

ES – Genomic Health v NanoString / Court of Appeals of Barcelona

Court of Appeals of Barcelona, 17 January 2025, Genomic Health, Inc. v NanoString Technologies, Inc., ECLI:ES:APB:2025:582

The plaintiff, Genomic Health, Inc., owner of EP2258872, validated in Spain as ES2433992, filed a patent infringement complaint against NanoString Technologies, Inc., and its subsidiaries, NanoString Technologies Spain, S.L., Izasa Scientific, S.L.U., and Oncogenomics, S.L., involved in the marketing of the so-called PROSIGNA® test in Spain.

The invention protected by patent EP872 “*Gene expression profiling in biopsied tumor tissues*” refers to a method for predicting survival in breast cancer patients based on the expression of the BAG1 gene. This gene is implicated in the regulation of apoptosis (programmed cell death), and its overexpression is associated with a better prognosis in breast cancer, indicating a lower probability of relapse after tumor removal.

In the claim, Genomic Health alleged that the PROSIGNA® test, which analyses a panel of 50 genes, including BAG1, directly infringes patent EP872. According to the plaintiff, even if the PROSIGNA® test uses a different technology which expands on the number of genes analysed, the use of the BAG1 gene makes the test directly fall within the scope of protection of the patent. Under such interpretation of the patent’s scope of protection, any method using BAG1 analysis to predict the survival of breast cancer patients without recurrence is protected by the patent, regardless of technical differences in the procedure.

However, the defendant, NanoString, argued that the method implemented by the PROSIGNA® test differed substantially from that of EP872. In particular, the PROSIGNA® test determines the risk of recurrence by comparing the expression profile of 50 genes in the patient with four previously established breast cancer subtypes. Although the BAG1 gene is part of the set of genes used in this process, its function is limited to contributing to assigning the patient to one of the cancer subtypes. However, the BAG1 gene does not have a direct correlation with the risk of recurrence, nor does it constitute a determining explanatory variable within the algorithm used by PROSIGNA®.

In a decision dated 19 May 2023, the first instance Court followed NanoString’s interpretation of the patent’s scope of protection, and therefore dismissed Genomic Health’s patent infringement claim. This same interpretation was later followed by the Court of Appeals of Barcelona, which also understood

that the PROSIGNA® test did not infringe EP872, as it relies on a multigene profile and on an algorithm in which BAG1 does not play a determining role.

In addition, the Court rejected the broad interpretation of the term “comprising” asserted by the plaintiff, Genomic Health. Both parties agreed that this term implies that the protected method may include additional steps not explicitly described, provided that they do not alter the technical subject matter of the invention. This interpretation is supported by the EPO Examination Guidelines, which state that “comprising” allows the addition of further features, provided that they do not render the invention impracticable. Furthermore, EPO case law, in particular Decision T 1023/02, specifies that the added steps must not contradict the technical purpose of the invention. Therefore, the term “comprising” in EP872 allows for the incorporation of additional elements, provided that they do not impair the functioning of the claimed method.

However, plaintiff Genomic Health argued that the term “comprising” broadens the scope of the protected method, making possible the analysis of genes other than BAG1. It pointed to the patent description, which referred to a particular embodiment where the expression level of one or more prognostic RNA is determined. The plaintiff further supported its position with a decision by the EPO Opposition Division dated 25 July 2016, which rejected the defendant’s restrictive interpretation of the patent’s scope of protection. The OD concluded that claim 1 covered the detection of one or more genes, including BAG1, without excluding the presence of other marker genes.

The defendants, on the contrary, argued that this interpretation unduly broadened the scope of the patent, granting protection that exceeded the invention described, and could render the method impracticable or unfeasible. Therefore, the question to be resolved was whether the invention’s technical subject matter covered only a prediction method based on the BAG1 gene as a single biomarker, or on other combinations of genes.

As seen above, the Court of Appeals considered that even if the word “comprising” allows the protected method to include additional steps not explicitly described, the latter must not detract from the essential purpose or functioning of the invention. This means that genes other than BAG1 could be analysed, but the method must remain focused on the analysis of the BAG1 transcript as an essential element for predicting survival, as derived from the wording of claim 1 of the patent, which focuses specifically on the analysis of the RNA transcript of the BAG1 gene as a predictive marker of the probability of long-term survival. Therefore, broadly including other genes could contradict the purpose of the patent, as can be inferred from the patent description itself and the examples.

A copy of the judgment (in Spanish) can be found [here](#).