Recent Patent Settlement Case In Korean Pharmaceutical Industry

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Background

- Importance of Generic Drugs in Korea
  - Price of generics – 80% of original brand drugs (much higher than in EU/US)
  - Partly due to obligatory National Health Insurance system where drug price is not important factor of doctor/patient' choice
  - Reversely, generics are important for sound public insurance system & non-insured disease/patients

- No Exclusive-Right-to-Sell of First Generic as based on Hatch-Waxman Act in US yet established
  - Expected to be introduced in 2015 according to Korea-US FTA signed in 2007 and made effective in 2012 (delayed for 3 years)
  - Incentives, magnitude, and exclusionary effect to delay generic expected to increase with the adoption

GSK Case – Facts 1

- Glaxo Group Ltd. & GlaxoSmithKline Developed *Ondansetron* to fight Nausea and subsequently Produced & Sold *Zofran* with *Ondansetron* API
  - Applied for manufacturing method patent for *Ondansetron* 1/25/1985
  - Patent registered 8/8/1992
  - Started to sell *Zofran* 1996 to take 48% M/S (2000)

- Dong-A, Korea's No.1 Pharmaceutical Company Separately Developed *Ondansetron*
  - Applied for a separate manufacturing method patent 7/16/1997, arguing independent 2 new methods of producing *Ondansetron*
  - Patent registered 5/29/1999
  - Started to sell *Ondaron* with *Ondansetron* API

GSK Case – Facts 2

◆ GSK Warn of Patent Infringement in March 1999

- Dong-A filed for a passive trial to confirm the scope of its patents immediately at Patent Court
- GSK filed a patent infringement suit in October 1999 at Seoul District Court

◆ GSK/Dong-A Signed 3 Agreements to End Suits 4/17/2000

① Conciliation Agreement to Settle the Disputes

- ✓ Dong-A stop production/sale of *Ondaron* for next 5 years
- ✓ Dong-A withdraw the filing of passive trial to confirm patent scope and shall not file any other patent suits against GSK
- ✓ GSK withdraw its patent infringement suit

GSK Case – Facts 3

② Sale & Supply Agreement for *Ondansetron*

- ✓ GSK grant national/public hospital sales rights of *Zofran* to Dong-A
- ✓ GSK give significant incentive for high sales performance
- ✓ Dong-A shall not develop/produce/sell any medications similar to *Zofran*

③ Exclusive Sales Rights of *Valtrex* (completely different medication, yet-to-be-released at the time)

- ✓ GSKs give € 70,000 cash/year for 5 years
- ✓ Dong-A shall not develop/produce/sell any medications similar to *Valtrex*

◆ Renewal of the 'Sale & Supply Agreement'

- Original agreement renewed after 5 year expiration & continue effective until present

GSK Case – KFTC Action & Appeal

- KFTC Conducted Pharmaceutical Sector Inquiry in 2010
  - Known to get inspired by EC's activity in 2009

- Inquiry Revealed GSKs/Dong-A Patent Settlement
  - Led to formal investigation and corrective measures in 2011
  - Found violation of Art. 19 (equivalent to Art. 101 TFEU) of Monopoly Regulation and Fair Trade Act ('MRFTA')
  - Fines of € 2 Million (GSK) & € 1.5 million (Dong-A)

- Case Appealed to Seoul High Court in 2011
  - Mostly Dismissed in 2012
  - Presently pending at Supreme Court for final review

GSK Case – Seoul High Court Decision

<Issue 1> Exemption for Exercise of Patent Rights

◆ Art.59, MRFTA - "This Act shall not apply to any act which is deemed as a justifiable exercise of the right under the Copyright Act, the Patent Act, the Utility Model Act, the Design Protection Act or the Trademark Act."

◆ Interpretation

- Finding whether 'justifiable exercise' or not shall depend upon principles of patent laws not competition laws
- Expressly adopted Scope of Patent test
- Explicitly acknowledged efficiency of patent dispute settlement while conscious of anti-competitive potential

GSK Case – Seoul High Court Decision

<Issue 1> Exemption for Exercise of Patent Rights

◆ Ruling

A. "The provision prohibiting the production and sale of *Ondaron* is a valid exercise of patent rights b/c there exist no clear evidence of patent invalidity or no infringement."

