Kluwer Patent Blog

A Little German Christmas Present and some Year's End Reflections

Thorsten Bausch (Hoffmann Eitle) · Tuesday, December 30th, 2014

Thanks to Miquel Montaña's brilliant Christmas post, we have learnt a lot about the *lucina sine (aut cum) concubitu* and the legal impact her involvement may have had for the application of Directive 98/44/EC to the event leading to the holidays that we have just been celebrating. While I must admit that even after having read Miquel's lucid post, I am still not a hundred percent clear on whether Jesus *in statu embryonis* would have fallen under article 6(2) of Directive 98/44/EC, I can at least confidently say that I am satisfied with the fact that certain questions are probably unanswerable and that the CJEU has generously left this one for the national courts to decide.

Which brings us to Christmas before the national courts, and in this regard it is a decision by the German Federal Court of Justice (*Bundesgerichtshof*) which perfectly fits into this season since it (i) provides a generous possibility („a present") to a patent proprietor who wants to amend his patent in invalidation proceedings and (ii) it deals with fatty acids, i.e. chemical compounds that are of particular biological relevance after a rich Christmas meal.

To be honest, though, the decision Fettsäuren (fatty acids, Court File X ZR 40/12) is not exactly new. It stems from September 2013 and has already been briefly reported in this blog here, but not in respect to the issue of allowability of amendments.

The facts, to the extent they are of relevance here, can be summarized as follows: Patentee wanted to amend the originally disclosed preferred range of **30**-100 wt.-% of certain fatty acids to be used in a medicament to a range of **80**-100 wt.-%. The nullity plaintiff objected to this amendment, relying on the fact that the application as filed nowhere disclosed the value "80 wt.-%", neither alone nor as a lower limit of any range.

What the application as filed did disclose, however, was a particularly preferred range of "greater than 85 wt.-%" and one example with a content of 84 wt.-%.

This was sufficient for the FCJ to hold that the limitation to 80-100 wt.-% is in conformity with Art. 123(2) EPC. The FCJ stated this (translation of paragraphs 26-29 of the decision):

2. Contrary to the Plaintiff's opinion, the subject matter of the patent in suit in the versions as defended in the appeal instance does not extend beyond the content of the documents as originally filed.

a) As regards auxiliary requests II and III, in which the value has been fixed at 85% by weight, this

is apparent from the fact alone that this value is already specified as being particularly preferred in the original application (cf. WO 00/48592, page 5, line 6).

b) Although the range of 80 to 100% by weight as claimed with the main request and with auxiliary request I is not expressly cited in the original application, it is, however, directly and unambiguously derivable therefrom as belonging to the invention.

Just like in the description of the patent in suit, a range of 30 to 100% by weight is also specified in the application as being preferred, and a range of 85% by weight is specified as being particularly preferred. It is apparent therefrom that the upper part of the first-mentioned range is preferred, but that, however, a value slightly below the value of 85% by weight that is deemed to be particularly suitable is also still deemed to be advantageous. The fact that this value does not constitute a strict limit is furthermore apparent from the already mentioned first formulation example that is also provided in the application, in which the proportion of EPA and DHA together is 84% by weight.

Thus, to summarize the above, the FCJ seems to have been of the view that a value (here: 80 wt.-%) is „directly and unambiguously derivable“ from the application as filed („kann ihr aber ebenfalls unmittelbar und eindeutig … entnommen werden“), even though the figure of 80 did not appear in this application at all, not even as a result of an unambiguous mathematical operation. With the same justification, patentee could have amended this range to, say, 83-100 wt.-%, 79-100 wt.-% or 75.5-100 wt.-%. So is 80-100 wt.-% really “unambiguously” derivable?

Considering the above and looking a bit into the year(s) to come, one wonders whether this will be the FCJ’s last word on this subject. The divergence to long-established EPO case law, where an amendment like this would never have been allowed, is so blatant that one must seriously wonder whether the application of apparently the same legal standard as in the EPO (*„directly and unambiguously derivable“*) can yield such different results. The FCJ’s landmark decision Olanzapine also seems to suggest that a stricter approach should be applied. Namely, if 80 wt.-% is unambigously derivable from a range of 30-100, preferably 85 to 100 wt.-%, why should then a combination of two substituents not be unambiguously derivable from two relatively short lists? For a neutral skilled reader, the „surprise element“ of being confronted with 80-100 wt.-% may even be higher than in the Olanzapine case, where he/she at least knew the two substituents, albeit not in combination.

With that, I wish you, dear readers of this blog, a happy New Year! It will surely bring us more interesting cases, perhaps on amendments, perhaps not. And to those readers who may be of the view that the FCJ has been far too generous with patentee in „Fettsäuren“, may it be a consolation that the patent was still declared null and void at the end of the day, even though this was “only” for lack of inventive step.

This entry was posted on Tuesday, December 30th, 2014 at 5:18 pm and is filed under G 1/93, OJ 1994, 541) *The 'gold standard'* of the European Patent Office's Board of Appeal is that *any amendment can only be made within the limits of what a skilled person would derive directly and unambiguously, using common general knowledge, and seen objectively and relative to the date of filing, from the whole of the documents as filed (G 3/89, OJ 1993,117; G 11/91, OJ 1993, 125).*">Amendments, Biologics, Germany
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