# Danish Maritime and Commercial Court revisits Gilead’s SPC for tenoforvir disoproxil

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Anders Valentin (Horten)

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As previously reported, in 2017 the Danish Maritime and Commercial Court declined to grant an application filed by Gilead to grant an injunction against Accord offering the pharmaceutical a combination product consisting of Emtricitabine and Tenofovir Disoproxil (TD), holding that the granted SPC was invalid (Ground-breaking decision on Gilead’s Tenofovir SPC in Denmark).
In a subsequent appeal decision rendered by the High Court (Eastern Division) on 7 March 2018, the decision of the Maritime and Commercial Court was overturned.

In that connection, the High Court (Eastern Division), inter alia, accorded decisive weight to a unilaterally retained expert statement obtained for the High Court hearing, pursuant to which a specialist doctor in July 1996 would have understood the wording “other therapeutic ingredients” in claim 27 as meaning compounds contributing to antiviral activity, especially for the treatment of HIV. Also, it was held that such a skilled person would have thought of a combination with another NRTI, and NNRTI or a protease inhibitor and that Emtricitabine was a promising NRTI candidate for the treatment of HIV and as such suggested for use in a combination treatment.

Against that background, the High Court (Eastern Division) held that it was not possible with the necessary certainty to rule out that claim 27 of the Basic patent also comprises a combination of TD with Emtricitabine. Consequently, the High Court (Eastern Division) concluded that the presumption in favor of the SPC’s validity had not been weakened to such an extent that there was a basis to set the SPC aside as invalid.

Furthermore, the High Court (Eastern Division) cited the fact that, at the time the ECJ had not yet ruled in C-121/17 regarding the construction of the SPC regulation, article 3, litra a).

In parallel proceedings between Gilead (et al) and Mylan, the Maritime and Commercial Court was given occasion to (re)consider the construction of Gilead’s SPC and its Basic patent in the light of the, by then, available decision from the ECJ in C-121/17.

The Maritime and Commercial Court concluded that it followed from the ECJ decision in C-121/17 that in the assessment of whether the at-issue SPC is valid, consideration needs to be taken of whether the combination of TD and Emtricitabine “necessarily and specifically” is comprised by the patent claims.

The court then cited Gilead’s unilaterally retained expert evidence that the number of active ingredients which a skilled person against the background of the Basic patent would consider combining with TD, would be limited to a list of 34 compounds of which 9 had been approved and 25 had not.

The Maritime and Commercial Court then went on to cite Mylan’s unilaterally retained expert who had stated that the designation “other therapeutic ingredients” need not necessarily be related to the treatment of HIV which opened up to a great number of combination options outside of Emtricitabine. In that connection, Mylan’s expert had perused patient journals from 1995 to July 1996 and observed that patients in Denmark, at the priority date, were both on a mono treatment and a combination treatment, and some even on a triple combination treatment.

Against this background, the court held that the invention in the Basic patent cannot be held as being specifically directed at the treatment of HIV, but at a large groups of viruses, including Hanta virus etc.

Furthermore, the court held that, based on Mylan’s expert evidence, the number of potential combinations pursuant to the Basic patent, would by far exceed a list of the 34 compounds, which the Gilead expert had testified to.

Consequently, the court agreed with Mylan that, based on the skilled person’s general knowledge and the prior art in 1996, the combination of TD and Emtricitabine would not necessarily in the light of the description in the drawing of the Basic patent, be comprised by the invention covered by the Basic patent, and that furthermore, that combination could not be regarded as having been specifically identifiable in the light of all the elements made available in the Basic patent.

On that basis, the Maritime and Commercial Court now found that the presumption in favor of the SPC’s validity had been weakened to such an extent that there were grounds to set it aside as invalid and the application for interlocutory injunction was therefore declined.