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(54) Title: CULTURED COLLECTION OF GUT MICROBIAL COMMUNITY

(57) Abstract: The present invention encompasses cultured collections of a gut microbial community, models comprising such cultures, and methods of use thereof.

**INTERNATIONAL SEARCH REPORT**

International application No.

PCT/US 12/28600

**A. CLASSIFICATION OF SUBJECT MATTER**  
 IPC(8) - C12N 1/20 (2012.01)  
 USPC - 800/9, 435/252.4  
 According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**  
 Minimum documentation searched (classification system followed by classification symbols)  
 USPC -- 800/9, 435/252.4, 435/243, 435/252.1

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)  
 PubWEST -- PGPB,USPT,USOC,EPAB,JPAB; Dialog Classic Files -- 654, 652, 349, 348, 340, 35, 65, 155; USPTO Web Page; Google Scholar; Search terms -- gnotobiotic animal model, mice, human, pig, gut microbiota, inoculation, colonization, transcriptome analysis, in vitro culture, phylotpicanalysis, arrays

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X -- Y	US 2004/0091893 A1 (GORDON et al.) 13 May 2004 (13.05.2004) para [0007], [0013], [0017], [0057], [0076], [0110], [0151], abstract	1, 2, 4, 6, 9, 12, 15 <u>3</u> , 5, 7, 8, 10, 11, 13, 14
Y	US 2010/0008949 A1 (FRANCIS et al.) 14 January 2010 (14.01.2010) para [0018], [0078]	3
Y	US 2010/0172874 A1 (TURNBAUGH et al.) 08 July 2010 (08.07.2010) para [0019], [0025], [0094]-[0095], [0116], [0128], [0129], [0146], [0160]	5, 7, 10, 13
Y	US 2005/0239706 A1 (BACKHED et al.) 27 October 2005 (27.10.2005) para [0155], [0306], [0313], Fig 31	8, 11, 14

Further documents are listed in the continuation of Box C.

* Special categories of cited documents:	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A" document defining the general state of the art which is not considered to be of particular relevance	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E" earlier application or patent but published on or after the international filing date	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&" document member of the same patent family
"O" document referring to an oral disclosure, use, exhibition or other means	
"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search 08 August 2012 (08.08.2012)	Date of mailing of the international search report <b>17 AUG 2012</b>
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Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Lee W. Young  PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774
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**INTERNATIONAL SEARCH REPORT**

International application No.

PCT/US 12/28600

**Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)**

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1.  Claims Nos.:  
because they relate to subject matter not required to be searched by this Authority, namely:
  
2.  Claims Nos.:  
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
  
3.  Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

**Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)**

This International Searching Authority found multiple inventions in this international application, as follows:  
This application contains the following inventions or groups of inventions which are not so linked to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I claims 1-15 directed to a model, the model comprising a gnotobiotic animal comprising a cultured gut microbial community and a composition, the composition comprising an in vitro cultured collection of a gut microbial community.

Group II claims 16-24 directed to a composition, the composition comprising a clonally arrayed culture collection of a gut microbial community. (For the purposes of this report, claims 17-24 are assumed to depend from claim 16.)

SEE CONTINUATION SHEET.

1.  As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2.  As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.
3.  As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4.  No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:  
1-15

**Remark on Protest**

- The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- No protest accompanied the payment of additional search fees.

## Continuation of Box III

Group III claims 25-33 directed to a method of determining the effect of a perturbation on a gut microbial community, a method of predicting variations in the abundance of a member of a gut microbiome of a host in response to a proposed diet, a method of predicting the abundance of a member of a gut microbiome of a host in response to a proposed diet, and a method of specifically manipulating the abundance of a member of a gut microbiome of a host to a target level by changing the diet of the host.

The inventions listed as Groups I-III do not relate to a single inventive concept under Rule 13.1 because under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The special technical features of the Groups are delineated as above. The shared technical feature of all Groups is a cultured gut microbial community and/or a gut microbiome. However, this is not an improvement over the prior art of US 2004/0091893 A1 to Gordon et al. (hereinafter "Gordon") that specifically teaches a cultured gut microbial community and/or a gut microbiome (para [0006] ?investigating changes resulting from commensal microflora colonisation of mammalian intestine?; [0007] ?commensal bacterium-colonized and germ-free intestine ?; para [0017] in vitro cell culture assays). Further as to Group I, Gordon teaches a model (para [0013] mouse model of intestinal-microbial interactions) comprising a gnotobiotic animal (para [0013], and ?germ-free mouse maintained in gnotobiotic isolator, ? para [0151]) comprising a cultured gut microbial community further wherein the gut microbial community comprises an in vitro cultured community (para [0017] in vitro cell culture assays). Group II requires a clonally arrayed culture collection. This special technical feature is not required by either of Group I or Group III. Group III further requires a method of determining the effect of a perturbation on a gut microbial community, a method of predicting variations in the abundance of a member of a gut microbiome of a host in response to a proposed diet, a method of predicting the abundance of a member of a gut microbiome of a host to a target level by changing the diet of the host. None of these are required by either of Group I or II.

Therefore the inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because they do not share a same or corresponding special technical feature and therefore lacks unity.