

However, before an analogy to the situation of dependent patents can be drawn, to solve the above problem, a number of open questions should be answered by the Federal Court of Justice, like what is a reasonable amount of royalty, whether the defendant still can raise a non-infringement argument, and others.

### *c) Conclusion*

The holdings in the *Olanzapine* and *Escitalopram* cases have heightened the level of disclosure in the prior art necessary to anticipate selection inventions. In addition to the discussion about the justification for allowing more selection patents, the limited exploitation thereof is another issue, once they are granted. In other words, the change in the patentability requirements could possibly just bring more but almost useless patents in so far as the basic patent is in force. This is even more so because a most adequate solution, the compulsory license, has hardly been used.

However, this issue may not be a real problem in jurisdictions whose laws allow the grant of compulsory licenses for dependent patents and try to use this legal instrument to a greater extent and as necessary.

## **D. Different view in other jurisdictions**

### **1. Selection Inventions in Korea**

Recently the Korean Supreme Court rendered its decisions on the patentability of enantiomer patents on the world's top blockbusters, namely Plavix and Lipitor.

#### *a) Clopidogrel Decision*<sup>276</sup>

Sanofi-Aventis' Korean Patent No. 103094 on dextro-rotatory<sup>277</sup> enantiomer of clopidogrel was challenged over the earlier patent claiming clopidogrel as racemate.<sup>278</sup>

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276 Supreme Court Decision [S. Ct.], (hereinafter 'Sanofi-Aventis') 2008Hu736, 2008Hu743, Oct. 15, 2009 (S. Kor.).

277 "Dextro-rotatory" and "levo-rotatory" is another way of indicating the chirality of each enantiomer. However, there is no fixed relation to the (R)- or (S)- enantiomer. For example, an (R) isomer can be either dextro-rotatory or levo-rotatory.

278 The prior patent disclosed especially "... is an asymmetric carbon atom. In fact, this formula represents both the dextro-rotatory molecule claimed as well as its levo-rotatory enantiomer."

Based on the facts that the prior patent explicitly disclosed the compound having one chiral centre and two enantiomers, the Supreme Court held that in order to deny the novelty of selection invention, the prior patent should disclose the specific concept specifically, or a person skilled in the art can learn the existence of the selection invention directly from the prior patent based on the disclosure thereof and common knowledge at the time of application<sup>279</sup>. Further, the Court stated that “since clopidogrel was specifically disclosed and the person skilled in the art acknowledged the racemate, its dextro-rotatory enantiomer, and levo-rotatory enantiomers as separate compounds, it is *not necessary* that the method of separation or possibility of separation of enantiomers from racemates to obtain enantiomers are disclosed *unless the invention is directed to the method to separate dextro-rotatory enantiomer...*”<sup>280</sup>

With regards to obviousness, the Court held that in order for inventive step not to be denied, all specific concepts in the selection invention must show *qualitatively different or qualitatively same but quantitatively superior effects* to that of the prior invention,<sup>281</sup> the effect should be clearly disclosed in the specification of the selection invention by either a description of qualitative differences or data supporting any quantitative advantages.<sup>282</sup> The Court also said that a two-fold superiority in platelet aggregation inhibition or around 1.6-fold superiority in acute toxicity to a prior art racemate could not be regarded as superior considering that the administration of one enantiomer gave around 2-fold better effects than that of a racemate which is a 50:50 mixture of enantiomers.<sup>283</sup>

#### b) Atorvastatin Decision<sup>284</sup>

The patent in issue was Warner Lambert’s Korean Patent No. 167101 claiming one enantiomer of atorvastatin, an anti-cholesterol drug sold under the brand name Lipitor<sup>285</sup> by Pfizer Inc.. The prior art disclosed atorvastatin as a racemate having two chiral centers as a common scenario.

279 Sanofi-Aventis, *supra* note 276, at Headnote 1.

280 *Id.*, at para 1.Na..

281 This requirement seems to be similar to those of I.G. Rule in U.K.

282 *Id.*, at Headnote 2.

283 *Id.*, at para 2.Na..

284 Supreme Court Decision [S. Ct.], (hereinafter ‘Warner Lambert’) 2008Hu3469, Mar. 25, 2010 (S. Kor.).

285 See also *supra* note 35 and accompanying text (Atorvastatin (Lipitor®) is the top-selling global drug from 2007 and 2009 with sales of over \$ 12.5 billion in 2009).

While citing the *Sanofi-Aventis*<sup>286</sup> case, the Supreme Court held that even though only the racemate of R-trans-heptanoic acid and S-trans-heptanoic acid was disclosed, considering that a carboxamide compound of formula I was acknowledged as separate 4 enantiomers and not as a mixture, a person skilled in the art could have acknowledged formula I's open-ring form, namely, R-trans-heptanoic acid and S-trans-heptanoic acid, as separate enantiomers, too, and thus that the prior art disclosed the R-trans-heptanoic acid.<sup>287</sup> The Court restated that the selection invention was recognized as separate enantiomers, not as a mixture, and it was not necessary to disclose the method of separation or the possibility of separation of the enantiomer from racemates unless the invention was directed to the method of separating the dextrorotatory enantiomer.

The Court also found it obvious since even under the consideration of hygroscopicity or solubility, which were argued by the patentee, there was no special disclosure in the specification which could show any qualitatively different or qualitatively same but quantitatively superior effects.<sup>288</sup>

## 2. Selection Inventions in Japan

It is rather clearly defined in Japan what a selection invention is; namely, where an invention with a generic concept is expressed in a cited reference, an invention with a more specific concept selected from the generic concept is called a "selection invention".<sup>289</sup> The Japanese Examination guidelines show how to determine the novelty of a selection invention as follows:

"... if a chemical substance is expressed merely by its name or its chemical formula in a publication, and if it is not clear that a person skilled in the art can produce the chemical substance on the basis of the description in the publication, *even in the light of the common general knowledge as of the filing*, the chemical substance does not fall under "an invention described in a publication" under Article 29(1)(iii)." <sup>290</sup>

The guidelines further state that the prior art disclosure of a generic concept neither implies nor suggests an invention unless the specific concept can be directly derived from the generic invention *considering the common general knowledge*.<sup>291</sup>

It is not certain whether the above 'common general knowledge' corresponds to the 'disclosure' requirement or 'enablement' requirement when determining an-

286 *Sanofi-Aventis*, *supra* note 276.

287 *Warner Lambert*, *supra* note 284, at para 1.Na..

288 *Id.*, at para 2. Na..

289 See Japanese Examination Guidelines, *supra* note 181, at 2.5.3.(3)(1).

290 *Id.*, at 1.5.3.(3)(2).

291 *Id.*, at 1.5.3.(4)(2).