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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/864,621	05/23/2001	H. Ralph Snodgrass	441472000110	3487

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EXAMINER	
CHEN, SHIN LIN	
ART UNIT	**PAPER NUMBER**
1632	

DATE MAILED: 04/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/864,621	SNODGRASS, H. RALPH	
	Examiner	Art Unit	
	Shin-Lin Chen	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 December 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) *12-28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2-26-04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicants' amendment filed 12-30-04, which was filed in accompany with a petition to revive the abandoned application and the petition was granted on 2-17-05, has been entered. Claim 1 has been amended. Claims 1-28 are pending and claims 1-11 are under consideration.

Claim Rejections - 35 USC § 101

1. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-11 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims are drawn to a library of molecular profiles of chemical compositions. On page 3, lines 23-24, the specification discloses "The library can be in the form of a database. A database may comprise more than one library for chemical compositions of different toxicity categories." A database is not considered patentable subject matter. Therefore, the instantly claimed invention is directed to a non-statutory subject matter.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant

art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1-11 read on a library of molecular profiles of chemical compositions having predetermined toxicities by contacting an isolated mammalian embryoid body with the chemical compositions, recording alterations in gene expression or protein expression in said mammalian embryoid body and compiling a library of molecular profiles for at least two chemical compositions.

The chemical compositions encompass therapeutic agents, neurotoxins, renal toxins, hepatic toxins, toxins of hematopoietic cells, myotoxins, agents that are toxic to cells of reproductive organs, teratogenic agents, carcinogens, agricultural chemicals, cosmetics, and environmental contaminants. The specification only discloses the protein expression profiles of mouse embryoid body treated with troglitazone or erythromycin compared to the control having no treatment of troglitazone or erythromycin. The chemical compositions set forth above include numerous different chemical compounds having different chemical structures, physical properties, and biological functions. They don't have common chemical structures, chemical activities, and biological functions. Common structural feature of the chemical compositions that would have a certain effect on the gene expression or protein expression pattern in a mammalian embryoid body has not been disclosed in the present invention. Further, different embryoid bodies derived from various mammal, such as humans, mice, rats, pigs, sheep, cows, whales, primates, dogs etc., would differ from each other physiologically, and their response to same chemical composition, not to mention different chemical compositions, could vary. Therefore, the pattern of 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. One skilled in the art at the time of the invention would not be able to anticipate the gene expression or protein expression pattern in the mammalian embryoid body treated with various chemical compositions other than the disclosed protein expression pattern of mouse embryoid body treated with either troglitazone or erythromycin. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed.

The limited information disclosed in the present invention is not sufficient to reasonably convey to one skilled in the art that applicants were in possession of the claimed libraries of molecular profiles of numerous different chemical compositions. Thus, it is concluded that the written description requirement is not satisfied for the libraries of molecular profiles of numerous different chemical compositions as claimed.

Applicant cites Atlantic Thermoplastics v. Faytex Corp., and argues that claims 1-11 are products by process claims, therefore, there is no need to define the products in terms of structural characteristics (amendment, p. 6-7). This is not found persuasive because of the reasons set forth above and that applicant only states "e.g. Atlantic thermoplastics v. Faytex Corp." but fails to point out how it is related to the product by process claims and there is no need to define the structural characteristics of products. The claimed invention is a library of molecular profiles, i.e. the patterns of gene expression or protein expression, of numerous different chemical compositions when said chemical compositions contact with an isolated mammalian embryoid body. As discussed above, the chemical compositions include numerous different chemical compounds having different chemical structures, physical properties, and

biological functions. They don't have common chemical structures, chemical activities, and biological functions. Further, different embryoid bodies derived from various mammal, such as humans, mice, rats, pigs, sheep, cows, whales, primates, dogs etc., would differ from each other physiologically, and their response to same chemical composition, not to mention different chemical compositions, could vary. Therefore, the pattern of 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. One skilled in the art at the time of the invention would not be able to anticipate the gene expression or protein expression pattern in the mammalian embryoid body treated with various chemical compositions other than the disclosed protein expression pattern of mouse embryoid body treated with either troglitazone or erythromycin. Thus, the written description requirement is not satisfied for the libraries of molecular profiles of numerous different chemical compositions as claimed.

4. Claims 1-11 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the library of protein expression profile of troglitazone and erythromycin in the mouse embryoid body, does not reasonably provide enablement for libraries of molecular profiles of numerous different chemical compositions in various mammalian embryoid bodies. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Claims 1-11 read on a library of molecular profiles of chemical compositions having predetermined toxicities by contacting an isolated mammalian embryoid body with the chemical

compositions, recording alterations in gene expression or protein expression in said mammalian embryoid body and compiling a library of molecular profiles for at least two chemical compositions. Claim 2 specifies the embryoid body is of human. Claims 6 and 7 specify the embryoid body is of non-human mammals, such as rodents. Claims 3-5 and 8-10 specify the chemical compositions are therapeutic agents, neurotoxins, renal toxins, hepatic toxins, teratogenic agents, carcinogens, agricultural chemicals, cosmetics, environmental contaminants etc.

As discussed above, the chemical compositions encompass therapeutic agents, neurotoxins, renal toxins, hepatic toxins, toxins of hematopoietic cells, myotoxins, agents that are toxic to cells of reproductive organs, teratogenic agents, carcinogens, agricultural chemicals, cosmetics, and environmental contaminants. The specification only discloses the protein expression profiles of mouse embryoid body treated with troglitazone or erythromycin compared to the control having no treatment of troglitazone or erythromycin. The chemical compositions set forth above include numerous different chemical compounds having different chemical structures, physical properties, and biological functions. Further, different embryoid bodies derived from various mammal, such as humans, mice, rats, pigs, sheep, cows, whales, primates, dogs etc., would differ from each other physiologically, and their response to same chemical composition, not to mention different chemical compositions, could vary. Therefore, the 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. One skilled in the art at the time of the invention would not be able to anticipate the gene expression or protein expression pattern in the mammalian embryoid body treated with

various chemical compositions other than the disclosed protein expression pattern of mouse embryoid body treated with either troglitazone or erythromycin. Applicants were not in possession of the claimed libraries of molecular profiles of numerous different chemical compositions. Thus, the present invention does not enable the use of the broadly claimed libraries of molecular profiles of numerous different chemical compositions.

Applicant cites Atlantic Thermoplastics v. Faytex Corp., and argues that claims 1-11 are products by process claims, therefore, there is no need to define the products in terms of structural characteristics (amendment, p. 6-7). This is not found persuasive because of the reasons set forth above and the reasons set froth above under 35 U.S.C. 112, first paragraph, written description rejection.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shin-Lin Chen whose telephone number is (571) 272-0726. The examiner can normally be reached on Monday to Friday from 9:30 am to 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for this group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Shin-Lin Chen, Ph.D.

SHIN-LIN CHEN
PRIMARY EXAMINER