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**Announcement no. 21**

**CCH's European NGAL urine patent revoked after a decision in the opposition case**

In December 2008, an NGAL patent was issued to Cincinnati Children's Hospital (CCH), against which BioPorto filed an opposition in February 2010. The opposition case has developed in a satisfactory manner, in that a decision was reached yesterday by the European Patent Office (EPO) in Munich. The patent has been revoked as the invention is not patentable. Abbott has a license to CCH's NGAL urine patent, to which the case pertained.

The patent in question, number EP1616184, "A method and kit for detecting the early onset of renal tubular cell injury", was issued in 2008 with the following principal claim:

A method for detection of a renal tubular cell injury which is an ischemic renal injury in a human patient, comprising the steps of:

- 1) contacting a urine sample obtained from a human patient with an antibody for a biomarker consisting of NGAL, appearing within the first 24 hours of the onset of the ischemic renal injury, to allow formation of a complex of the antibody and NGAL; and
- 2) detecting the antibody-NGAL complex.

As a result of the EPO decision, the patent has been revoked and the decision is expected to be available in writing within one month. After this, the decision can be appealed by CCH.

*The kidney biomarker NGAL*

Every year about 13 million people are struck by acute kidney injury worldwide, of whom about 4 million die. Nevertheless, there has been no real progress in methods of diagnosing kidney injury over the last half century. Existing methods, such as serum creatinine determination, only signal kidney failure 24-72 hours after the injury has taken place. In contrast, NGAL rises to diagnostic levels within a few hours of kidney injury and thus enables the physician to make vital clinical decisions before the damage progresses to potentially fatal renal shutdown. In addition to helping the patient, cost-benefit analyses show that implementing NGAL testing will contribute to reducing hospital costs in the management of kidney injury and its consequences.

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