Trade Related Aspects of Intellectual Property Rights (TRIPS): Protecting patents or patients?

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Learning objectives

1. What is the problem with access to affordable medicines?
2. What are TRIPS and the Doha Declaration?
3. What are compulsory licensing and parallel importing?
4. What happens when nations use TRIPS rights?
5. Cases: South Africa, Thailand, Brazil, India
6. What is American foreign policy on pharmaceuticals? How do TRIPS-Plus rules obstruct generics?
7. Impact on U.S. – Australia and parallel importation
8. Who decides trade policy?
The Problem

• Nations are obligated to respect pharmaceutical patents under World Trade Organization rules
• Global pandemics threaten the public health of the developing world
• Which side gives?

The dilemma, to put it succinctly, is simple. All member-nations of the World Trade Organization are obligated to respect pharmaceutical patents under the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement. Companies get temporary patent monopolies as a reward for their research and development. The time limit is 20 years, but due to delays for clinical trials and other processes, the effective patent period for pharmaceuticals is usually 11-14 years. This monopoly gives companies the ability to profit from their inventions. In the case of pharmaceuticals, it is not the actual product that is expensive to produce, but the research to invent the drug that makes pharmaceuticals expensive. This is the rationale for patent monopolies.
What Do Patents Do?

- Monopoly rights to originator, can sell product without competition for a given time
- *Process* patents: competitors can often circumvent
- *Product* patents: harder to circumvent
- *Method of use* patent: deliver orally or by injection
- Formulation (use): use elfornithine for sleeping sickness or to stop facial hair growth
- Short-term or long term
What are Generic Drugs?

• Use different process to come up with a product “bioequivalent” to the brand-name drug
• Reverse engineering
• 65% of US prescriptions
• 1984 Hatch-Waxman
  – Generic company can refer to original clinical trial data, which boosted generic production
  – Brand name company got new grounds to extend patent terms: FDA delays, tests on kids, etc.
Role of Patent Policy for Drugs - opposing views

- Key incentive to innovation
- Fairly compensates investments in Research & Development (R&D)
- Assures timely access to new life-saving drugs
- OR -
- Props up exorbitant pharmaceutical company profits in absence of actual innovation
- Perpetuates monopoly as long as possible by extending patent terms and durations
- Discourages fair competition by generics
Notes on Role of Patent Policy for Drugs - opposing views

The pharmaceutical industry faces political backlash on prices, crises in innovation and quality

Public outcry about high prices
The U.S. pays the highest prices in the world, leading to proposals for reimportation from Canada and other countries where policies control prices, and to modifying the lucrative Medicare Part D program.
Lower and middle income country public funds are strained

Higher prices are not justified by innovation. PhRMA, U.S. lobbying arm for brand-name drug companies, reports the industry spends only 19% of revenues on research & development. Few new drugs are being developed; most “new” products are slightly modified copies of existing drugs.

Scandals have undermined faith in quality controls for pharmaceuticals. Dangerous side-effects have been publicly reported for COX-2 inhibitors (which are painkillers) and several psychiatric drugs.
Pharma Political Strategy: Trade Agreements

A. Protect high prices in US market
   - Block re-importation to US (“parallel importation”)

B. Seek higher prices in other developed countries
   - Pharma argues that price controls in EU and elsewhere harm quality, access, innovation

C. Maintain IP structure in TRIPS, and extend IP rights in regional trade agreements with low and middle-income countries
   - “TRIPS-Plus” trade rules extend patents
   - Restrict production and sale of generics
   - Market to small number of wealthy individuals
Trade-related Aspects of Intellectual Property Rights (TRIPS)

- The TRIPS agreement has been in force since 1995
- High and middle-income nations already required to create patent/IP protection systems
  - Least Developed Countries: 2015
- First World nations generally hold most patents
- However “flexibilities” set limits to patent protection and recognize the right to health
Notes on Trade-related Aspects of Intellectual Property Rights

There is no such thing as an international patent. Patents are issued country by country. Until recently, many countries did not even have patent offices at all. So how are patents applied from country to country? By TRIPS.

The World Trade Organization is a inter-governmental organization that makes trade rules affecting all member states. Most countries in the world are members of the WTO. The WTO agreement on TRIPS sets up a minimum amount of Intellectual Property protection for all sorts of IP (primarily entertainment media, computer software, advertising and labeling, and pharmaceuticals.) This presentation addresses pharmaceuticals. Other IP applications also can affect health, including cigarette labeling, access to research information, etc.

