# Quetiapine patent invalidated in Denmark – also…

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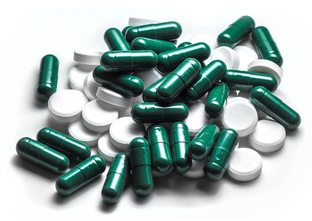

On June 17, 2016, the Danish Maritime and Commercial Court rendered judgement in a patent case between AstraZeneca and Teva and Accord regarding the validity of the DK part of EP 0 907 364. The patent-in-suit concerned a new formulation of the already known pharmaceutical substance quetiapine in a sustained release comprising the active substance quetapine and a gelling agent together with one or more pharmaceutically acceptable excipients.

On April 17, 2012, AstraZeneca had been granted an injunction against Teva's sale of the drug "Quetiapin Teva SR" and on December 20 2013, another injunction was granted against Accord's sale of the drug "Quetiapin Accord SR". (Subsequently, the patent has also been successfully enforced against Orion and Hexal in Denmark). Following the first two injunctions, AstraZeneca had filed suits (main actions) against both Teva and Accord, and the cases were tried together in the present case before the Maritime and Commercial Court.

The parties agreed that the requirement for novelty was met, and the dispute therefore only regarded the inventive step of the patent.

According to Teva and Accord, the assessment of inventive step should be based on the problem-and-solution approach. The parties argued that it was standard practice at the Danish courts to apply the problem-and-solution approach when assessing inventive step of European patents with effect in Denmark. The Maritime and Commercial Court agreed with Teva and Accord and applied the problem-and-solution approach holding that one must (i) determine the 'closest prior art', (ii) establish the 'objective technical problem' to be solved and (iii) consider whether the invention would have been obvious to the skilled person.

As regards the closest prior art, Teva and Accord argued that it was an article by Gefvert describing an experiment with quetiapine in an IR-formulation to be given three times a day to patients diagnosed with schizophrenia. According to the court-appointed experts, Gefvert contained a strong indication that quetiapine potentially could be used as an untypical antipsychotic remedy. Further, it was stated that given the importance of compliance with medication on schizophrenics, a more convenient dose regimen would be beneficial. The court agreed with Teva and Accord and, accordingly, Gefvert was considered the closest prior art.

Based on Gefvert, the court-appointed experts found that the objective technical problem was to provide a formulation of a pharmaceutical product that could be taken less frequently and that resulted in a more stable and uniform plasma concentration.

As for the last step of the problem-and-solution approach, it was undisputed that the person skilled in the art was a team consisting of an expert in the field of formulation of drugs and a clinician with experience within mental disorders. Teva and Accord argued that the lack of inventive step was due to the fact that the solution with the sustained release (the SR-formulation) did not differ from the prior art, since the prior art would have encouraged the person skilled in the art to solve the objective technical problem by providing a formulation with a sustained release of quetiapine. They further argued that it was routine procedure to make a formulation with sustained release of quetiapine and a gelling agent together with one or more pharmaceutically acceptable excipients. Accordingly, it was without inventive step.

On the other hand, AstraZeneca argued that the person skilled in the art did not have information about some of the physico-chemical and pharmacokinetic characteristics of quetiapine, and that this prevented the skilled person from making a formulation with sustained release.

Based on the court-appointed experts' opinion and specialist literature, the court found that it was general knowledge of a skilled person to make a SR-formulation by using a gelling agent and that HPMC (the gelling agent used) was a known and generally used gelling agent in that regard. This formulation was, among other, an obvious option as a solution to the technical problem. Thus, the invention was obvious to a person skilled in the art. The fact that there were other obvious solutions such as depot injections did not alter the fact that the solution of the patent was obvious.

As a secondary claim, AstraZeneca had argued that the patent should be kept in force in accordance with a limited claim. However, the court did not find that AstraZeneca had proven that the limited patent claim had inventive step and so the court ruled against AstraZeneca.

In accordance with the claims submitted by Teva and Accord, the Maritime and Commercial Court found that the patent was invalid due to the lack of inventive step. Accordingly, the court reversed the decisions made by the enforcement courts and acquitted Teva and Accord for the claims submitted by AstraZeneca.

Pursuant to section 480 of the Danish Administration of Justice Act, a judgment is not enforceable during appeal, and, accordingly, the lifting of a PI's will not take effect during an appeal. There is, however, a possibility in the Act for the court to deviate from this point of departure, if special circumstances apply. This was invoked by Teva and Accord, who applied to the court to order that in the event of invalidation, the court's decision should not be given suspensory effect and that the court therefore should order that the lifting of the PIs should take effect regardless of appeal.

According to Teva and Accord, it would be unreasonable maintain the effect of the injunction during an appeal when the same court had just found the patent invalid, since AstraZeneca could decide to lodge an appeal just to keep Teva and Accord off the market as long as the appeal was pending. They further argued that the European patent had been invalidated without recourse in several European jurisdictions and so there was no probable prospect of the decision by Maritime and Commercial Court being reversed in a potential appeal.

On the other hand, AstraZeneca argued that it was expressly emphasized in the legislative history of the Act that it should be an exception not to grant suspensory effect and that neither Teva nor Accord had given any information to provide a basis for deviating from the general rule. AstraZeneca further argued that because of the special nature of drugs, AstraZeneca would lose a significant share of the market within a short period of time causing a severe and irretrievable loss. In comparison, Teva's and Accord's loss would be limited.

Teva's and Accord's claim for suspensory effect was denied by the court – although it is difficult to envisage circumstances more special than when the invoked right has been invalidated.

We expect this decision to be appealed.

Reported by Cecilie Frost Adamsen