

Patent Right	Date	September 26, 2024	Court	Tokyo District Court, 40th Civil Division
	Case number	2023 (Wa) 70178		
- A case in which the court ruled that the medicines manufactured and sold by the Defendant cannot be presumed to have been produced by the manufacturing processes pertaining to the inventions in question under Article 104 of the Patent Act.				

### Summary of the Judgment

In this case, the Plaintiff alleges as follows: the manufacturing process (hereinafter referred to as the "Defendant's Process") pertaining to the products stated in the List of Defendant's Medicines attached to this judgment (hereinafter referred to as the "Defendant's Medicines") falls within the technical scope of the inventions (hereinafter referred to as the "Inventions") pertaining to the patents in question (which means the patents of Patent No. 6716464 and Patent No. 6768984; hereinafter referred to as the "Patents"); therefore, the Defendant's Process infringes the patent rights in question. Based on this allegation, the Plaintiff demands that the Defendant suspend manufacturing, sale, etc. of the Defendant's Medicines under Article 100, paragraph (1) of the Patent Act and also demands that the Defendant dispose of the Defendant's Medicines under paragraph (2) of the same Article.

In this judgment, the court ruled that the Defendant's Process is not considered to fulfill a constituent feature wherein "product temperature in the process of getting granules by drying is less than 40°C." The court then held as summarized below and determined that the Defendant's Medicines cannot be presumed to have been produced by the manufacturing processes pertaining to the Inventions based on Article 104 of the Patent Act.

The news release in question issued before the priority date of the Inventions (which means a news release posted on the Plaintiff's website on September 10, 2014; hereinafter referred to as the "News Release") included the following statement: "Obtained marketing approval for NPC-02 (zinc acetate) therapeutic agent for Wilson's disease: Nobelzin® 25mg and 50mg tablets (addition of a dosage form)." Nobelzin 25mg and 50mg capsules that had been sold by the Plaintiff before the News Release are therapeutic agents for Wilson's disease (copper absorption inhibitors) and encapsulated formulations whose active component is zinc acetate hydrate. A medicine pertaining to addition of a dosage form refers to a medicine that is the same with an already-approved medicine, etc. in terms of active component, administration route,

efficacy and effect, and dosage and administration, but differs from it in terms of dosage form or content. Taking this into account, the medicines pertaining to the News Release are found to be therapeutic agents for Wilson's disease (copper absorption inhibitors) and zinc acetate tablets whose active component is zinc acetate hydrate.

Under these circumstances, the medicines pertaining to the News Release are considered to be identical with a product produced by the Inventions. Therefore, it can be said that existence of those medicines has been externally published by posting of the News Release.

Consequently, it is reasonable to find that a "product" produced by the Inventions had been known to the extent that a person ordinarily skilled in the art can get a clue to manufacture the product as of the time before the priority date of the Inventions.

For the reasons described above, in this judgment, the court dismissed the Plaintiff's claims.