek access to affordable medicines.\(^{22}\) For example, the United States Trade Representative became enmeshed in disputes with the Brazilian government over its industry of manufacturing generic drugs shortly after the TRIPS Agreement took effect.\(^{23}\) And in March 2001, with the support of the Vice President of the United States, a pharmaceutical-industry coalition of 41 drug companies sued the South African government for IPR violation.\(^{24}\) At the time, South Africa had the highest HIV infection rate in the world.\(^{25}\) Nevertheless, the pharmaceutical industry felt that the government was violating their patent rights by including a clause in their Medicines and Related Substances Control Amendment Act stating: “The minister may prescribe conditions for the supply of more affordable medicines in certain circumstances so as to protect the health of the public, notwithstanding anything to the contrary contained in the Patent’s Act.”\(^{26}\)

In 2001, over 36 million people lived with HIV/AIDS, where some 70 percent of them were in Sub-Saharan Africa. In the wake of this public health crisis, which had been regularly featured in the world press, coupled with a large affordability gap of treating AIDS (see Exhibit 4 for information on the cost per treatment), major organizations pushed for greater affordability. For


\(^{24}\) Ibid. Note that the support provided by the US Vice President was then retracted in response to domestic pressure.


\(^{26}\) Ibid.
instance, Pfizer and Glaxo Wellcome were targeted by major OXFAM campaigns ("Patient Rights before Patent Rights"). The implications of disputes were as follows:

1. Lack of clarity for governments on what caveats and let-outs it could employ when constructing national policy consistent with the TRIPS Agreement.
2. Difficulties for firms when predicting future markets, forecasting that is crucial for making long-term investments in products for those markets.

These challenges showed that the TRIPS Agreement as is did not clearly ensure individuals have access to lifesaving drugs, did not level the playing field, and did not decrease uncertainty to allow businesses to operate.

Global Market Distribution and Profitability

Some critics have pushed back on the argument that weak IPR laws that allow generic competition, especially in the developing world, threaten innovation. Critics have noted that countries that need affordable lifesaving drugs are only a small piece of the pharmaceutical industry’s global market. For instance, in 2002, Africa accounted for just 1.3 percent of pharmaceutical sales (see Exhibit 5 for more on the global pharmaceutical market). As such, profit losses due to generic competition in developing countries are not extensive. Moreover, there is a concern that exclusively focusing on patent protection to incite innovation has lead profitability, rather than need, define research agendas. Even defenders of strong patent protection admit that it has been increasingly difficult to persuade companies to invest in drugs that attack diseases or conditions that afflict small and/or poorer populations. In other words, focusing only on patent protection to incentivize knowledge building has lead to a lack of innovation with respect to necessary, but non-lucrative domains.

Critics have also commented on the high profitability of the pharmaceutical industry, which has prompted questions regarding costs. For instance, in 2002, the pharmaceutical industry topped the list of most profitable industry (see Exhibit 6 for 2009 information on profitability). However, according to Richard Epstein at the Hoover Institute, the industry’s multibillion-dollar profits “conceal deep vulnerabilities.” He argues the following: “It is no accident that the shares of major pharmaceutical houses have been hammered over the past few years, even as profits appear to be at record highs. Wall Street values companies not only on current earnings but also on long-term prospects, which are cloudy at best for research pharmaceutical firms. Pfizer, for example, recently announced plans to cut one-fifth of its U.S. sales force, with a promise of further restructuring.”

32 Ibid.
Biopiracy

Some claim that new patent laws have no regard for the knowledge of indigenous people, leaving it vulnerable to theft by others. In fact, critics find that there exists a double theft issue: (1) “theft of creativity and innovation” and (2) “the exclusive rights established by patents on stolen knowledge steal economic options of everyday survival on the basis of indigenous biodiversity and knowledge.” For example, \textit{karela jamun} and \textit{brinjal} have been widely used in India to control diabetes; however, the US granted Cromak Research Inc. with a patent to use these plants in a cure for diabetes. This problem is then intensified given that patent challenges are extremely costly.

**DOHA DECLARATION ON THE TRIPS AGREEMENT**

The Doha Development Agenda or Doha Development Round began in November 2001, and as of 2009, this round of negotiations is still in progress. Spurred by the flurry of disputes that surrounded TRIPS, WTO members adopted a special Ministerial Declaration at the start of the WTO Ministerial Conference to clarify ambiguities between the need for governments to effectively address public health issues and the terms of TRIPS. Before the Doha meeting, the United States claimed that the language in the original TRIPS Agreement was flexible enough to address health emergencies; however, other WTO members insisted that clarity was necessary. Hence, the Doha Declaration on the TRIPS Agreement and Public Health was created.

The declaration affirmed that the TRIPS Agreement should not stand in the way of member governments acting to protect public health and affirmed members’ right to use the Agreement’s flexibilities. The Doha Declaration made clear that governments have the right to the following:

1. To determine what constitutes a national emergency and circumstances of extreme urgency;
2. To use compulsory licensing (giving permission to a non-patent-holder to produce without the consent of the patent-holder) for the domestic market via Article 31 of TRIPS;
3. To employ parallel importation (allowing countries to import a non-counterfeit product without the permission of the IP owner) via Article 6 of TRIPS; and
4. To establish its own IPR regime without challenge.

