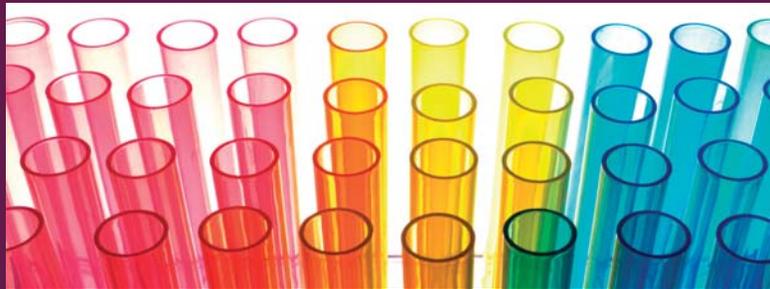


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# **LIFE SCIENCES**

9TH EDITION

**WHEN IS POST-PUBLISHED EVIDENCE  
ACCEPTABLE?**

VALEA

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# When is post-published evidence acceptable?

**Ronney Wiklund** and **Anette Romare** of **Valea** discuss an apparent trend in the European Patent Office's assessment of inventive step, in which the objective technical problem is redefined

In an article for *Managing IP* (July/August 2009 issue) we discussed that the EPO seems to have become stricter in its assessment of parameter claims with regard to sufficiency of disclosure and clarity.

We may now have noted a trend in the way the EPO assesses inventive step and alleged advantages in view of cited prior art and in relation to the evidence put forward by the applicant. The question we now seek to answer is under what circumstances the EPO can be expected to accept post-published evidence, in particular in instances when the technical objective problem has been reformulated during the course of the proceedings before the EPO.

## Introduction - inventive step

According to Article 52 (1) of the European Patent Convention, any inventions that are new, involve an inventive step and are susceptible of industrial application may be considered to be patentable inventions.

Article 56 of the EPC stipulates the general terms for the requirements of inventive step. By the terms of Article 56 an invention that is considered to be new shall be considered as involving an inventive step if, having regard to the state of the art, it is not obvious to a person skilled in the art.

Following the Raising the Bar initiative, the Guidelines for Examination in the European Patent Office have been adapted to existing case law at the EPO and a more thorough discussion about inventive step and the skilled person has been introduced in the Guidelines. It is now stated that the "problem-and-solution approach" should be applied when assessing inventive step and that any deviation from this approach should be exceptional (Guidelines C-IV, 11.5). A technical problem may be regarded as being solved only if it is credible that substantially all claimed embodiments exhibit the technical effects upon which the invention is based. Thus, the examiners at the EPO seem now to be explicitly directed to use the problem-and-solution approach as developed by case law.

That approach comprises the steps of 1) determining

the closest prior art, 2) in view of the closest prior art, establishing the technical objective problem to be solved, and 3) considering whether or not the claimed invention, starting from the closest prior art and the technical objective problem, would have been obvious to a skilled person.

## Alleged advantages and reformulation of the problem

A major issue in the problem-and-solution approach is the formulation of the "technical objective problem". This problem may be based on a technical improvement over prior art or on alternatives to what is previously known. A demonstrated advantageous effect of the claimed subject matter may support the presence of an inventive step.

The early EPO decision T20/81 set out a principle for how to treat alleged but unsupported advantages referred to by the applicant. It was concluded that when the asserted advantages had not been properly demonstrated in view of the closest prior art they could not serve as a basis for formulating a technical objective problem. This principle has later been confirmed in several decisions, such as T 181/82, T 912/94 and T 1051/97. When the applicant fails to make plausible that the advantages or effects of a claimed invention will be obtained for all embodiments of the claim, the technical objective problem may have to be reformulated. The new problem may be less ambitious than the problem originally formulated by the applicant. In cases where the problem is reformulated as finding an alternative there is a risk that the alternative is found to be too obvious to support an inventive step.

For example, in T235/04 the alleged advantage over prior art of certain hair dyeing compositions was a colouring intensity improvement. The experimental data did not make it credible that the technical effect could be obtained with all the claimed compounds. In view of the prior art, the technical problem was reformulated as the provision of alternative dyeing compositions. The claimed compositions were then considered obvious arbitrary choices in the light of the prior art.

A reformulation of the technical problem is normally allowed if the person skilled in the art would consider the reformulated problem to be related to the technical problem initially suggested in the application or to be derivable from the application (compare T 184/82, T 732/89, T 440/91 and T 13/84). The reformulated problem should not be inconsistent with earlier purpose and invention character statements in the application (T 155/85 and T 115/89).

An evaluation of case law renders it clear that it must be made plausible that the alleged technical problem is solved by the invention. For example, T 1003/99 relates to the stability of certain compounds as compared to a prior art compound. No evidence of an improvement in this respect was provided and the Board considered it implausible that improved stability was achieved within the whole claimed scope.

Further examples of recent decisions at the EPO concerning reformulation of the problem or alleged advantages are T 260/09, T 1621/08, T 1666/07, T 1151/07 and T 1114/06.

