Kluwer Patent Blog

Tenofovir – Danish Maritime and Commercial Court repeals PI

Anders Valentin (Bugge Valentin) · Thursday, January 17th, 2019

Gilead Sciences vs Sandoz – Round One
The history of the case started in 2018, where Gilead Sciences Inc., brought preliminary injunctions before the court against several companies. On 7 March 2018, the High Court of Eastern Denmark delivered a preliminary injunction against Accord Healthcare Limited, thereby reversing an earlier decision from the Danish Maritime and Commercial Court. The preliminary injunction was based on a SPC owned by Gilead. One of the grounds for delivering the PI was the existing interpretive uncertainty of article 3(a) of Regulation 469/2009 concerning SPCs for medicinal products, the court reasoned.

Shortly thereafter, on 24 April 2018, the Danish Maritime and Commercial Court ruled in a PI-case against Sandoz A/S regarding the same SPC, prohibiting the defendant, Sandoz, from producing and selling the drug “Padviram” in Denmark. The Danish Maritime and Commercial Court put great weight on the decision against Accord from the High Court as a basis for delivering the PI against Sandoz.

Sandoz did not agree with the PI and appealed the case.

Preliminary ruling from the ECJ
On 25 July 2018, the ECJ came with a preliminary ruling concerning the interpretation of article 3(a) of the SPC Regulation. The request for a preliminary ruling was made following legal proceedings in the UK between Gilead and several other companies regarding Gilead’s SPC.

The ECJ ruled that the combination of several active ingredients with a combined effect is ‘protected by a basic patent in force’ within the meaning of article 3(a), even if the combination is not expressly mentioned in the claims of the basic patent, if the following two tests are both satisfied:
1. the combination of those active ingredients must necessarily, in the light of the description and drawings of that patent, fall under the invention covered by that patent, and
2. each of those active ingredients must be specifically identifiable, in the light of all the information disclosed by that patent.

In addition, the ECJ, it could be argued, indicated that the SPC in question did not fulfil the above test, and that the SPC consequently was invalid. However, the court made it clear that it was for the national court to check whether this was indeed the cases.

Gilead Sciences vs Mylan

Following the ECJ decision, the Danish Maritime and Commercial Court concluded on 15 October 2018 in PI proceedings against Mylan S.A.S, that Gilead's SPC was invalid since the concerning product (the combination of tenofovir disoproxil and emtricitabine) did not fulfil the two tests put forward by the ECJ. Thus, the defendant, Mylan could sell its product on the Danish market.

The ruling created the asymmetric situation where Mylan S.A.S could sell their generic product, whereas both Sandoz and Accord were prohibited from selling their generic product due to the preliminary injunctions against them.

Since the appeal of the Sandoz-PI was scheduled late January 2019, Sandoz brought a new case to the Danish Maritime and Commercial Court concerning repeal of the PI in the hopes that this repeal case would be decided before the appeal of the PI.

Gilead Sciences vs Sandoz – Round Two
Repeals of preliminary injunctions are seldom seen in Danish patent cases. In fact, there was only one prior Danish decision concerning repeal of a PI when Sandoz brought the repeal proceedings before the court.

For the preliminary injunction to be repealed, Sandoz had to prove that the conditions for the court's grant of the preliminary injunction no longer were fulfilled, which Sandoz was able to do on 20 December 2018 when the Danish Maritime and Commercial Court repealed the preliminary injunction from 24 April 2018 against Sandoz.

Two judges, the majority, reasoned that none of the expert witnesses stated that the combination of tenofovir disoproxil and emtricitabine was covered by the basic patent. By referring to the ECJ decision, the majority consequently ruled that the combination of tenofovir disoproxil emtricitabine was not covered by the basic patent and, thus, that the preliminary injunction against Sandoz should be repealed.

However, the decision was not unanimous. One dissenting judge referred to the Sandoz appeal case which was scheduled late January 2019 and reasoned that the view of the evidence was to be carried out by the High Court in the appeal case. Consequently, this judge refused to consider the evidence in this case which led to the criteria of termination of the injunction not being met

The reasoning from the dissenting judge is very surprising, given that the law is clear with respect to repeal of preliminary injunctions; If the conditions for grating a preliminary injunction are longer satisfied, the preliminary injunction must be repealed. Herein is an obligation to specifically view the new evidence presented before the court, and we do not believe that this can be declined by the court by referring to an appeal case scheduled on a later time.

Reported by Patris Hajrizaj

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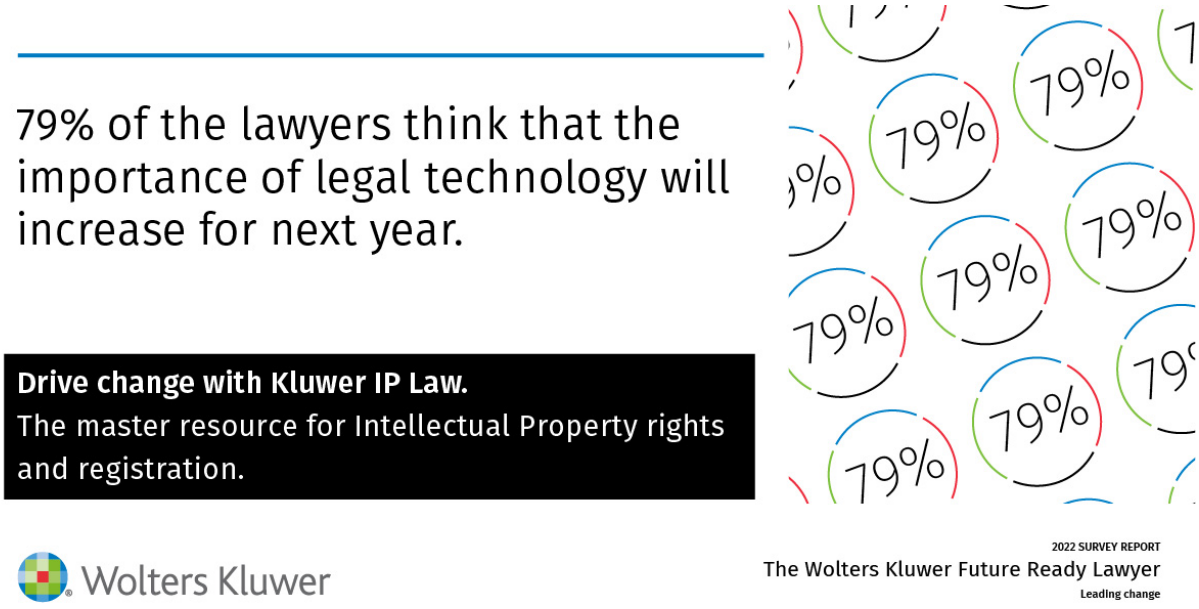

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