3D → Trade
→ Human Rights
→ Equitable Economy

3D → Trade - Human Rights - Equitable Economy
Maison des Associations - Rue des Savoises 15
1205 Genève - Switzerland
T +41 22 320 21 21 - F +41 22 320 69 48
www.3dthree.org - info@3dthree.org

The impact of trade-related intellectual property rights on access to affordable medicines and human rights

Outline of a presentation to the NGO Forum for Health
30 September 2004

• About 3D

3D → Trade - Human Rights - Equitable Economy (3D → THREE) is a not-for-profit NGO based in Geneva, Switzerland, that promotes collaboration amongst trade, development and human rights groups, to ensure that trade rules are developed and applied in ways that achieve an equitable economy.

Our objectives are the following:

1. To promote **collaborative efforts** between people working to achieve an equitable economy.
2. To strengthen the **capacity** of human rights advocates to raise their concerns with trade decision-makers.
3. To encourage the use of **human rights rules and mechanisms** to support efforts to promote an equitable economy.
4. To ensure **accountability** of all economic actors.

• The regime: how trade-related intellectual property rights affect access to medicines

- Trade-related intellectual property (IP) rules, particularly patents, grant exclusive commercial rights that can increase the cost of drugs. This affects access to affordable medicines, which is a crucial part of the right to health and the right to life.

- The WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) is the first multilateral trade agreement to set a minimum standard of IP protection in all countries members of the WTO.

- In order to limit the negative impact of IP rules, the TRIPS Agreement allows countries to use a number of policy flexibilities to reduce the cost of drugs.

• Policy flexibilities: the Doha Declaration on TRIPS and Public Health

-Freedom to use these flexibilities was reaffirmed by the Doha Declaration on TRIPS and Public Health of November 2001.

- These TRIPS flexibilities include, amongst others:

- **Compulsory licensing**: the ability of the relevant authorities to grant and define when to issue a license to manufacture or import a generic drug without the consent of the patent holder, as long as the patent holder is compensated.
- **Exhaustion of patent rights:** the ability to decide when patent holders lose their exclusive right over the sale of drugs. This enables the importation of patented drugs from countries where patent rights have already ended and are less expensive (termed “parallel importation").

- **Exceptions to patent rights:** an example of such an exception is to allow national pharmaceutical companies to import, manufacture and test a drug prior to the expiry of the patent, in order to obtain regulatory approval, thereby ensuring that generic drugs are quickly made once the patent runs out (termed "bolar provision").
- **Prohibition of anti-competitive practices:** This provision gives states the ability to penalize pharmaceutical patent owners that abuse their dominant position in contractual relationships and engage in prohibitive pricing.

- The TRIPS Agreement also granted delays to developing countries for the application of the patent rules:

- Developing countries were granted until January 2000.
- Developing countries that previously did not have patents on products such as drug molecules have until January 2005 to implement them. India, is the main beneficiary of this delay.
- Least developed countries (LDCs) were granted at least until 2006 but the Doha Declaration increased this deadline until 2016.

- **A further mechanism: the WTO General Council Decision of 30 August**

- This decision is a waiver to the TRIPS Agreement limit on the export of drugs under compulsory license. It is an import/export mechanism that allows States with insufficient drug manufacturing capacity to fully benefit from compulsory licensing.

- It is important that developing countries pass implementing legislation as soon as possible. This is due to the fact that India, the main exporter of generic drugs, will have to implement TRIPS patent rules in January 2005 and will only be exempt from the export limitations if it uses the General Council mechanism.

- **TRIPS-plus threats: bilateral and regional trade agreements:**

- Many countries are coming under increased pressure, through technical assistance and bilateral and regional trade agreements, to sign up to even stricter IP rules (termed TRIPS-plus rules) that would undermine these hard-won flexibilities.

- **Extension of the patent term for unreasonable delays:** "adjustments" of three to five years for "unreasonable delays" in granting a patent. Such provisions effectively extend the patent term beyond the TRIPS twenty year period.
- **Compulsory licensing restrictions:** limitations on the export of drugs under compulsory license. This would undermine the mechanism of the WTO General Council Decision.
- **Parallel import restrictions:** limitations on imports of patented drugs from other countries. This would be contrary to the spirit of the Doha Declaration which allows Members the freedom to decide their own regime.
- **Exclusive rights over test data:** owners of patented drugs that have not yet been marketed or registered in a country are granted exclusivity over test data for five years if the drug is new or three years if it is a known chemical entity. This protection means that patients need to wait up to five years before generic versions of the drug are available. The TRIPS Agreement does not grant these rights.
- **Marketing authorization:** drug regulatory authorities' are given the power to require generic manufacturers to get the consent of patent owners in order to use test data for marketing authorization. Since generic manufacturers cannot afford to re-do these tests, this could effectively undermine compulsory licensing.

- **Recommendations**

- It is crucial to ensure that countries don't sign up to TRIPS-plus agreements that would jeopardise their ability to fulfil their human rights obligations.

- Use human rights rules and mechanisms to limit the impact of strict IP rules on the right to health and the right to life:

    - **UN human rights treaty monitoring bodies:** encourage them to recommend that trade-related intellectual property rules should not undermine human rights obligations.
    - **UN Special Rapporteur on the Right to Health:** encourage the Rapporteur to make specific recommendations to States or submit individual complaints to him on how trade-related intellectual property rules violate the right to health.

- **Possible Actions**

- Lobby your national government to use the policy flexibilities allowed by TRIPS and reaffirmed by the Doha Declaration on TRIPS and Public Health, particularly compulsory licensing and parallel imports, to obtain cheaper generic medicines.
- Lobby your national government to pass legislation implementing the 30th August Decision to suit your country's needs in generic drugs.
- Lobby to ensure that your trade negotiators do not sign on to TRIPS-plus rules in bilateral or regional trade agreements.
- Ask your parliamentarians to vote against any TRIPS-plus rules that could undermine your country's ability to facilitate access to medicines.
- Ensure your health ministries are aware of the impacts of trade-related intellectual property rights on the right to health and the right to life.
- Submit reports to the United Nations human rights treaty monitoring bodies.
- Submit cases where trade-related IP rules have hindered access to medicine to the UN Special Rapporteur on the Right to Health.