3. PATENT INFRINGEMENT:

Sandoz AG v. Kotobuki Pharmaceutical Co.
Tokyo District Court (29th Div.)/ Dec. 16, 1992/ 91(Wa)6609
Patent Law §29

PREVENTION OF PATENT INFRINGEMENT:

Action for injunctive relief to prevent the manufacture and sale of defendant's drug for preventing asthma.

FACTS

Sandoz, a Swiss company, owns a Japanese patent granted October 22, 1990 relating to ketothiphene fumarate (KEF). At the time of the KEF application, KEF was already publicly known to be chemically effective for reducing allergic symptoms.

Sandoz initially filed its patent application relating to a preventive or curative agent for allergic diseases. Sandoz later amended its patent claim and described the allergic diseases more specifically to include "asthma" and "stomach irregularities." Sandoz then further amended the claim to limit the description to a preventive agent for allergic asthma. For conformity, the description in the working examples was also changed from "effective for curing allergic symptoms" to "effective for preventing allergic symptoms." With this amendment, the patent was finally granted.

On July 13, 1990, Kotobuki obtained approval from the Ministry of Health for the manufacture and marketing of its drug containing KEF in capsule form in which KEF is the sole effective ingredient. The drug was also listed as one for which national health insurance is applicable.

Sandoz sued Kotobuki in Tokyo District Court seeking an injunction preventing Kotobuki from infringing its patent.

ISSUE

Whether the term "preventive agent" as used in the patented invention can mean only a pharmaceutical product for people who are not sick to maintain their healthy condition and, if so, whether the defendant's product, which is a curative drug for sick people, falls within the scope of the patent claim.

ARGUMENTS

1. "Preventive" or "Curative"

Kotobuki argued that, in view of file wrapper estoppel and the teaching of the prior art, the claim at issue should be interpreted narrowly to cover only the use of KEF by healthy people to maintain their healthy condition. Kotobuki raised the fact that its product had been approved as a "curative" drug under the Drug Affairs Law, and argued that the patent claim ought to be construed to cover only a "purely" preventive drug.

Sandoz argued that the term "preventive agent for allergic asthma" means a drug to prevent a patient from having an allergic asthma attack. The disclosure in the specification supports this argument, Sandoz claimed, and there was no substantive change in scope during the prosecution regarding this point. Accordingly, file wrapper estoppel would not apply.

2. File Wrapper Estoppel and Drug Affairs Law Defense

Kotobuki argued that the Drug Affairs Law distinguishes between curative drugs and preventive drugs. By making the various amendments to its patent application, Kotobuki argued, Sandoz gave up protection for KEF as a "curative agent," and is now estopped from attempting to recapture that protection.

Sandoz argued, however, that the amendments it made during the prosecution were solely for clarification purposes, and had nothing to do with an expansion or narrowing of scope. Sandoz also argued that under Drug Affairs Law practice, approval of a drug as a "curative drug" does not necessarily mean that the drug cannot also be used as a "preventive drug."

HOLDING

The court held that Sandoz had shown that it was likely to prevail on the merits regarding the patent infringement issue. Accordingly, the court enjoined Kotobuki from producing or selling its KEF drug. The injunction was granted for the following reasons:

(a) Allergic asthma is caused by an antigen antibody reaction. Without the presence of specific antigens to cause production of antibodies, it is unclear whether or not someone is suffering from asthma. Moreover, it is unlikely that asthma-preventing drugs would be administered to those who do not show any allergic symptoms. The claimed invention should be interpreted as being a preventive drug for those who have once experienced allergy-related attacks and who want to avoid the occurrence of such attacks in the future.

(b) The Drug Affairs Law covers three general categories of drugs: diagnostic, treatment and prevention. However, as Sandoz argued, classification in one category does not necessarily negate the possibility of use in another category as well.

COMMENT

The main issue in this case is the meaning of "preventive drug." Kotobuki argued for a strict interpretation of the term under the doctrine of file wrapper estoppel. The court settled on a meaning somewhere between "treatment" and "prevention," probably closer to "mitigation." The court rejected Kotobuki's arguments because nothing in the claim implies that it is limited to a "purely preventive" drug. (For details of the Sandoz patent and substantive issues, see a case report on *Sandoz AG v. Kowa Yakuhin Kogyo KK et al.*, AIPPI Journal, March 1993, pp 3–22.)

In a precedent case, the Supreme Court held that claim interpretation should be based on the wording of the claim, unless it is insufficiently clear or apparently erroneous. (*Boehringer Mannheim GmbH v. Patent Office*, 62 Gyoke 3, 8 March 1991.) In that case, however, the Supreme Court construed the claim wording strictly in a very literal sense, rejecting the liberal interpretation made by the lower court. It is worth noting that the trial court showed flexibility in interpreting the claim wording in the Sandoz case.

Under Japanese law, a claim of patent invalidity can be made only before the Patent Office, not the courts. Patent Office decisions are only appealable to the Tokyo High Court, not the district courts. This is the reason why Kotobuki, the defendant in this district court case, did not raise the issue of patent invalidity, but only claim interpretation, when making its arguments based on the prior art. The prior art is considered relevant in infringement cases only for claim interpretation purposes, not for deciding validity.

(Jinzo Fujino, Director of Operations, Morrison & Foerster, Tokyo)