

EIP

EPO Board of Appeal applies the G2/21 test for post-published evidence

The EPO Board of Appeal decision on T 0852/20 has recently been published. It is another decision using the new test under G 2/21, which set out when post-published evidence can be relied upon for inventive step, reframing the older case law, some of which imported a test for plausibility.

The decision does not use the guidance set out in T 0116/18 (the case from which G 2/21 was referred) for interpreting the new test. This is unsurprising because the oral proceedings for T 852/20 happened on the same day that the decision on T 0116/18 was issued.

The present case concerned a small molecule medicament called vemurafenib and the differences in water solubility and bioavailability of two crystalline forms of this substance. Vemurafenib is an approved anti-cancer drug sold under the name Zelboraf, which is used to treat late-stage melanoma.

It was accepted by both the proprietors and the opponent that form 1 of vemurafenib, claimed in the patent, exhibited better properties than form 2 known in the prior art. But the opponent alleged that this effect was demonstrated solely in the post-published evidence provided by the proprietors and initially argued that it was not plausible based on the application as filed.

The Board in the present case referred to the test set out by the Enlarged Board directly, i.e.:

"a patent applicant or proprietor may rely upon a technical effect for inventive step if the skilled person, having the common general knowledge in mind, and based on the application as originally filed, would derive said effect as being encompassed by the technical teaching and embodied by the same originally disclosed invention."

The Board considered that the skilled person could not derive the improved properties of form 1 over form 2 from the application as filed (see decision point 3.5 onwards). They wrote that the relevant parts of the description appear instead to teach the skilled person to formulate vemurafenib in an amorphous form, not a crystalline form because of improved bioavailability and water solubility. There is no teaching in the application that crystalline form 1 would be better than crystalline form 2.

The teaching referred to by the Board can be understood since patent is a divisional case. The granted parent claims relate to an amorphous form of vemurafenib.

From this, the board considered that the skilled person would not have derived the purported technical effect as being encompassed by the technical teaching, nor would they have derived it as being embodied by the same originally disclosed invention. Therefore, the effect cannot be taken into account for formulating the objective technical problem.

In view of this, the Board considered form 1 to be a mere alternative and found the claims to lack inventive step over the prior art.

It seems unlikely that this decision would have been decided differently using a plausibility test. Nonetheless, the Opposition Division considered in its 2020 decision that the data should be considered and decided in favour of the proprietors for inventive step on that basis.

It is not clear from the wording alone how the test is G2/21 is supposed to be applied, and this decision adopts a different approach from T 0116/18. It may take some time for the practical application of the G2/21 test to become clear.