TRIPS balances the IP rights of patent-holders with certain flexibilities intended to protect public health. These include compulsory licensing and “parallel importation” / reimportation.
Compulsory Licensing

• Article 31 of TRIPS states governments “may be permitted” to issue compulsory licenses for “public non-commercial use”

• This may be done after the government has “made efforts to obtain authorization…. on reasonable commercial terms”

• Negotiation may be waived in the cases of “national emergency” but the patent holder must still be informed

A government may essentially “break a patent” if after negotiating with the owner of the patent it cannot make a valid commercial deal with the manufacturer. So say you are an African health minister, and your health budget is so small that you can’t afford to pay full price for HIV medications. You must first try to negotiate a price with the drug manufacturer to buy the medications in bulk at a discount price. The company reduces the price, but not enough that you can treat enough people with the limited money you have. If after negotiation, you still cannot get a price you want, you may issue a compulsory license to manufacture that drug without the patent-holder’s permission.
Compulsory Licensing

• Can be used to bring down prices in negotiations
• Cannot be exported or “take away” a patent
• Patent-holder must be “paid adequate remuneration.”
  Company still gets some money (0.5% to 5%)
• Used by the United States in pharmaceuticals and high tech

The United States has threatened to use a compulsory license for the drugs Tamiflu and ciprofloxacin in the bird flu and anthrax scares. The companies needed YEARS in these two cases to make a national stockpile. After the federal government threatened them, they licensed the patent to other generics manufacturers who produced enough to make a stockpile.
Doha Declaration

- WTO Statement reaffirming and clarifying the TRIPS agreement - 2001
- “…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**.”

A lot of Third World countries were concerned about disputes related to access under the TRIPS agreement. In 2001, a group of nations made a statement called the Doha Declaration (the WTO meeting was in Doha, Qatar) stating their interpretation of the TRIPS agreement. This language has been adopted by the WHO, so it is now official policy.
• “Each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.”
• “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.”

Setting up a patent system of their own devising is a sovereign right of nations. Countries are given autonomy on this and many other issues.

This essentially is saying that “we can use a compulsory license whenever we want and for whatever we want.” Unlike other disputes in the WTO, a compulsory license dispute is appealed not the WTO but to that nation’s judicial system or review board.
Parallel Importing

• Patent protection extends only to the first sale, after that it is “exhausted”
• Option A: import from a country that exports it for a cheaper price
• Option B: Go to India

What does a nation do if it wants to issue a compulsory license, but doesn’t have the facilities to make the drugs?

It does parallel importing (or “grey importing”) from another nation. Patent protection only works on the first sale; if I’m Tylenol and sell you a bottle of Tylenol for $2, and you turn around and sell it for 20 cents, I have no control over that. Similarly, if two countries have different drug prices for the same medicine, that country can import from the second country and save money.
Indian Generics

• India is a generic drug powerhouse and did not have pharmaceutical patents until 2005. They have experience knocking off drugs.
• A country that cannot make a medicine can now just import a generic of the drug from India
• 80% of Doctors without Borders AIDS medicine in Africa comes from India
• Indian companies like Cipla and Ranbaxy also supply much of the U.S. market with generics.
• As the “pharmacy of the world” what happens to Indian patent law affects the entire world
Notes on Indian Generics

Under the 1970 Patent Act, India only recognized patents on pharmaceutical processes not products. Thus if you made the same product using a different method, it was still okay to sell it. This gave India experience in making generic drugs and giving it some of the cheapest drugs in the world. As a result of TRIPS, India had to change its patent laws in 2005 to start recognizing product patents. Some Indian pharmaceutical companies also supported this change because they are starting to be able to develop their own products and they want patent protection too.

AIDS activists, Doctors without Borders, and progressive parties in India were very concerned that the rule changes might hurt the public health in India and abroad if strong public health and public interest provisions were not put into the law. Almost all of the amendments offered by the Left Front were accepted, but activists still remained critical of the bill. So far no patents yet have been accepted. There are active legal battles in India on particular patent applications.
In Summary

• Under TRIPS and the Doha Declaration, nations have the sovereign right to “break” patents and can make patent systems of their own choosing

• These rights are *not limited* to just public health emergencies (something often claimed in the media or by drug companies)
“The Deal”

• The widely understood “deal” is that pharmaceutical companies are supposed to make their money in the First World and sell their medicines at cost in the developing world.

• But this arrangement still threatens pharma
  – Threat of “grey market” reimportation to the U.S.
  – Threat of instigating calls for lower prices in the U.S.

