

REMARKS

Summary of the Office Action

Claims 1-12, 17, and 18 are pending in this application following entry of the present amendment. Claims 1-2, 4-11, and 17 are rejected under 35 U.S.C. § 103(a) for obviousness over Devarajan in view of either Sampath et al. (U.S. Patent No. 6,498,142 B1; hereinafter "Sampath") or the Cincinnati Children's Hospital Medical Center Study (Press Release dated March 31, 2005, http://www.eurekalert.org/pub_releases/2005-03/cchm-ssp033005.php; hereinafter "the CCHMC Press Release"). Claim 3 is rejected under 35 U.S.C. § 103(a) for obviousness over Devarajan in view of either Sampath or the CCHMC Press Release and further in view of Betsuyaku et al. (Amer. J. Respir. Crit. Care Med. 159:1985-1991, 1999; hereinafter "Betsuyaku"). Claim 12 is rejected under 35 U.S.C. § 103(a) for obviousness over Devarajan in view of either Sampath or the CCHMC Press Release and further in view of Azizova et al. (Brit. J. Radiol. Suppl. 27:30-35, 2005; hereinafter "Azizova"). Claims 1-12 and 17 are provisionally rejected for obviousness-type double patenting over claims 29-40, 43, and 45-50 of copending U.S. Application No. 12/743,027 in view of Devarajan and either one of Sampath or the CCHMC Press Release. Claims 1-12 and 17 are provisionally rejected for obviousness-type double patenting over claims 15-34 of copending U.S. Application No. 12/531,986 in view of one or more of Devarajan, Sampath, the CCHMC Press Release, and Azizova. Finally, claims 1-12 and 17 are provisionally rejected for obviousness-type double patenting over claims 1-14 of copending U.S. Application No. 12/375,585 in view of one or more of Devarajan, Sampath, the CCHMC Press Release, and Azizova. By this reply, amends claim 1, adds new claim 18, and addresses each of the rejections.

Support for the Amendment

It is respectfully requested that the claims be amended without prejudice, without admission, without surrender of subject matter, and without any intention of creating any estoppel as to equivalents. Support for the amendment to claim 1 is found in the specification, e.g., at page

4, line 33, through page 5, line 2. Support for new claim 18 is found in the specification, e.g., at page 3, lines 18-26. No new matter is added by the amendment.

Rejections under 35 U.S.C. 103(a)

Applicant has amended claims 1-12, 17, and 18 to exclude the detection or assessment of kidney injuries. None of the publications cited by the Office, whether considered singly or in combination, teaches or suggests the method of present claims 1-12, 17, and 18.

The Combination of Devarajan with Sampath or the CCHMC Press Release Fails to Render Present Claims 1-2, 4-11, 17, and 18 Obvious

Applicant previously characterized each of the cited publications in the Reply to Office Action filed on May 2, 2012, which is incorporated herein by reference. In short, Devarajan discloses detection of the onset of renal tubular cell injury (RTCI) by utilizing NGAL as a biomarker for this purpose only. Nowhere does Devarajan teach or suggest methods of using NGAL to assess the severity of an injury to an organ or tissue *other than the kidney*, as is acknowledged by the Office (Office Action, p. 3-4).

Neither Sampath nor the CCHMC Press Release cures the deficiencies of Devarajan since these publications also fail to teach or suggest methods of using NGAL to assess the severity of an injury to an organ or tissue *other than the kidney*. Sampath describes the use of morphogens to treat chronic renal failure, while the CCHMC Press Release describes the use of NGAL as a biomarker for diagnosing kidney failure. Thus, no combination of Devarajan with either Sampath or the CCHMC Press Release teaches or suggests the method of present claims 1-2, 4-11, 17, and 18. This rejection may now be withdrawn.

The Combination of Devarajan and Betsuyaku with Sampath or the CCHMC Press Release Fails to Render Present Claim 3 Obvious

Devarajan, Sampath, and the CCHMC Press Release, which are limited to kidney injury, are discussed *supra*.

