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Public Prior Use of a Pharmaceutical Preparation (T 2458/09)

Thorsten Bausch (Hoffmann Eitle) · Monday, October 20th, 2014

Although more than 20 years have passed since the Enlarged Board of Appeal issued its decision G 1/92, there is still little case law which provides guidance on how to establish the structure and properties of a particular medicament in a manner so as to be able to rely on the same as a piece of prior art in opposition proceedings.

In G 1/92, the Enlarged Board rejected the notion of T 93/89 that the ingredients of a commercially available product are not made available to the public unless there is reason for experts to investigate its composition by chemical analysis, and it held that the chemical composition of a product is state of the art when the product as such is available to the public and can be analyzed and reproduced by the skilled person. While this finding seems to imply that such an analysis can in principle be performed, little has been said by the Boards on how to establish the chemical and structural composition of a commercially available pharmaceutical preparation in a manner so as to qualify as state of the art. In particular, it remained unclear whether analytical data was sufficient proof or whether more evidence is required (as in T 952/92), at least if and when available to the opponent, such as for instance a declaration setting forth the exact structural and functional features of opponent's prior product. It also remained undecided whether the opponent (at least if he is the originator of the prior art product) is required to prove his case "up to the hilt" or whether the evidence needs to be assessed "on the balance of probabilities".

These questions have now been addressed by Board 3.3.02 in its decision T 2458/09. During the appeal proceedings, the patentee argued that it was not sufficient for the originator as an opponent to just rely on analytical data showing the composition and construction of the prior art formulation. Patentee submitted that the opponent as originator of the alleged prior use should rather prove his case "up to the hilt" (see e.g. T 472/92).

The originator resisted that. From his perspective, the filing of declarations involves the risk of making proprietary information available to his competitors, and is not necessary for the Board to come to a conclusion on the merits of the case.

In the end, the opponent prevailed and the revocation of the patent by the first instance was confirmed. In its decision T 2458/09, the Board seems to agree with T 952/92 insofar as public availability of a composition does not require a complete analysis of a prior art product and the possibility of an exact reproduction. Quite in contrast, the Board accepted that some uncertainty about the actual structure and composition of the commercial product does not disqualify the same as prior art, and even used this product as the closest prior art and starting point for the assessment

of inventive step. In doing so, the Board acknowledged that this situation is similar to an exemplary embodiment in a written prior art document which may also not be reproducible with absolute certainty.

Specifically, the Board held that “the skilled person takes the information that has been made publicly available when selecting a prior art product”, and concluded that, for a commercial preparation, this is the information made available to the public by means of routine analysis performed by the skilled person. Adopting a very practical approach which seems to reflect reality in the development of generic formulations, the Board approved of the opponents’ approach to combine information which was available from published documents, and analytical data for establishing the composition and structure of the commercial preparation.

T 2458/09 is also interesting from a procedural point of view, since it includes a long and detailed discussion on the admissibility of late filed means of attack and defense by both parties, confirming the EPO’s latest tendencies to be quite strict with any late-filed submissions or requests unless clearly prompted by developments that one party could not predict and/or if the admission of late-filed requests was appropriate in view of procedural fairness to the parties. Moreover, the decision includes an unusually lengthy discussion on claim construction (almost 5 pages) confirming the EPO’s view that the subject-matter claimed has to be read in its broadest technically meaningful sense and that the examples cannot be used to artificially restrict the subject-matter claimed. This is also in line with the case law in Germany (see FCJ Decisions Gelenkanordnung Xa ZR 36/08, Bodenseitige Vereinzelungseinrichtung X ZR 255/01 and Ziehmaschinenzugeinheit X ZR 49/09).

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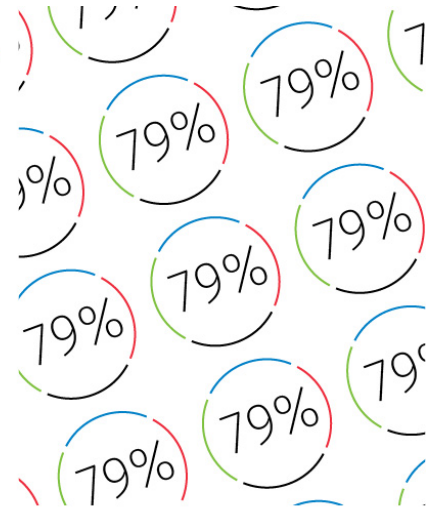
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