

Unfair Competition	Date	October 28, 2024	Court	Tokyo District Court, 40th Civil Division
	Case number	2024 (Yo) 30029		
<p>- A case in which the court held that when a patentee, etc. of an original drug gives a false response under the Patent Linkage System to the effect that the patent for the original drug and the patent for a generic drug conflict with each other, and if there are special circumstances under which the act of giving such response is found to be significantly inappropriate in light of the purpose of the Patent Linkage System, that act constitutes the unfair competition set forth in Article 2, paragraph (1), item (xxi) of the Unfair Competition Prevention Act as an act of making false allegations that harm the business reputation of a business competitor who applies for marketing approval for the generic drug.</p>				

### Summary of the Decision

The obligor made an allegation (referred to below as the "Allegation") to the Ministry of Health, Labour and Welfare, etc. to the effect that the act of marketing so-called biosimilars of the pharmaceutical product stated in the Attachment "List of the Obligor's Product" attached to this decision (referred to below as the "Obligor's Product") infringes the patent right stated in the Attachment "List of the Patent Right" attached to this decision (this patent is referred to below as the "Patent" and the patent right for the Patent is referred to below as the "Patent Right").

In this case, the obligee argues that the Allegation constitutes the unfair competition set forth in Article 2, paragraph (1), item (xxi) of the Unfair Competition Prevention Act (referred to below as the "UCP Act") and is likely to harm the business interests of the obligee, and seeks a provisional disposition to issue an injunction against the following act, by designating the right to claim for an injunction based on Article 3, paragraph (1) of the UCP Act as the right to be protected by the provisional disposition. The major issue of this case is whether the Allegation is illegal or not.

The obligor must not make an allegation to the Ministry of Health, Labour and Welfare and the Pharmaceuticals and Medical Devices Agency to the effect that the act of marketing the pharmaceutical product stated in the Attachment "List of the Pharmaceutical Product" attached to this decision (referred to below as the "Obligee's Product") infringes the Patent Right.

The court held as below regarding the criteria for determining the illegality of an act of making an allegation under the Patent Linkage System, and presented its case-

specific determination that the Allegation is not illegal.

It is reasonable to consider that when a patentee, etc. of an original drug gives a false response under the Patent Linkage System to the effect that the patent for the original drug and the patent for a generic drug conflict with each other, and if there are special circumstances under which the act of giving such response is found to be significantly inappropriate in light of the purpose of the Patent Linkage System, that act constitutes the unfair competition set forth in Article 2, paragraph (1), item (xxi) of the UCP Act as an act of making false allegations that harm the business reputation of a business competitor who applies for marketing approval for the generic drug.

When comprehensively taking into account various circumstances revealed in this case, it cannot be said that the Allegation is significantly inappropriate in light of the purpose of the Patent Linkage System, and special circumstances as mentioned above cannot be found.

Accordingly, it cannot be said that the obligor's act of making the Allegation constitutes the unfair competition set forth in Article 2, paragraph (1), item (xxi) of the UCP Act.