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## Danish Maritime & Commercial Court turns down PI application due to lack of inventive step

Anders Valentin (Bugge Valentin) · Tuesday, September 11th, 2018

AstraZeneca had filed an application for interim relief based on two patents, DK/EP 1250138 T4 (“EP 138”) and DK/EP 2266573 T3 (“EP 573”) against Sandoz, which conceded that to the extent that the patents were valid, the Sandoz product “Fulvestrant Sandoz” infringed upon the two patents.

Sandoz took the position, however, that the patents should be held invalid for lack of inventive step, arguing that both patents-in-suit make mention of articles detrimental to inventive step (articles by Howell et al. and McLeskey).

In 2015, the EPO Opposition Division upheld EP 138 after the appellant withdrew its opposition. In that connection, EPO held that Howell et al. and McLeskey in combination did not take away inventive step.

In a subsequent decision, in 2017, the EPO Opposition Division held EP 573 invalid for lack of inventive step and the Opposition Division noted in that connection that it disagreed with the conclusion reached in relation to EP 138, now holding that in combination with the knowledge derived from the articles by Howell et al. and McLeskey there was no inventive step.

The Maritime and Commercial Court held that the EPO decision regarding EP 573 must result in a material weakening of the presumption in favour of that patent being valid, and the fact that the decision had been appealed by AstraZeneca could not lead to a different assessment, even if the EPO appeal had suspensive effect.

Based on an analysis of Howell et al., McLeskey and further citations filed for the Danish proceedings, the court arrived at the conclusion that the skilled person would have had a reasonable expectation of success by using a formulation from McLeskey, and that the invention to the skilled person would therefore be obvious in relation to the prior art.

Consequently, the Danish Maritime and Commercial Court held that AstraZeneca had neither rendered probable or proven that it was the proprietor of an exclusive right that could be infringed, and so the application for interim relief was turned down.

It is very rare for a Danish court to turn down applications for interim relief based on an inventive step defense.

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