

There may no longer be Hope in Inventive Step, but Recognizing a Problem may also help

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Thorsten Bausch, Charlotte Richards-Taylor, Arianna Bartolini (Hoffmann Eitle)

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As was rightly noted on this [blog](#), the skilled person's "hope" of solving the objective technical problem using the means that led to the (later claimed) invention, has disappeared from the [Guidelines for Examination](#). What we are left with is the (perhaps) more objective "expectation of some improvement or advantage (see T/83)". Interestingly, this expectation of "some improvement or advantage" no longer appears to be so closely linked to the objective technical problem than the language previously used in the Guidelines. Whether this will in the future give rise to more problems for applicants or patentees remains to be seen. In any case, it may be a good point in time to remind ourselves that even recognizing a problem and its roots can (at least sometimes) be an invention of itself.

Art. 52(1) EPC reads:

"European patents shall be granted for any inventions, in all fields of technology, provided that they are new, involve an inventive step and are susceptible of industrial application."

As is laconically stated in the [Case Law Book](#), 9th Edition:

The application of Art. 52(1) EPC presents a problem of construction as there was no legal or commonly accepted definition of the term "invention" at the time of conclusion of the Convention in 1973. Moreover, the EPO has not developed any such explicit definition since. Art. 52(2) EPC is merely a negative, non-exhaustive list of what should not be regarded as an invention within the meaning of Art. 52(1) EPC.

Nonetheless, there may perhaps be the perception that an invention is to be defined as the (more or less ingenious) solution to a particular problem. The EPO's Problem and Solution Approach may be conducive to such an understanding. According to the Guidelines for Examination, this approach essentially consists of the following steps:

- (a) identifying the "closest prior art",
- (b) assessing the technical results (or effects) achieved by the claimed invention when compared with the "closest state of the art" established,
- (c) defining the technical problem to be solved as the object of the invention to achieve these results, and
- (d) examining whether or not a skilled person, having regard to the state of the art within the meaning of Art. 54(2) EPC, would have suggested the claimed technical features in order to obtain the results achieved by the claimed invention.

From this, you would perhaps think that the "technical problem to be solved" (the objective technical problem) is a more or less artificial construct that is objectively derived from the results or effects achieved by the invention when compared with the closest state of the art. Inventive step only comes in the last step (d) where it is examined whether the skilled person would have suggested the claimed solution in order to solve the objective problem.

However, as the decision [T_2321/15](#) by the Technical Board of Appeal 3.3.07 shows, such an understanding would be too narrow. In certain cases, the invention may also reside in recognizing a particular problem, whereas the subsequent solution thereof may appear relatively trivial.

Facts of the Case

European Patent No. 2 034 951 related to a method for formulating storage stable and easily rehydratable dried pharmaceutical compositions, which are used as chemo-embolic compositions.

Claim 1 of the main request read as follows:

A method for formulating a dried product suitable for direct administration to an animal as an embolic agent after rehydration to form a suspension comprising:

- (i) a freezing step in which particles of polymer matrix swollen with water and having absorbed therein a non-volatile biologically active compound are cooled to a temperature below the freezing point for water;*
- (ii) a lyophilisation step in which the cooled particles from step (i) are subjected to a reduced pressure at which ice sublimates for a period during which at least a portion of the absorbed ice sublimates and water vapour is removed; and*
- (iii) a packaging step in which the dried particles are packaged;*

characterised in that the packaging step is carried out under reduced pressure and the package containing the particles is substantially airtight and has an interior under vacuum; and the particles are substantially spherical in shape and the particle sizes are selected such that upon rehydration in 0.9wt% saline at room temperature, the average particle size is in the range 40 to 2000 micrometers.

The opposition division revoked the patent on the ground of lack of inventive step. D4 disclosed the preparation of PVA porous microspheres comprising an active agent for embolization, by a method involving a freeze-drying step, and was taken as the closest prior art. The OD came to the conclusion that the sole difference in view of D4 was that the sealing process was carried out under vacuum, and considered sealing under vacuum obvious, since it was commonly known that residual air in lyophilized microspheres inhibited the rehydration process, and it was an obvious measure to overcome this problem by applying a vacuum, which was also known from D11 and D17.

Recognition of an unknown problem

The patent proprietor filed an appeal against this decision, arguing that the problem to be solved by the contested patent was the improvement of the rehydration of the particles and the resolution of the buoyancy problem, which was due to the presence of air pockets in the particles.

The Board agreed that it was not known before that air penetrated the pores of the particles and caused a high buoyancy when rehydrated. The invention was thus found to reside in the recognition of this unknown problem linked with said air pockets in the particles.

The Board further considered that it was true that rehydration of a vacuum stored product was generally known, but not in relation to the problem of the present invention concerning embolic particles. As D4 did not mention the presence of air pockets in the porous microspheres and any of the associated problems, starting from D4 the skilled person would not have been motivated to change the process to perform the sealing process under vacuum conditions, i.e. the question asked was would (not could) the skilled man have added a sealing and storage step under vacuum.

Consequently, the Board agreed with the appellant that the problem posed by the contested patent is an unrecognized problem in D4 and acknowledged inventive step on this basis.

Conclusion

Decision T 2321/15 thus came to the interesting conclusion that the discovery of a yet unrecognized problem may give rise to patentable subject-matter in spite of the fact that the claimed solution may be, once the root of a problem has been identified, retrospectively trivial and in itself obvious. As such, T 2321/15 is not the first decision of its kind, but rather follows a long tradition starting with [T_2/83](#) itself, which was confirmed in [T_764/12](#). It may thus be prudent for parties applying the problem-solution-approach to include the recognizability of the objective problem and its cause into their considerations.