

Patent Right	Date	September 26, 2024	Court	Osaka District Court, 21st Civil Division
	Case number	2022 (Wa) 3344		
<p>- A case in which the court found a patent infringement and partially (about 78%) upheld the Plaintiff's claim for compensation for damage in a patent infringement lawsuit pertaining to a patent (the "Patent") for an invention titled "Freeze-dried preparation containing high-purity PTH and method for producing the same."</p>				

### Summary of the Judgment

In this case, the Plaintiff, who holds a patent right pertaining to the Patent, alleged that the Defendant's act of manufacturing and selling a medicine by a method that falls within the technical scope of the inventions stated in Claims 1 and 13 in the claims of the Patent (the "Inventions") constitutes infringement of the same patent right, and demanded that the Defendant suspend manufacturing, etc. of the medicine and dispose of its inventory, withdraw an application for NHI price listing, etc., and compensate damage.

The issues (summary) of this case are [i] whether the Defendant's Method falls within the technical scope of the Inventions, [ii] whether there are grounds for invalidation (violation of the clarity requirement, violation of the support requirement, and violation of the requirement to involve an inventive step), and [iii] the amount of damage (marginal profit, specified quantity, reversal, royalty rate, etc.).

In this judgment, regarding Issue [i], in relation to the structure of Constituent Feature 1C ("is a method characterized in that it suppresses contact between solution containing PTH peptide and ozone of 0.1 ppm or less contained in the air within the same facility for manufacturing sterile injectables") of which fulfillment is disputed, the court determined that the Defendant's Method fulfills the same constituent feature. Regarding allegation of Issue [ii], that is, violation of the clarity requirement, the court ruled that a person ordinarily skilled in the art can easily understand that the problem can be solved if contact with ozone is suppressed by an appropriate method, taking into account the purpose of the Inventions stated in the description (to provide a freeze-dried preparation containing high-purity PTH peptide by suppressing contact with ozone), etc., and cast aside the allegation. Regarding allegation of violation of the support requirement, the court also ruled that a person ordinarily skilled in the art can recognize that the problem of the Inventions, that is, to provide a method for manufacturing a freeze-dried preparation containing high-purity PTH peptide, can be solved by

suppressing contact with ozone since the description clearly states that generation of a related substance induced in the air environment within a medicine manufacturing facility is caused by ozone with strong oxidative power, and cast aside the same allegation. Regarding allegation of lack of an inventive step, the court ruled as follows: the primary prior art is not found to disclose a technical idea of suppression of oxidization, which is used as a means for solving the problem in the Inventions, and it is not found that there is a motivation for suppressing contact with ozone of 0.1 ppm or less; the Inventions are found to have a prominent effect. Based on this ruling, the court cast aside the allegation. On that basis, the court upheld the Plaintiff's claims for an injunction against manufacturing and for disposal, but dismissed claims for withdrawal of an application for NHI price listing, etc. Regarding compensation for damage, the court found 10% of the quantity sold by the Defendant to be the specified quantity in light of the market trends of manufactured medicine and the fact that the Inventions made a great contribution to mass production of medicine. The court thus found reversal of presumption for 10% of the quantity sold by the Defendant and found the royalty rate for the specified quantity to be 15%.