

# The TRIPS Plus Enforcement Landscape

Regional Consultation and Planning Workshop  
Use of TRIPS Flexibilities to Access Affordable ARVs in  
Asia

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# TRIPS Agreement and IP enforcement

- TRIPS increased obligations on member on IP enforcement with imposition of minimum requirements
- Article 41 of TRIPS sets out main principles of enforcement:
  - There should be provisions in domestic law to take action against IP infringement
  - **Enforcement procedures must be applied to avoid creation of illegitimate barriers to trade**
  - Procedures must be fair and not unnecessarily complicated or costly and shouldn't likely to lead to unreasonable time limits or unwarranted delays.
  - Must be some form of review of first decisions made by administrative or judicial bodies
  - Members do not have to establish a separate judicial system to enforce IPRS



# TRIPS Agreement and IP enforcement



- Articles 51-60 dealing with obligations of WTO Members at their national borders e.g. seizing and inspecting imports is only required for “counterfeit trademarks or copyright pirated goods”
- Article 60 of TRIPS deals with Criminalization, only required for wilful trademark counterfeiting or copyright piracy on a commercial scale
- Important to remember that IP rights are private rights. Patent infringement cases should be settled in a civil court, and should be brought by right holder
- Criminalizing patent infringement diverts limited state resources to enforce private rights

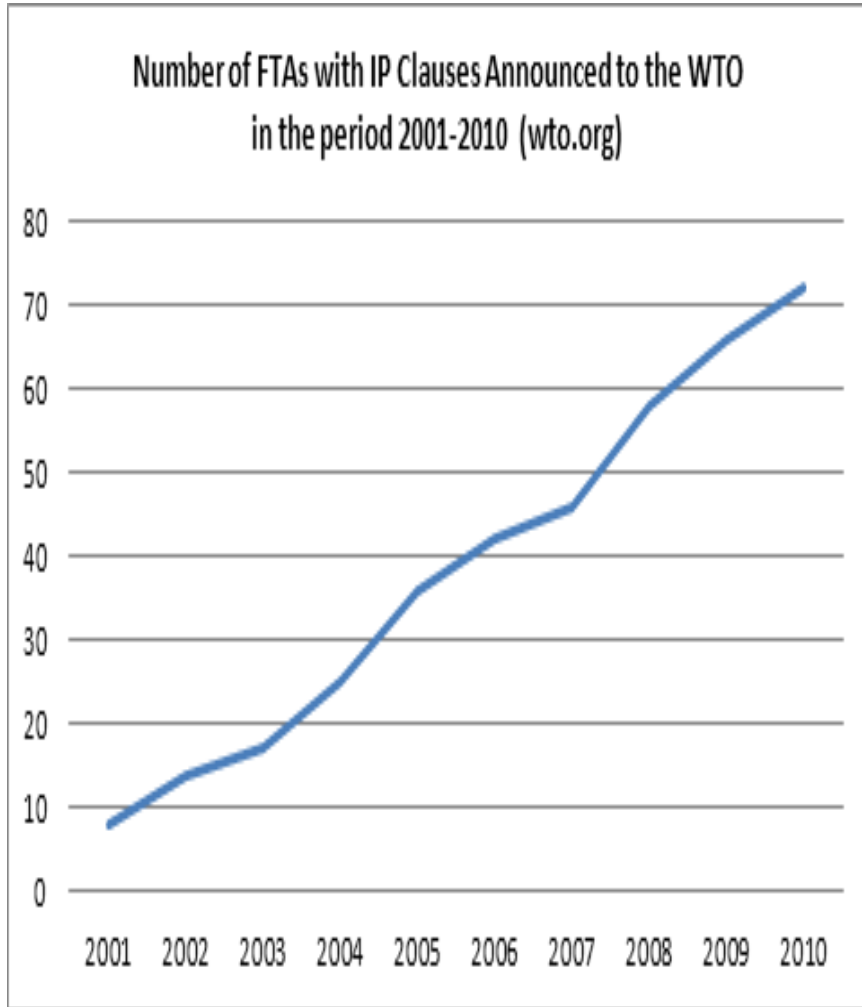


# Definition of counterfeit: TRIPS

- **"counterfeit trademark goods"** shall mean any goods, including packaging, bearing without authorization a **trademark** which is identical to the trademark validly registered in respect of such goods, or which cannot be distinguished in its essential aspects from such a trademark, and which thereby infringes the rights of the owner of the trademark in question under the law of the country of importation
- Counterfeit Trademark and copyright violations more easily established through visual inspection
- Very difficult to determine product/process patent infringement, even if it is exact copy without testing/producing other evidence, and without technical and legal expertise.



