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- UK Patents Court invalidates another sustained-release formulation patent.
- Who is "the skilled person" in formulation patents?
- Different European countries decide differently on the same patent.

AstraZeneca held a UK patent for the antipsychotic drug quetiapine, which is marketed by AstraZeneca under the brand name Seroquel ®. The UK patent and supplementary protection certificate for the drug quetiapine as such expired on 23 March 2012, and competing pharmaceutical companies wanted to enter the market with this drug.

However, AstraZeneca also held a second European patent, valid in the UK, for a sustained-release formulation of quetiapine, marketed as Seroquel XR ®. AstraZeneca hoped to extend its monopoly on quetiapine drugs with this second patent (EP (UK) 0907364) which essentially claimed the drug together with a gelling agent, in a sustained-release formulation.

A number of pharmaceutical companies (Teva UK Limited, Teva Pharmaceutical Industries Limited, Accord Healthcare Limited, Intas Pharmaceuticals Limited, Hexal AG and Sandos Limited) started an invalidity action at the UK Patents Court to try to have the sustained-release patent revoked. These opposing companies argued that the claims of the patent were not inventive over a prior art document describing pharmacokinetic studies on immediate-release formulations of quetiapine. They argued that, based on these studies it would have been obvious for a skilled person to formulate the drug with a gelling agent to give sustained release.

On the other side, AstraZeneca argued that it would not have been obvious because sustained release could instead be achieved by administering a larger dose of the known immediate-release formulation, and that the skilled person would have chosen this route. Moreover, AstraZeneca argued that the skilled person would not have a reasonable expectation of success in providing a sustained-release formulation due to the known *in vivo* metabolism profile of

quetiapine. The patent explained the possible problem of water-soluble drugs such as quetiapine which can "dump" the active agent immediately into the body instead of acting as a sustained-release formulation as intended.

In the UK Patents Court, Mr Justice Arnold judged the patent invalid for lack of inventive step.

The judge found the prior art to show that the pharmacokinetics of quetiapine were linear and therefore a sustained-release formulation of quetiapine could readily be prepared by a skilled person using a known gelling agent, without any inventive skill. This follows previous UK judgements in which sustained release formulations were found to be obvious over the drug as such.

The UK Patents Court revoked the sustained release patent and AstraZeneca subsequently filed an appeal at the UK Court of Appeal. Whilst the Court of Appeal has not yet released its judgement at the time of going to press with this Newsletter, Forresters attended the Court of Appeal hearing.

AstraZeneca argued at the Court of Appeal that the "skilled person" in this case should be seen as a team led by a clinician and merely including a formulator. With this argument, AstraZeneca hope to remove the common general knowledge of a formulator from the inventive step considerations and instead focus on what a clinician would have instructed a formulator to prepare. The opposing companies submitted that the skilled person should be seen as a team of a clinician and a formulator, and that these people would have engaged in an equal dialogue at the priority date. It will be interesting to see whether the Court of Appeal defines the skilled person as a team where one member has more input than another.

It is also interesting to note that the very same European patent was found to be valid by the equivalent of the UK Patents Court in the Netherlands. This is yet another example of different patent courts in Europe reaching opposite conclusions on the same set of facts, and highlights the need for a unified patents court in Europe, as presently under development by the European Parliament.