ANTI-COUNTERFEITING INITIATIVES: LIKELY IMPLICATIONS FOR TRADE IN GENERIC MEDICINES

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The Context

- Global harmonization of intellectual property laws, in particular patents, poses serious challenge to producers of generic drugs in developing countries
  - India has a vibrant generic pharmaceutical industry that developed after the Government designed the country's patent law (in 1970) to facilitate its growth
    - √ The industry is a major global supplier of generic medicines
- Generic pharmaceutical industry faced the charge of producing "counterfeit" or "sub-standard drugs"

Use of the term “Counterfeit Goods” in the Multilateral Context

- Introduced in the trade lexicon in the Tokyo Round of GATT negotiations
- WHO initiated steps to address the issue of counterfeit medicines at the Conference of Experts on the Rational Use of Drugs held in Nairobi in 1985

GATT and Counterfeit Goods' Trade

- Use of the term "Trade in counterfeit goods" was first made in the global context in 1978
  - US proposed an agreement on "commercial counterfeiting"
    - √ "Counterfeit merchandise" according to the United States was any article to which a ***spurious trademark or trade name*** was affixed
  - Intent was to develop a GATT disciplines to "prevent counterfeit goods from entering or re-entering commerce"
- No agreement was reached in the Tokyo Round

GATT and Counterfeit Goods' Trade (cont.)

- Counterfeit goods' trade was included in the work programme of the GATT in 1982
  - Agreement on using the GATT framework to address the *trade aspects* of commercial counterfeiting
- Group of experts appointed as a part of the work programme in the post-1982 Ministerial meeting noted that "counterfeiting is an infringement of intellectual property rights" ***in general and that it was not restricted to trademarks alone***
- Stage set for the inclusion of the "Trade Related Aspects of Intellectual Property Rights and Trade in Counterfeit Goods" in the Uruguay Round Mandate
  - "... the need for a multilateral framework of principles, rules and disciplines dealing with international trade in counterfeit goods."

“Counterfeit Medicines” and the WHO

- Recommendations of the Conference of Experts on the Rational Use of Drugs held in Nairobi
  - WHO, together with other international and intergovernmental organisations, should study the feasibility of setting up a clearing house to collect data and to inform governments about the nature and extent of counterfeiting
- World Health Assembly took note of this recommendation and adopted resolution WHA41.16
  - Requested the WHO DG to initiate programmes for prevention and detection of export, import and smuggling of falsely labelled, ***“counterfeited”*** or ***“substandard”*** pharmaceutical preparations
- Resolution WHA47.13 on the rational use of drugs, and Resolution WHA52.19 on the revised drug strategy requested the DG to support Member States in their efforts to combat the manufacture, trade and use of counterfeit medical products

“Counterfeit Medicines” and the WHO (cont.)

- WHO initiatives on problems of counterfeiting received a fillip through the International Conference “Combating Counterfeit Drugs: Building Effective International Collaboration” (2006)
  - Declaration of Rome adopted by the Conference recommended that WHO should take the lead in the establishment of an International Medical Products Anti-Counterfeiting Taskforce (IMPACT) comprising of governmental, non-governmental and international institutions
    - √ ... aimed at improving cooperation between various stakeholders to take measures against counterfeit medical products

Definition of "Counterfeit": WHO's Approach

- WHO definition of counterfeit medicines
  - Medicines that are "deliberately and fraudulently mislabelled with respect to identity and/or source"
  - Counterfeiting can apply to both branded and generic products
    - √ Counterfeit medicines may include products with correct ingredients or with wrong ingredients, without active ingredients or with insufficient active ingredients of with false packaging
- IMPACT definition
  - A medical product is counterfeit when there is false representation in relation to its identity, history or source
    - √ Applies to the product, its container or other packing or labelling information
  - Counterfeiting can apply to both branded and generic products
    - √ May include products with correct ingredients/components, with wrong ingredients/components, without active ingredients, with incorrect amounts of active ingredients, or with fake packaging
- WHO definitions alludes to the problem of fakes and/or "sub-standard" medicines

Definition of "Counterfeit": In GATT/WTO

- US/EC proposal in Tokyo Round of the GATT
  - Defined counterfeit goods as
    - √ Any imported goods with false representation of a trademark that is entitled to protection under the laws of the country of importation and which is legally registered, where such registration is required by the country of importation
- TRIPS Agreement defines
  - "Counterfeit trademark goods"
    - √ "... 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"
  - "Pirated copyright goods"
    - √ "... copies made without the consent of the right holder or person duly authorized by the right holder in the country of production and which are made directly or indirectly from an article where the making of that copy would have constituted an infringement of a copyright or a related right under the law of the country of importation
- GATT/WTO definitions on "counterfeiting" alludes to ***trademark violations and not to patent violations***

