Intellectual property and public health: meeting the challenge of sustainability

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Progress in the decade since Doha

- Widened global awareness of public health problems, including those affecting developing countries
- Substantially increased funding for procurement and distribution of necessary treatments, especially for HIV/AIDS, malaria and tuberculosis
  - Enabled by generic pricing
- New R&D and production/distribution mechanisms established
  - For example, DNDi and Medicines Patent Pool
- Stakeholder participation widened (*e.g.*, Gates Foundation)
- Improved cooperation among multilateral institutions

IP policy remains highly politicized

- Case of South Africa Medicines Act led to Doha Declaration
  - Misuse of TRIPS Agreement
  - Inadequate institutional response entailed long-term damage
- TRIPS Agreement embodies well-known flexibilities, as recognized by Doha Declaration
- Common appreciation of nature of global public health problems not matched by cooperative approach to solutions
  - Stakeholder conflicts persist

Patents, Politics and Budgets

- WHO-pioneered essential medicines concept involves medicines largely unprotected by patent
  - Selected with budgetary considerations in mind
  - Some key essential medicines under patent (*e.g.*, second line ARVs)
- Patents remain relevant for newer treatments with increased efficacy, and will be relevant in the future
- Governments remain constrained in taking advantage of TRIPS flexibilities
  - Continuing politicization reflected in EU response to Thai licenses
- Budgets are constrained and involve prioritization
  - Classically framed choice between "guns" and "butter"
  - Budget issues not limited to developing countries

Trends for the coming decade

- IP-related negotiations shifted to bilateral and regional forums
- Major emerging market countries more important in multinational originator company strategic planning
- Intensified competition between originator branded generics and other generics in developed and developing markets
  - Increased merger and acquisition activity
- R&D and production focus shifting from small molecule to biologicals
  - Presently biologicals markets less saturated

Trends for the coming decade

- Increasing geographic distribution of R&D on drugs and vaccines
  - Reflects originator focus on emerging markets, as well as new information technologies
- R&D shifting toward computer modeling and data mining
  - “Bioinformatics revolution” raises new IP issues
- Government stepping in to address R&D gaps
  - USNIH National Center for Advancing Translational Sciences
  - Government downstream role may be enhanced
- Financial crisis leading to general government expenditure cutbacks, putting foreign aid medicines procurement funding at risk

Starting from First Principles

- All people would be entitled to a baseline standard of access to medicines based on the essential medicines concept pioneered at WHO
- All governments would be able to provide – or ensure the provision of – more advanced medicines within the reasonable budgetary capacity of the nation
- Sufficient financial incentive would be available to ensure that funds are invested in R&D on new drugs and vaccines, either through government funding or private sector initiative
- The prescribing of drugs and vaccines would be based on the best interests of the patient and not on the commercial interests of medicines suppliers
- Adequate regulation and enforcement would be undertaken to ensure that medicines are of the necessary quality and safety

Essential Medicines Plus

- International financing mechanism for procurement and distribution of essential medicines based on WHO concept
  - National contributions based on per capita GDP
  - Purchasing through open tender (potentially with geographic allocation)
  - Global Fund, PEPFAR, UNITAID, already established for HIV/AIDS and others
  - Medicines Patent Pool model can be extended to additional patented essential medicines
- Does not require radical transformation of international economic framework

Advanced Treatment Opportunity

- Treatments outside essential medicines should be available taking into account budgetary constraints and fair treatment of non-national developers
  - Option to purchase from originator at fair compensation price determined by originator, or from third-party with fair royalty
  - Royalty to reflect risk-adjusted R&D costs, taking into account level of economic development
- Royalty guidelines established by multilateral negotiation
- Royalty determinations subject of neutral international arbitration
  - Minimum royalty payable on transaction, final royalty established by arbitration
- Consistent with TRIPS principles, but may require technical modification

Continuous stream of innovation

- Patent system stimulates concerted efforts, with recognized distortions
  - May be improved, and could operate under royalty system
- Open source option under consideration, but medicines R&D different than software development
  - Clinical development expensive and high risk; long-term liability for adverse reactions
  - Downstream purchasers (*e.g.*, public health systems, pharmacy benefits providers) might fund later stage development in exchange for lower prices
- Product development partnerships for neglected diseases
- NIH NCATS approach
- R&D Treaty proposal at WHO may open discussion

Rational prescribing

- Medicines supply paradox
  - Profitability for suppliers depends on promoting consumption
  - Medicines consumption inherently entails risk to patient
- Best interests of patient must be focus of system, not commercial interests of suppliers
  - Rational prescribing a long-standing tenet of WHO guidance

Quality and safety

- Protection of supply chain is within reasonable capacity of regulators, producers and distributors
- Regulators expected to assure efficacy in approval processes
- Resource limitations suggest need for improved regional and international cooperation in rulemaking and implementation
- Rules designed to protect integrity of supply chain should not be abused for commercial advantage

Role of trilateral institutions

- WHO pursues core function of strengthening public health systems, including through identifying and providing essential medicines, strengthening systemic responses to pandemic disease
  - Forum for negotiating improved rules
- WIPO continues to provide technical support in areas such as patent databases, identifying R&D licensing opportunities, public-health-sensitive technical training, supporting Medicines Patent Pool
  - Multilateral rulemaking may remain divisive
- WTO continues core function of promoting liberalized trade and resolving disputes
  - WTO Agreement, including TRIPS, must guard against "mercantile excess", such as by protecting transit routes

Role of non-governmental organizations

- NGOs played central role in drawing attention to gaps in access to medicines
- New institutions such as DNDi and Medicines Patent Pool founded through work of NGOs
- Context growing more complex as relationships with originators have increased
  - In-licensing of molecules for R&D
  - Voluntary licensing of patented medicines for use in developing regions
- Tolerance required on all sides for cooperative relationships to bear fruit
  - Arrangements are fragile at early stages

Integrated global medicines policy

- Institutions other than WHO, WIPO and WTO important in coming decade for improving global medicines supply
  - Financing expertise, e.g., World Bank
  - Transfer of technology, e.g., UNCTAD
  - Procurement, e.g., Global Fund, UNITAID, UNICEF
  - R&D and production, e.g., DNDi, Gates Foundation, Medicines Patent Pool
  - Intergovernmental technical expertise, e.g. South Centre
  - Issue identification, advocacy and problem-solving, e.g., MSF, Oxfam, KEI, HAI, TWN; policy analysis, ICTSD
- Suggests potential value of Global Medicines Coordination Council for information-sharing and strategic planning

Final thoughts

- Development and supply of medicines a complex undertaking, depending also on evolution of science
- Coming decade likely to be characterized by restrained government spending, necessitating more efficient solutions
- Stakeholders find it easier to agree on public health needs than on mechanisms for solutions
- Multilateral institutions may assist by promoting cooperation among diverse stakeholders