Patents and Public Health 2016: Selected Developments and Issues

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INTERNATIONAL IP ROUNDTABLE
FRIDAY, APRIL 8 – SATURDAY, APRIL 9, 2016
WILLIAM S. BOYD SCHOOL OF LAW, UNIVERSITY OF NEVADA LAS VEGAS
Three Topics

- United Nations Secretary General's High Level Panel on Access to Medicines
- Excessive Pharmaceutical Prices and Competition Law: Part II
- Lexmark v. Impression Products (Fed. Cir 2016)
THE UNSG HLP/EAG PROCESS

- HLP appointed by Secretary General: http://www.unsgaccessmeds.org/#homepage-1
- Expert Advisory Group members multilateral organization representative, NGO and independent academic
- Secretariat UNDP/UNAIDS
- Arising out of Commission on HIV-AIDS and the Law Recommendation
- Timeline envisages completion by HLP of Report to SG by end of June, 2016
Preliminary sessions in various fora

- Request for submissions due February 2016
- More than 180 submissions from wide range of stakeholders
  - Including 2 Global Health Law Committee submissions; one included as materials (i.e. nonvoluntary licensing for essential medicines patents)
- Meetings and Global Dialogues in London (March 9-10) and Johannesburg (March 16-17) (Dialogues webcast)
Meetings of HLP/EAG in Glenn Cove, New York, March 31-April 2

Glaxo announces new global patent policy at commencement of Glenn Cove meeting, different strategies at different country income levels

Multilateral organizations initial skepticism largely transforms into substantial support

Global support across a wide spectrum of stakeholders

Confirmation of support from UN Secretary General

Draft report in preparation

Constraints in discussing prospective outcomes
EXCESSIVE PHARMACEUTICAL PRICING AND COMPETITION LAW

- Grows out of work for UNDP on using competition Law to promote access to health technologies, briefly discussed last year
- Formally submitted to Senate Finance Committee staff Grassley/Wyden
- Two principal lines of inquiry/recommendation:
  - Transforming judicial perspective on addressing excessive pricing "as such"
  - Addressing issue of determining pharmaceutical R&D costs, as predicate to assessing reasonableness of pricing
US courts traditionally view excessive pricing as a potential symptom of underlying anticompetitive practice, but hesitant to address excessive prices standing alone.

Patents and regulatory marketing exclusivity are granted based on legislative action and may be considered lawful ("pristine") monopolies, allowing whatever price the market will bear.

Protection of public interest is a major objective of antitrust/competition law, and should be used to address economic conduct injurious to the public based on monopoly/dominant position, even if acquired lawfully.

Other countries allow competition actions based on excessive pricing as such, but in most instances with some hesitation.
Judicial hesitance based on difficulties of determining reasonable base price, and in assuming role of price regulator

Problem in US is that Congress has difficulty acting (e.g., influenced by lobbying), and alternative mechanism of addressing prices needed

Second part of article addresses determining cost of R&D

Methodologies specified

Some recent confirmation from senior Pharma R&D sources

Consistent with internal budgeting and reporting practices
TRANSLATING INTO ACTION

- Recent decision of Indian Competition Commission in respect to Monsanto genetically modified seed pricing
- Project initiated for two Asian country competition authorities that have requested it
- Review of competition laws and technical support if and as decision made to initiate excessive pricing actions
- For US, longer-term time horizon, at this stage putting concept into matrix of possibilities
Unsurprisingly, Federal Circuit in February affirms its own wisdom.

Bases support for national patent exhaustion on non-acceptance of differential rewards secured outside United States, and on misreading of territoriality principles.

Dissent prefers placing burden on patent-owner seller to introduce contract restrictions.
Petition for certiorari filed

Supreme Court potentially more sympathetic to concerns regarding global competition