# The Proliferation of FTAs and IP enforcement



- Failure of WTO Cancun Ministerial 2003 bilateral trade agreements proliferated
- US has concluded and signed FTAs with 17 countries, some bilateral, others regional
- EU has concluded or is negotiating FTAs with MERCOSUR, Andean countries, CAFTA, India, Korea, ASEAN and several others
- EU also announced that their focus would be IP enforcement



# The broader enforcement agenda



## Technical Assistance

WIPO-WTO agreement

Model laws

## World Health Organization

IMPACT Working Group on Counterfeit Medicines

## OECD

Studies on Economic Impact of Counterfeiting and Piracy  
Weak methodology and data

## Interpol

fight IPR crime, links to terrorism

## Global Congress on Anti-Counterfeiting and Piracy

WCO, Interpol, WIPO and Industry



## The TRIPS Agreement

Mandatory obligations on IPR enforcement for WTO member states

Room for flexibilities for implementation

## WTO

### TRIPS Council

### Dispute Settlement

### Accession Protocols

### Group of Eight

Coordinated IP enforcement strategy

## Anti-Counterfeiting Trade Agreement (ACTA)

## Bilateral/Bilateral FTAs - EPAs

TRIPS-Plus enforcement obligations

## US Special 301 Report

EU strategy on IPR enforcement in third countries

## The World Intellectual Property Organization

Advisory Committee on IP Enforcement (ACE)

## World Customs Organization

Standards and model law to strengthen IPR enforcement via border measures

## Universal Postal Union

Increase involvement of postal administrations in IPR enforcement

# (1) IP enforcement Measures through unilateral measures



- US passed the *Omnibus Trade and Tariff Act* of 1988
- Establishes a watch-list for countries who are threatened with trade sanctions or withdrawal of trade preferences for non-compliance with US expectations of IP protection
- 2012 report placed 26 countries on watch list **Philippines , Vietnam**
- 13 countries on Priority Watch List (for intense bilateral discussion) including **China, India, Indonesia and Thailand**
- China *'In 2011, China's State Intellectual Property Office (SIPO) issued "Draft Measures for Compulsory Licensing of Patents" for public comments. A number of companies and governments, including the United States, provided comments ...The United States is concerned that many stakeholder concerns were not reflected in the final document. The United States looks forward to working with the Government of China to ensure that the implementation of these measures is consistent with China's international obligations'*



# (1) Unilateral measures

- **India** *“The United States urges India to provide an effective system for protecting against unfair commercial use, as well as unauthorized disclosure, of test or other data generated to obtain marketing approval for pharmaceutical and agricultural chemical products. The United States also continues to encourage India to address its judicial inefficiencies and to strengthen criminal enforcement efforts, including by imposing deterrent level sentences and giving IPR prosecutions greater priority.”*
- **Malaysia** has been removed from the Watch List after making significant strides, including passing copyright amendments that strengthen copyright protection, stepped-up IPR enforcement, and promulgating regulations to protect pharmaceutical test data”





## (2) Enforcement Agenda of EU

- Enforcement at cornerstone of EU IP objectives, Lisbon Agenda goal to make EU most competitive knowledge based economy by 2010
- In 2003, EU enacted regulation extending IPRs to customs authorities beyond copyright piracy and trademark counterfeit goods to include patents, GIs and border measures
- In 2005, EU commissioned a study to determine strategy to enforce IPRs in 3<sup>rd</sup> countries
- Resulting large increase in bilateral technical assistance aimed at increasing capacity of judges and enforcement officials to enforce IP
- EU-US 2006 Transatlantic agreement prioritizing IP enforcement
- 2006 G8 summit in Russia delivered an IP strategy statement: “Combating International Property Rights Piracy and Counterfeiting” strategies include:
  - keeping spotlight on trade in counterfeit goods
  - building capacity in developing countries to enforce IP
- 2007 saw development of guidelines border measures and technical assistance to developing countries by G8



## (2) Seizure of goods in transit

- EC adopted Regulation 1383/2003 aimed ostensibly at protection of IPRs granted in EC Member States
- In 2008, Regulation was implemented by EU officials, seizure of generic medicines in transit at various EU ports in France, UK, Holland, Germany
- Seizures led to detention of medicines including AZT and Abacavir from India destined to e.g. Brazil, Nigeria, Ecuador carried on into 2009 and led at least 17 incidents.
- Medicines were either delayed and in most cases returned to India, some claims that medicines destroyed
- Article 51 of TRIPS requires Members to control imported goods protected by trademarks and copyrights
- EC argues that Article 51 can be extended to include goods in transit and asserts that Regulation merely enacts what is implied by Article 51



## (2) Seizure of goods in transit continued...

- GATT Article V permits the control of goods in transit provided they are not subjected to “unnecessary restrictions”
- India also cited TRIPS Article 41.1 which requires that enforcement of IP not create barriers to legitimate trade
- Developing countries argue that EC regulations and border measures violate Article V of GATT, Doha Declaration and EC regulation 816/2006 operationalizing the 30 August 2003 Decision
- Exchange of letters between EC, India and Brazil, request for establishment of WTO Dispute panel
- Matter settled “out of court”?