Other Approaches

- INTERPOL's IP crime initiative
  - Does not distinguish clearly between trademark counterfeiting and copyright piracy
    - "Trademark counterfeiting and copyright piracy are serious Intellectual Property (IP) crimes that defraud consumers, threaten the health of patients, cost society billions of dollars in lost government revenues, foreign investments or business profits and violate the rights of trademark, patent, and copyright owners"

Anti-counterfeiting and piracy: Recent Developments

- Outcome of a series of initiatives taken a wide range of agencies
  - Industry having deep-seated interests in intellectual property
  - Governments of the G-8 countries in general and the United States and Japan, the European Commission in particular
  - Intergovernmental organisations including
    - The WIPO, the WHO, the WCO, the OECD and the INTERPOL

Global Congress on Combating Counterfeiting

- Public-private initiative hosted by the WCO and the INTERPOL
  - Collaborating Institutions
    - √ WIPO
    - √ Global Business Leaders Alliance Against Counterfeiting (GBLAAC)
      - Sixteen companies, representing a broad cross-section of products categories and industry sectors, backed the Alliance when it was established and includes Coca Cola, Gillette, Procter & Gamble, Unilever, Novartis, Daimler Chrysler, General Motors, BP and Philip Morris International from the tobacco industry.
    - √ International Trademark Association (INTA), the International Security Management Association (ISMA)
- Focus on effective enforcement to prevent proliferation of counterfeited and pirated products

G-8 Initiative on Counterfeit Goods' Trade

- Gleneagles Summit (2005) discussed the need to strengthen IPR enforcement to prevent counterfeiting
  - ... in areas such as the seizure and retention of suspected counterfeit or pirated goods, the destruction of such goods and the equipment used to produce them, and the use of clear, transparent and predictable judicial proceedings, policies and guidelines related to intellectual property enforcement
  - ... work closely with developing country partners to strengthen legislation, and build and help to improve national anti-counterfeiting, anti-piracy and enforcement capacities through shared best practices, training and technical assistance
- Heiligendamm Summit (2007) gave operational directions to address the problem of counterfeiting by adopting Guidelines for
  - Customs and Border Enforcement Cooperation designed to strengthen the cooperation and coordination among national customs and law enforcement administrations,
  - Technical Assistance on intellectual property rights protection to interested developing countries, as well as a mechanism to better coordinate existing G8 technical assistance to such countries with a view to building the necessary capacity to combat trade in counterfeited and pirated goods in order to strengthen intellectual property enforcement.

Enforcement Agenda of US and the EU

- Special 301 investigations by the US
- Seizure of generic medicines by the EU

US Initiatives

- Special 301 investigations
- US-led APEC initiative : “Anti-Counterfeiting and Piracy Initiative” (2005)
  - Model Guidelines on reducing trade in counterfeit and pirated goods by protecting against unauthorized copies
  - Preventing the sale of counterfeit goods over the Internet
  - Raising public awareness on IP protection and enforcement efforts, and securing supply chains

EU: Strengthening Enforcement of IPRs

- Council Regulation (EC) No 1383/2003
  - Customs action against goods ***suspected of infringing certain intellectual property rights*** and the measures to be taken against goods found to have infringed such rights
    - √ Customs authorities
      - Can take action against goods suspected of being counterfeit or pirated even before the right-holder has applied for action, if they have sufficient grounds for suspecting that goods infringe an intellectual property right
      - May suspend the release of the goods or detain them for a period of three working days from the moment of receipt of the notification by the right-holder and by the declarant or holder of the goods, in order to enable the right-holder to submit an application for action
  - Extended the scope of coverage of the counterfeit and pirated goods beyond trademarks and copyrighted products and included products protected by patents, plant variety protection laws and geographical indications

EU: Strengthening Enforcement of IPRs (cont.)

- Commission Directive 2004/48/EC on the enforcement of IPRs
  - Approximating legislative systems to ensure a high, equivalent and homogeneous level of protection in the internal market
- TRIPS-plus features of the Directive
  - Power for the authorities to seize documentary evidence relating to the suspected infringement and the suspected goods themselves
  - Obligation for the court to provide information on the source of infringing goods
  - Preliminary injunctions that may be provided in advance of a decision on the merits of a case
  - Seizure of offender's bank accounts and other assets and profits to ensure payment of due damages
  - Recall of infringing goods at the offender's own expenses
  - Choice for the right holder of either lump sum damages (up to double normal royalties or license fees) or compensation for lost profits

EU: Strengthening Enforcement of IPRs (cont.)

