Defending the Channels of Essential Goods:
IP, Trade and Public Welfare

Panel on IP as an obstacle to (legitimate) trade –
Basic policies, customs regulations & goods in transit

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The India–EU Transit Case

Genesis

- Seizures of Indian generic medicines in transit through Schiphol airport (The Netherlands) in 2008
- Based on patent applications by originator pharmaceutical companies pursuant to EU IP Border Measures Regulation 1383/2003
- Customs notification to patent holder followed by attorney notification to shipper/declarant
  - Attorneys request consent to surrender and destruction of medicines
  - Regulation 1383/2003 authorizes destruction based on shipper/declarant failure to object
- Merck/Dupont requests surrender and destruction of Dr. Reddy's losartan bound for Brazil
  - Cargo returned to India following acknowledgment of Dutch patent
- Glaxo authorizes release of Aurobindo/UNITAID abacavir bound for Nigeria, but Dutch customs refers to criminal prosecutors
  - Cargo detained for extended period and released only after high-level political intervention (e.g., by WHO)

Path to WTO dispute

- India, Brazil and others raise issue in WTO TRIPS Council and demand concrete assurance from EU of reformed rules and practices
- EU references problems of internal regulatory structure, autonomous Dutch patent law and judicial decision (based on “production” or “manufacturing fiction”), and effects of “Medi-Fake” initiative (plus general public health motivation)
- Pharmaceutical originators distance themselves from practice (e.g., attribute problem to under-supervised lawyers), issue statement
- India and Brazil formally request consultations with EU and The Netherlands at WTO

India Theory of Case as Reflected in Request for Consultations*

- GATT Article V mandates freedom of transit, precluding unreasonable regulation
- Paris Convention Article 4*bis*, incorporated in TRIPS Agreement, establishes principle of independence of patents
  - India's decision to grant or deny protection may not be interfered with by unreasonable extension of Dutch patent law
- EU Regulation interferes with prospective operation of 30 August 2003 compulsory license for export waiver, and is inconsistent with Doha Declaration on TRIPS Agreement and Public Health
- Nothing in TRIPS Agreement sufficient to overcome GATT freedom of transit mandate

***Presenter is co-counsel for India in dispute**

Present Status: published information (as of 12 July 2011)

- Two rounds of productive consultations held in Geneva (July and September 2010)
  - WTO rules mandate confidentiality of consultations
- 10 December 2010 EU-India ministerial-level meeting in Brussels
  - EU Trade Commissioner commits to cessation of practice and legislative reform
  - Indian Minister of Trade accepts resolution of dispute pending finalization of legal details
- Phillips/Nokia joined case pending before ECJ
- European Commission adopts proposal for a replacement regulation (late May 2011)
  - Lengthy legislative process ahead
- No seizures reported since early 2009

Public Welfare in Policy

- Flow of generic medicines worldwide highly dependent on freedom of transit
  - Patent strategies taking advantage of high protection at major transit ports (Schipol, Dubai, Singapore, etc.) has significant potential for interrupting supply
  - Re-routing succeeds only when alternative ports are not subject to extra-protective rules
- Key in the EU-India transit case was prompt NGO and legal attention forcing backtrack by originator companies. Would have been more difficult had practice become embedded
- Problem of "counterfeit" or falsified drugs different than the patent case, and ties into ACTA and WHO discussions

ACTA and Transit

- Draft negotiating proposals (including from EU) would have extended mandatory right to holders of all forms of IP to request seizure of goods in transit, as well as *ex officio* authority to customs
- India strongly objected to transit extension, especially as tied into patent case
- Final text (footnote 6) excludes patents and undisclosed information from section on border measures, therefore from transit provisions
- Final text allows, but does not require, customs authorities to seize in transit goods based on other forms of IP (*ex officio* or on right holder application)
  - Raises GATT Article V issue, and general question of territorial extension of IPRs (see, e.g., opinion of Advocate General in Philip/Nokia and ECJ judgment in Commission v. France)
  - For *ex officio* transit seizures, ACTA provides no evidentiary requirement regarding bases of "suspicion"

WHO and the "counterfeits" problem

- WHO responsibility to protect and promote public health
- IPRs issues conflated with public health concerns
  - Border measures authority used to inhibit importation of *bona fide* generic products
  - African legislation promoted by EU bases infringement on foreign registrations (e.g., CTM can be used to prevent import into Kenya)
    - Kenya High Court suspends application of legislation to medicines on constitutional and human rights grounds
- Role of originator pharmaceutical industry with IMPACT regulatory effort questioned by developing country WHO members

Objective to disaggregate IPRs and public health

- Preventing trade and distribution of substandard counterfeit or falsified medicines the legitimate objective
- Requires investment in improved regulatory monitoring, public and private sector supply chain management
- Availability of reasonably priced generics serves to undercut rationale for illegal activity
- WHO work program addressing subject matter

Trade, IPRs and Public Welfare

- Trade in generic pharmaceutical products essential to protecting global public health
  - India serves as a low-cost provider to much of developing world
  - On supply side, Brazil, China, Israel, Jordan, South Korea and others play important roles, and increased intra-regional supply an objective in Africa and Latin America
- Data on "counterfeit" trade highly anecdotal for all sectors; US Government Accountability Office unable to verify source of purported FBI and other studies
- Risk that IP border measures become new generation of trade barriers with attendant impact on consumers
  - Risks heightened in present uncertain economic environment