\textsuperscript{34} Ibid.
\textsuperscript{36} Compiled from WHO website: \url{http://www.who.int/medicines/areas/policy/doha_declaration/en/index.html}.
The original TRIPS Agreement was also amended. Although compulsory licensing was permitted under the original agreement, countries without domestic manufacturing capacity could not take advantage of this right. Moreover, because of the stipulation that the majority of products created under compulsory licensing needed to be for the domestic market, countries with capacity constraints could not import generic medicines made under compulsory licenses. On August 2003, the WTO waived this export restriction.\(^{40}\) However, controversy surrounding TRIPS still remain. Debate on how the world can balance the need to incentivize innovations, including innovations that meet the needs of the poor, with the need to ensure access to essential medicines continues.

\(^{40}\) Ibid.
Exhibit 1
Introduction to the World Trade Organization

History: The WTO was officially established on January 1, 1995, and its primary objective is to “help trade [of goods, services, and intellectual property] flow smoothly, freely, fairly and predictably.” The WTO was developed through a series of trade negotiations, or rounds, held under the General Agreement on Tariffs and Trade (GATT), which was established over 50 years ago. WTO was created during the 1986-1994 Uruguay Round, which was the last of the GATT rounds. While the WTO is relatively young, the foundational trading system was conceived in 1948, as GATT has provided much of the rules for the WTO system.

Primary Activities: The WTO is not a static organization. While the WTO is responsible for administering and monitoring a system of rules governing the trade of goods, services and intellectual property, the WTO also acts as a forum for negotiating these rules. As such, the current trade agreements are renegotiated from time to time, and new agreements can be added. The WTO’s primary activities can be stated as follows:

- Negotiating the reduction or elimination of obstacles to trade (import tariffs, other barriers to trade) and agreeing on rules governing the conduct of international trade (e.g. antidumping, subsidies, product standards, etc.).
- Administering and monitoring the application of the WTO's agreed rules for trade in goods, trade in services, and trade-related intellectual property rights.
- Monitoring and reviewing the trade policies of WTO members, as well as ensuring transparency of regional and bilateral trade agreements.
- Settling trade disputes among WTO members regarding the interpretation and application of the agreements.
- Building capacity of developing country government officials in international trade matters, through technical assistance and training programs.
- Assisting the process of accession of some 30 countries who are not yet members of the organization.
- Conducting economic research and collecting and disseminating trade data in support of the WTO's other main activities.
- Explaining to and educating the public about the WTO, its mission and its activities.
- Cooperating with other international organizations.

WTO Structure: Based in Geneva, Switzerland, the WTO has 153 members, accounting for over 97 percent of world trade. Approximately 30 other countries are negotiating membership. WTO decisions are made by the entire membership, and is typically by consensus. The top decision-making body is the Ministerial Conference, which convenes at least once every two years. Below the Ministerial Council is the General Council, which is comprised of one ambassador from each member country. The General Council meets several times a year in the Geneva headquarters. The General Council acts as the Trade Policy Review Body and the Dispute Settlement Body as well. At the next level are the Goods Council, Services Council and

42 Compiled from WTO website: http://www.wto.org/english/thewto_e/whatis_e/wto_dg_stat_e.htm
Intellectual Property (TRIPS) Council, and all three bodies report to the General Council. Numerous specialized committees, working groups and working parties report to one of these three bodies or the General Council directly. All WTO members may participate in all councils, committees, etc. The Appellate Body, Dispute Settlement panels, and plurilateral committees, however, are not open to all WTO members. The WTO organization chart is as follows:\textsuperscript{43}

\textsuperscript{43} Compiled from WTO websites: http://www.wto.org/english/thewto_e/whatis_e/tif_e/org2_e.htm and http://www.wto.org/english/thewto_e/whatis_e/inbrief_e/inbr02_e.htm.
Exhibit 2
Primer on Public Goods Problem

Types of Goods

There are four types of goods: (1) private goods; (2) club goods; (3) common goods or common-pool resources; and (4) public goods. These four categories of goods are based on two criteria,
excludability and subtractability (or rivalrousness). A good is excludable “if people can be prevented from using it” (e.g., cable television and computer software are excludable in that people can be excluded from the consumption of a good) and a good is subtractable or rivalrous “if one person’s consumption of good necessarily diminishes another person’s consumption of it” (e.g., lumber is rivalrous in that a person cannot use wood that has been used by another).  

<table>
<thead>
<tr>
<th>Rivalrous</th>
<th>Excludable</th>
<th>Non-Excludable</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Private Goods (e.g., food, clothing, houses)</td>
<td>Common Goods / Common-Pool Resources (e.g., clean water, fish)</td>
</tr>
<tr>
<td>Non-Rivalrous</td>
<td>Club Goods (e.g., satellite television)</td>
<td>Public Goods (e.g., air, fireworks, national defense, intellectual property)</td>
</tr>
</tbody>
</table>

### Knowledge or Information Goods

Knowledge, the good that the TRIPS Agreement seeks to protect and encourage, is a public good. The traditional definition of public goods is two-fold:

1. Public goods are *non-excludable*. They produce benefits that everyone can enjoy. In other words, one cannot exclude any individual from enjoying the benefits of a public good.
2. Public goods are *non-rivalrous*. The good is not zero-sum; the consumption of a public good by one person does not detract from another’s consumption of the good.