### (3) Proliferation of Anti-Counterfeiting Legislation in the EAC and Beyond

- EAC comprises of 5 countries , 4 of which are LDCs, no need to comply with TRIPS pre-July 2013, no pharmaceutical patents till 1 January 2016
- Initiatives to use TRIPS Flexibilities could be endangered by proliferation of “anti-counterfeiting” legislation, which could prevent use of TRIPS flexibilities:
  - Tanzania, Subsidiary Merchandise Marks Act, 2008;
  - Kenya , Anti-Counterfeiting Act ,2008;
  - Uganda, discussing a Counterfeit Goods Bill since 2008, Tabled in Parliament in early 2011
- Draft EAC Anti-counterfeit and Bill are being discussed
- Kenyan Law found to be unconstitutional in 2012



## (3) Conflation of generic and counterfeit medicines

- Substandard medicines pose a real threat to patients
- Attempts to address problem by adopting IP enforcement measures can result in:
  - The conflation of intellectual property concerns with medicine quality which is traditionally dealt with by Drug Regulatory Authorities
  - Delegation of IP enforcement to authorities with no adequate competency to determine IP infringement **or** medicines' quality and efficacy;
  - Divert substantial public resources which should be used to ensure quality, safety & efficacy to defend private rights;
  - Unwarranted delay of 'legitimate' medicines



### (3) Conflating generic and counterfeit medicines

- Chirac foundation together with 6 West African Heads of State (Benin, Burkina Faso, Niger, Central African Republic, Congo-Republic and Senegal) in 2009 called an international treaty to fight counterfeit medicines





## (4) Anti-counterfeiting trade Agreement (ACTA)

- ACTA negotiations commenced in 2007
- Negotiated by a closed group, aim is to achieve a common agenda on IP enforcement on counterfeiting and piracy
- ACTA negotiating internally but suggestions of being exported to DCs
- [Australia](#), [Canada](#), [Japan](#), [Morocco](#), [New Zealand](#), [Singapore](#), [South Korea](#), and the [United States](#) signed ACTA in October 2011. In January 2012, [European Union](#) signed
- After EU signature, Rapporteur resigned saying “I want to send a strong signal and alert the public opinion about this unacceptable situation. I will not take part in this masquerade”
- New ACTA Rapporteur has recommended that ACTA should be rejected by EU Parliament
- Switzerland has refrained from signing, nobody has ratified
- Extensive protests over legality of ACTA
- ACTA Referred to European Court of Justice, judgment awaited



## (4) Anti-counterfeiting trade Agreement (ACTA)

- Draft ACTA text refers to trademark and other forms of IP including copyright & data protection. Patents excluded after extensive protests
- Draft text border measures could result in the destruction of goods for any object found to “infringe” a trademark, even if not a counterfeit
- Danger of border measures being used by originator companies to impede trade in generic medicines
- Definition of border measures should not exceed TRIPS Agreement definition on trademark counterfeiting and copyright piracy
- Customs officials do not have the capacity to check patent infringement at a border
- Border measures should not be applied to goods in transit, only to imported goods







## (5) MEDICRIME Convention

- Agreement negotiated at the Council of Europe
- Criminalizes the counterfeiting of medicines
- In October 2011, Austria, Cyprus, Finland, France, Germany, Iceland, Italy, Israel, Portugal, Russia, Switzerland, and Ukraine all signed the MEDICRIME Convention
- Becomes valid after ratification by 3 countries
- **only international legal instrument criminalizing**, at the **penal** level, the manufacturing and distribution of “*counterfeit*” medical products
- Definition of counterfeiting is “*a false representation as regards identity and/or source*” of any medical product
- Extremely broad definition of counterfeit including copyright, trademarks, patents



# Determining a Constructive Agenda

- Develop adequate measures to show no tolerance for substandard medicines, brand or generic
- Questions around whether IPR enforcement is best modality:
  - IPRs are private rights
  - Not suitable to ensure safety and efficacy of medicines.
- National drug regulatory authorities should implement safety and efficacy measures for medicines
- Countries should develop and implement policies that balance access to medicines and IPR protection
- This would increase affordability of medicines, creating efficient market disincentives against spread of substandard drugs.

