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## South Korea

### Strict Patentability Standards Applied Against Selection Inventions

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#### Sanofi-Aventis v. CJ et al., Supreme Court, Case 2008 Hu 736, October 15, 2009

The Korean Supreme Court has held that a patent covering an enantiomer and its medicinal use lacks novelty if the prior art disclosed the racemate and its medicinal use, while also recognizing the existence of enantiomers. The decision affirmed the lower Patent Court and Intellectual Property Tribunal decisions to the same effect.

Further, the Court also held that a patent for a specific salt of an enantiomer lacks inventiveness, requiring such "selection invention" patents to describe qualitatively different effects or quantitative data supporting superior working effects over the prior art. On this issue, the Court also held that working effects not "properly" described in the patent to meet the above description requirements should not be considered in assessing inventiveness.

The decision is very significant, being the first case dealing with the patentability of an enantiomer (compound *per se*) patent. It is also significant in that it sets forth extremely strict standards for the patentability of selection inventions in Korea.

### Selection Inventions

A selection invention is based on a genus concept disclosed in the prior art, but can be patented in most jurisdictions if it provides a superior working effect not obvious from the prior art. Such patents are also becoming very important in the pharmaceutical field, as many new drugs are based on improvements to known molecules and compounds.

In Korea, selection inventions could be patented if: (1) the prior art does not specifically disclose the species concept constituting the selection invention (*i.e.*, novelty); and (2) all of the patent claims provide a qualitatively different or quantitatively superior working effect over the prior art (*i.e.*, inventiveness). However, recent Korean decisions have applied even tougher standards, as exemplified by the above Supreme Court decision.

### Background

Sanofi's patent covered an enantiomer (clopidogrel, the active pharmaceutical ingredient of Plavix), specifically a dextro-rotatory optical isomer ("d-isomer"), its salt (clopidogrel hydrogen sulfate), and a pharmaceutical composition (for blood-platelet aggregation inhibiting and anti-thrombotic activities). Twenty local companies sought to invalidate Sanofi's patent, citing: (i) clopidogrel and its medicinal use were disclosed in the prior art; and (ii) clopidogrel hydrogen sulfate lacks superior working effects over clopidogrel hydrochloride and racemate hydrochloride (argued to be disclosed in the prior art).

The cited prior art was a patent covering clopidogrel's racemic mixture, disclosing a general formula and working example for the corresponding racemate compound.

### Supreme Court Decision

#### Novelty

Based on the above facts, the Supreme Court held that clopidogrel lacked novelty, citing the prior art disclosure of its racemate compound and the statement that "these compounds, which have an asymmetrical carbon, may exist in the form of two enantiomers" and that the invention relates to both enantiomers and their mixture. Thus, citing the above prior art contemplation of possible isomers, the Court held that clopidogrel was "specifically" disclosed.

The Court noted that such prior art did not need to describe a process (or even the possibility) of actually separating the racemate to obtain the isomer.

Further, the Court held that clopidogrel's use also lacked novelty, since the prior art already "specifically" disclosed clopidogrel and described "a therapeutic composition having blood-platelet aggregation inhibiting activities and antithrombotic activities containing the above compound and a pharmaceutically acceptable carrier" (in essence, finding that the use of the racemate defeated the novelty of the isomer's use).

#### Inventiveness

On inventiveness, the Court held that a selection invention patent must clearly describe its superior effects over the prior art, by either a description

of qualitative differences or data supporting any quantitative advantages. In this case, the Court noted that the patent contained no such descriptions of a "qualitatively" different effect, lacked data supporting superior working effects (*e.g.*, crystallization, non-hygroscopicity or water-solubility), and was otherwise silent on other advantages which may exist (*e.g.*, reduced convulsions, lower chronic toxicity, etc.) Thus, the Court held that in the absence of such descriptions or data, extrinsic evidence supporting inventiveness could not be considered.

On the inventiveness of clopidogrel hydrogen sulfate based on platelet aggregation inhibition/anti-thrombotic activity and acute toxicity (data for which were described in the patent), the Court held that a two-fold and 1.6-fold superiority, respectively, in platelet aggregation inhibition/anti-thrombotic activity and acute toxicity over the prior art racemate hydrochloride was simply insufficient.

## Significance

We believe that this decision will have a large and negative impact on the patentability (and hence, future enforceability) of selection inventions in Korea.

First, its novelty standard is much stricter than those in other leading patent jurisdictions. Here, the Court held that an enantiomer *per se* and its medicinal use lack novelty over a prior art racemate and its medicinal use – by comparison, the novelty of the enantiomer's medicinal use would be upheld in Japan.

Second, far more stringent description requirements are applied against selection inventions, compared to other inventions. The Sanofi patent (for clopidogrel hydrogen sulfate) provided superior pharmaceutical working effects over the prior art, but the Court held that the patent must contain supporting data, and that "qualitative" descriptions alone (*e.g.*, "remarkably superior in terms of hygroscopicity") did not suffice.

Further, such "defects" cannot be later cured by amendment or data submission. This requirement ignores the basic reality that such quantitative data in many cases is simply unavailable when the original patent is drafted.

Third, the Court closely linked inventiveness to description requirements, holding that working effects not described in a patent (to meet selection invention description requirements) must be excluded when assessing inventiveness. This means that no matter how great the selection invention's actual working effect, those not "properly" described in the specification (*i.e.*, meeting the above stringent description requirements tailored for selection inventions) must be ignored when assessing inventiveness.

Such high novelty and description standards espoused by the Supreme Court will clearly operate as high barriers against the patenting of selection inventions in Korea, not to mention the enforceability of many selection invention patents which have already been issued (often under seemingly more lax standards). This is in clear contrast to the policies of other leading patent jurisdictions, and will be a major cause of concern for many patentees (particularly in the pharmaceutical field).

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