



Patents and Public Health 2016: Selected Developments and Issues

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INTERNATIONAL IP ROUNDTABLE

FRIDAY, APRIL 8 – SATURDAY, APRIL 9, 2016

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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

THE UNSG HLP/EAG PROCESS

- ▶ 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)

Developments

- ▶ 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
- ▶ Major US Pharma/business lobbying groups petition Sen. Hatch (February 18, 2016) urging all resources of US government devoted to intervening with work of HLP (Bio, PhRMA, NAM, NFTC, US Chamber, USCIB): <http://www.uscib.org/uscib-content/uploads/2016/02/Multi-Industry-Letter-on-UNHLP-2.18.16.pdf>

PROCESS CONTINUES

- ▶ 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
- ▶ Initially presented at Irvine symposium; now article forthcoming:
http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2719095
- ▶ 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

JUDICIAL APPROACHES

- ▶ US courts traditionally view excessive pricing as 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 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 hesitance

JUDICIAL APPROACHES

- ▶ 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

LEXMARK V. IMPRESSION PRODUCTS

- ▶ 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

U.S. SUPREME COURT

- ▶ Petition for certiorari filed
- ▶ Supreme Court potentially more sympathetic to concerns regarding global competition