JAPAN

JFTC's attitude towards Reverse Payment

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t > pT

// *t* // is a generic drug makers' waiting period to enter the market by patentee's reverse payments. "*p*" is a probability that the patent will be judged as valid in the lawsuit. "*T*" is a remaining patent term. Thus, "*pT*" is an expected value of remaining patent term as valid. If "*t>pT*", reverse payments have an effect to delay the entry. Can't seem to correct these line breaks

Below is an excerpt of the report "Competition and Research and Development Incentives in the Pharmaceutical Market – Through Examinations of the Impact of the Entry of Generic Drugs on the Market," dated October 7, 2015 by Competition Policy Research Center.

See: http://www.jftc.go.jp/houdou/pressrelease/h27/oct/151007_files/151007gaiyou.pdf

Japan Fair Trade Commission Report

1. The situation of generic drugs in Japan

1) The share of generic drugs in Japan

The share of generic drugs in the ethical drug market in Japan has been rising as a result of a number of policies to promote the use of generic drugs. Compared with Western countries, however, the share remains at a lower level (for example, 49% in Japan, 92% in the US and 83% in Germany between October 2013 and September 2014).

2) Systems characteristic of the ethical drug market in Japan

a. Price regulation system

The retail prices of drugs are determined by the state. Under the price regulation system, the public prices of generic drugs, when newly introduced to the market are, in principle, 60% of the public prices of original drugs. The prices will then be changed on a regular basis in light of the prevailing market prices (wholesale prices set freely by manufacturers to medical institutions and other organisations). Unlike in the EU or the US, direct price competition in the consumer (patient) market does not appear to be active.

b. Patent linkage and ex-ante coordination

As for issues related to patent infringements by generic drugs, it is regarded as a precondition in the EU and the US to resolve the issues through patent infringement suits that are filed by the manufacturers of original drugs against the manufacturers of generic drugs. In Japan, on the other hand, if the patent for the active ingredients of original drugs remains valid, approval for the manufacture and sale of generic drugs will not be granted; this is termed "patent linkage". In addition, the manufacturers of both original and generic drugs examine possible patent issues between the original and generic drugs, and then they report its results to the government (the Ministry of Health, Labour and Welfare; ex-ante coordination.

3) Economic analysis related to the market structure

Unlike in the US, in Japan, price competition between original drugs and generic drugs is limited even after the market entry of generic drugs, compared with price competition among generic drugs. However, if the share of generic drugs exceeds a certain level, it is possible in the future that the prices of original drugs will also fall to a similar extent to the fall in the prices of generic drugs as a result of pressure from the competition.

2. The situation in the EU and the US

1) Trends of prices

In general, after the entry of generic drugs, in line with their prices, the prices of original drugs also fall significantly.

(2) Existence of activities that may have any competition law concerns (reverse payments)

In the EU and the US, the manufacturers of original drugs sometimes file patent infringement suits against the manufacturers of generic drugs, even after the expiry of key patents related to original drugs, such as the active ingredients, on the grounds of the continued existence of other related patents and other factors. In such suits, there are cases where, at the point of the settlement, the manufacturers of original drugs make large payments for the manufacturers of generic drugs – known as 'reverse payments' These cases are considered to be anti-competitive practices, done in order to delay the market entry of generic drugs.

3. The implication for Japan

Under the system and market structure in Japan, the country is considered to be an environment in which reverse payments, which potentially become a competition issue as in the EU and the US, are less likely to take place. However, if the share of generic drugs continues to grow and the pressure of the competition from generic drugs increases, incentives for engaging in reverse payments may increase in the same manner as in the EU and the US in the future. For this reason, it is necessary for the JFTC to carry out monitoring as needed and consider ensuring that the Anti-Monopoly Act is actively applied to such cases.

Practical tips

In Japan, no competition law cases – where reverse payments (pay for delay) became a direct issue – exist and discussion among academics has not fully begun. Professor Odagiri, ex JFTC Commissioner, gave the following reasons why it is difficult for actual reverse payments cases to arise in Japan: 1) ANDA's 180-day exclusivity, to be enjoyed by first filer does not exist, 2) even if one is successful in preventing a first filer's entry, it cannot prevent the entry of others, 3) drug price reduction by a generic's entry is not as severe as it is in the US, 4) unlike ANDA's paragraph IV filing, patent linkage requires no infringement of the original drug maker's product patent, or use patent.

