



The IGWG Mandate and UNCTAD's Work on Public Health, Innovation and TRIPS Flexibilities in Developing Countries

**Maastricht University/Stockholm Network
15 April 2008**

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Overview of presentation

- The IGWG mandate and implications for UNCTAD
- UNCTAD's work on local pharmaceutical production in developing countries
- Conclusions





IGWG mandate & UNCTAD

- Draft a global strategy (GS) and plan of action (PA) for R&D relevant to diseases that disproportionately affect DCs (Resolution WHA59.24)
- Draft GS element 4.1(b): promote TOT and production of health products in DCs through investment & capacity building; reference to UNCTAD as involved stakeholder





UNCTAD & pharmaceutical production

- UNCTAD Commission on Investment, Technology & Related Financial Issues: 2005 recommendation for Secretariat to
 - assess ways for DCs to develop domestic productive capability in the supply of essential drugs
 - in the context of investment, TOT & IP
 - in collaboration with pharmaceutical industry



Production of generic medicines in DCs & LDCs - Rationale

- Facilitated access to medicines
- Generic competition may generate innovation
- Investment opportunities for pharmaceutical industry
- Building of local pharmaceutical capacity





Facilitated access to medicines (1)

- Generic competition often results in price decreases
 - Evidence from DCs and USA
 - Need for several generic producers
 - Need for large markets → regional collaboration among DCs/LDCs desirable
- National health security → no exclusive reliance on donations or private sector patent policies (although these are important, e.g. Roche's tech transfer initiative)



Facilitated access to medicines (2)

- IP protection is one among many factors affecting price in DCs - but an important one
 - Introduction of product patents in lower & middle income DCs could result in price increases of 12%-200% (studies by Fink and Watal)
 - Doha Declaration (para 3) recognizes concerns about IP effects on drugs prices
 - Many drugs are off-patent in LDCs, but these depend on imports of patented products
- Lack in DCs of competition policy to monitor prices



Generic competition as a source of innovation

- IPRs: exclusive rights are incentives for inventors to invest in R&D (but: need for market demand)
- But innovation also needs competition
 - Monopolies are major disincentive to product improvement → Competition as a main driver of innovation
 - Simplified treatment regimes or adaptation to local conditions (e.g. Ranbaxy: sustained release formulation of Bayer's antibacterial drug ciprofloxacin)



The importance of the public domain

- New ideas are mostly developed on the basis of existing know-how
- Prerequisite for follow-on innovation: technological skills
→ (-) in DCs
- Technological learning through imitation & reverse engineering (RE)
- Product patents in DCs prevent RE
 - LDC transition periods
 - Broad experimental use exemptions
- European countries: pharmaceutical products in public domain until 1970s/India until 2005