For example, clean air is a public good. Everyone can freely enjoy clean air, and one person’s consumption of clean air does not impact another individual’s consumption of clean air. Similarly, intellectual property is a public good because the use of information is non-excludable (one cannot exclude other persons from using information) in its benefits and non-rivalrous (knowledge can be used without exhaustion) in its consumption.

### Public Goods Problem

Because a public good is non-excludable and non-rivalrous, a public goods problem ensues: the good is not sufficiently provided. The optimum amount of a public good is not likely to be produced or provided in a free market. Individuals working in their own self-interests are unable to provide public goods in desired quantities. For instance, consider an entrepreneur who stages a fireworks show at a stadium, and charges an admissions fee to those who watch the show at the stadium. Each person will seek to “free ride” by allowing others to pay for the show, and then watch the show for free from his/her backyard, a neighboring hill, etc. Arguably, few individuals will pay the entrepreneur. As such, the entrepreneur will not be compensated for her efforts. If this problem cannot be solved, valuable goods and services – ones people otherwise would be willing to pay for – will not be created or provided.

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Intellectual property, absent IP protection, faces a similar public goods problem due to a free-rider problem. Once a cure for a particular disease is created, the use of that information is non-excludable. Copyists can free-ride on the efforts of the creators of the cure, and as such, the entrepreneurs who dedicated time and resources to provide a service or good will not derive sufficient benefits for their investment. Few individuals will pay the original entrepreneurs for the innovation, as they can free-ride by copying the innovation or purchase the good from copyists, who offer the good at a lower price than the innovator. As copyists did not invest in the R&D of the product, prices do not need to be set to offset R&D costs. Without intervention, desirable intellectual property like pharmaceutical products that cure malaria or HIV/AIDS, will be underproduced.
Exhibit 3
Drug Prices and Patent Costs

Source: Lanjouw 1997.45

Exhibit 4
The Affordability Gap of Treating AIDS in 1999

<table>
<thead>
<tr>
<th></th>
<th>Switzerland</th>
<th>Kenya</th>
<th>Uganda</th>
<th>Zambia</th>
</tr>
</thead>
<tbody>
<tr>
<td>Population</td>
<td>7 million</td>
<td>30 million</td>
<td>23 million</td>
<td>10 million</td>
</tr>
<tr>
<td>People with HIV</td>
<td>17,000</td>
<td>2,100,000</td>
<td>820,000</td>
<td>870,000</td>
</tr>
<tr>
<td>Cost of treating all infected people with antiretroviral drugs at global market prices, about $12,000 a person a year (USD)</td>
<td>204 million</td>
<td>25 billion</td>
<td>10 billion</td>
<td>10 billion</td>
</tr>
<tr>
<td>Cost of treatment as % of GDP</td>
<td>0.08</td>
<td>238</td>
<td>154</td>
<td>336</td>
</tr>
<tr>
<td>Public health care spending as % of GDP, 1998</td>
<td>7.6</td>
<td>2.4</td>
<td>1.9</td>
<td>3.6</td>
</tr>
<tr>
<td>Total health care spending as % of GDP, 1998</td>
<td>10.4</td>
<td>7.8</td>
<td>6.0</td>
<td>7.0</td>
</tr>
</tbody>
</table>

Source: UNDP Human Development Report 2001

Exhibit 5
Pharmaceutical Sales in the Global Market, 2002\textsuperscript{46}

Source: IMS Health 200

### Exhibit 6
### Fortune 500 Top Industries by Profitability

<table>
<thead>
<tr>
<th>Industry Rank</th>
<th>Industry</th>
<th>2008 Profits as % of Revenue</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Network and Other Communications Equipment</td>
<td>20.4</td>
</tr>
<tr>
<td>2</td>
<td>Internet Services and Retailing</td>
<td>19.4</td>
</tr>
<tr>
<td>3</td>
<td>Pharmaceuticals</td>
<td>19.3</td>
</tr>
<tr>
<td>4</td>
<td>Medical Products and Equipment</td>
<td>16.3</td>
</tr>
<tr>
<td>5</td>
<td>Railroads</td>
<td>12.6</td>
</tr>
<tr>
<td>6</td>
<td>Financial Data Services</td>
<td>11.7</td>
</tr>
<tr>
<td>7</td>
<td>Mining, Crude-Oil production</td>
<td>11.5</td>
</tr>
<tr>
<td>8</td>
<td>Securities</td>
<td>10.7</td>
</tr>
<tr>
<td>9</td>
<td>Oil and Gas Equipment, Services</td>
<td>10.2</td>
</tr>
<tr>
<td>10</td>
<td>Scientific, Photographic, and Control Equipment</td>
<td>9.9</td>
</tr>
</tbody>
</table>

Source: Fortune 500 2009

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