May 22, 2012
Announcement no. 8
BioPorto's NGAL cut-off patent: assessment of the decision in the opposition case

With reference to BioPorto's Announcement no. 7, issued today, BioPorto's patent attorney Susanne Høiberg has now had the opportunity to review the existing grounds for the decision of the European Patent Office (EPO) to reject BioPorto's NGAL cut-off patent, which has been issued in Europe. Høiberg concludes that the decision is erroneous and therefore expects that there will continue to be a fully valid and appropriately applicable NGAL cut-off patent in Europe after a future appeal. The EPO's comments on the decision and Høibjerg's/BioPorto's assessment of them are found in the main below.

The decision specifying that the patent is to be withdrawn is based on an assessment by the EPO's Opposition Division that the patent is insufficiently described (Art. 83 of the EPC). The EPO's Opposition Division justifies this by also stating that:

1) The cut-off threshold value of 250 ng/mL of NGAL, which is a central element in the method, is not sufficiently substantiated and is set so low that patients without renal affection will be classified as having a renal affection. The Opposition Division is of the opinion that there is no need to discuss statistics in detail and refers to passages in the patent itself stating that the cut-off threshold value is set too low.

This argument is still based on an erroneous calculation of the specificity, which results in the diagnosis of much too large a share of patients who do not have a renal affection as having a renal affection. This same calculation error was found in the Opposition Division's preliminary and non-binding opinion and has not been changed, despite BioPorto's information stating that this error leads to a completely erroneous result.

2) It has not been rendered probable that the method can diagnose all types of renal affection; it has not been rendered probable that chronic kidney injury, for instance, can be diagnosed using this method.

It is not the purpose of the invention to differentiate between different types of renal affection as the decision implies. The method is capable of diagnosing a renal affection, regardless of the type of renal affection, with sufficient probability for a diagnostic assay.

On the other hand, the Opposition Division finds that there is sufficient basis in the patent for:

- not having to specify a certain point in time for sample-taking in relation to when the initiation of insult has occurred;
- not requiring the method used for carrying out an assay of the NGAL concentration to be specified in the claim.

The decision by the Opposition Division has been suspended until a final decision is issued in the appeal, which is being filed with the EPO's Technical Board of Appeal. As a result, the patent is still in force due to the appeal and, in principle, the patent can be enforced in court. A likely time frame for the appeal is two years.

BioPorto is appealing the decision today and will submit material in the case in late September 2012.

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