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Ground-breaking decision on Gilead's Tenofovir SPC in Denmark

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Just as the case has been in other European jurisdictions, Gilead is currently attempting to enforce its (Danish) SPC for the combination of tenofovir disoproxil (as fumarate) and emtricitabine in Denmark.

In the first decision regarding Gilead's enforcement of this SPC in Denmark, the Danish specialty patents court, the Maritime and Commercial High Court, turned down Gilead's application for an interlocutory injunction against Accord on 26 October 2017.

The one claim (claim 27) of the basic patent on which the SPC is based, claims an optional combination of tenofovir with "other therapeutic ingredients" and it was Gilead's position that the person skilled in the art would construe "other therapeutic ingredients" as emtricitabine.

While the Court held that Gilead had rendered it probable that the SPC (in principle) was infringed, notably, the Court sided with Accord's argumentation that the SPC should be held invalid as Accord had not only rendered it probable that the patent-in-suit was invalid, but in fact proven that to be the case.

Citing CJEU case law (C-322/10 "Medeva" and C-493/12 "Eli Lilly") as well as the DKPTO Guide Lines on SPCs – which state that a combination product consisting in the two active ingredients A and B are considered as protected, when A and B are stated in a patent claim – the Court concluded that

"Emtricitabin does not appear in the wording of claim 27, just as emtricitabin is not described by way of chemical name or structural formula or comprised by a Markush formula. In that connection, the Court notes that the designation "other therapeutic ingredients" in claim 27 cannot be regarded as a sufficient specification of either chemical name, structure or Markush formula or functionality. Against that background, the Court finds that Accord has proven that the contested SPC is invalid."

It is, as yet, unclear whether decision has been or will be appealed, but as it is extremely rare for Danish courts to turn down PI applications based on invalidity defenses, it would not be surprising if the decision were to be appealed.

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This entry was posted on Saturday, October 28th, 2017 at 5:57 pm and is filed under [Denmark](#), [SPC](#), [Validity](#)

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