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Injunctions granted in Denmark in Fingolimod-cases

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As with many other jurisdictions the fight over Novartis' contested Fingolimod-patent (EP 2 959 894) (the "patent-in-suit") is raging on in Denmark. Two recent cases from June and July yielded positive results for the patent proprietor in cases against Viartis and Zentiva respectively.

The cases initially begun in Denmark in the spring of 2022, where Novartis sought preliminary injunctions ordered against Glenmark, Viartis, and Zentiva on the basis of the patent application for the soon to be granted patent-in-suit.

However, both the Danish Maritime and Commercial High Court and a few months later the Danish Eastern High Court concluded that only a granted patent with effect in Denmark may form the basis of judicial proceedings in Denmark, including preliminary injunctions. This decision was not a foregone conclusion as the opposite result have been reached in other jurisdictions, such as in France after the decision of the Tribunal Judiciaire de Paris which also regarded the application of the patent-in-suit.

When the patent-in-suit was granted, proceedings were quickly initiated in Denmark – this time with a focus on the question of validity. First up was Zentiva before the Danish Maritime and Commercial High Court. The presumption of validity was challenged by Zentiva on the grounds of insufficient description of the invention and lack of inventive step.

The Court granted the preliminary injunction against Zentiva as the majority of the presiding judges found that the presumption of validity had not been sufficiently weakened. However, one of the three judges gave a dissenting opinion concluding that the invention lacked inventive step. The injunction was granted on the condition that Novartis deposit a security of DKK 20.000.000.

A few months later an injunction was granted against Viartis by the same court against Novartis depositing a security of DKK 10.000.000. However, the invoked grounds for invalidity by Viartis were lack of novelty and lack of basis in the parent application. The Court found that there were not sufficient grounds to set aside the EPO's decision and reasoning regarding lack of basis, and similarly that neither a press release nor a presentation both released by Novartis (which were both claimed as closest prior art) were novelty-destroying.

Finally on 11 July 2023, as the latest development in the saga, the Danish Eastern High Court made its' decision as 2nd instance in the case against Zentiva. In addition to the grounds of invalidity raised in the 1st instance, the case also included a claim of lack of basis.

Regarding the question of basis, the Court stated that – as in many other jurisdictions and as at the EPO – the assessment must be made using the Gold Standard, whereby amendments must lead to subject matter which results in the skilled person being presented with technical information which he would derive directly and unambiguously, using common general knowledge, from the application as filed.

Using the Gold Standard, the Court found through an analysis of the parent application and the application for the patent-in-suit that there was sufficient basis in the parent application for the daily dose (of 0,5 mg) entailed in the patent-in-suit. In this respect it was concluded that the granting process at the EPO had not been clearly erroneous regarding basis, which was also the conclusion regarding insufficient description, where the Danish Eastern High Court mostly followed the reasoning of the Court in 1st instance.

However, the main point of contention – the question of inventive step – was still to be decided.

Essentially, the EPO had found that even though the closest prior art (which stated that a daily dose of 1,25 mg had shown very promising results) did hint at even lower dosages having a sufficient therapeutic effect, the rest of the prior art included a “Teach Away”, which would dissuade the skilled person from considering that a dosage as low as 0,5 mg daily would be effective. The dissenting opinion of the judge in 1st instance in the case against Zentiva disregarded this conclusion, and found that no such “Teach Away” was present in the prior art.

The Danish Eastern High Court, possibly acknowledging that there were very real doubts about the validity of the “Teach Away”-argument, went into to a very thorough analysis using the problem and solution approach. In Danish case law, and especially in preliminary injunction cases, it is rare that the Court offers a very detailed description of its reasoning and grounds for its’ decision. But in this case the Court made lengthy conclusions on a number of key issues such as the closest prior art to be used in the assessment and the effect on the “Teach Away”-argument by a number of articles, which were part of the prior art.

The Court concluded that even if the skilled person could possibly consider it obvious that a dose of less than the 1.25 mg daily would have the necessary therapeutic effect, there is no basis for assuming that the skilled person would have a reasonable expectation that a dose as low as 0.5 mg daily would be therapeutically effective.

The majority decision of the Maritime and Commercial High Court in 1st instance was therefore upheld. With these proprietor friendly decisions Novartis seems – for now at least – to come out ahead in the Danish courts.

In a wider context these decisions support a trend in Danish case law on preliminary injunctions where it is very difficult for the alleged infringer to topple the presumption of validity. This is further exacerbated but the fact that Court appointed experts, who normally hold considerable sway with Danish judges, are not allowed in preliminary injunction proceedings.

This is of course in stark contrast to other jurisdictions where Court appointed experts play a central role in preliminary injunction cases, which may also be one of the possible explanations of the proprietor negative decisions we have seen elsewhere in Europe in the Fingolimod-proceedings.

Reported by Anders Valentin and Frederik Buhl Brinckmann.

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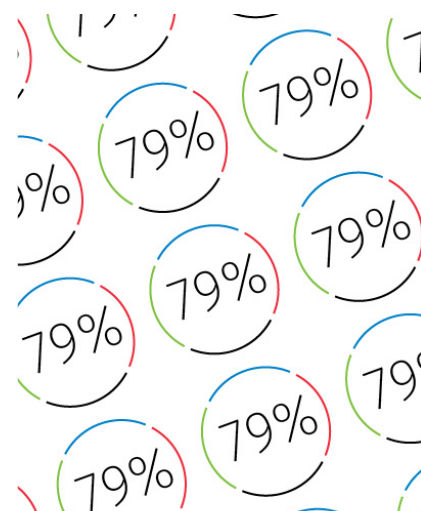
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