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19 March 2009

(54) Title: DIAGNOSTIC AND TREATMENT METHODS FOR CHARACTERIZING BACTERIAL MICROBIOTA IN SKIN CONDITIONS

(57) Abstract: The present invention relates to methods for characterization of bacterial skin microbiota to provide diagnostic, therapeutic, and preventive measures for alleviating skin conditions. In certain embodiments, the invention relates to characterization of bacterial skin microbiota associated with psoriasis and related diagnostic, therapeutic, and preventive measures for alleviating psoriasis. These methods will be useful for detecting, diagnosing, and monitoring individuals who have or are at risk of certain skin conditions.



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INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 08/1769

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A01N 63/02 (2008.04)

USPC - 424/93.4, 424/93.44

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 - 424/93.4, 424/93.44

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

USPC - 424/93.4, 93.1, 184.1

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

Electronic Databases Searched: USPTO WEST (PGPB, USPT, EPAB, JPAB); Google Scholar;

Search Terms Used: psoriasis, psoriatic, Propionibacterium, acne, p. acn , treatment, cure, heal, cell, skin, Streptococcus, NGS

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 6982273 B1 (Majeed et al.) 3 January 2006 (03.01.2006) entire document, esp. (col. 2 ln. 55, col. 4 ln. 50-65)	1-28
A	US 2006/0286054 A1 (G�mez) 21 December 2006 (21.12.2006) entire document, esp: abstract	1-28

☐ Further documents are listed in the continuation of Box C.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"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)

"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

"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

"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

"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

"&" document member of the same patent family

Date of the actual completion of the international search

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Date of mailing of the international search report

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INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 08/71769

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 as 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.

--see extra 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.:
1-28

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.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 08/71769

Continuation of Box III Observations where unity of invention is lacking:

This application contains the following inventions or groups of inventions which are not so linked as 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 1-28 are directed to a method of treating psoriasis, a method for monitoring treatment of psoriasis, and a method for diagnosing psoriasis in a patient.

Group II: claims 29-32 are directed to a method of diagnosing a skin disease by performing quantitative polymerase chain reaction wherein the skin disease is selected from the group consisting of atopic dermatitis, acne, alopecia, seborrhea, dandruff, and pemphigus.

Group III claim 33 is directed to a kit for determining a bacterial signature comprising at least one nucleic acid selected from the group consisting of SEQ ID NO:5, SEQ ID NO:6 and SEQ ID NO:8.

Group IV claim 34 are directed to an isolated nucleic acid fragment comprising SEQ ID NO:6 or SEQ ID NO:8.

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

Groups I has no special technical feature in common with the other groups. Groups II - IV share the common technical feature of probes used to quantify or identify bacterial populations. However, this is not an improvement over the well known and common art of quantifying or identifying bacterial species as exemplified by US 6,821,770 B1 to Hogan (23 November 2003) that teaches a method of identifying microbial organisms wherein a biological sample containing nucleic acids is hybridized with a collection of polynucleotide probes (abstract). Further Groups II - IV contain more than one species of the generic invention, specifically, SEQ ID NO:5 a universal probe for quantitation of all eubacteria, SEQ ID NO:6 a genus-specific probes for *Propionibacterium* sp, and SEQ ID NO:8 a genus-specific probe for *Streptococcus* sp. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The different nucleotide sequences represented by SEQ ID NO: 5, 6, and 8 are different species because the nucleotide structures are not common to one another but are different because they are composed of unique nucleic acid sequences.