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Presumption of validity in preliminary injunction proceedings

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In August 2023, the Patent and Market Court of Appeal (PMCA) found, to the surprise of many practitioners in the Swedish IP community, that the presumption of validity had been overturned just a couple of months after the same court had found, in a parallel case, that the same patent in suit was presumed valid. However, looking more closely at the details of these four cases, the outcome is not surprising, and the further guidance provided by the PMCA on how the presumption of validity may be challenged is welcomed.

Background

The four decisions relate to the Fingolimod patent, EP 2 959 894 (EP 894). Fingolimod is a medicinal product to be used in the treatment of multiple sclerosis. Shortly after the grant of EP 894, preliminary injunction (PI) proceedings were initiated against several different generic companies. In three of the four cases, the Patent and Market Court (PMC) rejected the request for a PI as the court found that EP 894 would probably not be upheld in its granted wording. The plaintiffs appealed the decision to the PMCA, which did not grant leave to appeal. The decision to reject the PI request was thereby upheld.

However, in the fourth case, initiated after the first three cases, the PMC granted a PI against the generic companies. The main reason for this was that the generic had not filed a revocation action regarding EP 894. When the revocation action against EP 894 had been filed, the plaintiffs requested a re-assessment of the PI decision. In its decision, the PMC set its previous PI decision aside and removed the PI. The plaintiffs appealed the decision and requested that the PMCA should grant the PI against the generic companies in question. The PMCA granted the plaintiffs' appeal and revoked the PMC's decision to set the PI aside (PMÖ 1644-23).

With the decision from the PMCA granting a PI against the generic companies in the fourth case, the plaintiffs filed a new request for a PI against the first three generic company groups. Despite the PMC's initial assessment that EP 894 would not be upheld, the PMC found reasons to grant the PI requests against the three remaining defendants (three separate groups of generic companies). The defendants appealed the decisions and requested that the PMCA should reject the PIs. The PMCA granted leave to appeal (PMÖ 7680-23, PMÖ 7681-23 and PMÖ 7696-23).

Decisions

In the first case, PMÖ 1644-23, the PMCA stated that the mere fact that the evidence already presented before the European Patent Office provided reasons to question the assessment of the patentability of EP 894 did not, as a rule, constitute deficiencies or errors that could overturn the presumption. Based on this conclusion, the PMCA did not find that the evidence presented and known during the prosecution could overturn the presumption of validity. The defendant had also presented new evidence that, upon review by the PMCA, was not found to present any new and additional information not already known during prosecution. Finally, the defendant argued that the Technical Boards of Appeal (TBOA) had made a faulty assessment of inventive step based on the documents and arguments presented.

However, the PMCA rejected the argument and, relying on the summary nature of the PI proceedings, found that the court should not, at this stage, re-examine the evidence or the legal analysis of the file before the TBOA, regardless of whether there might be scope for such conclusions in a final examination of the validity of the patent.

In the three other cases, PMÖ 7696-23, 7680-23 and 7681-23, the PMCA held that, contrary to its assessment in PMÖ 1644-23, there should be some room to consider substantive deficiencies in the original decision to grant the patent. Thus, a substantive review should be allowed if the defendant points to deficiencies in the original decision that give reason to question the outcome, already in a brief overview.

According to the PMCA, this order was also appropriate and reasonable since it would limit the risk that preliminary injunctions are wrongfully granted. Turning to the specifics of the decisions of the TBOA, the PMCA held that a preliminary review of the presented evidence gave cause to question the documents on which the TBOA had based its decision and the conclusions that the TBOA had drawn from these documents. Consequently, the PMCA proceeded to examine the prior art documents in detail. Upon a substantive review, the PMCA found that the TBOA's applied starting point for the skilled person was contradicted by the prior art and held it plausible that the invention was going to be revoked. Thus, the PI requests were dismissed.

Comment

As an observer, it may be confusing that the Patent and Market Courts of Sweden can reach different conclusions regarding the same patent. However, it should be stressed that the burden of proof to overturn the presumption is on the defendant. If the defendant does not question the validity of a patent, the patent will be presumed valid, as has also been established by the European Court of Justice. The cases also highlight that the question of the validity of a patent will only have an *inter partes* effect until it has been finally decided.

Based on a large number of decisions, it can be concluded that it is possible to overturn the presumption of validity if the defendant can provide:



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- evidence of formal errors during prosecution;
- new evidence or circumstances not considered by the patent authority; or
- evidence that the patent authority's decision is substantively wrong.

The clarity provided by the PMCA may result in more extended PI proceedings since defendants are likely to put more effort into dissecting the patent authority's decision and arguing that it is substantively wrong. How this will be balanced in relation to the summary nature of preliminary proceedings remains to be seen.

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