Patent landscaping in the field of medicines: policy and technical options

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Genesis of public health concern with patent information gaps

- Efforts to ramp-up government and NGO procurement of HIV-AIDS treatments from 2000 onward confronted lack of information concerning patent status of antiretroviral medicines and other supplies
  - Whether ARVs could be procured from India or other generic sources depended on whether medicine was patented in importing (and exporting) country
  - Issues connected with use of TRIPS flexibilities linked to patent status
    - Regulatory review exemption, limited exception, compulsory licensing, parallel importation
- Insecurity inhibited public-health authorities and multilateral agencies, adding to product costs and administrative burdens associated with procurement process
  - Experiences of UNAIDS, UNICEF, World Bank, Global Fund
  - See, e.g., World Bank Procurement Guide, available at http://siteresources.worldbank.org/INTPROCUREMENT/Resources/Technical-Guide-Procure-HIV-AIDS-Meds.pdf (pgs.14-18)

Evolution of interests and response

- Paragraph 7 of Doha Declaration authorizing LDC non-enforcement of patents was, in part, response to absence of reliable patent information
  - Permitting practice of providing procurement certification of non-enforcement
- 2003 MSF Study "Drug patents under the spotlight" represented pioneering effort to determine patent status of antiretroviral medicines in sub-Saharan Africa
- Though issue raised with national, regional and multilateral agencies, patent governance bodies slow to respond to concerns over information gaps
- Range of interest in patent system transparency has substantially expanded during course of this decade as awareness of systemic impact of information gaps increased

Evolution of interests and response

- Research and development participation expands as public-private initiatives assume greater role
  - Expansion of interest beyond private sector industry and related university laboratories
    - Initiatives such as DNDi and FIND confront patent thicket and technology licensing opportunities
    - Progress dependent on cross-licensing of patented technologies
  - Bayh-Dole type incentives an evolving international “norm”
    - Publicly-funded researchers increasingly interested in patents
- H5N1 access/benefit-sharing and research issues present linked paradigmatic policy issues
  - Sovereign control over genetic/biological resources
  - Global emergency response and IP
  - How will models function in real-time crisis?

Multiple stakeholders in medicines patent landscaping discussion

- Patient-consumers
  - Patent status of medicine determines price and availability
  - Patents may incentivize new treatments and/or block avenues of research
- Governments
  - Patents determine allocation of public health budget and availability of treatment
  - Patents serve industrial policy purposes, including in development of pharmaceutical sector
  - Funding requirements of public health oriented multilateral institutions and foreign aid programs affected by patent status
  - Benefit sharing arising from rights in genetic resources linked to patents
- Researchers
  - Patents provide financial incentive and stimulate funding
  - Patents "securitize" technology, facilitating licensing and transfer
  - Patents define openness of field of innovation: patent thicket may inhibit research
  - Researchers operate within broad range of contexts: private enterprise, public institution, nongovernmental organization

Multiple stakeholders in medicines patent landscaping discussion

- Producers
  - Patents determine profit margins: separate originator and generic markets
    - Of US $650 billion global pharmaceutical market, US $550 is from sales of patented medicines
    - Patents define geographic opportunities
- Investors
  - Information concerning patents, including validity and geographic scope, determine value of investment
  - Investor community increasingly concerned with assessing risks associated with patent landscape
- Service Providers
  - Private database managers, multilateral and regional patent organizations, technical consultants and patent lawyers have economic interests in nature of solutions
- Non-governmental organizations
  - Patent status of medicines affects capacity to fulfill access mission
  - Research-oriented NGOs have multiple interests in patent status

Transparency as first principle

- Transparency should be first principle of international patent system
  - Information concerning presence or absence of patent essential to consumers, researchers, potential competitors and government policy-makers
  - Uncertainty concerning patent status raises costs by inhibiting competition and increasing risk premiums
  - Patent bargain presumes disclosure of invention in exchange for market exclusivity; absence of information concerning patent undermines social bargain
    - Patent technical information is essential part of landscape
  - System intended to provide transparency may be subject to strategic manipulation; proper design of system critical

Beware law of unintended consequences

- Consequences of international patent transparency not entirely foreseeable
  - Better information should provide roadmap to opportunities for research, generic production and market access, lowering costs to consumers
  - Revealing gaps in geographic scope of patent protection may stimulate increase in geographic scope of patent filings, or stimulate demands for “true international patent”, exacerbating market access restrictions
- In principle, better information should lead to better policy decisions, but this depends upon quality of governance

Problems with present system: technical disclosure language

- Technical language of patent does not readily link to end-product medicine (drug, vaccine, diagnostic, etc.)
  - Patent application on new entity or biological typically filed prior to product development
    - Search must be for underlying technology
    - Follow-on applications may reference INN
  - Application often filed in name of natural person, though assignee (real party in interest) identified
  - Medicines product information leaflets typically do not identify relevant patents (nor do Securities and Exchange Commission public filings)
  - Medicines often covered by multiple patents with differing expiration dates, and patented technology may be in-licensed from third parties