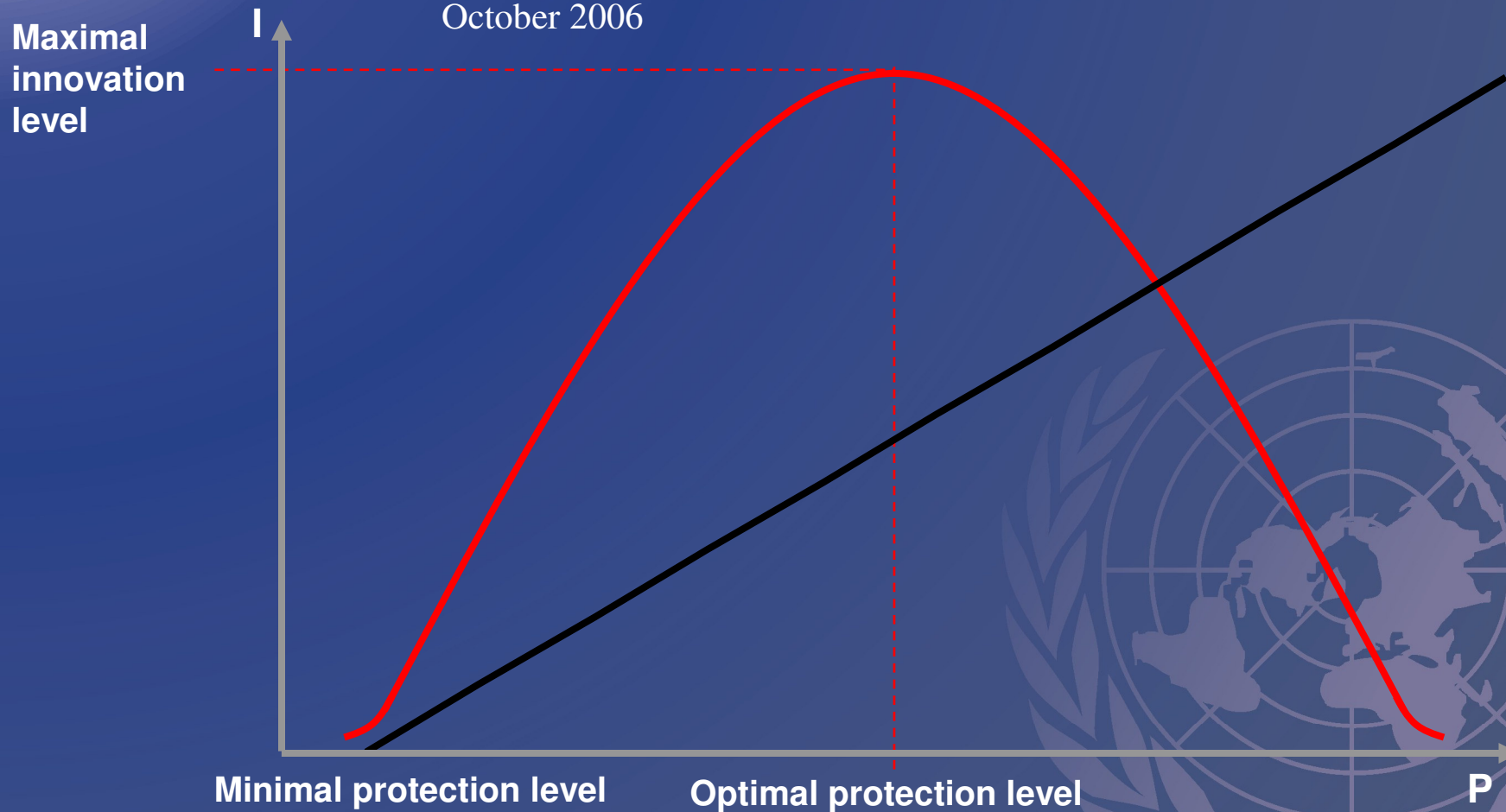
Striking a balance (1)

- Governments must provide balance between need for IP protection and need for access by competitors & researchers to technology-related information (public domain)
- UNCTAD policy analysis & technical assistance on implementation of TRIPS flexibilities
- TRIPS: leeway where to draw the line between IP-protected area and public domain
- More exclusive rights → more innovation?



Striking a balance (2): Patents as a Policy Measure Protection (P) vs. Innovation (I)

Source: Swiss Federal Institute of Intellectual Property,
October 2006





Striking a balance (3)

- Where is the optimal protection level to reach maximum of innovation?
- Historical evidence: no «one-size-fits-all» model (Europe, USA, Rep. Korea)
 - Early stages of technological development require broad public domain for indigenous learning
 - Advanced stages of development require higher level of protection of technological assets
 - Even technologically advanced economies depend on competition and follow-on innovation



Foreign investment & local production of pharmaceuticals

- In many DCs & LDCs: low level of local expertise (e.g. APIs) → need for foreign support: pharmaceutical companies interested in DC & LDC markets
- Low purchasing power → need to create regional markets
 - Economies of scale/pooled procurement
- Generics producers from India & Europe have indicated interest in certain local producers
 - Provided the domestic IP regimes leave room for generic competition /TRIPS flexibilities



The Local Production Initiative

- Broad international initiative headed by Germany
 - BMZ: Overall coordination
 - UNCTAD: Government advice & training courses on IP & investment frameworks
 - UNIDO: Economic feasibility studies, promotion of business partnerships, plant-level advice
 - GTZ: Production-related assistance & equipment
 - action medeor: training of pharmacists
 - Bank for Reconstruction (KfW): funding of SMEs



A beneficiary: Pharmakina

- Located in Bukavu/DR Congo
- Independent business since 1999
- Technical & financial support from GTZ & action medeor
- World's leading producer of quinine (for anti-malarials)
- Since 2005: production of HIV drug «Afri-Vir»
 - Combination therapy: 3 ingredients in one pill (stavudine, lamivudine, nevirapine)
 - Costs per patient: 15 Euros per month
 - At present: therapy for 200 locals
 - Envisaged: WHO prequalification (for international procurement)
 - Capacity to produce 180,000 pills per day





Conclusions

- IPRs: important incentives for innovation, but they presuppose existing expertise and require market demand (neglected disease issue, IGWG)
- First step to innovation in DCs is technological learning through RE → need for public domain
- Broad monopolies are disincentives to product improvement → need for competition → need for public domain
- No «one-size-fits-all» model: level of IP protection needs to reflect particular level of development
- TRIPS provides flexibilities for these purposes



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