

## JAPAN

## First ruling on damages due to drug price reduction

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Chugai Pharmaceutical sought an injunction against DKSH's importation of maxacalcitol active pharmaceutical ingredient and against Iwaki Seiyaku etc's sales of the defendants' products. A judgment to the following effect became final and binding: the manufacturing method in question was considered to be equivalent to the patented invention and to fall within its technical scope (judgment of March 24 2017, the Supreme Court and judgment of March 25 2016, the Grand Panel of the IP High Court).

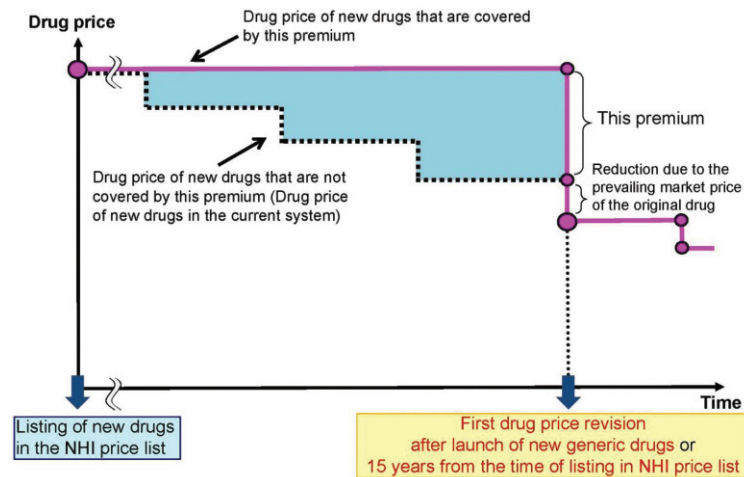
Subsequently, Chugai claimed damages against Iwaki etc who sold maxacalcitol formulations as follows: (i) the market share of the plaintiff's product (Oxarol Ointment) declined due to sales of the defendants' products; and (ii) the drug prices and transaction prices of the plaintiff's products (Oxarol Ointment and Oxarol Lotion) declined due to NHI price listing of the defendants' products.

### Judgment of July 27 2017, Tokyo District Court

The Tokyo District Court (Presiding Judge Okinaka) ordered payment of the following damages: (i) Y203,632,798 to be paid by the defendant Iwaki, Y118,159,458 to be paid by the defendant TAKATA Pharmaceutical, and Y168,223,686 to be paid by the defendant POLA Pharma based on the loss of market share of the plaintiff's product; and (ii) Y579,169,686 to be paid by the defendants based on the decline of the drug price of the plaintiff product. The decision regarding (ii) is as follows.

### Drug price

Drug price refers to the average cost per



unit of a given brand that is necessary for authorised insurance medical institutions and pharmacies to provide a given drug. Authorised insurance medical institutions and pharmacies must charge patients and health insurance associations based on the drug price. On the other hand, no regulations have been imposed on the prices of drugs sold by pharmaceutical manufacturers and distributors (such as wholesalers). However, regulations regarding drug prices are applicable to the amounts charged by medical institutions, etc, thus the prices of drugs sold by pharmaceutical manufacturers and distributors are determined based on the drug prices in practice.

### Declining drug prices and transaction prices

The plaintiff had actually obtained profits from maintenance of prices of the plaintiff's products in accordance with the pricing premium system for the promotion of new drug development and the elimination of off-label use until the defendants' products were included in the NHI price listing. Inclusion of the generic drugs of the defendants in the NHI price listing caused a decline in the prices of the plaintiff's products on April 1 2014.

It can be recognised that if the defendants' products, which infringe the patent right, had not been included in the NHI price listing, the prices of the plaintiff's products would not have been dropped. Therefore, the defendants should be liable for damages relating to a decline in the prices of the plaintiff's products which arose from inclusion of the defendants' products in the NHI price listing.

The defendants assert that maintenance of drug prices cannot be considered to be a legally protected benefit and is based inherently only upon the results of drug price policy established by the Ministry of Health, Labour and Welfare (MHLW). However, the pricing premium system for the promotion of new drug development and the elimination of off-label use actually exists. Moreover, as long as new drugs satisfy prescribed requirements, the pricing premium arising from the aforementioned system is uniformly applicable to such drugs. Such premium is not discretionally stipulated by MHLW. Therefore, maintenance of drug prices can be considered to be a legally protected benefit. Thus, defendants' assertions cannot be accepted.

Regulations regarding drug prices are applicable to amounts charged by medical institutions, etc. Thus, the prices of drugs sold by pharmaceutical manufacturers and distributors are determined based on the drug prices. It can be recognised that inclusion of the prices of the defendants' products in the NHI price listing caused a decline in the prices of the plaintiff's products, and the prices of the plaintiff's products in transactions between the plaintiff and Maruho fell along with the aforementioned decline.

The agreement between the plaintiff and Maruho was reasonable. It could be expected as a matter of course that a decline in the prices of the plaintiff's products would cause a decline in the prices of the plaintiff's products in transactions between the plaintiff and Maruho. In fact, the rate of a decline in the prices of the plaintiff's products in transactions between the plaintiff and Maruho was al-

most the same as that for the relevant drug prices. Therefore, all declines in the prices of the plaintiff's products in transactions between the plaintiff and Maruho can be deemed to constitute damages that fall within the scope of reasonable and probable legal causation regarding inclusion of the defendants' drugs in the NHI price listing.

### **Practical tips**

The claims made separately by Astellas Pharma and Shionogi constitute a previous example of a case in which the question was raised as to whether the damages caused to brand-name pharmaceutical companies arising from price reduction as an exception could be computed as lost profits. However, both claims were resolved by settlement, and no judgments regarding the same were made.

This is the first decision regarding whether the decline in premium pricing would constitute damage and the Court affirmed. Based on this judgment, brand-name pharmaceutical companies may be able to obtain not only damages due to decline of market share but also damages due to decline of premium pricing.