- Legal/Legislative Proposal to Combat Counterfeit Medicines for Human Use (2008)
  - Three areas of regulation of medicinal products where improvements to the regulatory framework can make a real contribution to protecting against counterfeit medicinal products
    - √ Medicinal products placed on the market (i.e. issues of traceability, product integrity, and distribution chain)
    - √ Medicinal products brought into the Community without being placed on the market (i.e. issues of import/export and transit)
    - √ Active ingredients supplied to the manufacturer of medicinal products placed on the market (i.e. regulation of active substances)

Seizure of generics in the EU

- Action taken as a part of the "MEDI FAKE" campaign launched in October 2008
- More than 20 instances of seizures while generic drug consignments were "goods in transit"
  - Some examples
    - √ Losartan (hypertension) produced by Dr Reddy's Laboratories Ltd *en route* to Brazil
    - √ Clopidogrel (blood thinner) produced by Ind-Swift Laboratories *en route* to Columbia
    - √ Two consignments of Cipla Limited destined for Peru containing Rivastigmine (for Alzheimer's disease) and Alanzapine (antipsychotic medicine)
    - √ Antiretroviral medicine abacavir shipped from India by Aurobindo Pharma to Nigeria
- Implications for the bilateral Comprehensive Economic Partnership Agreement being negotiated between India and EU

Anti Counterfeiting Trade Agreement (ACTA)

- Initiated in 2008 jointly by US, EU and Japan
- Currently being negotiated between 11 countries
  - US, Japan, EU including its 27 Members, Canada, Australia, New Zealand, Switzerland, Singapore, South Korea, Mexico and Morocco

Elements of ACTA

- International cooperation among parties for sharing of information between law enforcement agencies, including customs and other relevant agencies
- Establish enforcement practices to promote strong intellectual property enforcement in coordination with right holders and trading partners
- Extensive legal framework designed to ensure that the authorities and the right holders have the appropriate tools for strong IPR enforcement, including
  - *Ex officio* authority to take action against infringers;
  - *Ex officio* authority to customs authorities to suspend import, export and trans-shipment of suspected IPR infringing goods;
  - Destruction of IPR infringing goods and seizure of equipment and materials, used to make IPR infringing goods;
  - Authority to seize and forfeit illegal proceeds connected to IPR infringements
  - Measures to ensure seizure and destruction of suspected IPR infringing goods

Perspectives on ACTA

- United States Trade Representative
  - ACTA will complement the Administration's work to encourage other countries to meet the enforcement standards of the Agreement on TRIPS, and to comply with other international IPR agreements"
  - ACTA will complement a wide range of other trade policy tools that USTR and other agencies use as part of our long-standing and enduring efforts to help protect U.S. intellectual property overseas, working in cooperation with our foreign trading partners and with US right holders
  - ACTA will respect the WTO Declaration on TRIPS and Public Health
    - √ USTR is working to ensure that the agreement that results from the on-going negotiations lives up to this commitment
- Pharmaceutical Research and Manufacturers of America (PhRMA)
  - ACTA must "require each member state to provide both criminal and administrative remedies for drug counterfeiting offenses, *without the need to prove threatened or actual harm*, accompanied by tough, deterrent penalties"
  - "Laws must provide administrative and criminal law enforcement officials with the full range of enforcement tools needed to investigate and defeat sophisticated counterfeiting operations"

US and EU on ACTA: Differing Perceptions

- US
  - Seeks "coverage similar to the enforcement provisions of intellectual property chapters of US free trade agreements (FTAs) negotiated with ACTA partners Australia, Korea, Morocco and Singapore
    - √ Agreements provide for among other things, criminal penalties and procedures in cases of wilful trademark counterfeiting or copyright piracy on a commercial scale; border measures in cases involving trademarks and copyrights; and civil remedies for all intellectual property rights (e.g. patent, trademark, copyright) with appropriate limitations that ensure consistency with US law".
- EU
  - FTAs involving the EU have border measures applicable to the infringement of all intellectual property rights : EU – Korea FTA
    - √ "Each Party shall ... adopt procedures to enable a right holder, who has valid grounds for suspecting that the importation, exportation, re-exportation, customs transit, transhipment, placement under a free zone, placement under a suspensive procedure or a bonded warehouse of goods infringing an intellectual property right may take place, to lodge an application in writing with competent authorities, administrative or judicial, for the suspension by the customs authorities of the release into free circulation or the detention of such goods".

Way Forward for IBSA

- Need to emphasise that the Agreement on TRIPS “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” (Doha Agreement on TRIPS and Public Health)
- “Counterfeiting” should be clearly defined keeping in view the flexibilities available under the TRIPS Agreement
- Attempts made by the pharma majors to equate “ counterfeited” and “sub-standard” medicines should be challenged

Thank you