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GENERIC PHARMACEUTICALS

-- Note by Korea --

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More documents related to this discussion can be found at <http://www.oecd.org/daf/competition/generic-pharmaceuticals-competition.htm>.

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DEVELOPMENTS IN LAW ENFORCEMENTS RELATED TO THE ADOPTION OF SYSTEM MONITORING ANTICOMPETITIVE BEHAVIORS IN THE PHARMACEUTICAL SECTOR

1. Overview

1. The Korea Fair Trade Commission (KFTC) conducted “a fact-finding investigation on IPR in pharmaceutical sector (the fact-finding investigation)” in June 2010 to figure out current condition of signed agreement and disputes related to IPRs in the industry. The authority conducted the investigation via documents on 48 pharmaceutical companies’ ethical drugs being sold, approved or being applied for approval; recent developments in patent disputes; and signed contractual agreement regarding ethical drugs.

2. The KFTC investigated the pay-for-delay deals between pharmaceutical companies by analyzing the materials obtained from the fact finding investigations, and also distributed the Best Trade Practices to induce voluntary correction of unfair contractual practices. In particular, regarding the pay-for-delay deal between GlaxoSmithKline (GSK), a multinational pharmaceutical, and Dong-A Pharmaceutical (Dong-A), a company ranked No.1 in sales in the domestic market, the Commission concluded that the originator and the generic maker formed a cartel to share the market, and imposed remedies and surcharges of about 5 billion won in Oct 2011

3. After conducting the fact-finding investigations on pharmaceutical sector, drug approval system in Korea had changed a great deal in 2012. That is, as KORUS FTA came into effect in March 2012, subsequently the Approval-Patent Linkage System (APLS) was adopted, systems concerning marketing prevention and exclusive sales right which are at the center of the APLS will be implemented in 2015 after three years of grace period.

4. In the past, policies for drug sales approval and patent registration were enforced separately, so authorities were able to grant approvals to generic makers upon their applications even for patented drugs. Patent disputes were resolved in patent trials. However, when the APLS is fully implemented, generics of patented new drugs could face suspension of its marketing approval for a certain period of time (the marketing prevention system), and the first applicant for generic drug approval who have successfully challenged a patent of an original drug will be able to sell the generics exclusively for a certain period (the exclusive sales right).

5. Due to the enforcement of Approval-Patent linkage system, it is expected that there will be increase in both patent disputes among pharmaceuticals and pay-for-delay deals. In responding to such possible changes, the KFTC is working on to implement a system monitoring anti-competitive behaviors in the pharmaceutical industry.

2. Antitrust enforcements on pay-for-delay case: a GSK-Dong-A Pharmaceutical case

2.1 Background of the case

6. After conducting a fact-finding investigation in 2010, the KFTC detected violations by reviewing a series of contracts made between GSK and Dong-A which are suspected as entering into a pay-for-delay agreement.

7. GSK, an originator, was selling its new drug “Zofran” manufactured using an active ingredient “Ondansetron” in the anti-nausea market, and process patent of Zofran was effective by 25 Jan 2005. Dong-A, a competitor of GSK, acquired a patent after devising a process different from that of GSK and started selling “Ondaron”, a generic drug of Zofran, in Sep 1998 with a price tag amounted to 90% of the price of Zofran. In March 1999, GSK sent a notice of warning to Dong-A, stating that Dong-A infringed GSK patent and subsequently in May 1999 Dong-A filed passive trials to confirm the scope for patents against GSK. The patent dispute between the two was initiated as GSK, in response to the trials filed, brought a patent infringement suit in Oct 1999.

2.2 Findings

8. In the court proceedings, GSK and Dong-A exchanged a letter of intent in Dec 17th 1999 and signed a settlement agreement (withdrawal of litigation) and a sales agreement of Zofran and Valtrex in April 17th 2000. Under the agreements, although GSK already secured sales and distribution networks for Zofran, the company forced withdrawal of “Ondaron” from the market and provided Dong-A with the right to sell the drug in public/national hospitals with conditions attached that Dong-A will not develop, manufacture, and sell drugs which could become competing products of Zofran and promised to offer 25% of sales amount to Dong-A when exceeding 80% of sales target and gives 7% of sales amount as an incentive starting from three years of sales. Besides regarding its new drug Valtrex (an anti-viral medication) which GSK considered selling directly on its own, GSK endowed the exclusive right to sell Valtrex to Dong-A and promised to award 100 million won annually to Dong-A for five consecutive years regardless of sales volume.

2.3 Relevant market definition

9. In handling the pay-for-delay deal between GSK and Dong-A, the KFTC defined the relevant market as the “serotonin antagonists anti-nausea market” which is the fourth level under the ATC classification used by the WHO, and also the market for anti-nausea which uses Ondansetron as an API (fifth level under the ATC classification). Zofran represented about 50% of share in the market for 4th level under the ATC classification, and more than 95% in the market for 5th level.

2.4 Illegality of behavior

10. The KFTC concluded that the agreement constitutes an act of “delay”, excluding Ondaron, the only competitor drug which was already sold, from the market and preventing Dong-A from developing and selling competing products in the future.

11. In addition, the KFTC decided that the behavior in which GSK awarded the right to sell Zofran in national/public hospitals and the exclusive right to sell Valtrex to Dong-A constitutes an act of “payment.”

