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Dutch Court of Appeal Mixes Cocktail of CJEU SPC Case Law

Rik Lambers (Brinkhof) · Friday, December 14th, 2018

In a recent decision The Hague Court of Appeal mixes a cocktail of SPC case law of the Court of Justice of the European Union. The ingredients: 1/3 Sanofi, 1/3 Boehringer and 1/3 Gilead and a sniff of Georgetown. Shake well with the skilled person's common general knowledge and the basic patent's description (warning: do not add post-published evidence). The result: an obvious combination product and a combination-SPC that should not have been granted after the grant of a mono-SPC for a product that constitutes the subject-matter of the invention covered by the basic patent. The taste: bitter for the SPC holder.

MSD's (combination) SPCs

The bitter taste of the CoA's decision was in this case for Merck Sharp & Dome ('MSD'). MSD markets the product Inegy, a medicine used to lower the levels of "bad" LDL cholesterol and triglycerides in the blood and raise the levels of "good" HDL cholesterol. The active substances in Inegy are ezetimibe and simvastatin.

MSD was granted an SPC for the product *ezetimibe*, if desired in the form of a pharmaceutically acceptable salt thereof, on the basis of its patent EP 0 720 599 (the Basic Patent). This mono-SPC expired in April 2018. MSD was also granted an SPC on the basis of the same Basic Patent for the product ezetimibe in combination with *simvastatin* (the SPC of the case at hand). Further, again on the basis of the same Basic Patent, MSD had also applied for an SPC for the combination of ezetimibe and *rosuvastatin*. The patent office had rejected this application.

District Court: ezetimibe + rosuvastatin

The patent office's rejection of the ezetimibe + rosuvastatin SPC application was confirmed by The Hague District Court in *merits* proceedings in April 2018. The District Court considered that – referring to the CJEU's Actavis/Sanofi judgment (C-443/12) – that the "core inventive advance" of the Basic Patent was providing a new group of azetidinones useful as hypocholesterolemic agents, ezetimibe being one of them. Ezetimibe should be considered the "innovative active ingredient" and being protected "as such" by the Basic Patent. Cholesterol biosynthesis inhibitors were *not* considered to be protected "as such" (were not considered "innovative active ingredients"), and while an (unlimited) group of inhibitors were mentioned, rosuvastatin was not (and not even specified in the claims, other than simvastatin).

In view of the CJEU's interpretation of Article 3 SPC Regulation in Actavis/Sanofi (C-443/12) and also Actavis/Boehringer (C-577/13), the District Court concluded that in these circumstances,

while a mono-SPC (ezetimibe) was already granted on the basis of the same Basis Patent, there was no room for the grant of a combination-SPC (ezetimibe + rosuvastatin). The District Court considered that MSD had been able to enforce its mono-SPC against a combination of ezetimibe and a biosynthesis inhibitor (including rosuvastatin), and therefore already had enjoyed supplementary protection for the rights that flowed from its Basic Patent. (For different, Hungarian take on this subject, see this post on this blog).

Court of Appeal: ezetimibe + simvastatin

In the preliminary injunction case before the Court of Appeal (23 October 2018 decision in Dutch available here), Teva c.s. were involved in the marketing of generic versions of the ezetimibe and simvastatin combination product. MSD requested an injunction on the basis of its ezetimibe + simvastatin combination-SPC. The million dollar question put before the Court of Appeal was, unsurprisingly, whether the combination-SPC was invalid in view of article 3 SPC Regulation.

The CoA first considered, on the basis of the CJEU's Actavis/Sanofi, Actavis/Boehringer and Georgetown case (C-484/12), that in principle a mono- and combination-SPC can be granted on the basis of the same basic patent (Georgetown), under the condition that the combination product concerns a "totally separate innovation" (Sanofi), or the combination product – independently from the mono product – constitute the subject-matter of the invention covered the basic patent (Boehringer).

The CoA then turned to the CJEU's Teva/Gilead judgment (C-121/17), and referred to the CJEU's consideration that the rules for determining what is 'protected by a basic patent in force' within the meaning of Article 3(a) SPC Regulation are those relating to the extent of the invention covered by such a patent, just as is provided in Article 69 of the EPC and the Protocol on the interpretation thereof (par. 32 Gilead), to be determined by the skilled person on the basis of his common general knowledge (par. 47-49 Gilead), while taking into account for such an assessment results from research which took place after the filing date or priority date of the basic patent would run counter to the SPC Regulation (par. 50 Gilead). (See this post on this blog on the CJEU's venture into the EPC provisions.)

The CoA applied the Gilead teaching on the case at hand. The CoA considered that it follows from the Gilead judgment that it is insufficient that the description of the basic patent only states that the combination of a product – the latter being protected by an (independent) claim – with another (known) product is also part of the invention. The description should at least substantiate such a statement, to the extent – at least – that the skilled person understands on the basis of the description and his common general knowledge that the combination product provides a solution for other or further problems or provides benefits, other and independent of the problems solved and benefits provided by the (mono)product claimed according to the independent claim of the patent.

The CoA considered that the skilled person would not derive from the description of the Basic Patent that the ezetimibe + simvastatin combination constitutes a separate invention. The combination is not specifically discussed, and the description does not mention that the combination solves problems or provides benefits. The skilled person would not conclude on the basis of his common general knowledge that the combination would constitute a separate invention. According to the CoA the "skilled person would find it obvious to research a combination of a compound according to the invention" (i.e. ezetimibe) with a statin. The

combination with simvastatin would – absent any indication to that end – not "surprise" the skilled person and would therefore not occur to him as a separate invention. The description does not mention any prejudice to making this combination. Information on the beneficial effect of the combination cannot be taken into account to answer the question whether the skilled person would consider the combination an invention at the priority date (cf. par. 49-50 Gilead).

The CoA therefore concludes that the SPC was granted contrary to – at least – Article 3 (c) SPC Regulation, and confirms the dismissal of MSD's infringement claim.

As a final remark, in its decision the CoA takes note of parallel proceedings in France, Germany, Ireland, Spain, Italy, Belgium, Greece, Portugal, Czech Republic, Norway and Austria. The CoA also notes that – as far as decisions have been rendered – different national courts have come to different conclusions (which are not discussed in the CoA's decision). As to the CoA's cocktail, it tastes a bit like German beer: the Regional Court of Dusseldorf came to a similar conclusion three weeks before the CoA's decision (1 October 2018 decision). The German Regional Court offered some further thoughts on what the Dutch CoA would (later) call an obvious research for the skilled person:

> "[T]he Chamber does not believe it is necessary for the active ingredient/the combination of active ingredients to be entitled to an independent inventive step in isolation, with the result that the inventive step would need to be reviewed as part of Art. 3 c) SPC Regulation. Such an understanding can be ruled out due to the same arguments that were cited in connection with Article 3 a) SPC Regulation. The inventive step exists under the postulate of the respective national law of the member state, which is relieved of the decision-making competency of the CJEU. The Chamber therefore also avoids translating the expression "core inventive advance" with "central inventive step", since this comes all too close to equality with inventiveness. The term used by the CJEU must be seen in the context of the SPC Regulation. It must be comprehended autonomously, from a purely patent-law perspective. With this term, the CJEU takes account of the fact that the delay in commercial exploitation is to be compensated only for the part of the invention that makes up the core of the inventive step constituting the subject matter of the Basic Patent."

Different states, different tastes, same result.

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