



EPO Practice on Post-filed Experimental Evidence Approved by the UK Court of Appeal

In its decision in *Generics (Mylan) V Yeda & Teva*, the UK Court of Appeal considered the extent to which subsequent evidence can be relied upon for the determination of inventive step. The Court closely followed the approach adopted by the EPO to the consideration of such evidence. The decision provides a useful summary of the manner in which the technical contribution provided by a patent is assessed.

Yeda Research and Development Company Limited was the proprietor of a patent directed to a synthetic polypeptide which is useful for the treatment of relapsing-remitting multiple sclerosis. Teva Pharmaceuticals Limited were an exclusive licensee under the patent and market such a product as Copaxone. Generics (UK) Limited, who trade as Mylan, filed an action for revocation of the patent and a declaration of non-infringement for a product that they intended to launch. One of the arguments advanced by Mylan to attack the validity of the patent was obviousness in light of a lack of technical contribution.

In the first instance proceedings before the High Court, the judge held that the technical contribution of the patent was that the claimed polypeptides caused less irritation at the injection site and/or a reduced incidence of systemic side effects compared with polypeptides known in the art, which had higher molecular weights. The Examples in the specification were found to make such effects plausible.

The argument presented by Mylan relied upon the results of two clinical trials. They submitted that results obtained after the priority date of the patent showed that the claimed polypeptides were not in fact associated with advantages over the high molecular weight polypeptides described in the prior art. At first instance this approach was rejected. The Judge held that if a patent specification made a technical effect 'plausible', it was not open to Mylan to mount a challenge to the existence of that effect by the use of later evidence. This legal point has now been reconsidered by the Court of Appeal.

In order to assess the manner in which the technical contribution of a patent can be challenged, the Court of Appeal sought guidance from, amongst others, leading EPO decisions. Thus, the Court considered the EPO decision in *AgrEvo T939/92* which concerned a claim to a large class of compounds said to possess herbicidal activity. In that case, the Board of Appeal decided that a technical effect can only form the basis for consideration of inventive step be recognized when it can be fairly assumed to be produced by substantially all of the claimed compounds. The

court also considered the EPO decision in Johns Hopkins T1329/04 which found that it is necessary that a patent specification must contain enough information to make it plausible that a technical effect is achieved before the technical effect can form the basis for consideration of inventive step.

Taking these decisions into account, the assessment of the technical contribution of a patent was summarised by the Judge in the following terms:

- i. Article 56 of the EPC is in part based on the underlying principle that the scope of the patent monopoly must be justified by the patentee's contribution to the art;
- ii. if the alleged contribution is a technical effect which is not common to substantially everything covered by a claim, it cannot be used to formulate the question for the purposes of judging obviousness;
- iii. in such circumstances the claim must either be restricted to the subject matter which makes good the technical contribution, or a different technical solution common to the whole claim must be found;
- iv. a selection from the prior art which is purely arbitrary and cannot be justified by some useful technical property is likely to be held to be obvious because it does not make a real technical advance;
- v. a technical effect which is not rendered plausible by the patent specification may not be taken into account in assessing inventive step;
- vi. later evidence may be adduced to support a technical effect made plausible by the specification;
- vii. provided the technical effect is made plausible, no further proof of the existence of the effect is to be demanded of the specification before judging obviousness by reference to the technical effect propounded.

As noted above, in the present case, the first instance judge had held that if the patent specification contained enough evidence to make it plausible that the reduction in molecular weight enabled the advantages claimed by the patent, it was not possible for a third party to attack the patent on the basis that that advantage did not in fact arise. The Court of Appeal disagreed.

In considering this issue, the Court of Appeal agreed that evidence which is relied on to show that the invention was an obvious step for the skilled person to take must be evidence which would have been available to the skilled person at the time. However, before determining whether an invention would have been obvious at the priority date, it is first necessary to answer the question: what is the invention? The Appeal Court indicated that it was therefore permissible to consider evidence as to the true nature of the advance made by the invention. Thus, post-published evidence could be used to determine whether or not any a particular technical advance has actually been achieved by a claimed product or method.

The evidence adduced by Mylan to attack inventive step was therefore found to be admissible.

However, on the facts of the case, the Court of Appeal held that the evidence relied upon did not prove the lack of a technical contribution.

The Court of Appeal therefore upheld the decision of first instance, dismissing the revocation action and refusing the declaration of non-infringement.

The present case shows how there is consistency between the UK Courts and the EPO in the consideration of inventive step. It also demonstrates how later filed evidence can be used in the assessment of inventive step. However, from the Patentee's point of view such evidence can only be relied upon if the technical effect is made 'plausible' by the original patent specification. The amount of information required for an effect to be plausible will depend upon the facts of a given case.

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For more information, please contact:

Tom Carver - tcarver@jakemp.com
Andrew Clark - aclark@jakemp.com
Ravi Srinivasan - rsrinivasan@jakemp.com