

Same case, different outcomes: exploring the application of G 2/21 by different Boards of Appeal

In a fascinating development of post-G 2/21 case law, decisions T0314/20 and T1525/19 reach opposite conclusions on near-identical subject-matter when considering whether post-published data can be used to support a technical effect. The decisions highlight the continued issue of ambiguity surrounding the decision of G 2/21, as well as the divergence in its application by different Boards of Appeal.

Background

[G 2/21](#) establishes that a patent applicant or proprietor can 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". We have previously reported on the decision of G 2/21 [here](#). Nonetheless, almost two years on, there remains considerable uncertainty in applying the somewhat nebulous guidance of the Enlarged Board of Appeal, for representatives and adjudicators alike.

The patents at issue in [T0314/20](#) (EP2187879) and [T1525/19](#) (EP2395984) both related to combinations of linagliptin (a DPP-IV inhibitor) and empagliflozin (an SGLT-2 inhibitor). This combination was described as being suitable for the treatment or prevention of conditions such as type 1 or 2 diabetes.

Claim 1 in T0314/20 simply claimed a pharmaceutical composition comprising the two therapeutics, while the claim at issue in T1525/19 further specified the dosages of linagliptin and empagliflozin. Nonetheless, it was undisputed that these amounts of linagliptin and empagliflozin were standard for each compound, and that they were not associated with any particular effect. Thus, the "essence" of the invention remained the combination of linagliptin with empagliflozin.

In both cases, the prior art disclosed combinations of SGLT-2 inhibitors and DPP-IV inhibitors in general terms. Consequently, a key issue of each decision was what effect, if any, could be attributed to the specific combination of linagliptin and empagliflozin.

The patentee argued that the claimed combination was particularly effective at increasing active GLP-1 concentrations. The patentee attempted to support this effect in each case by filing post-published data, which demonstrated that the claimed combination of empagliflozin and linagliptin increased the plasma level of active GLP-1 in patients with diabetic diseases in a stronger and more prolonged manner than other combinations tested. In this regard, the effect on active GLP-1 concentrations was a known effect of DPP-IV inhibitors, but had not been previously reported for SGLT-2 inhibitors (either in the prior art or the application as filed).

Thus, both decisions hinged on whether this post-published data could be considered.

The approach of T0314/20

In T0314/20, Board 3.3.04 began with a discussion of the general principles set out in G 2/21. The Board identified several challenges in applying this new standard. For one, it was noted that the requirements "encompassed by the technical teaching" and "embodied by the same originally disclosed invention" were not used in pre-G 2/21 discussions of "plausibility", and so their relation to this existing case law remained to be established. Further, the Enlarged Board had not expressly defined these requirements or explained the purpose they served (T0314/20, r. 6.12.4 and 6.12.5).

In dealing with these challenges, the Board turned to the decision of T0116/18 (T0314/20, r. 6.13).

The analysis of T0116/18

The referring case of G 2/21, T0116/18 had provided a detailed interpretation of the Enlarged Board's decision. There, Board 3.3.02 had identified the purpose of G 2/21 as preventing speculative or "armchair" inventions. The decision treated (i) "being encompassed by the technical teaching" and (ii) "embodied by the same originally disclosed invention" as two cumulative requirements, such that each must be met in order to consider a technical effect.

The above reasoning was endorsed by Board 3.3.04 in the present case. However, Board 3.3.02 had then provided the following interpretation of requirements (i) and (ii) of point 2 of G 2/21:

"[F]or requirement (i) of order no. 2 to be met, the purported technical effect together with the claimed subject-matter need only be conceptually comprised by the broadest technical teaching of the application as filed. This in turn means that said effect need not be literally disclosed in it by way of a positive verbal statement (see also point 11.13.1 below). Instead, for example, it may also be sufficient that the skilled person, having the common general knowledge in mind, and based on the application as filed, recognises that said effect is necessarily relevant to the claimed subject-matter.