In T 260/09, the alleged problem was stated as the provision of a medical device improving treatment of vascular disease. The solution was a coated medical device with certain coating arrangements involving two substances for release. The experimental evidence provided in the application related to only one substance. The closest prior art disclosed stents coated with mixtures of two substances and having a top coat. It was concluded that the alleged improvement over prior art was implausible from the

application itself. The experimental evidence included only one of the two substances and could not support the alleged problem. The technical problem was reformulated as the provision of an alternative medical device for treating vascular diseases and its solution was found obvious.

In conclusion, the applicant has to show that it is plausible that a technical problem based on an advantage over the closest prior art is solved by all embodiments of the broadest claim. Merely referring to alleged advantages, while leaving out the evidence in support of the advantages, is not sufficient for correctly formulating the objective technical problem. The question then arises when and to what extent the technical effect has to be demonstrated.

### Demonstrating alleged advantages - when and what?

From case law it has been established that no technical objective problem and inventiveness can exist when there are no technical issues to be solved (Guidelines C-IV, 11.5.2, and T 22/82). For broad claims, a guiding principle of inventiveness was laid down in T 939/92, which concerned the provision of further compounds with herbicidal activity as the technical effect that was the sole reason for alleged inventiveness. It was held that no inventive step can be recognised, if it is not made credible that all compounds as claimed provide the asserted technical effect. Of importance, though, is that this ruling does not apply if the technical effect is not the sole reason for an alleged inventiveness.

Furthermore, the EPO may consider post-published

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evidence – evidence filed after the filing date of the application – when deciding whether an alleged problem is solved.

In T 1151/07, the proprietor submitted further experimental tests during the appeal procedure and the board finally held that these tests supported the assertion that the defined technical problem had been plausibly solved.

T 1621/08 indicates that in oppositions the opponent may benefit from filing experimental tests, which indicate that the alleged advantages were not credible. In that case, the problem was reformulated to a less ambitious problem.

In the much-debated case T 1329/04 post-published evidence was found non-acceptable. It was held that post-published evidence may not serve as the sole basis for establishing that the application solves the alleged problem. The issue was whether or not the post-published document included the first disclosure going beyond speculations of an alleged effect. As stipulated by the board, “enumerating any and all putative functions of a given compound is not the same as providing technical evidence as regards a specific one”.

The view taken in T1329/04 has been confirmed in subsequent decisions, notably taken by the same board, 3.08.08 (for example T 861/08, T 710/05). In T 1306/04 it was ruled that a general use of a peptide for diagnosing diseases in the application did not render it plausible that the problem of diagnosing of a more specific disease was solved. Post-published evidence was not taken into consideration. We conclude, therefore, that post-published evidence may be considered by the EPO when it is not the sole basis for an alleged problem and when the application as such provides a plausible solution to the problem. Whether or not there is a plausible solution must be decided on a case-by-case basis, taking into consideration the content of the application as filed and common general knowledge and established teachings in the art at the priority date. Indeed, in decisions following T1329/04 this question has been further reviewed and it appears that under proper circumstances it will still be possible to rely on post-published evidence.

Indeed, in T 433/05 and T 1336/04, post-published evidence was accepted despite the lack of experimental evidence of the alleged effects in the applications, as it was found plausible that the alleged problems were solved at the priority date.

Further decisions have confirmed that post-published evidence may be considered when information in an application as such, and also in view of what is known in the art, makes it bona fide plausible that an alleged problem is solved.

In 578/06 it was stated that the EPC requires no

experimental proof for patentability, as long as it is made plausible that the problem is solved. Post-published evidence was considered although application information concerning the alleged advantages was only mentioned in a theoretical manner.

It may not be required to provide absolute proof of the achievement of an effect in order that it be considered plausible. For example, the protective immunity of a vaccine need not be demonstrated in the target organ-

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## **Examiners at the EPO seem now to be explicitly directed to use the problem-and-solution approach as developed by case law**

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ism, if the data indicates that it is a useful vaccine candidate (see T 716/08)

### **An exceptional decision**

After evaluation of the decisions taken in view of T 1329/04, we believe that the ruling concerning non-allowance of post-published documents is exceptional. Accordingly, when an application only mentions a putative or general function without providing description or evidence of the function, post-published evidence may be questioned, particularly when the teaching of the prior art largely contradicts the alleged function. Thus, we believe that in most cases it will be possible to rely on post-published evidence.

The determination of whether or not a problem is solved by a claimed invention should be made on the basis of the information in the application in view of common general knowledge at the priority date. Post-published evidence may only be used to back-up the teaching arrived at. In a case where the problem is found not to be solved by the invention, the objective technical problem may have to be reformulated in a less ambitious way and there is a risk that inventive step will be denied.

### **Advice on applications**

When initially formulating the objective technical problem, care should be taken to ascertain that the problem is solved over the broadest scope of the invention, less the problem be later reformulated by the EPO into a less ambitious problem and that its solution be found to lack inventive merit. Any alleged technical effect should be supported by information and preferably technical evidence as to why and how the effect is achieved. If possible, the information and the evidence should already be included in the priority application, or at least in a following application. The applicant should also be prepared to provide further evidence during examination of the application.

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