Access to Medicines and Health Innovation in Asia – A Comparative Law and Policy Approach

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Presentation Outline

- Context
- Research and Experimentation Exception
- ‘Pay for Delay’ Agreements
- Concluding Thoughts

Context

› COVID-19
› treaty-making has become increasingly difficult
› science and innovation has become more complex

Why a Comparative Law and Policy Approach?

- Patent law is made at the national level, subject to constraints imposed by treaties to which the country has subscribed
- Treaties provisions are often vague and reflect compromises reached during negotiations
- Allows countries to formulate provisions related to patent law that they believe are tailored to their respective needs
- Developing countries are most interested in the experience of other countries when formulating their own provisions

Research and Experimentation Exception

- Permits scientific research related to a patented invention without a license within the scope defined by national legislation
- Public policy rationale: to facilitate the dissemination and advancement of technical knowledge
- Allowing the patent owner to prevent experimental use during the term of the patent would frustrate part of the purpose of the requirement that the nature of the invention be disclosed to the public

International Law on Exceptions to Patent Rights

› TRIPS Article 30

› Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

Findings and Observations

- All Asian jurisdictions which have research and experimentation exception have codified the exception in their respective patent laws
- Asian jurisdictions have not made a distinction in their patent laws that explicitly clarifies whether the exception applies to commercial or non-commercial research, or whether it applies to research/experimentation on or with a research tool
- Asian jurisdictions that do not have a codified research and experimentation exception are either LDCs (Lao PDR and Nepal), or in the case of the Maldives, has 'graduated' from LDC status
  - Lao PDR, Nepal and Maldives are biodiversity hotspots; local institutions at a disadvantage with respect to R&D on genetic resources

‘Pay for Delay’ Agreements

1. What are ‘Pay for Delay’ Agreements?
2. Methodology
3. China
4. Korea
5. Japan
6. Lessons from the East Asian Experience

What Are 'Pay for Delay' Agreements?

- Contracts where a patent owner enters into an agreement with a rival who promises not to enter the market until after a fixed date and to refrain from challenging the validity of the patent (or to withdraw existing challenges), in exchange for direct or indirect compensation
- Generally found in the pharmaceutical industry, i.e., between pharmaceutical patent owners and generic companies
- Compensation may include the generic company being given exclusive rights to market patented product(s) of the owner
- Also called reverse payment agreements, since the payment goes in the opposite direction of a typical patent license

Relevant TRIPS Agreement Provisions (1)

- Article 8
  - Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.
  - Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonable restrain trade or adversely affect the international transfer of technology.

Relevant TRIPS Agreement Provisions (2)

- Article 40
  - Members agree that some licensing practices or conditions pertaining to intellectual property rights which restrain competition may have adverse effects on trade and may impeded the transfer and dissemination of technology.
  - Nothing in this Agreement shall prevent Members from specifying in their legislation licensing practices or conditions that may in particular cases constitute an abuse of intellectual property rights having an adverse effect on competition in the relevant market. As provided above, a Member may adopt, consistently with the other provisions of this Agreement, appropriate measures to prevent or control such practices, which may include for example exclusive grantback conditions condition preventing challenges to validity and coercive package licensing, in the light of the relevant laws and regulations of that Member.

Methodology

Using a comparative law and policy approach, my research project examined ‘pay for delay’ cases in China and Korea, and contrasts them with the situation in Japan, where despite having advanced generic medicines production capabilities and an attractive domestic market for medicines, there have been no public cases to date where authorities were required to assess the legality of ‘pay for delay’ agreements.

The Shadow of *FTC v. Actavis* (2013)

- While U.S. Supreme Court cases are not binding law for other countries, the Actavis has had a strong influence in other jurisdictions regarding how 'pay for delay' agreements should be assessed.
- U.S. Supreme Court case that established a binding legal precedent (in the U.S.) that the legality of reverse payment agreements under antitrust law should be determined by a rule of reason analysis.
- Patent on Solvay – a drug used to treat low testosterone levels. Involved a deal to share in Solvay's profits while 2 generic manufacturers committed to refraining from entering the market until approximately 5 years before the patent expired, and to abandoning any challenges to Solvay's patent.
- Rule of Reason analysis: a methodology whereby competition authorities or courts attempt to evaluate the pro-competitive features of a restrictive business practice against its anticompetitive effects to determine whether the practice should be prohibited as a matter of antitrust or competition law. Decided on case-by-case basis.