As regards the second requirement (ii) formulated in order no. 2, namely that the effect must be derivable as being embodied by the same originally disclosed invention, in the board's view, the following question is to be asked: would the skilled person, having the common general knowledge on the filing date in mind, and based on the application as filed, have legitimate reason to doubt that the technical teaching at issue, i.e. the purported technical effect together with the claimed subject-matter, is an embodiment of the originally disclosed invention, i.e. the broadest technical teaching of the application as filed?"

Here, Board 3.3.04 noted an inconsistency in the reasoning of T0166/18 (T0314/20, r. 6.13.6 to 6.13.8). The decision had previously stated it was the requirement(s) defined by the Enlarged Board in point 2 of the order that had to be applied, rather than simply using any rationale developed in the previous plausibility case law. However, when defining how to meet requirement (ii) of point 2 of the order of decision G 2/21, the test described was effectively equivalent to the "ab initio implausibility" standard described in the referring questions.

T0314/20 notes that at no point in G 2/21 was the ab initio implausibility standard endorsed by the Enlarged Board. Similarly, at no point in G 2/21 was it mentioned that a technical effect "need not be literally disclosed in it by way of a positive verbal statement" (T0314/20, r. 6.13.9).

Interestingly, on the second point, Board 3.3.04 states the following (T0314/20, r. 6.13.11):

"[T]his Board considers that the passages of decision G 2/21 referred to by decision T 116/18 do not lead to the conclusion that the standard of disclosure that applies to Article 87 EPC..., Article 123(2) EPC or Article 54(1) EPC... is excluded when assessing whether the technical effect on which the patent applicant or proprietor relies is (i) encompassed by the technical teaching that the skilled person, with the common general knowledge in mind, would understand at the filing date from the application as originally filed "as the technical teaching of the claimed invention", and (ii) embodied by the same originally disclosed invention."

From the above, it might be inferred that Board 3.3.04 intentionally left open the possibility of employing legal principles developed in relation to the "gold standard", when assessing requirements (i) and (ii) as set out above.

The Board's approach in the present case

Turning to the present case, Board 3.3.04 observed that the application as filed had disclosed the combination of empagliflozin and linagliptin at an equal level of preference to other combinations of DPP-IV and SGLT-2 inhibitors. Further, the pharmacological examples of the application had disclosed successful results in vivo when empagliflozin was combined with linagliptin, saxagliptin or sitagliptin.

By contrast, the purported technical effect relied upon by the patentee for inventive step was an increase in plasma levels of active GLP-1, which was stronger and more prolonged in time than the one achieved by other combinations.

The patentee argued that the application as filed disclosed the claimed combination as providing an increase in active GLP-1 plasma levels; how strong or prolonged this effect was compared to other combinations of SGLT2 and DPP IV inhibitors was not to be considered in relation to G 2/21, but rather was a consideration for the “downstream assessment of inventive step” (T0314/20, r. 6.27).

This line of reasoning was rejected, as the technical effect relied upon by the patentee rested on experimental data that did not confirm the technical teaching conveyed by the application as originally filed. Indeed, the opposite effect had been shown in the application – there, the claimed combination reportedly achieved the same increase in GLP-1 plasma levels as combinations of empagliflozin with sitagliptin and saxagliptin (T0314/20, r. 6.28). This approach appears similar to that taken in [T0852/20](#) by Board 3.3.02, wherein the advantages alleged for a particular polymorph of vemurafenib were not taken into account for formulating the objective technical problem, because that polymorph and the supposedly inferior polymorph were presented equally by the application as filed.

It was also argued that the technical effect relied on did not change the nature of the claimed invention since the claimed combination was disclosed in the application as originally filed and no additions or changes to this combination were required to arrive at this effect.

