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Patentee has the Burden of Proof in Pharma Patent Infringement Case - *Bayer Pharma AG v. Lotus Pharmaceutical Co.*

According to the rule of allocation of burden of proof in the Taiwan Code of Civil Procedure, the plaintiff of a civil patent infringement lawsuit shall prove that an allegedly infringing product has fallen within the claims of the patent, for example, by submitting a compelling infringement expert report. In a recent pharmaceutical patent lawsuit (*Taiwan Intellectual Property Court 2020 Mingzhuansuzi No. 11 Judgment*), the Taiwan Intellectual Property Court (IP Court) ruled against the plaintiff who refused to provide the infringement expert report of the allegedly infringing product and failed to meet the burden of proof.

Case Fact

"Bayer Pharma Aktiengesellschaft" (patentee and plaintiff; hereafter "Bayer") is the patentee of the invention patent "A pharmaceutical composition for use as a contraceptive" (patent certificate: no. I276436, hereafter "'436 patent"). Bayer filed a lawsuit and claimed that "Lotus Pharmaceutical Co." (alleged infringer and defendant; hereafter "Lotus") infringed the patent for importing and selling "Gveza 3mg/0.02mg Film-coated tablets" (hereafter "the drug at issue"). However, instead of providing an expert report on the drug at issue, Bayer provided the expert report of another lawsuit, namely that on the infringement of "Gveza 3mg/0.03mg Film-coated tablets" (labelled as Bayer Exhibit 10, hereafter "Bayer 3mg/0.03mg expert report"). The IP Court deemed that Bayer failed to meet the burden of proof and dismissed the case.

Main Technical Features of the '436 Patent

Below is an analysis of the technical features of claim 1:

(1A) A pharmaceutical composition for inhibiting ovulation, comprising:

(1B) as a first active agent, drospirenone, in an amount corresponding to a daily dosage, on administration of the composition, of from about 2 mg to about 4 mg,

(1C) and, as a second active agent, 17α-ethinylestradiol (ethinylestradiol) in an amount

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corresponding to a daily dosage of from about 0.01 mg to about 0.05 mg,

(1D) together with one or more pharmaceutically acceptable carriers or excipients.

(1E) the drospirenone is in micronized form or sprayed from a solution onto particles of an inert carrier.

Key Argument

Does the Bayer expert report of "Gveza 3mg/0.03mg Film-coated tablets" prove that the technical feature "micronized" of the drug at issue reads on claim 1 of the '436 patent?

Bayer's Allegation

Lotus had admitted that the active composition (drospirenone and ethinylestradiol) of the drug at issue was the same as that in Gveza 3mg/0.03mg Film-coated tablets of the other case (*Taiwan Intellectual Property Court 2018 Mingzhuansuzi No. 3 Judgment*), and the only difference was the amount of ethinylestradiol. Thus, Bayer could naturally prove that the drug at issue must comprise micronized drospirenone with the expert report of Gveza 3mg/0.03mg Film-coated tablets.

IP Court's Opinion

The IP Court deemed that Bayer did not prove that the drug at issue fell within the claims of '436 patent and dismissed the motion.

Specifically, the IP Court reasoned that the Bayer 3mg/0.03mg expert report is insufficient to serve as the expert report of the drug at issue:

(1) **The subject of Bayer 3mg/0.03mg expert report** is Gveza 3mg/0.03mg Film-coated tablets (3.0 mg Drospirenobe/0.03 mg Ethylestradiol). Thus, the subject analyzed **is not the drug at issue ("Gveza 3mg/0.02mg Film-coated tablets") in form.**

(2) **The Bayer 3mg/0.03mg expert report focuses on tablets that have undergone the process of tablet manufacturing** (e.g., Disintegrant mixes with filler, drospirenone is added to make granules, and then the resulting granulate is dried, grinded, mixed, lubricated and pressed into tablet in order)**. The finished condition of the drug at issue cannot be inferred from the analysis of the finished tablets.** Therefore, Bayer 3mg/0.03mg expert report cannot be used to determine the tablet condition of the drug at issue.

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(3) According to Article 277 of Code of Civil Procedure, a party bears the burden of proof with regard to the facts which he/she alleges in his/her favor, which is the allocation of the burden of proof. Thus, Bayer shall meet the burden of proof and provide the expert report of the drug at issue. However, Bayer claimed that the expert report would cost millions of dollars, and stated that the court should consider the proviso of Article 277 of Code of Civil Procedure ("except either where the law provides otherwise or where the circumstances render it manifestly unfair") and shift the burden of proof. Such a claim seems to be Bayer's attempt to evade the burden of proof, as it was not the manifestly unfair circumstances between the parties provided in proviso of Article 277.

Moreover, Bayer is a world-renowned multinational pharmaceutical corporation with a long history, and it is obvious that its finances and medicine expertise is without a doubt. It is needless to shift the burden of proof due to unequal ability and financial distribution of the parties. In addition, the drug at issue is available on the market, and no party holds more evidence than the other.

Wisdom Suggested Strategies

The critical reason for Bayer's failure in the appeal was that Bayer refused to provide the expert report of the allegedly infringing product, and only provided circumstantial evidence which cannot prove that the drug at issue reads on the claims of '436 patent.

This case shows that for pharmaceutical patent infringement lawsuits in Taiwan, the court often deems that the patentee shall bear higher burden of proof considering the patentee of a pharmaceutical patent usually has deep pockets, rather than reduce the burden due to the higher costs of the expert report. Patentees of pharmaceutical patents should therefore pay more attention to such opinion of the court.

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