Kluwer Patent Blog

T1085/13: A crystal-clear test for purity

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This recent decision from an EPO Board of Appeal is a rather satisfying development in how patentability (especially novelty) of purity claims is assessed at the EPO. This case may be seen as patentee-friendly, particularly for the pharmaceutical sector, as it likely extends protection for APIs. It will become especially important to review this case law when facing a novelty-only (Art. 54(3)) prior art document cited against a purity claim.

This decision is also likely to have implications for patenting enantiomers and proteins, as well as applications where purity of components is key: high-conductivity applications, high reflectivity surfaces, fuel cells, solar energy applications, catalysts, coatings…the list goes on!

First, a flying summary of the previous case law (**T 990/96**) is that a single disclosure of a compound together with a way of manufacturing it was considered a novelty-destroying disclosure for that compound in **all purities**. Even if the claimed level of purity was not disclosed, the EPO would draw upon the skilled person's general knowledge of purification procedure to arrive at any other purity. To argue against this novelty objection, the applicant would face the burden of showing that the claimed purity could not be achieved – not only with the purification technique disclosed in the prior art document, but by **all** conventional purification techniques.

In the present decision, the Board has drawn a helpful and clear line in the sand: any time "well-known" purification procedures are relied on to obtain a compound with a certain purity, it becomes a question of obviousness, **not novelty**.

This is satisfying for two reasons: lawyers will appreciate that this case brings things further into line with the gold standard of a single, direct and unambiguous disclosure. The benefit for applicants will be a chance to immediately eliminate novelty objections, bringing them one hurdle closer to obtaining a granted patent.

Take away 1 – Think your argument through to the end. Then think a little further.

The claim at issue read:

1. Amorphous Lercanidipine Hydrochloride having a purity of at least 99.5% determined by HPLC analysis and containing less than 0.5% of crystalline Lercanidipine Hydrochloride

The main prior art document taught a method of preparing the claimed compound, and one of the other prior art documents taught a particular HPLC separation method for the claimed compound.

One question for the Board was whether it would be obvious for the skilled person to use this HPLC method to separate and isolate pure compound after making it according to the procedure described in the other document. This argument initially seems to have merit when you see a nicely formed HPLC peak.

The Board here went a little further than just thinking about the separation of the compound in the HPLC column, however. It was noted that the HPLC eluent contained various additives, such as sodium perchlorate and perchloric acid. Although the skilled person would undoubtedly be able to separate pure compound from the reaction impurities, what about the small amount of additive left behind from the eluent after the solvent was evaporated? How would this be removed?

The Board's view is that there was no obvious way to remove these additives. This is a satisfying illustration that, even when an argument appears to have a reached a conclusion, following it just one step further can reveal its flaws. In this case, the key was thinking about how to obtain the pure compound as a final product and not in an eluent.

Take away 2 – Patenting Strategy

This case law has clear relevance for the pharmaceutical industry.

If improved purification methods are discovered, patenting these (and their products) sometime after an initial application to the general API is filed could be a good strategy to obtain longer protection – perhaps by up to eighteen months.

As a result of this decision, an application claiming a specific API purity may be patentable over an earlier disclosure of the API, even if that disclosure includes information on its purification. This was unlikely to be the case previously. Of course, there is also the question of whether there are any obvious prior art techniques that could be used to achieve the claimed purity – if not (which is certainly possible), then the applicant will be able to obtain a patent.

This may be of particular interest in the 18-month publication window, especially when any prior art documents will only be considered for assessing novelty.

Take away 3 – Cast doubt on what has been done before

A simple tactic, but an effective one. This case turned on the fact that the applicant was able to file experimental evidence demonstrating that it was not possible to achieve the level of purity that a prior art document disclosed, which would otherwise have been novelty destroying.

In fact, the Board was satisfied with a single result showing that the disclosed purity was not obtained – much to the consternation of a third party observer during examination proceedings. Arguably, this is because if a purification method is not reproducible, then it cannot be novelty destroying.

Therefore, if you have data showing that the purification in the prior art does not produce your claimed purity, this may be sufficient to over overcome a novelty objection. The argument is that the prior art disclosure does not always produce the claimed purity, is not reproducible, and hence not enabled.

Take away 4 – Common general knowledge – handle with care!

The Board in this case issued a crystal-clear reminder about using common general knowledge as part of a novelty argument. A passage quoted in this decision that deserves painting on the walls of European patent firms and offices alike reads:

Common general knowledge can be used in order to assess how the skilled person would **understand** the disclosure of the prior art, but cannot be used to **supplement** it.

It can be all too tempting – especially when possessing relevant technical knowledge – to assert that common general knowledge would be enough to fill any gap in a novelty argument. However, the fact that a gap exists at all usually means that a novelty objection is not valid.

In the context of purity claims, and remembering that we are considering novelty objections, a helpful example is:

It is permissible to use general knowledge of HPLC to **analyse** the purity of an existing reaction product made by a disclosed procedure (to see if it falls within the scope of a claim)

It is not permissible to use general knowledge of flash chromatography to **further purify** that reaction product to obtain a purer product having the claimed purity.

If facing a novelty objection that uses the common general knowledge, be thorough in assessing its validity and identify the areas where an extra step in thinking (or indeed acting) might be needed. On the other hand, in opposition and court, extra care is required!

Final Thought

Something to keep in the back of your mind for purity cases: a founding assumption of these types of cases is that it is desirable to achieve ever-increasing purity in the first place. While in pharmaceutical cases, it is generally true that companies will always strive to attain purer and purer compounds, this motivation may not always be present in other industries, at least to the same extent. It may be that different levels of purity are associated with certain technical effects in their own right, rather than purity for purity's sake.

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