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Danish court dismisses application for a PI based on a patent application (Fingolimod)

Anders Valentin (Bugge Valentin) · Thursday, July 7th, 2022

In a highly principled matter, the Danish Maritime and Commercial High Court has ruled to dismiss Novartis' application for a preliminary injunction against Glenmark, Zentiva, and Viatris based on the patent application EP 2 959 894 (the "894-application"). The patent application is for a pharmaceutical patent on the treatment of multiple sclerosis.

The EPO Examining Division initially declined to grant the 894-application for lack of novelty. However, on appeal in October 2021 the EPO Technical Board of Appeal decided to remit the 894-application to the Examining Division to grant the patent on the basis of a single patent claim from Novartis' main request.

On that basis, in March/April 2022 Novartis filed an application for a PI against Glenmark, Zentiva, and Viatris at the Danish Maritime & Commercial Court claiming patent infringement. At the time there was no formal decision to grant from the EPO (and there still is not).

The defendants challenged the legal basis of filing a PI application on the basis of a patent application (as opposed to a granted patent) due insufficient cause of action/legal interest. Novartis, however, argued that the Examining Division would, in the near future, grant the patent and in any event most likely before an oral hearing could be scheduled.

Novartis argued that it had a legitimate interest in having the PI application admitted and expedited prior to grant in order to ensure that a PI could be issued without delay as soon as the patent was granted. Also, Novartis argued that it would constitute a violation of the Enforcement Directive, should the Court dismiss a PI application on the basis of a patent application, as the enforcement of that patent would be delayed and, consequently, not effective.

On the other hand, the defendants argued that the Enforcement Directive only relates to intellectual property rights which have been issued and, thus, have legal effect. Thus, whether the enforcement of the patent (when it is issued) is not 'effective' pursuant to the Enforcement Directive, must be assessed when the patent has been issued and is enforced. This does not provide patentees with an option to enforcement patent applications.

The parties further disagreed on when a patent might be granted and offered different prospective dates for the expected grant (and subsequent validation) varying from June 2022 to early 2023.

The Court, which consisted of 5 members (as opposed to usually 3 members) due to the principled

nature of the issues at hand, noted that it is a presupposed condition for commencement of legal proceedings that there is sufficient cause of action/legal interest at the time of commencement of legal proceedings.

The Court then held that since there was no formal decision to grant from the EPO, it is uncertain when the patent will have effect in Denmark. This indicates that the Court, on one hand, held a door open so that enforcement after a 'decision to grant' has been made by the EPO would be possible, but on the other hand generally rejected enforcement prior to a 'decision to grant'.

The Court also noted that there was a risk (although the Court deemed such a risk to be limited) that the patent could still be amended.

Consequently, the Court ruled that Novartis had not lifted its burden of proof with respect to sufficient cause of action/legal interest, and the Court dismissed the case without hearing the subject matter.

This decision is the first if its kind and is currently on appeal at the Danish High Court (Eastern Division).

Zentiva and Glenmark were represented by BUGGE VALENTIN.

Reported by Anders Valentin and Patris Hajrizaj

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