China

› *AstraZeneca v. Jiangsu Aosaikang Pharmaceutical (2021)*

- Bristol-Myers Squibb and AstraZeneca jointly develop saxagliptin, a medicine used to treat Type II diabetes
- In 2011, Jiangsu Vcare PharmaTech Co., Ltd. Files a request for invalidation of the saxagliptin patent in China.
- BMS and Jiangsu Vcare enter into a settlement agreement – Jiangsu Vcare withdraws challenge to patent within 5 days of signing the agreement, BMS agrees not to sue Jiangsu Vcare for patent infringement up until 1 January 2016. Patent expires in March 2021.
- BMS assigns patent rights to AstraZeneca; AstraZeneca files infringement lawsuit against Jiangsu Aosaikang in 2020. Lower court rules for Aosaikang, because Aosaikang began manufacturing within the permitted period.
- AstraZeneca appeals to the IP Court of the Supreme People's Court. Files motion to withdraw the appeal in April 2021.

China

› *AstraZeneca v. Jiangsu Aosaikang Pharmaceutical (2021)*

- Supreme People's Court allows withdrawal, but pronounces that:

reverse payment agreements in the pharmaceutical sector are subject to antitrust scrutiny utilizing the following factors:

1. Does the contract potentially eliminate or restrict competition in the relevant market or otherwise constitute a monopolistic agreement?
2. Does the contract substantially prolong the duration of the patent holder's market exclusivity and delay or exclude market entry by generic drug applicants?
3. Where the reverse payment settlement involves a covenant not to challenge the underlying patent, whether, had the generic drug applicant not withdrawn its petition for invalidation, the patent could have been invalidated.
4. Whether unjustified compensation has been offered to the generic firm for withdrawing its request for patent invalidation, as this could be evidence that the patent could likely have been invalidated.

Korea

- GlaxoSmithKline and Dong-A deal (2011)
  - Case involves Zofran, an anti-nausea medicine for which GSK had process patent
  - Dong-A developed a generic using different process, patented it, and had already begun to sell it in Korea
  - Dong-A agrees to withdraw its product from the market (unreasonable restraint on competition); awarded right to sell Zofran in national/public hospitals and an anti-viral, Valtrex + 100 million won (the reverse payment)
  - Market defined as 'serotonin antagonists anti-nausea' market, Zofran represented between 50%-95% of the market
  - E-mails show GSK saying difficult to prove patent infringement, but need to file suit to secure settlement
  - KFTC decision upheld by Seoul High Court and Supreme Court
- AstraZeneca and Alvogen Korea, Co., Ltd. Deal (2022)
  - Alvogen suspended its plan to release a generic version of Zoladex, a treatment for prostate and breast cancer developed by AstraZeneca, in return for exclusive rights to sell 3 types of products made by AstraZeneca
  - KFTC fines AstraZeneca and Alvogen

Japan

- No reported litigation or action by competition authorities over reverse payment contracts to date
- Possible reasons:
  - no exclusivity for generic first filers and first successful patent challengers?
  - pharmaceutical patent challenges by generics often rejected by Japanese courts?
  - price differential between patented medicines and generics are less than elsewhere?
  - more likely:
    - *generics under legal obligation to ensure stable supply when seeking registration*
    - *patent linkage forces patent owners to agree on price w/ generics for national health insurance system (usually negotiated with multiple generics)*

Lessons from the East Asian Experience

- *Countries across Asia may wish to review the standards by which reverse payment agreements will be evaluated*

  Rule of Reason v. Per Se; Capacity of Competition Authorities

- *Countries in Asia may wish to consider complementing their competition review of reverse payment agreements with appropriate health laws and policies*

  In Re: Opana ER Antitrust Litigation (2022), FTC (2017)

  Lessons from the Japanese example

- *Developing countries may consider requesting technical assistance and capacity building from East Asian countries that have either experienced cases involving reverse payment agreements, or have developed a strategy to deal with the issue, to inform their own response to this issue*

Concluding Thoughts

- Countries will increasingly exercise their policy options within the permitted scope of their international agreements
- The increasing importance of the interface between competition law and intellectual property law
- Re-thinking patentability in the age of AI – it's not just a copyright issue

Thank You!