The Board disagreed, and emphasised it is not enough that the claimed invention is disclosed in the application as originally filed in terms of its technical features and that these same features (possibly) achieve this effect without requiring any modification. Rather, it is the purported technical effect relied on for inventive step that must be derivable by the skilled person, having the common general knowledge in mind, and based on the application as originally filed, as being encompassed by the technical teaching and embodied by the same originally disclosed invention (T0314/20, r. 6.29).

Thus, the Board found that the skilled person would not derive the increase in plasma levels of active GLP-1 relied on by the patentee as being encompassed by the technical teaching of the claimed invention and embodied by the same originally disclosed invention. The patentee was unable to rely on the purported technical effect.

The approach of T1525/19

In T1525/19, Board 3.3.07 similarly turned to the general principles set out in G 2/21 when determining whether claim 1 of auxiliary request 1 met the requirements of Article 56 EPC.

However, in this case, the Board came to the opposite conclusion and allowed the post-published evidence to be considered when establishing the technical effect of the invention. The Board concluded that “decision G 2/21 does not preclude taking into account the overadditive effect of GLP-1 levels produced by the combination of linagliptin and empagliflozin in claim 1, as confirmed by D62 and D64”, where D62 and D64 are the post published data.

The Board held that by knowing the mode of action of linagliptin and SGLT-2 inhibitors from the common general knowledge and the application as filed – linagliptin increases GLP-1 levels and SGLT-2 inhibitors promote glucose urinary excretion – it was clear that the application as filed was generally directed to the combination of linagliptin with SGLT-2 inhibitor for improving glycaemic control by increasing both GLP-1 levels and glucose excretion.

Consequently, the Board held that the fact that the combination increases GLP-1 levels in an overadditive manner did not change the nature of the effect assigned to the combination of the invention. Instead, the Board stated that “[i]t merely relates to a difference in intensity, which becomes relevant when quantification is necessary for comparison with the closest prior art”.

In addition, the Board held that the effect shown in the post-published data was embodied by the teaching of Example I in the application as filed. Their reasoning was that Example I

demonstrated that linagliptin and empagliflozin produce a postprandial additive excursion of glucose, which subsequently meant that there was a synergistic interaction between the two active agents. The Board held that a synergistic interaction meant that either linagliptin enhanced the effect of empagliflozin or empagliflozin enhanced the effect of linagliptin, or they both enhanced the effect of each other. Thus, because two out of the three options suggest that empagliflozin enhanced the effect of linagliptin on GLP-1 levels, the skilled person would consider it likely that the overadditive glucose excursion observed in Example I was at least partially due to an increase in the effect on GLP-1 levels compared with linagliptin monotherapy. It was therefore concluded that requirement (ii) of G 2/21 as discussed above was met.

The Board therefore defined the objective technical problem more ambitiously than in T0314/20 as the provision of an improved pharmaceutical dosage form for reducing glycaemia (T1525/19, r. 7.3.9).

Final thoughts

It is inevitable that some variability will be seen in applying a qualitative standard such as the one set out in G 2/21. Nonetheless, such explicit disagreement of the Boards in the above cases is remarkable.

From a practical standpoint, Board 3.3.07 in T1525/19 applied a broad interpretation of "being encompassed by the technical teaching" and "embodied by the same originally disclosed invention", and is consistent with Board 3.3.07's previous interpretation of these terms. By contrast, the approach taken in T0314/20 by Board 3.3.04 requires a more specific disclosure of the precise technical effect being relied upon in support of an inventive step.

In view of the above, one cannot help but wonder if a greater degree of ambiguity has been introduced by the decision of the Enlarged Board, compared to that afforded by the pre-G 2/21 "plausibility" case law. It remains to be seen whether a more consistent framework will emerge as further cases address this issue.

Our partner, [Richard Gillard](#), was involved in both cases, and he would be happy to review and answer any questions.

For more detailed advice in relation to any of the issues discussed above, or for advice relating to other matters regarding European practice, please do not hesitate to get in contact with your E+F representative or email us at elkfife@elkfife.com. More information about the authors can be found at the links below:

