The Undiscovered Country in Multilateral IP Regulation: evolving competition law doctrines for regulating patent abuse

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INTERNATIONAL WORKSHOP ON THE IMPACT OF THE TRIPS AGREEMENT ON KEY SECTORS AND ITS CONTINUING RELEVANCE IN THE CONTEXT OF REGIONAL AND BILATERAL TRADING AGREEMENTS

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KEY IDEAS

- At the level of multilateral rules competition law is available as a substantial counterweight to overprotection of patents and related IP
- Developing (including emerging market) country competition authorities are initiating more intensive enforcement of competition law as it relates to patents
- Effective use of competition law requires improved elaboration of certain core doctrines, including those relating to "excessive pricing" and "essential facilities“
- There is likely to be a concerted reaction from the multinational business community

Multilateral Competition Regulation and Patents

- That competition law is weakly regulated at the multilateral level is a well-documented story tracing back to the Havana Charter for an International Trade Organization
  - Followed by UNCTAD negotiations, competition on WTO Singapore agenda, competition working group at WTO, work program suspended (*see* Public Policy and Global Technological Integration 1996 – SSRN: 1989042)
- WTO TRIPS Agreement references competition law in a non-restrictive manner leaving substantial flexibility
  - Incorporation of national treatment significant
  - See Are the Competition Rules in the WTO TRIPS Agreement Adequate? 2004 – SSRN: 917108

Sherman Antitrust Act Origins and the Chicago School

- US Supreme Court in seminal Standard Oil Company of New Jersey v. United States, 221 U.S. 1 (1911) decision identified protection of the individual as the core objective of antitrust law:

  "the main cause which led to the legislation was the thought that it was required by the economic condition of the times … combinations known as trusts were being multiplied, and the widespread impression that their power had been and would be exerted to oppress individuals and injure the public generally."

- Under the influence of the Chicago School antitrust/competition law in the United States shifted its focus to maintaining competition among producers, and away from consumer protection
  - See, e.g., 1995 Department of Justice and Federal Trade Commission Intellectual Property Licensing Guidelines

Doctrinal Gaps Flow from Producer Focus

- Use of competition law to protect interests such as public health requires that attention be redirected toward consumer protection
- The impact of monopoly or abuse of dominant position falls more directly on the individual consumer/patient than on potential producer competitors
- Doctrines relating to "excessive pricing" and "access to essential facilities" are not well developed in US or EU competition law
  - EU law somewhat better developed, in particular regarding essential facilities
  - Canada uses excessive pricing as basis for controlling prices of patented medicines

Competition Law and Control of Excessive Pricing

- Pricing involves a bilateral relationship between producer and consumer
- Market dominance can be defined in terms of control over welfare of individual consumers and/or purchasing groups
- Patents provide basis for dominance within potentially narrow therapeutic class (down to individual drug)
  - Consumer with life-threatening disease does not have freedom of choice - demand is inelastic

Determining What Is "Excessive"

- Starting is baseline of "reasonable price“
- Manufacturing costs generally known
- Cost of R&D the element with greater indeterminacy
- Most of paper devoted to methodology for construction of "reasonable price" through determination of cost basis including R&D costs
- Not an insoluble problem

METHODOLOGIES

- Cost-plus profit, adjusted for risk
  - Preferred approach
- Reference pricing
- Bargaining between monopoly supplier and monopsony purchaser
- Cost based on corporate assessments of acquisition targets
- Cost based on reporting of R&D and related expenditures to tax authorities
- Cost based on securities and exchange commission reporting

ADJUSTING FOR RISK

- Drug development risk varies in relation to number of unknowns
- Government (e.g., NIH) funds basic research seeking to reduce unknowns and concomitant risk factors
- Level of risk varies depends on structure of investigating institutions (e.g., single or multi-focus)
  - Multi-focus institutions typically subdivide budget among research units
- Certain costs should be excluded
  - Basic research funded by government, executive salaries above established limits, opportunity cost of money, tax incentives

Supra-baseline “Excess”

- After determining cost: must establish what constitutes a price "excessive" in relation to it
- Establishing an acceptable norm of profitability can be accomplished by comparison with others in the same industry, or with others in other industries
- Difficulty with comparing other Pharma originators is that historical pricing practices may reflect excess
- In recent cases where the medical community and public have been "shocked" by pricing practices, may not be difficult to determine that prices are excessive, but establishing reasonable price plus profit may be necessary for remedial purposes

PUSHBACK TO BE ANTICIPATED

- Historic multinational business community resistance to multilateral competition rules may be diminishing as threats grow
- US Chamber of Commerce response to activities of Chinese competition authorities founders on absence of rules
- Benefits of rules may begin to exceed risks of being enforcement targets

PRESERVING DOCTRINAL FLEXIBILITY

- Developing countries should be wary of surrendering flexibilities
- Developing country competition authorities should promote development of doctrine suitable to country conditions
- Cooperation among developing country competition authorities should promote investigative capacity, doctrinal development and enforcement capacity