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

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TRIPS Agreement and impact on IP enforcement

• LDCs exempt from enforcement until 1 July 2013 subject to further extension by TRIPS Council
• TRIPS increased obligations on member states 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 wilful trademark counterfeiting or copyright piracy on a commercial scale
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 the Anti-Counterfeiting Trade Agreement (ACTA)

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 IP 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

**World Intellectual Property Organization**
- Advisory Committee on IP Enforcement (ACE)

**World Customs Organization**
- Standards and model law to strengthen IP 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 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
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;
  - Reports of Legislation in Zambia and Malawi
- Draft EAC Anti-counterfeit and Bill are being discussed
- Several stakeholders have expressed concerns about public health impact

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
- Court suspended powers of Anti-Counterfeit Agency to interfere with importation and distribution of generics pending ruling on the substance (Source: HAI-Africa)
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
• Reports are that a revised Bill was tabled before Parliament

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”?
   – Overly broad definition can have serious implications for generic medicines: see 23 April 2010 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 wilful trademark infringements or copyright piracy on a commercial scale
   – Article 41 of TRIPS: provide safeguards to prevent the abuse of IP enforcement Procedures
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 detain goods, seal off any place (in Kenya w/o warrant) can easily be abused
   - Judicial oversight important

4. Goods in Transit
   - Some legislation criminalizes the transit/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 invoking enforcement mechanisms

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 public health 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