Betsuyaku , which describes determining the level of HNL (NGAL) in bronchoalveolar lavage fluid from subjects with emphysema, fails to cure the deficiencies of Devarajan, Sampath, and the CCHMC Press Release. In particular, Betsuyaku fails to teach or suggest that the measurement of NGAL in the bronchoalveolar lavage fluid from a subject can be used to assess the severity of an injury in the subject. Betsuyaku also fails to teach or suggest that NGAL levels should be measured in a subject within 12 hours after the injury has occurred. Thus, no combination of Devarajan and Betsuyaku with either Sampath or the CCHMC Press Release teaches or suggests the method of present claim 3. This rejection may now be withdrawn.

The Combination of Devarajan and Azizova with Sampath or the CCHMC Press Release Fails to Render Present Claim 12 Obvious

Devarajan, Sampath, and the CCHMC Press Release, which are limited to kidney injury, are discussed *supra*.

Azizova describes multi-organ failure in patients exposed to accidental radiation exposure (Abstract). Azizova is silent on the measurement of NGAL for any purpose, and certainly fails to teach or suggest that the measurement of NGAL in a subject exposed to radiation can be used to assess the severity of the injury. Azizova also fails to teach or suggest that NGAL levels should be measured in a subject within 12 hours after the injury has occurred. Thus, no combination of Devarajan and Azizova with either Sampath or the CCHMC Press Release teaches or suggests the method of present claim 12. This rejection may now be withdrawn.

Rejections for Obviousness-type Double Patenting

Claims 1-12 and 17 are provisionally rejected for obviousness-type double patenting over claims 29-40, 43, and 45-50 of copending U.S. Application No. 12/743,027 in view of Devarajan and either one of Sampath or the CCHMC Press Release. The Office should withdraw the “provisional” rejection and permit this application to issue as a patent since it has a filing date that is earlier than that of U.S. Application No. 12/743,027 (M.P.E.P. § 804(I)(B)).

Claims 1-12 and 17 are also provisionally rejected for obviousness-type double patenting over claims 15-34 of copending U.S. Application No. 12/531,986 in view of one or more of Devarajan, Sampath, the CCHMC Press Release, and Azizova. Claims 15-34 of copending U.S. Application No. 12/531,986 (now allowed claims 15-26 and 35-46) recite methods of diagnosing or monitoring the presence of renal injury. Present claims 1-12, 17, and 18 have been amended to *exclude kidney injury* as a type of injury that is assessed for its severity. Thus, present claims 1-12, 17, and 18 are distinct from, and non-obvious in view of, the claims of U.S. Application No. 12/531,986.

Alternatively, the Office should withdraw the “provisional” rejection and permit this application to issue as a patent since it has a filing date that is earlier than that of U.S. Application No. 12/531,986 (M.P.E.P. § 804(I)(B)).

Claims 1-12 and 17 are provisionally rejected for obviousness-type double patenting over claims 1-14 of copending U.S. Application No. 12/375,585 in view of one or more of Devarajan, Sampath, the CCHMC Press Release, and Azizova. Claims 1-14 of copending U.S. Application No. 12/375,585 (now pending claims 1-3, 7-12, and 15-17) recite methods of diagnosing or determining the risk of developing acute renal failure. Present claims 1-12, 17, and 18 have been amended to *exclude kidney injury* as a type of injury that is assessed for its severity. Thus, present claims 1-12, 17, and 18 are distinct from, and non-obvious in view of, the claims of U.S. Application No. 12/375,585.

Alternatively, the Office should withdraw the "provisional" rejection and permit this application to issue as a patent since it has a filing date that is earlier than that of U.S. Application No. 12/375,585 (M.P.E.P. § 804(I)(B)).

CONCLUSION

In view of the above amendments and remarks, Applicant respectfully submits that present claims 1-12, 17, and 18 are in condition for allowance, and such action is respectfully requested.

If there are any charges or any credits, please apply them to Deposit Account No. 03-2095.

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Respectfully submitted,

By  _____

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