B. "Yet, the 3 agreements went beyond the justifiable scope and cannot be deemed to be a valid exercise of patent rights," considering that

① the original agreement also stipulated that the prohibition lasted 3 more months after the patent expired on 1/25/2005 and remained effective until present

GSK Case – Seoul High Court Decision

<Issue 1> Exemption for Exercise of Patent Rights

◆ Ruling

② It prohibited the production and sale of products that could have been produced in different methods from *Ondansetron* and in competition with *Zofran*

③ It restricted the R&D, production and sales of products similar to *Valtrex* that has no implication on the disputed patent rights

④ It reversely granted the patent infringer considerable economic benefits beyond normal magnitude and anti-competitive intent can be inferred from this situation

GSK Case – Seoul High Court Decision

<Issue 1> Exemption for Exercise of Patent Rights

◆ Reasoning A

- If a party acknowledges that it has infringed upon another's patent and agrees to measures so that there is no further infringement (including, stop of production of product at issue and stop of usage of method at issue), even if there is latter determination that there was no infringement,

- this can be deemed to be valid exercise of patent rights and not in violation of competition laws as long as it is not obvious that the patent at issue is invalid or that the competing enterpriser has not infringed upon the patent.

GSK Case – Seoul High Court Decision

<Issue 1> Exemption for Exercise of Patent Rights

◆ Reasoning B

- However, “the conduct shall be an unfair exercise of patent rights and subject to competition laws” when

① If it is obvious that the patent at issue is invalid or that the competing enterpriser has not infringed upon the patent and the patentee and the competing enterpriser agree to limit competition in the market, or

GSK Case – Seoul High Court Decision

<Issue 1> Exemption for Exercise of Patent Rights

◆ Reasoning B

② If any such agreement stipulates that the competing enterpriser shall not release related products even after the patent expires, or

③ In cases of [method patents], if any such agreement prohibits the research, production and sale of products similar to the product produced by the patented method, regardless of the production method, or

GSK Case – Seoul High Court Decision

<Issue 1> Exemption for Exercise of Patent Rights

◆ Reasoning B

④ If any such agreement prohibits research or experiments that the competing enterpriser could conduct without patent infringement until the expiration of the patent, so that the competing enterpriser cannot release products immediately after expiration of the patent and in effect, extends the monopoly of the patentee, or

⑤ If any such agreement prohibits the R&D or release of related products that have no direct relation to the patent at issue.

GSK Case – Seoul High Court Decision

<Issue 2> Anti-Competition Effects w/r/t *Ondaron*

◆ Ruling

- "The agreement to restrict the production and sale of the competing product *Ondaron* even after the patent expires is a violation of Art. 19 of the MRFTA."

◆ Reasoning

- The agreement reduced the production of anti-nausea medication based on *Ondansetron* and thus evidently restricted competition in the relevant market.
- Even if it was a fact that other competing medications were put on sale in market and consumers had opportunities to choose, the anti-competition effect is not mitigated.

GSK Case – Seoul High Court Decision

<Issue 3> Anti-Competition Effects w/r/t Medication Competing with *Zofran* and *Valtrex*

◆ Ruling

- "Restriction of Dong-A's R&D and production of medication in potential competition with *Zofran* or *Valtrex* is found anti-competitive."

◆ Reasoning

- Joint marketing b/w the two companies by way of granting exclusive rights to sell can be efficient and pro-competitive.
- But it does not justify such restrictions b/c same joint marketing effect can be achieved by alternative ways, *e.g.* limiting sales of third party's competing products, etc.

Conclusion

- Generally agreed that pay-to-delay theory is possible in Korea where exclusive rights for first generic is not established presently
  - Introduction of exclusive rights designed similar to Hatch-Waxman Act system in 2015 will create increased incentives for reverse payments

- Currently Scope of Patent test is Effective Standard
  - KFTC and Seoul High Court depended upon the test to find the agreements in violation of MRFTA
  - Removing existing strong competitor was found lessening consumer choice/welfare
  - Two panels of Courts for each plaintiff reached identical conclusion to dismiss GSK/dong-A's appeal

Conclusion

- Supreme Court's Final Decision Draws Much Attention
  - Establishment of exclusive rights in 2015 designed close to Hatch-Waxman Act system may create increased incentives for reverse payments
  - Despite of successful construction of National Health Insurance system, worsening financial source requires lower medication price
  - Rule of Reason test adopted by *Actavis* Decision in US may be found of reference to Supreme Court to structure reasoning for final decision

- Under either test, critical factor to find liability could be the amount of reverse payment and/or litigation cost that should be balanced with justifications partly in relation with validity of patent rights
  - In Korea where litigation cost including attorney fees is substantially cheaper than US, lower payment amount can be a good indicator of anti-competitive intent

Thanks.

Q & A

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