• And: What happens when the “other” countries are “middle-income” (like Taiwan, India, Brazil, South Korea)?
Where is the money made?

<table>
<thead>
<tr>
<th>Region</th>
<th>Percentage of World Population</th>
<th>Percentage of Drug Market</th>
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<tbody>
<tr>
<td>North America</td>
<td>9</td>
<td>42</td>
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<tr>
<td>Europe</td>
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<tr>
<td>Japan</td>
<td>2</td>
<td>11</td>
</tr>
<tr>
<td>Africa, Asia, and Middle East</td>
<td>72</td>
<td>13</td>
</tr>
<tr>
<td>Latin America</td>
<td>7</td>
<td>9</td>
</tr>
</tbody>
</table>
In Practice

- When developing nations actually use their TRIPS rights, the pharmaceutical industry and the United States government react strongly.
- The general trend is that the United States does not want nations to exercise those rights.
- The pharmaceutical industry is politically powerful in the United States.

Using those rights is another story. The pharmaceutical industry has contributed over $94 million to U.S. political campaigns since 2000. The Pharmaceutical Research & Manufacturers of America (PhRMA) is a top 25 lobbying association. Its present CEO was formerly an influential member of Congress. Until recently, the head of American foreign aid was a former CEO of Eli Lilly.
South Africa

- Passed a law in 1997 for compulsory licensing and parallel importation of AIDS medications
- The HIV cocktail price was $10,000 per person, prices could be reduced 50-90%
- Clinton/Gore Administration, Podesta brothers, and PhRMA pushed against the law. South Africa did not back down

Nearly half of health spending in South Africa was going to paying for drugs. PhRMA called the new drug law “piracy” and hired the brother of the chief of staff to lobby for them.
HIV/AIDS drug access on trial

- Western pharmaceutical companies sued in South Africa
- The target of the lawsuit?
  - Nelson Mandela!
- Gore went to war with South Africa and sanctions and a cutoff to foreign aid were being prepared
- American embassy staff in South Africa were against the action
- France, Germany, and Switzerland were involved as well

“On 30 April, 1998, the US placed South Africa on the '301 Watch List', usually a preparation for economic sanctions. Congressman Rodney Frelinghuysen of New Jersey (where Bristol Myers is based) introduced a provision into the Foreign Operations (Aid) Bill to cut off all aid to South Africa until Mandela's proposals were dropped.”

The Observer (U.K.) - “How drug giants let millions die of Aids”
http://www.guardian.co.uk/Archive/Article/0,4273,3943293,00.html
Gore on Trial

- Al Gore was harassed by AIDS activists (Health GAP, ACT-UP) during campaign events for helping pharmaceutical companies sue S. Africa
- Gore backed off in Sept. 1999
- Pharmaceutical industry moved to support Bill Bradley, Gore’s opponent
South Africa Lawsuit

- After an international campaign involving Oxfam, Doctors without Borders, and AIDS groups, the 39 pharmaceutical companies withdrew their lawsuit in 2001
- The companies agreed to settle the case
- A legal precedent was not established for other developing nations to follow because the lawsuit ended in a settlement
- International outcry led to the Doha Declaration on TRIPS and Public Health
Thailand

- Former prime minister, Thaksin Shinawatra, was pushing for a USA-Thailand free trade agreement (FTA)
- The FTA could have undermined Shinawatra’s “30 baht plan” for health
- When the P.M. was overthrown by the military for corruption, the FTA was put off, while the military pursued economic nationalism
- One of these decisions was to issue compulsory licenses for Efavirenz, Kaletra, and Plavix

Thailand has a universal health care plan called the “30 baht plan” where all people are covered who register for 30 bahts at a local hospital. All care after that is free because health is a human right in Thailand. Thaksin Shinawatra was a big business tycoon who, as prime minister, started this plan. Ironically, the free trade agreement he was negotiating with the United States could undo his health care plan by limiting Thailand’s TRIPs rights. The King of Thailand and the military overthrew him for corruption in 2006 (not related to the health plan or FTA)
Thailand

- Abbott Laboratories responded by withdrawing all new medicines from Thailand, including Aluvia (heat-resistant Kaletra)
- Abbott reduced annual prices for Kaletra from $2200 per person to $1000 per person globally
- Thailand is now on a watchlist of countries who violate intellectual property laws
- Will Thailand’s new government and health minister continue the policy? Policy is being reviewed.

