

## Must a PI be upheld after first instance invalidation...?

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In a recent decision rendered by the Danish Maritime & Commercial Court (the "MCC"), Novartis successfully defended its position that even if the patent-in-suit had been invalidated by the EPO Opposition Division, there were no grounds to lift a PI as the patent-in-suit (DK/EP 2 292 219 - Rivastigmin) must be upheld as valid and enforceable pending a final decision by the EPO BoA considering also that furthermore Novartis held two utility models reflecting the patent-in-suit which had not been invalidated and had also served as basis for the PI granted.

Prior to main proceedings in Denmark, the MCC had granted a PI against the generics company, Orifarm. Novartis then filed a mandatory main action in the course of which the parties posed a number of questions to court-appointed experts regarding, inter alia, the alleged invalidity of the patent-in-suit. Orifarm was allowed, under protest by Novartis, to include three of the questions and answers from the court-appointed experts in support of the claim that no presumption of validity should apply.

Before the main action was concluded, the EPO Opposition Division, however, invalidated the patent-in-suit citing EPC 100(c), 123(2) and 76. Orifarm then applied for the MCC to lift the injunction arguing that no presumption of validity could now be held to apply and that consequently the grounds for upholding a PI no longer existed.

In its application Orifarm cited, inter alia, the fact that Novartis had appealed the first instance decision and that this should be accorded suspensive effect - citing a court of appeal's decision, which lifted a PI under allegedly similar circumstances. Also, Orifarm argued, The Swedish Tingsrätt had lifted a parallel PI in place for Sweden for the same reasons as those invoked by Orifarm in Denmark.

Finally, Orifarm pointed to the fact that the patent-in-suit had been invalidated in several other European jurisdictions including the UK and Germany.

The MCC, however, found in favor of Novartis holding that the principles of EPC 106 should apply and so the patent-in-suit must be presumed valid and enforceable pending the outcome of the decision of the EPO BoA. Furthermore, the MCC held, each of the two utility models remained in force and so on balance there were insufficient grounds for not lifting the PI.

The decision is currently under appeal.