Intellectual property and public health: current challenges for the balance between innovation and access

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IP AND HEALTH

- Sector which evidences most profound tensions
- Society dependent on health technologies for welfare
  - Core obligation of government
- Industry claims high dependence on strong IP rights
  - Permits capital aggregation for investment in R&D
- Many nuances to consider between “poles”

SHAPING OF GLOBAL POLICY ENVIRONMENT

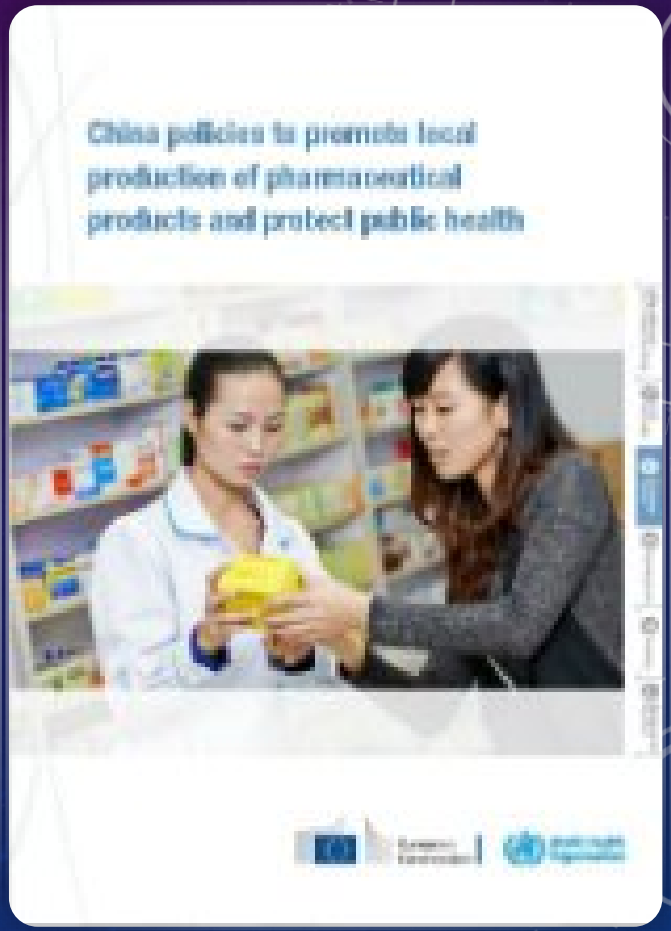
- WTO TRIPS Agreement substantially engineered by originator pharmaceutical industry based in USA-Europe- Japan
  - Addressing “misappropriation”
- Major test in South Africa at height of HIV-AIDs epidemic (1996-2001)
  - Stark conflict between exigent public health needs and industry patent interests
  - Industry overreach generates backlash
- Response is Doha Declaration on TRIPS Agreement and Public Health (2001)

FORUMS AND POLITICS SHIFT

- Industry shifts focus out of WTO to bilateral, regional and plurilateral negotiations
  - Substantially enhances regulatory-based market exclusivity
  - Links patents to regulatory approval process
  - Confirms IP subject matter of investment protection
- More recent demands
  - Extends market exclusivity to biologics
  - Provides industry with access to challenge formulary, reimbursement and pricing decisions
  - Initiates coverage of competition procedures and rules

UNIVERSAL HEALTHCARE (UHC)

- F. M. Abbott – Recent study of China policies and practices regarding local production for WHO (2017)
- Key distinguishing characteristic of China policies is commitment to Universal Healthcare flowing from President Xi
- The commitment to UHC frames China's approach to IP and innovation because solutions must be capable of wide implementation and usage



HETEROGENEITY

- Although possible to approach in terms of "interest baskets" (LICs, NICs & HICs), preferred approach to IP, innovation and access is probably country-specific
- Large "emerging economy" countries such as China and India face different challenges than less densely populated emerging market economies, and LMICs more generally
- China is investing and attracting substantial FDI toward R&D, especially in biotech
- Presumed longer-term objective of reducing dependence on foreign originator products, and entering export arena

CHINA-SPECIFIC FACTORS

- Chinese population experiencing high incidence of cancer which makes development and introduction of new treatments urgent
- China has substantial and growing population of PhD level research scientists capable of carrying out advanced R&D
- China has substantial production infrastructure, including for APIs, with certain limitations
- China has complex procurement and distribution system for medicines, presenting challenges and opportunities

CHINA-SPECIFIC FACTORS

- China's more centralized governance structure appears to provide opportunity for better coordinated long-term planning

- Assuming commitment to UHC, China will face substantial challenge in determining appropriate incentive package to generate R&D while maintaining reasonable budget for healthcare

- Governments have a variety of policy instruments available to calibrate IP and access system, but IP only one element of healthcare and policy

CHINA CALIBRATION

- From a IP standpoint, alternatives include voluntary and mandatory licensing systems, research exemptions, interest-specific exceptions (e.g., regulatory review)
    - Providing an abbreviated pathway for introduction of generics, including biogenerics, essential
- Scope and duration of exclusive marketing rights based on approval of new medicines, including biologics, a critical question
- Use of creative structures: public-private partnerships, push and pull subsidies

CHINA CALIBRATION

- Other policy instruments include:
  - Price controls, which apparently have been problematic within China
  - Implementation and enforcement of competition law rules, including with respect to excessive pricing
  - Avoidance of restrictive international commitments, e.g., plurilateral agreements which limit policy options

POSITIVE MULTILATERAL AND REGIONAL OPTIONS

- Potential participation in WHO treaty-based R&D burden-sharing arrangements
- Regional supply and procurement arrangements
    - Avoidance of commitments regarding "trade secret" protection of pricing data
- Information-sharing among national authorities, including IP, exclusive marketing rights, procurement/pricing, competitive markets