The difference in ANDA under the Hatch-Waxman Act (1 and 2 above) and the regulation on drug prices (3 above) could constitute reasons why it is difficult for actual reverse payments cases to arise in Japan.

How about 4 above? For the product patent and the use patent, approval by the MHLW will not be granted unless the JPO issues an invalidation decision, however it is possible to settle by reverse payments during an invalidation trial. As the product is not yet launched, a stable supply obligation will not be an obstacle to accept brand name company's reverse payments settlement offer for generic drug makers.

Therefore, irrespective of 4 above, reverse payments cases could arise theoretically. However, as no product patents were invalidated so far and only a few use patent were invalidated, in reality the incentive for the generic drug makers to file invalidation trial and the incentive for the brand name company to settle by reverse payments is not high. Therefore, for the product patent and the use patent, (not 4 above) but a low invalidation rate may be the reason why it is difficult for actual reverse payments cases to arise in Japan.

For the formulation patent and the method patent, the Japanese patent linkage system requires advance adjustment between the brand name company and the generic drug maker before NHI price listing. At this advance adjustment stage, a generic drug maker can withdraw NHI price listing and delay the launch of generic drugs by adjustment. Thus, irrespective of patent linkage system, reverse payments cases could arise theoretically. However, because of 1 and 2 above, multiple generic drug makers can enter the market simultaneously and a brand name company usually does advance adjustment with multiple generic drug makers.

Unless a brand-name company adjusts with all these generic drug makers, a generic drug's entry will not be enjoined. Thus, a brand name company should make payments to multiple generic drug makers to delay the launch. If this expense does not match the profit of enjoining generic drugs' entry, the brand name company will lose any incentive to make such a payment.

If at least one generic drug maker does not accept settlement, this generic drug maker will acquire market share in advance. Thus, a generic drug maker's incentive to accept reverse payments will not be high unless all the generic drug makers accept such an offer. Therefore, at advance adjustment stage, 1 and 2 above, may be the reasons why it is difficult for actual reverse payments cases to arise in Japan. Under this advance adjustment, even if a brand-name company and generic drug makers cannot adjust, generic drug makers can apply for NHI price listing on their own responsibility.

Thus, in many cases no adjustment is made and the generic drugs are launched, and the brand-name company files a patent infringement lawsuit. During this infringement lawsuit, reverse payment cases could arise theoretically. However, in reality, as the generic drug maker launched with their own responsibility, they will try to comply with stable supply obligation after the launch, and the incentive to accept reverse payments from the brand-name company will become low. Therefore, after launch, stable supply obligation, rather than a patent linkage system, may be the reason why it is difficult for actual reverse payments cases to arise in Japan.

And so, what is the reason actual reverse payments cases have not arisen in Japan so far? Europe shares the same system as Japan, in the sense that no ANDA exists and a regulation on drug price does exist, however actual reverse payments cases have arisen in Europe. Thus, these differences in the system alone cannot fully explain the reason. In my view, Japanese companies' attitude towards regulatory authority may be the actual reason. Japanese companies have a mentality of fearing offending MHLW by not complying with a stable supply agreement and wish to avoid being a 'first penguin' while the JFTC is monitoring.

The JFTC has a strong interest in reverse payments and is planning actively to apply the Anti-Monopoly Act. Indeed, the JFTC unofficially interviewed several pharmaceutical companies regarding reverse payments. Around four years have passed since this report was issued and it is close to holding an 80% share of generic drugs by September 2020. As this report points out, incentives for engaging in reverse payments may increase and an actual case may arise. If reverse payments are considered, it is indispensable to review whether there is an issue under the Anti-Monopoly Act. How Japan-specific factors, in comparison with US and Europe, influence the decision is worthy of attention.

In July 2019, Teva, Endo and Teikoku settled with California State in the Pay for Delay lawsuit. Although this is a US case, it is notable that a Japanese company was involved.