Asian Sentinel – “Thailand’s Bittersweet Victory over Big Pharma “
Asian Sentinel – “The Drug Wars”
• Brazil has followed suit and issued a compulsory license for Efavirenz (May 2007)
• Anti-retroviral spending in 2006 was $475 million
• The government will save $30 million with the license

Brazil has the most successful AIDS prevention and treatment plan in the developing world. All HIV/AIDS patients are treated for free by the government, and the government has kept the prevalence and incidence rate low.

The Economist – “Brazil’s AIDS programme: A conflict of goals”
http://www.economist.com/world/la/displaystory.cfm?story_id=9154222
Rwanda

- Rwanda notified the WTO that it will parallel import AIDS medications from Canada (October 2007)
- Canada has a program called “Access to Medicines Regime” to provide developing nations with high-quality lifesaving drugs and medical devices
• Bill Clinton *now* says he supports Thai and Brazilian efforts to compulsorily license HIV/AIDS medicines
• He has been working to make deals between drug companies, generics companies, and developing nations. His foundation is providing legal assistance for Rwanda’s AIDS medication imports.

Bill Clinton and his Clinton Foundation say they support Thailand and Brazil’s efforts to get cheaper access to HIV/AIDS drugs.

The Guardian – “*Clinton backs violation of Aids drug patents*”
http://www.guardian.co.uk/print/0,,329818608-106925,00.html
India

- The 1970 Patents Act
- A top generics manufacturer
- Most important exporter of AIDS medications to the developing world
- Will the 2005 changes to the patent act threaten this?
- Will more changes be made to the act?

India had very high prices for medicine until in 1970, the government changed the patent laws to make most drugs generic. Only processes could be patented, not products. This let India become a major generics player in the world and is especially important for generic AIDS drugs in Africa.
## Indian Pharmaceutical Exports

<table>
<thead>
<tr>
<th>Year</th>
<th>Crores of Rupees</th>
</tr>
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<tbody>
<tr>
<td>1980-1</td>
<td>35.1</td>
</tr>
<tr>
<td>1985-6</td>
<td>106.59</td>
</tr>
<tr>
<td>1990-1</td>
<td>371.40</td>
</tr>
<tr>
<td>1995-6</td>
<td>2044.8</td>
</tr>
<tr>
<td>2003</td>
<td>5259</td>
</tr>
</tbody>
</table>

(1 crore = Rs. 10,000,000)
American Foreign Policy on Pharmaceuticals
World Health Organization

- U.S. had the WHO representative for Thailand removed for writing a critical op-ed in the *Bangkok Post* about the USA-Thailand Free Trade Agreement
- U.S. pushed the former WHO head, Lee Jong-wook, to promote American drug company priorities
- The new chief Margaret Chan has criticized the Thailand compulsory license but since backed off after criticism.

*Asia Times* – “World health: a lethal dose of US politics”
Bilateral Trade Agreements

• These agreements restrict compulsory license rights guaranteed under TRIPS (TRIPS-Plus)
• Undermine purpose of WTO. Trade negotiations should be multilateral involving all countries, not just the few we can “bully”
• Bipartisan Trade Promotion Authority Act of 2002 says that bilateral treaties must protect intellectual property like the United States does
• Also calls for U.S. to respect Doha Declaration

Notes on Bilateral Trade Agreements. The U.S. contends that TRIPs sets a minimum for patent protection, not a maximum. Patent regimes that protect patents MORE than TRIPs would are called TRIPS+ (the TRIPs minimum plus more restrictions for countries, and greater rights for patent-holders). Other countries, including India, China and Brazil, call for limiting negotiations on IP to the multilateral WTO level, where less powerful countries can benefit from banding together.

Jagdish Bhagwati has made very critical remarks about the United States’s free trade agreements with other nations. Bhagwati is a very strong free trade advocate but has denounced these bilateral trade agreements and the inclusion of TRIPs into the WTO negotiatons.

http://www.cfr.org/publication/6118/bilateral_trade_treaties_are_a_sham.html
“The Bipartisan Trade Promotion Authority Act of 2002, the applicable US legislation for bilateral FTAs, states explicitly that Trade-Related Intellectual Property Standards, or TRIPS, are by law non-negotiable and must reflect a standard of protection similar to that found in US law. “

TRIPS-Plus Conditions in Bilaterals Obstruct Access to Generics

- Data Exclusivity
  - Generic companies *can’t* use originator’s clinical trial data to establish safety and effectiveness of drugs for 5 years or longer, even if no patent in place
  - May also obstruct compulsory licenses
- “Evergreening” rules extend patents
  - Example: CAFTA 15.9.6(b) requires extension of the patent term *for an indeterminate period*, to compensate a patent holder for unreasonable reduction of patent term due to the market approval process. In contrast, U.S. law grants only a 5-year extension.
- Linkage: Requires licensing authorities to verify complex patents
- Includes plants and animals as patentable
Bilateral Trade Agreements

