REMARKS

Summary of the Invention

As a preamble to the formalities and detailed remarks made in response to the Office Action dated November 9, 2011, Applicant wishes to point out that the present patent application concerns the novel use of NGAL levels in certain bodily fluids to determine that a human subject does not have acute renal failure (ARF) and is not at immediate risk of developing ARF. This is not the mere reciprocal of the prior U.S. Patent Application Publication No. 2009/0170143 by the same inventors and an additional inventor. The receiver operating characteristics curve (Fig. 1) underlying the present application is based on a larger number of patients and shows an asymmetry with respect to the asymptotes corresponding to 100% diagnostic sensitivity and 100% diagnostic specificity for ARF or its subsequent development, allowing cutoff levels giving a negative predictive value of 100% to be obtained (please see page 5, lines 8-26 of the application). There is certainty that none of the patients classified as not having ARF developed ARF at any later stage of observation. The disclosures point to the possibility of establishing a useful test to exclude the presence or immediate risk of ARF, which has not been contemplated in the cited prior art.

Summary of the Office Action

Claims 1-3, 7-12, and 15-17 are pending in this application following entry of the present amendment. The Office objects to claims 7-14 for improper form. The Office rejects claims 1-3 and 7-14 under 35 U.S.C. § 112, second paragraph, for indefiniteness. The Office rejects claims 1-3 and 7-14 under 35 U.S.C. § 112, first paragraph, for lack of written description. Claims 1-3, 7, and 12-14 are rejected under 35 U.S.C. § 102(e) for anticipation by Uttenthal et al. (U.S. 2009/0170143; hereinafter "Uttenthal"). Claims 1-3 and 7-14 are rejected under 35 U.S.C. § 102(e) for anticipation by Devarajan et al. (U.S. 2005/0272101; hereinafter "Devarajan I"). The Office rejects claims 1-3 and 7-14 under 35 U.S.C. § 103(a) for obviousness over Uttenthal. Claims 1-3, 7, 9-10, and 12-14 are rejected under 35 U.S.C. § 103(a) for obviousness over Mishra et al. (Lancet 365:1231-1238, 2005; hereinafter "Mishra"). Claims 1-3 and 7-14 are provisional rejected for obviousness-type double patenting over claims 1, 4-13, 15, and 30 of copending Application No. 11/722,025. Claim 8 is provisionally rejected for obviousness-type double patenting over claims 1, 4-13, 15, and 30 of