

REMARKS

Claims 1-28 were pending in the present application. Claims 1-11 are rejected and claims 12-28 are withdrawn from consideration. Claim 1 has been amended. Support for this amendment is found throughout the specification. For example, support for this amendment may be found at page 9, lines 1-5. Thus, no new matter has been added by this amendment.

With respect to all amendments and cancelled claims (and/or subject matter related thereto), Applicants have not dedicated or abandoned any unclaimed subject matter and moreover have not acquiesced to any rejections and/or objections made by the Patent Office. Applicant reserves the right to pursue prosecution of any such subject matter in future continuation and/or divisional application.

Also, filed herewith is a Petition for Revival of an Application for Patent Abandoned Unintentionally under 37 CFR 1.137(b), as well as the petition fee. Reconsideration and allowance of the pending claims in view of the remarks presented herein, is respectfully requested.

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Rejections under 35 U.S.C. 112 § 112, First Paragraph

The Office has rejected claims 1-11 under 35 U.S.C. 112, first paragraph, for allegedly failing to comply with the written description requirement. Applicant respectfully traverses this rejection for the reasons provided below.

The Examiner's contends that the chemical compounds lack "...common chemical structures, chemical activities, and biological functions" and therefore "...alterations in gene expression or protein expression in various mammalian embryoid bodies responding to numerous different chemical compositions would not be predictable at the time of the invention." (Office Action, page 3). Applicant respectfully submits that the instant specification fully complies with the written description requirement. Moreover, Applicant notes that claims 1-11 are product by process claims. Accordingly, Applicant does not need to define the products in terms of structural

characteristics. See, e.g., Atlantic Thermoplastics v. Faytex Corp., 970 F.2d 834, 844 (Fed. Cir. 1992). Withdrawal of this rejection is respectfully requested.

The Office has rejected claims 1-11 under 35 U.S.C. 112, first paragraph, for allegedly failing to comply with the enablement description requirement. Applicant respectfully traverses this rejection for the reasons provided below.

The Examiner's contends that the chemical compounds "...include numerous different chemical compounds having different chemical structures, physical properties, and biological functions" and therefore "...alterations in gene expression or protein expression in various mammalian embryoid bodies responding to numerous different chemical compositions would not be predictable at the time of the invention." (Office Action, page 5). Applicant respectfully submits that the instant specification fully complies with the enablement requirement. Moreover, as discussed above, claims 1-11 are product by process claims. Accordingly, Applicant does not need to define the products in terms of structural characteristics. See, e.g., Atlantic Thermoplastics v. Faytex Corp., *supra*. Withdrawal of this rejection is respectfully requested.

Rejections under 35 U.S.C. §103

Claims 1-11 are rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over over Spielmann et al., 1997 (In Vitro Toxicology, Vol. 10, No. 1, p. 119-127) in view of Craig et al., 1996 (Biomarkers, Vol. 1, No. 2, p. 123-135) and Wobus et al., 1999 (US Patent 6,007,993). The Examiner alleges, that

"...it would have been obvious for one of ordinary skill at the time of the invention to substitute the MTT cytotoxicity assay as taught by Spielmann with detection of gene expression as taught by Craig or detection of protein expression as taught by Wobus to establish molecular profiles of different chemical compositions by treating a mammalian embryoid body with said chemical compositions because both Craig and Wobus teach testing the effect of a teratogenic agent on embryoid body by determining the resulting gene expression pattern and it was known in the art to determine the effect of a

chemical compound by detecting the alteration of gene expression or alteration of protein expression in an embryoid body because it was known in the art to determine the effect of a chemical compound by detecting the alteration of gene expression or alteration of protein expression." (Office Action, bridging paragraph, page 8-9).

Applicant traverses this rejection for the reasons provided below.

