The Potential Impact of TRIPS Plus IP enforcement Provisions on Access to Medicines in Africa

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IP enforcement and the TRIPS Agreement

Basic principles of IP Enforcement

- IPRs are private rights granted by the State
- The primary responsibility for IPR enforcement are the right holders, not the state
- IPR infringement: not easily determined for all IPRs
- Historically, countries had policy space to regulate IPR enforcement

TRIPS Agreement

- Right holders seeking global "minimum standards" of IPR protection and enforcement
- Flexibilities exist in the enforcement of IP
- TRIPS+ rules further erode flexibilities and policy space for development

TRIPS Agreement and impact on IP enforcement

- Key elements of IP enforcement in TRIPS Article 41:
  - There should be provisions in domestic law to take action against IP infringement
  - **Enforcement procedures must not create legitimate barriers to trade**
  - Procedures must be fair and not unnecessarily complicated or likely to lead to delays
  - Must be some form of review of first decisions made by administrative or judicial bodies
  - Members are not obliged to establish a separate judicial system to enforce IPRs
- **TRIPS Article 61** Criminal procedures and penalties are only required where there is **willful trademark counterfeiting** or **copyright piracy on a commercial scale**
- **TRIPS Article 46** The measure imposed should be **proportional** to the seriousness of the infringement

Broader Enforcement Agenda

- Developed countries shifted focus to IP enforcement over past years
- US-EU 2006 Trans-Atlantic Agreement prioritizing IP enforcement
- 2006 G8 summit in Russia 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
- Development of guidelines on border measures by G8 in 2007
- G8 Communiqué issued in 2008 encouraging acceleration of negotiations to establish ACTA
- December 2010, MEDICRIME convention adopted by CoE, 19 countries signed including Guinea and Morocco, Ukraine ratified

The Broader Enforcement Agenda

(Source: Viviana Munoz Tellez, South Centre)

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

Interpol

fight IPR crime, links to terrorism

Global Congress on Anti-Counterfeiting and Piracy

WCO, Interpol 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

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

Seizure of goods in transit

- EC adopted Regulation 1383/2003 allowing border measures on pharmaceuticals
- In 2008, Regulation was used to seize generic medicines in transit at various EU ports in France, UK, Holland, Germany
- Led to seizure/detention of medicines including AZT and Abacavir from India & China headed to e.g. Nigeria, Ecuador on at least 19 occasions
- Article 51 of TRIPS requires Member States suspend importation of counterfeit trademark or pirated copyright goods
- Critics argued that EC regulations and border measures violate inter alia, TRIPS Article 41, Article V of GATT, Doha Declaration
- WT/DS408 - European Union and a Member State - Seizure of Generic Drugs in Transit
- Resolved after consultations between India, Brazil, EU 7-8 July; 13-14 September 2010

Impact of IP Enforcement on Medicine access

- Substandard medicines pose a real threat to patients
- Attempts to address problem by adopting IP enforcement measures can result in:
  - The Conflation of IP 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 legally produced medicines

Proliferation of Anti-Counterfeiting Legislation in the EAC and Beyond

- EAC comprises of 5 countries , 4 of which are LDCs,
- 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 Policy and Bill are being discussed
- Several stakeholders have expressed concerns about public health impact of legislation

Kenya's Anti-counterfeit Act of 2008

- Anti-counterfeit Act adopted in 2008
- Broad definition of counterfeit conflates quality and IPR issues; legitimate generics fall under definition of "counterfeits"
- Up to 90% of medicines in Kenya are generics (Source: HAI-Africa).
- Act was challenged before the High Court in July 2009 by three petitioners living with HIV
- Court passed preliminary judgment in favor of petitioners on 23 April, 2010
- Final judgment in 2012 found Act to be unconstitutional. Legislation Pending revision

Uganda's Counterfeit Goods Bill

- Up to 93% are generics (Sources: IPS, HEPS-Uganda).
- Counterfeit Goods Bill – discussed since 2008. Initial definition of "counterfeit" very similar to Kenya's law, TRIPS-plus. Included patents
- HAI/TWN/UNDP/OSI: co-sponsored an expert discussion on the Bill (Entebbe, September 2009).
- Bill examined from public health perspective: TRIPS-plus definition of "counterfeit", contradiction with other laws, border measures, criminal sanctions
- Workshop with Parliamentarians, government & civil society 2012
- Reports are that a revised Bill was tabled before Parliament

UNDP Discussion paper: Anti-counterfeit laws and public health: what to look out for

Key elements of anti-counterfeiting legislation

- Meeting held by EAC/GIZ/UNDP on EAC anti-counterfeiting Bill and policy, December 2010

1. Definition Problems – what constitutes a "counterfeit"?

- TRIPS only uses the term counterfeiting to refer to trademark and copyright
- Overly broad definition can have serious implications for generic medicines: see 2012 ruling by Kenyan High Court
- Patents should not be included in anti-counterfeiting legislation

2. Criminal liability

- IPRs are private rights, should be enforced by right holder
- Criminalization requires the use of government resources to enforce private right
- Article 61 of TRIPS criminalizes only **willful** trademark or copyright piracy on a **commercial scale**
- Article 41 of TRIPS : provide safeguards to prevent the abuse of IP enforcement

Key elements of anti-counterfeiting legislation

3. Powers of Seizure and Storage

- Laws giving broad powers to government to intercept and inspect any place, seize and detail goods, seal off any place (in Kenya w/o warrant) can easily be abused
- Legislative provisions should be in conformity with constitutional and human rights principles
- Judicial oversight important

4. Goods in Transit

- Some legislation criminalizes the transit/trans-shipment of counterfeit goods
- Anti-counterfeiting legislation should not pose a barrier to legitimate international trade, should comply with GATT obligations on freedom of transit

Key elements of anti-counterfeiting legislation

5. Rules of Evidence

- Should prevent abuse of enforcement right by state or right holder
- Complainants should first establish their rights before alleging violation

6. Liability for loss or damage to goods

- Any person who suffers loss due to wrongful seizure, removal or detention should be compensated
- Should be a mechanism to hold responsible any person who allows loss or damage of legitimate goods

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 create legal and policy environment that enables implementation of health MDGs, including Goals 4, 5, and 6 by using TRIPS flexibilities as per UNAIDS/UNDP/WHO policy Brief on TRIPS and access to ARVs