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Pay-for-Delay Settlements and Competition

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I am very glad to be here today and to have a chance to discuss the issues of competition policy and 'pay-for-delay' settlements (also known as 'reverse payment' or 'exclusion payment' settlements) in the pharmaceutical industry. Thanks to Mr. Marcus Meier's presentation, I realized that the problem of pay-for-delay settlements is one of the most challenging issues in contemporary competition law and policy. As Mr. Meier most excellently introduced the United States' experience in dealing with pay-for-delay settlements to us, I believe Korean participants in here could get some valuable insights in dealing with the *similar* issues in Korea.

Because the issues of pay-for-delay settlements has so many complex and tangled sub-problems (e.g., high risk of new drug development, cut-throat competition between brand name and generics drugs, restrained health care budget, uneasy relationship between antitrust and patent, split decisions of courts, Supreme Court's denials of certiorari, unclear regulatory statues, and etc), it is beyond my ability to discuss every possible aspect of the issues in detail. So I would like to limit my discussion to three topics: first, the U.S. Supreme Court's continuous denials of certiorari in pay-for-delay cases; second, Kohl Bill; and last, Korean approach to the potential problem of pay-for-delay settlements.

1. Supreme Court's continuous denials of certiorari

Federal courts have varied wildly in their opinions on legality of pay-for-delay settlements. Moreover, the Supreme Court has consistently denied all certioraris in pay-for-delay cases. Just one month ago, in March 2011, the Court denied certiorari in the case of *Louisiana Wholesale Drug Co., Inc., et al. v. Bayer AG, et al***.** (Section 1 of the Sherman Act). In June 2009 the Court also denied certiorari in the case of *Arkansas Carpenters, et al. v. Bayer AG and Bayer Corp., et al.* (Section 1 of the Sherman Act). In 2006 the Court denied certiorari in the case of *Shering-Plough Corp. v. FTC* (Section 5 of the FTC Act). It seems to me that the Supreme Court sent some signals to Federal Trade Commission ("FTC") and Department of Justice ("DOJ").

My first question to Mr. Meier is this: Whether FTC has a kind of strategy of persuading the Supreme Court to hear a pay-for-delay case in the foreseeable future, if yes, what is it?

2. Legislation

I read an article saying that the U.S. Senator Kohl has tried to introduce a legislation to prohibit pay-for-delay settlements. I think most participants in here, including me, are interested in 'Kohl Bill.' I will be glad to listen to background and foreseeable future of Kohl Bill from Mr. Meier.

3. Korean Context

Unlike the U.S., the structure of pharmaceutical industry in Korean can be characterized as medium- and small-sized generic drug companies with low level of pharmaceutical technology. In addition, Korea does not have any regulatory statute equivalent to the Hatch-Waxman Act. For these reasons, it is hard to say that the *same* kind of problems that pay-for-delay settlements in Hatch-Waxman patent litigations have raised in the U.S. would happen in Korea. Indeed, to my best knowledge, there has been no reported case in which brand name companies agreed to pay generic competitors to stay out of market. But, of course, it is also hard to say that there is a zero possibility of pay-for-delay settlements in the future.

Anyway, in March 2001, Korean Fair Trade Commission (KFTC) revised its '지식재산권의

부당한 행사에 대한 심사지침'('Guideline on Abuse of Intellectual Property Rights'[1]) to deal with the potential problem of pay-for-delay settlements. The Guideline III.5 says that there is a *high possibility of illegality* of pay-for-delay settlements under some circumstances, e.g., the parties to the settlement in question are competitors each other, the objective of the settlement is related with restrains of competition, the settlement is purported to delay market entry after the expiration date of the patent, the parties already recognized that the patent in question was invalid, or the invalidity of the patent is certain.[2] These circumstances may lead a prima faces case. However, it should be noted that courts do not have to follow the Guideline.

The Guideline also illustrates a hypothetical case of pay-for-delay settlement in the pharmaceutical industry. The Guideline only refers to the applicability of Art.19 (Prohibition of concerted acts] of the Monopoly Regulation and Fair Trade Act ("MRFTA")[3] to pay-for-delay settlements, but it seems to me that either Art. 3-2 (Prohibition of abuse of market dominance) or Art.23 (Prohibition of unfair trade) also can be applied.

Among other Paragraphs of Art.19, it seems that Para.1 (Prohibition of price-fixing), Para.2 (Prohibition of market division), and Para.9 (Prohibition of any agreement causing substantial restraints of competition) may be applied to regulate pay-for-delay settlements. Even if a pay-for-delay settlement amounts to horizontal price-fixing, Art. 19. requires KFTC to apply the rule of reason to it. This is the big difference between Korean competition law and the U.S. Antitrust jurisprudence. However, KFTC has applied *de facto* the per se rule to price-fixing cases. So if KFTC find that a pay-for-delay settlement amounts to horizontal price-fixing or market division, the per se rule would be applied. (Otherwise the rule of reason would be applied.) But before applying the per se rule, KFTC must previously decide whether a pay-for-delay settlement

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[1]Unofficial English version of the Guideline, 'Review Guideline on Undue Exercise of Intellectual Property Rights' ("Guideline") is downloadable at KFTC's website, <http://eng.ftc.go.kr/files/static/Legal_Authority/Review%20Guidelines%20on%20Undue%20Exercise%20of%20Intellectual%20Property%20_Rights.pdf>. The authentic text is only Korean version. English version may mislead foreign readers.

[2] See Guideline, p. 22. Guideline describes pay-for-delay settlements as "Unfair agreement in patent dispute"(특허분쟁과정의 부당한 합의).

[3] Unofficial English version of MRFTA is downloadable at KFTC's website, < http://eng.ftc.go.kr /files/static/Legal_Authority/Monopoly%20Regulation%20and%20Fair%20Trade%20Act_Aug%203%202007.pdf>. The authentic text is only Korean version. English version may mislead foreign readers.

amounts to horizontal price-fixing (or market division) or not. In this sense, KFTC and courts are supposed to take a case-by-case approach to pay-for-delay settlements, and there is no room for the per se rule (legal or illegal) approach.

While the Guideline stipulates a presumption of illegality of pay-for-delay settlements, MRFTA the rule of reason. With regard to the difference between the Guideline and the MRFTA, I will be glad to listen to Mr. Meier's comment. I really appreciate Mr. Meier for his stimulating contribution in more developing the issues of pay-for-delay settlements in Korea. Thank you!