To establish a *prima facie* case of obviousness, the prior art reference(s) must teach or suggest all the claim limitations, there must be some suggestion or motivation to modify the reference or to combine reference teachings and there must be a reasonable expectation of success. M.P.E.P. § 2143. Both the suggestion and the reasonable expectation of success must be founded in the prior art, not in the Applicant's disclosure. See *In re Vaeck*, 20 USPQ2d 1438, 1442 (Fed. Cir. 1991). Applicant respectfully submits that a *prima facie* case of obviousness has not been made by the Examiner.

Spielmann relates to the use of embryonic stem cells in cytotoxicity screening assays. Cell death or inhibition of cell differentiation, was the endpoint used to assess cytotoxicity of the test chemicals in the Spielmann screening assays. Cell death or inhibition of cell differentiation, as endpoints, do not serve to identify the mechanism or biological pathway impacted by the test chemical as might a molecular profile. As noted by the Examiner, Spielmann does not teach or suggest creating molecular profiles of gene expression or protein expression. Therefore, Spielmann either alone or in combination cannot render the claimed invention obvious.

Craig relates to the detection of expression of known developmentally-regulated genes in top minnow embryos exposed to a teratogen. Craig does not record alterations in genomic expression in a *mammalian* embryoid body contacted with a chemical and compiling a library of such molecular profiles. In fact, Craig teaches away from the use of a mammalian system by stating that her assay avoids "the inefficiencies inherent in the mammalian embryo system by circumventing the high cost and time commitments associated with traditional teratology studies" (page 123, left column, second full paragraph). In addition, Applicant notes that the methods of the

present invention works with expression of both known and unknown genes and does not require preselection of known developmentally-regulated genes. Accordingly, Craig does not remedy the deficiencies of Spielmann and cannot render the claimed invention obvious either alone or in combination.

Wobus is cited for allegedly teaching protein expression. Wobus teaches detection of reporter gene expression driven by a known developmentally-regulated promoter and requires preselection of known developmentally regulated genes. Wobus does not teach or suggest recording alterations in genomic expression as required by the present claims. Further, Wobus requires preselection of known developmentally related genes. In contrast, the methods used to produce the libraries of the present invention work with the expression of both known and unknown genes and does not require preselection of known developmentally regulated genes. Accordingly, like Craig, Wobus does not remedy the deficiencies of Spielmann. Therefore, Wobus cannot render the claimed invention obvious either alone or in combination.

Applicant further submits that the Examiner has not shown a suggestion or motivation to combine the Spielmann reference with the Wobus or Craig references, nor has the Examiner shown that there is a reasonable expectation of success. The Examiner merely states that “one of ordinary skill in the art would have been motivated to do so in order to generate a gene or protein expression profile” and that “according to the collective teachings of Spielmann, Craig and Wobus, with a reasonable expectation of success.”(Office Action, page 9). Accordingly, Applicant respectfully submits that a *prima facie* case of obviousness has not been made and request withdrawal of this ground of rejection.

Claim 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Serbedzija et al., 2001 (US Patent 6,299,858) in view of Spielmann et al., 1997 (In Vitro Toxicology, Vol. 10, No. 1, p. 119-127). Applicant traverses for the reasons provided herein below.

Serbedzija relates to the use of a teleost embryo, specifically a zebra fish embryo, in a screening assay. In particular Serbedzija relates to methods of screening of an agent for

angiogenesis activity, toxic activity and an effect on cell death. Serbedzija does not specifically teach or suggest the recording alterations in genomic expression in mammalian embryoid bodies as required by the instant claims. In fact, Serbedzija teaches away from the use of a mammalian system (see col. 11, lines 65-67 and col. 12, lines 1-25). Spielmann does not remedy this deficiency for reasons argued herein above. Accordingly, withdrawal of this ground of rejection is respectfully requested.

CONCLUSION

Applicants have, by way of amendments and remarks presented herein addressed all issues that were raised in the outstanding Office Action. Applicants respectfully contend that this Amendment has overcome the rejections and that the pending claims are in condition for allowance. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 441472000110. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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Respectfully submitted,

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