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### **BioPorto's cutoff patent for NGAL, the new renal biomarker – grant proceedings stayed**

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With reference to BioPorto's earlier announcements concerning its NGAL patent rights, viz. announcement no. 11 of July 30, 2008 and no. 23 of December 12, 2008, it is hereby notified that the European Patent Office (EPO) has suspended the issuance of BioPorto's NGAL cutoff patent in Europe, EP1831699. According to information received from the EPO, this is because Cincinnati Children's Hospital (CCH) has issued a writ of summons before the Maritime and Commercial Court claiming that the right to the grant of patent belongs to CCH. The writ has not yet been served on BioPorto.

The writ is attached to EPO's communication and alleges that BioPorto has encroached on the claimant's invention explained by showing that there are points of similarity between the claimant and defendant's respective patent applications. The claim is not supported by any form of documentation. BioPorto naturally takes full responsibility and credit for its invention, "The determination of neutrophil gelatinase-associated lipocalin (NGAL) as a diagnostic marker for renal disorders", EP1831699, and is of course its sole inventor and proprietor. It therefore might seem that the writ has been served to delay the grant of patent as a tactical maneuver in connection with license negotiations. BioPorto will receive retrospective damages should any party have sold NGAL diagnostic tests in Europe and CCH's claim is not subsequently upheld.

The EPO has already made a detailed evaluation of all the documents of the case during the examination process and has concluded that CCH and BioPorto have made two different inventions. The EPO has therefore not found the similarities claimed to exist by CCH. BioPorto's NGAL cutoff patent concerns the measurement of NGAL as a diagnostic marker of renal disorders. The patent differs from other NGAL patent applications by determining the cutoff levels for NGAL that are necessary to distinguish the higher levels of NGAL that are indicative of renal disorders from the lower levels that can be due to other diseases. CCH's patent concerns the diagnosis of a single type of renal injury, namely ischemic injury. It is BioPorto's assessment that this patent is of little practical importance, because ischemic kidney injury cannot be distinguished by means of NGAL measurements from kidney injuries due to other conditions. It follows that the CCH patent is not expected to find commercial application.

The summons is not expected to interrupt the course of current license negotiations.

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