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The invalidity defense in Danish PI proceedings – the times are changing

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The Danish Maritime & Commercial Court recently granted an interlocutory injunction in a patent dispute relating to 2nd medical use claims (Novartis v. Orifarm Generics case A-0006-14)).

The Novartis patent claim language included a specification for a TTS (transdermal therapeutic system) for administering Rivastigmine in the treatment of Alzheimers:

"Rivastigmine for use in a method of preventing, treating or delaying progression of dementia or Alzheimer's disease,
wherein the rivastigmine is administered in a TTS and the starting dose is that of a bilayer TTS of 5 cm2 with a
loaded dose of 9 mg rivastigmine, wherein one layer: …" (highlighted by me).

When Orifarm Generics launched a TTS of the same dosage and size Novartis filed an application for an interlocutory injunction with the Maritime and Commercial Court in its capacity as IPR specialty court (since 1 July 2013 also in relation to interlocutory injunction cases).

Before 1 July 2013 interlocutory injunction applications were heard exclusively by Bailiff's court departments and as they were not specialized in IPR it had come to be generally accepted that invalidity defenses were (extremely) rarely successful and in any event never when based on alleged lack of inventive step.

In the Maritime and Commercial Court, however, technical judges join legal judges in the adjudication of interlocutory injunction cases and as a result it has been expected that a defense based on invalidity could have more merit than in the past when the Bailiff's courts most often simply took it as the factual basis of a case that the patent was valid and therefore readily dismissed invalidity defenses without much, if any, deliberation.

In the present case, the Maritime and Commercial Court was given the opportunity to consider in detail an invalidity defense regarding both allegedly lacking novelty and inventive step.

Although the analysis offered by the Court is somewhat cursory (as, regrettably, is often the case with written decisions from Danish courts), it does, however, deal with both the allegation of lacking novelty and inventive step.

Both allegations were turned down by the court, but the decision's scarce wording does suggest

that an invalidity defense will in fact be taken under due consideration by the Maritime and Commercial Court and there is now no reason to dismiss off hand – as was the case under the old system – the notion that a defense based exclusively on lack of inventive step may indeed be successful – provided the evidence sufficiently supports such a contention.

It should be noted, that the Maritime and Commercial Court cannot invalidate a patent in the course of interlocutory injunction proceedings and an action must therefore also be brought on the merits if the aim is to have the patent invalidated.

Having dismissed the invalidity defense, the Court then ruled on alleged patent infringement of the 2MI claim language and found that by way of the wording of the PIL and SmPC, Orifarm carried out an indirect marketing, which was prohibited pursuant to the Danish Patents Act. Also, the Court ruled, due to the description of the initial and subsequent dosages in the PIL and SmPC, the PIL and SmPC were both in contravention of the Danish Act on Fair Marketing Practices and should therefore be withdrawn from the market also.

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