Existing patent to medicine links

- US FDA Orange Book lists all drugs approved for sale in the United States and corresponding list of US patents claimed to cover such drugs, including date of expiration (which may include patent term extension)
  - available at http://www.fda.gov/cder/ob
  - Drugs listed and searchable by proprietary name, active ingredient, FDA applicant and patent number
- Patent information supplied by holder of FDA application for approval; not verified by FDA
  - Structure and operation of US Hatch-Waxman ANDA system creates incentives for strategic "gaming" of Orange Book patent listings, leading to significant problems
    - see U.S. Federal Trade Commission, Generic Drug Entry Prior to Patent Expiration: An FTC Study (2002), *available at* <http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf
- Orange Book is source of research leads (e.g., patents can be traced into PCT system), but geographic scope of information technically limited to United States
  - Does not address patent status in foreign countries
  - Does not address medicines unapproved by FDA
- See also Health Canada Patent Register
  - available at http://patentregister.ca

Problems with present system: independence of patents effects

- Independence of patents generates high information search costs
  - Information concerning filing, prosecution, amendment, grant, payment of fees, revocation are determined on country-to-country basis
  - Electronically searchable databases - public and private - cover OECD and some developing countries patent offices, but large gaps remain
    - OECD patent offices offer fee-paid search relying on electronic systems
  - WIPO PCT PatentScope system increasingly valuable as international search tool, but problem, inter alia, of geographic scope remains
    - PCT nominally requires national phase office to provide information concerning patent grant, but such obligation not consistently met
    - WIPO IP Statistics Division attempting to remedy feedback gap

Associating patents with medicines: potential remedies

- *Third-party researchers*, public and/or private, could be chartered to establish and maintain database linking available medicines with current patent data (associating medicines with patents and researching country-to-country status)
  - Mechanism could be overseen by health centric (e.g. WHO) and/or intellectual property centric (e.g., WIPO) multilateral institution
  - Requires substantial commitment of technical experts, confronting similar issues to national and/or regional patent offices in terms of cost and availability of experts
  - Would not automatically resolve developing country patent status information gap

Associating patents with medicines: potential remedies

- *Patent holder driven* model would rely on information concerning patent status provided by patent holders, along the lines of US FDA Orange Book model

- *"Reasonably effective"* Orange Book model highly dependent upon robust US litigation system and challenges to validity of patents initiated by applicants for generic marketing approval -- as substitute for FDA verification of patent validity
  - Challenges strongly encouraged by 180-day marketing exclusivity granted to first successful patent challenger and highly lucrative US pharmaceutical market
  - Also, government oversight by US Federal Trade Commission

- Without comparable patent-challenge incentive or robust multilateral verification system, high potential for strategic gaming by patent claimants
  - Responsibility for maintaining integrity of system could not reasonably be placed on national civil litigation systems because of high administrative costs

Associating patents with medicines: mixed public-private database

- Patent holders supply information linking patents with medicines to multilateral (or other) organization combined with third-party data verification
  - Reduce burden of technical information gathering and assessment by public (or publicly supported) institutions
  - Provide system for periodic updates of information
- Requires enforcement mechanism to prevent strategic gaming by patent claimants; penalty must be sufficiently great to act as *ex ante* deterrent
  - Would require distinguishing good and bad faith misinformation
    - Case 1: patent claimant has good faith belief that reported patent is valid and in force
    - Case 2: patent claimant knowingly supplies false information concerning patent validity or status

Associating patents with medicines: policy questions

- Are multilateral governance mechanisms sufficiently robust to operate patent-medicines information system that would be reliable and deter strategic gaming?
- Would a more limited approach of relying upon third-party research of patent status on a narrowed range of medicines be more realistic?
- Will enhancing transparency of international patent system encourage or discourage research and development, and opportunities for generic supply?

Freedom to operate analyses

- Policy issues similar to patent-medicine linking
  - Technical feasibility moving ahead of policy planning
    - Significant evolution of information technologies within past 5 years
- May already be feasible to establish centralized (or cross-linked) publicly-accessible database of FTO analyses that have been conducted with respect to different fields of public health technology
  - Illustrative examples of open-access FTOs presented at this symposium
  - Voluntary submissions to hosted web FTO database may be combined with suitable disclaimer of liability
  - Third parties might contribute additional data, separate from data provided in initial report
  - Site could be hosted by multilateral organization (e.g., WHO or WIPO), by NGO, or other

Creating FTO analyses

- Relatively simple FTOs could list expired patents in relevant fields of technology where reasonable expectation of public domain character of previously patented technology would exist
- Establishing more comprehensive multilateral FTO resource bank would raise a number of questions:
  - What institutions would undertake the analyses, and with what technical support?
  - What technical fields would be given priority?
  - What format would be adopted for reports?

Creating FTO analyses

- What mechanism would be used to update information as patent landscape is constantly evolving?
- What presumptions would be established in connection with “reliance”
  - Would multilaterally chartered FTO provide basis for good faith reliance? With what consequences for liability and/or continued use?
- How would liability of FTO provider issues be handled?

Creating FTO analyses

- What parties would be entitled to have input into the process?
  - Would parties claiming to hold patents be entitled to submit information?
  - Would third parties be entitled to challenge patent claimant information?
  - Would there be a mechanism for resolving disputes?
- How would such a project be funded?

Combining approaches

- A combination of voluntarily contributed and newly-funded FTOs might be considered for a single database resource
- Pilot projects -- such as those presented at this symposium -- should help provide guidance regarding options
- “Spin-off” of project to create FTO analyses database should include enhanced training of technical experts to analyze patent submissions. In addition, project should lead to development of new and better patent search tools.