12. Dong-A, the largest pharmaceutical in Korea, has significant marketing power and at that time it already developed and introduced “Ondaron” to the market, registered other process patent, and filed passive trials to confirm the scope for patents in the Korean Intellectual Property Tribunal. Meanwhile, GSK at that time was internally exchanging emails stating that it is hard to find concrete evidences

showing that Dong-A infringed GSK patent, and there is a need to file patent infringement suit to secure advantages in a settlement process with Dong-A.

13. After the two companies agreed to withdraw litigations and signed the sales right agreement, market share of Zofran increased from 47.5% in 2000 to 47.7% in 2001. However in 2005 at a time when more generics were introduced to the market after Zofran patent expired, Zofran's market share fell drastically to 14.1% in 2009 from 32.9% in 2005. The KFTC conducted economic analysis on the case and estimated that the agreement enabled GSK to generate about 16 billion won in sales though such unfair trade practices.

2.5 Measures imposed

14. The KFTC concluded that the agreement between GSK and Dong-A violated Article 19(1) of the MRFTA, and subsequently imposed 5 billion won in surcharge and non-compete clause injunction. Dong-A and GSK appealed the KFTC decision but the High Court and the Supreme Court both ruled for the KFTC decision in Oct 31st 2012 and Feb 27th 2014 respectively, concluding that the agreement on withdrawal of "Ondaron", a competing drug of "Zofran" constitutes unreasonable restraint on competition.

2.6 Result of imposing measures

15. The investigation on the case is meaningful since the case demonstrated the need for consistent monitoring on pay-for-delay deals after the adoption of the Approval-Patent Linkage System as it was turned out that pharmaceutical companies have sufficient causes to enter into pay-for-delay agreements even when there was no approval-patent linkage scheme in place. Also the case is meaningful since it served as a warning to such practices which have become routine in pharmaceutical industry.

3. Policy improvements: Introduction of a system monitoring anticompetitive activities in pharmaceutical market

16. The Approval-Patent Linkage System in pharmaceutical sector is consisted with patent registration, notice, and marketing prevention and exclusive sales right. The registration and notification system has enforced since March 2012, and the marketing prevention and exclusive sales right system will be implemented in March 2015.

17. The registration and notification systems which are already in place enable patentees to list their patent to the patent list (Green List) and they are the systems under which generic makers applying for marketing approval of their generics related to listed patents to the Ministry of Food and Drug Safety (MFDS) must notify the patent owner of the application to the MFDS for market approval.

18. Under the marketing prevention system, when a patent owner of new drug concluded that a generic drug applied for marketing approval violates the patent, the patentee can seek suspension of approval granted to the generic drug and the MFDS can suspend the approval as much as 12 months. The exclusive sales right system is a scheme to increase incentives for generics' entry into market under which an exclusive sales right for as much as 12 months is conferred to the first applicant for generic drug approval who has successfully challenged a patent of an original drug. The marketing prevention system and the exclusive sales right system are both under legislation process.

19. Both the marketing prevention and exclusive sales right system under the Approval-Patent Linkage system contain restraints on entry of generics related to patent disputes. Due to the restraints, patent disputes are much likely to increase between originators hoping to block the sales of generics and generic makers trying to receive exclusive rights to sell generics. As product patents of blockbuster drugs are soon to be expired, drug patent disputes have increased every year. In particular, patent litigation costs

are relatively low and the average litigation period is less than one year which is much shorter than other countries.

20. In order to monitor pay-for-delay deals between pharmaceuticals which are expected to increase after the adoption of Approval-Patent Linkage System, the KFTC plans to introduce a regulation requiring pharmaceuticals to submit documents related to agreements on dispute settlements or exclusive sales right when the companies made such agreements.

21. Considering the followings: that the approval-patent linkage system contains restraints on market entry; there are limited pharmaceuticals who can challenge patents; and after seeing the success in challenging patents, other generic makers' willingness to challenge patents would be enhanced, the KFTC's surveillance over pay-for-delay deals is extremely needed to restrain the unreasonable exercise of patent rights in pharmaceutical industry.

22. Especially under the current drug pricing system in Korea, drug prices can be lowered depending on generics' entry on to the market, therefore the entry of generics into the market has huge impact on welfare promotion for Koreans as consumers can have access to the generics which are offered at lower prices but have same effectiveness comparing with the original new drug.

23. The KFTC has had consistent consultations with the Ministry of Food and Drug Administration, the Ministry of Health and Welfare and the Korea Intellectual Property Office, so that the Approval-Patent Linkage system would be more toward competition promotion. Revision of the Pharmaceutical Affairs Act is announced to be implemented and includes policies pushed forward by the KFTC now.

4. Conclusion

24. The KFTC concluded the GSK-Dong A pay-for-delay case in 2011 and distributed the Best Trade Practice in a bid to create an environment where businesses sign contracts in a reasonable manner, and by doing so the KFTC has continuously put efforts to correct anti-competitive contractual practices in the pharmaceutical industry.

25. As part of preparation for the enforcement of the Approval-Patent Linkage System, the Commission is working on to implement a system that monitors anti-competitive behaviors in the pharmaceutical industry. Starting from next year, the KFTC will beef up its monitoring efforts on pay-for-delay deals after it starts to receive documents on dispute settlement agreements from pharmaceuticals.

26. In the future, the Commission will make efforts to reinforce consumers' rights to make choices and their access by continuously monitoring unfair trade behaviors in the pharmaceutical market so that fair competition would be facilitated in the pharmaceutical market which is a monopolistic market protected by patent right.