

(Non-)Obviousness of Alternative Solutions – Considerations for Successful Inventive Step Arguments

When it comes to inventive step, Applicants and Patentees commonly try to argue for superior effects of the claimed subject-matter, while Opponents try to deny the existence of such effects. But what is the situation if there is no evidence for any superior or advantageous technical effects?

Is inventive step out of reach?

Not always. Although evidence for certain improvements is helpful for the acknowledgement of an inventive step, there is also the option of arguing for a non-obvious alternative solution. This strategy of argumentation usually requires more sophisticated and well thought-out arguments to lead to acceptance.

Some recent Board of Appeal decisions provide some helpful insights and illustrate possible strategies for arguing the presence of an inventive step successfully.

1. T 1180/18 (inventive as non-obvious alternative)

Decision T 1180/18 was published on December 22, 2020 and relates to European patent application EP 05 380 116.3 for *“Therapeutic human albumin solutions with low prekallikrein activator (PKA) activity and process for obtaining them”*.

According to the claimed invention, purified albumin solutions are provided, wherein antithrombin is only partially extracted therefrom to reach a remaining level of antithrombin in the solution which is

sufficient to inhibit PKA activity. The closest prior art to the claimed invention was seen as a document discussing the preparation of albumin solution with increased purity by carrying out steps for separating and eliminating detrimental contaminants such as PKA.

Starting out from the closest prior art, the objective technical problem to be solved by the claimed invention was determined by the Board of Appeal as the provision of an alternative process for the production of albumin solutions by plasma fractionation.

Interestingly, while the claimed process may in fact appear more cumbersome than prior art processes, the invention in question was nevertheless considered an alternative solution not rendered obvious by the prior art. In this case the relevant cited prior art does not suggest to incorporate (or retain) an inhibitor of PKA activity in the albumin solution but instead aims to remove and reduce the PKA content altogether.

The claimed process of partial extraction of contaminants and thus reaching PKA inhibition by different means was then seen

as an alternative solution not having been rendered obvious by the prior art.

Based on these arguments, it was possible to reach a positive decision for the patentee without having to file and rely on additional experimental data.

2. T 63/17 (inventive as non-obvious alternative)

Decision T 63/17 was published on December 23, 2020 and relates to European patent application EP 09 787 605.6 for *“Stable immunogenic protein having multiple cysteine molecules, process therefor and composition thereof”*.

According to the claimed invention, a specific protein region is expressed, purified and refolded using specific washing and refolding steps recited in the claims in question. The closest prior art to the claimed invention was seen as a document discussing recombinant production of a protein with a slightly different protein sequence and using a different protocol for washing and refolding.

During appeal proceedings, the Applicant provided experimental evidence to prove a higher yield of the claimed method. Based on said evidence, the Applicant sought to reformulate the problem in a more ambitious manner than merely the provision of a non-obvious alternative.

However, irrespective of the evidence submitted, the Board of Appeal already acknowledged the presence of an inventive

step as an alternative solution not rendered obvious by the relevant prior art. The Board's reasoning included the recognition that a necessary adaptation of washing and refolding steps leading to purified recombinant protein cannot be obtained by mere routine experimentation.

Following this recognition and in the absence of any evidence to the contrary, the Board already acknowledged the presence of an inventive step for the claimed non-obvious alternative.

The additional experimental evidence allegedly supporting technical effects and advantages was available in this case as a safety net. However, since the arguments for a non-obvious alternative were already successful in convincing the Board of the presence of an inventive step, said evidence was not even required for a positive decision and grant of a patent.

3. T 1778/18 (not inventive as non-obvious alternative)

Decision T 1778/18 was published on December 18, 2020 and relates to European patent application EP 09 158 328.6 for a *“G-CSF liquid formulation”*.

According to the claimed invention, a liquid formulation of G-CSF is provided with a defined pH value of between 4.1 and 4.3. The closest prior art to the claimed invention was seen as a document disclosing a similar liquid formulation of G-CSF having a pH value of 4.0.

During the proceedings, it was determined from the cited prior art that similar liquid formulations of G-CSF aggregate at pH values above 5.0 when tested at elevated temperatures. Moreover, the skilled person was considered to be aware of the problem of lower patient tolerance of injection solutions with pH values lower than 4.0.

Without any further experimental evidence to the contrary, it appeared obvious to use any of the pH values between pH 4.0 and 5.0 for an alternative formulation. The Board thus further considered the selection of the pH range between 4.1 to 4.3 from the range between 4 and 5 to be arbitrary in the absence of any evidence suggesting otherwise.

Accordingly, the claimed invention was considered a mere alternative which, in the absence of difficulties for the skilled person to work in the claimed range, was obvious in view of the prior art.

If there would have been any indication on file that, for example, the claimed pH range between 4.1 and 4.3 strikes an optimal balance between (storage) stability and patient tolerance, an inventive step would likely have been recognized. Thus, it may have been profitable for this case to install a safety net by preparing and submitting useful experimental evidence instead of relying solely on arguments for a non-obvious alternative.

4. Summary and suggestions

The three cases summarized above are useful examples for the current Case Law of the European Patent Office regarding non-obviousness of alternative solutions. However, it is usually a quite delicate matter to argue for the presence of an inventive step based on non-obvious alternatives alone.

In case that experimental evidence may be available to support some kind of advantage over the prior art, it should always be introduced into the proceedings at least as a safety net (see, for example, case 2. above). However, in case that such evidence cannot be produced for any reason, even more attention should be paid to developing convincing arguments in support of non-obviousness of the alternative solution.

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