- Recent agreements include TRIPS-Plus conditions: Central America Free Trade Agreement-CAFTA, Jordan, Perú, South Korea
- U.S. concedes that data exclusivity is not a barrier to compulsory licenses
- But data protection rules still obstruct generics in Guatemala, even if no patent
- U.S. and pharma oppose compulsory licenses in Thailand for cancer, other conditions
Data exclusivity rights are separate from patent rights. Advocates have been concerned that TRIPS would allow a compulsory license to override a patent right, but that companies could still use data exclusivity rights to block a compulsory license. In May, 2007, the U.S. renegotiated some of the TRIPS-Plus provisions of a trade agreement that had already been signed with Peru, and has since stated in writing that the data exclusivity right will not be considered an obstacle to compulsory licenses. This stance could change. And even though compulsory licenses are clearly legal, the U.S. continues to support the pharmaceutical industry in pressuring Thailand not to proceed to issue compulsory licenses for cancer drugs and other conditions.

Data exclusivity rules still apply in Peru and Central America, including to drugs with no patent. They have been used to force affordable generic drugs off the market in Guatemala, even if generics are already being sold in the U.S..
Opposition to TRIPS Plus

• U.S. Representative Henry Waxman, Chair of House Oversight Committee, has written letters concerning this and the pro-industry tilt of American trade policy
• U.S. trade negotiating objectives for 2002-7 have expired. Congress will reconsider in 2009
• WHO has recommended that countries avoid trade agreements that restrict access to medicines in developing countries
Notes on Opposition to TRIPS Plus

Rep. Henry Waxman has criticized the TRIPS-Plus limitations built into treaties like the Central America Free Trade Agreement (CAFTA).
“A report by a WHO-mandated independent commission recently recommended that as a general rule governments should avoid bilateral free-trade treaties that reduce access to medicines in developing countries.”

Where is the public health community?

• Is it being cut out of the discussion?
  – What roles does it have in decision-making?
  – How is it represented and when?
  – How strong is that representation?
  – What prospects are there for the future?
Trade Advisory Committees:
Pharma: 20   Public Health: 0

• **Pharmaceutical Industry** - Representatives serve on at least 5 advisory committees:
  – ACTPN (Advisory Committee for Trade Policy and Negotiations)
  – Chemical, Pharmaceuticals, Health Science Products and Services (ITAC 3, of the Industry Trade Advisory Committee on Chemicals, Pharmaceuticals)
  – Customs Matters and Trade Facilitation (ITAC 14)
  – Intellectual Property Rights (ITAC 15)
  – Standards and Technical Trade Barriers (ITAC 16)
• Total Pharma Representatives on All Advisory Committees: 20.
Trade Advisory Process: Who Is Involved?

“New stakeholders in the trade process, such as public health...have limited or no participation in the formal committee system, even though topics such as intellectual property are of interest to them.”

Govt. Accounting Office Report 2002
Health Professionals need to be involved

• Trade policy will only represent those present
• It is up to the public health community to bring their concerns to the table

Many public health and tobacco control organizations wrote to the U.S. Trade Representative in 2005 calling for public health representation on trade advisory committees. The groups included CPATH, the American Public Health Association, the American Nurses Association, the American Cancer Society, the American College of Preventive Medicine, Physicians for Social Responsibility, and the California Conference of Local Health Officers. Members of Congress continue to campaign with these groups for a meaningful public health role in trade policy.
More Information

- Doctors without Borders Campaign
  - www.accessmed-msf.org/
- Consumer Project on Technology
  - www.cptech.org
- Abbot’s Greed (Thailand)
  - www.abbotsgreed.com
- Universities Allied for Essential Medicines
  - www.essentialmedicine.org
- CPATH – Center for Policy Analysis on Trade & Health
  - www.cpath.org
- American Medical Student Association
  - http://www.amsa.org/global/
Summary

• TRIPS is an important Agreement for global health
• Compulsory licenses are a tool nations may use
• Patent protection should not come at the expense of public health according to the Doha Declaration
• India’s patent laws are critical to the world because of their generic drug industry
• Thailand, Brazil, and Rwanda have used compulsory licenses
• The United States and other developed nations work against TRIPS rights at the WHO and with bilateral treaties and with lawsuits
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