The UPC's Approach to Validity – What Can We Learn From The Reasoned Decision In The 10X Genomics v NanoString Technologies First PI Application?

The UPC Munich local division's decision (ACT_459746/2023 –available here) on 10x Genomics' first application for a PI against NanoString Technologies provides a valuable insight into the approach of the UPC when considering the validity of a patent, including in the context of applications for preliminary measures. It is of particular interest to note the references in the decision to various validity tests applied under EPO practice, which suggest that EPO practice and case law will be important touchstones to the judges of the UPC when assessing validity.

In the decision, the claimants 10x Genomics, Inc. and President and Fellows of Harvard College were awarded a preliminary injunction against three NanoString Technologies entities. A thorough investigation of the validity of the asserted patent was carried out at the hearing as part of the various factors to be assessed in relation to whether to grant a preliminary injunction, and the court's decision discusses validity in detail. The court considered the required level of confidence in the validity of the patent for a preliminary injunction to be granted and held that:

"a preponderance of probability is necessary, but also sufficient. It must therefore be more probable for a sufficiently certain conviction of the court that the patent is valid than that it is not valid" (A-IV 4).

In this regard, the court placed the burden on the defendant to demonstrate that the patent is probably invalid. However, the court noted that, under Rule 206.2(d) and Rule 211.1 of the UPC's Rules of Procedure, the claimant must be prepared to provide evidence on the validity of the patent in the event that the defendant's arguments endanger the validity of the patent.

The court considered that validity was to be assessed independently, without following any particular approach taken by national courts and without taking into account general statistics regarding the frequency of successful validity challenges. Nonetheless, the outcome of EPO opposition or other court proceedings (none of which were relevant here) could be considered. A case-by-case assessment was required, and indeed the court proceeded to carry out a fairly comprehensive validity analysis, reviewing novelty, inventive step, sufficiency and added subject matter in some detail.

In this regard, the court appeared to apply standards that closely followed those set by the EPO. Thus, in relation to novelty, the court stated that:

"In order to be able to identify a lack of novelty, the subject matter of the invention must clearly, unambiguously and directly result from the prior art. This applies to all claim features. The standard for the disclosure content of a publication is what can and may be expected from an average person skilled in the relevant art in terms of knowledge and understanding" (A-IV 6).

This standard seems to arise directly out of the EPO's established case law that "for an invention to lack novelty, its subject matter must be clearly and directly derivable from the prior art", and that the disclosure of a publication is "determined by what knowledge and understanding can and may be expected of the average skilled person in the technical field in question" (10th edition of the case law of the boards of appeal, I.C.4).

Part of the discussion on novelty also related to the interpretation of particular terms used in the claims and the extent to which the description could be used to argue for a broader interpretation of the claims. The court based its interpretation of the terms in particular on the skilled person's general understanding of the terms in the claims (also referring to expert reports in this regard), although they did also give consideration to the description of the patent. For example, the term "cell or tissue sample" was found not to encompass genomic DNA isolated and amplified from a cell. The respondent's argument that the description allegedly did not exclude such an embodiment was considered but rejected in view of the skilled person's general understanding of the term. The consideration given by the court both to the wording of the claims and to the description for interpretation purposes is generally in line with EPO practice, although there is diverging EPO case law regarding the extent to which the description can be referred to for interpretation purposes.

Turning to inventive step, the court began its assessment by determining the closest prior art, putting emphasis on the purpose of the prior art embodiment over the number of identical technical features:

"The (closest) prior art to be used for determining lack of inventive step is usually a prior art document disclosing an object developed for the same purpose or with the same aim as the claimed invention and having the most important technical features in common with it, i.e. requiring the fewest structural changes. An important criterion in choosing the most promising starting point is the similarity of the technical task. In this respect, more weight should generally be given to aspects such as the designation of the subject matter of the invention, the formulation of the original task and the intended use as well as the effects to be achieved than to a maximum number of identical technical features" (A-IV 7).

This chimes with EPO practice where, in selecting the prior art, "*the first consideration is that it must be directed to a similar purpose or effect as the invention*" (Guidelines for Examination, section G-VII, 5.1).

The court then proceeded to evaluate inventiveness over various documents and document combinations in detail, with emphasis on technical considerations relating to reasons to modify prior art teaching or combine the teaching of documents. This emphasis may reflect the involvement of technically qualified judges able to make their own assessment on technical issues – the panel of the local division that heard the cases included a technically qualified judge with a relevant background, with one of the legally qualified judges also having a university degree in molecular biology, as explicitly highlighted by the court at A-IV 4 of the decision.

The court's detailed assessment of technical considerations in relation to inventive step is similar to the approach taken by the EPO, whose tribunals also contain technically qualified members. In particular, the court emphasized that there needed to be specific reasons for the skilled person to turn to a second document if it was to be used to supplement the teaching of the closest prior art. Merely asserting that the skilled person would combine the teaching of two documents because there would be no insurmountable objections to arrive at the invention was considered to rely on an impermissible *ex post facto* analysis. The court's approach is generally in line with the EPO's practice when assessing obviousness, in particular that "*the point is not whether the skilled person could have arrived at the invention by adapting or modifying the closest prior art but whether the skilled person* ***would have done*** *so because the prior art provided motivation to do so*" (Guidelines for Examination, section G-VII, 5.3).

Finally, the court referred to the EPO's standards for sufficiency of disclosure by noting that:

"A successful defence of insufficient disclosure requires raising serious doubt, substantiated by verifiable facts, that a skilled reader of the patent would not be able to carry out the invention on the basis of his general knowledge of the subject matter" (A-IV 8).

This mirrors the standard set out at the EPO's Guidelines for Examination, section F-III, 1, which states that an objection of lack of sufficient disclosure presupposes that there are serious doubts, substantiated by verifiable facts.

One further interesting aspect of the decision for comparison with EPO practice is the court's treatment of contingent amendments offered by the claimants in relation to validity. Following preliminary remarks given by the court at the start of the hearing, the claimants filed an amended set of claims in the form of an auxiliary request before the main discussion had begun.

At the EPO, there would be a risk that auxiliary requests filed during a first instance hearing would be considered late-filed and inadmissible. However, one circumstance in which an auxiliary request filed during a hearing might be admitted is if the request was filed in response to a new issue which was only raised at the hearing. The court's decision to allow filing of the auxiliary request does not therefore seem to be particularly divergent with the EPO's practice. Ultimately, however, no decision had to be taken on the auxiliary request because the court was persuaded that the claims of the patent as granted were valid.
The approach to the various substantive requirements for validity taken by the Munich local division in this decision will be comfortingly familiar to those with experience of opposition proceedings before the EPO. The decision suggests that EPO practice and case law are likely to have a strong influence on assessment of validity at the UPC. It will be interesting to see whether a similar approach is taken by other local divisions and other central divisions of the UPC.

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