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(71) Applicants (for all designated States except US):  
**MONOSOL RX, LLC** [US/US]; 6560 Melton Road, Portage, IN 46368 (US). **MOUNT SINAI HOSPITAL** [CA/CA]; 600 University Avenue, Toronto, Ontario M5G 1X5 (CA).

(72) Inventors; and

(75) Inventors/Applicants (for US only): **DEMETRIOU, Michael** [CA/US]; 2 Twain Street, Irvine, CA 92612 (US). **DENNIS, James** [CA/CA]; 17 Mapledawn Road, Etobicoke, Ontario M9C 2V7 (CA). **LAU, Ken Siu-kwong** [CA/CA]; 510-80 Forest Manor Road, Toronto, Ontario M2J 1M6 (CA).

(74) Agents: **FESSENMAIER, Martin** et al.; Rutan & Tucker, LLP, 611 Anton Blvd., Suite 1400, Costa Mesa, CA 92626 (US).

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Published:

- with international search report (Art. 21(3))
- before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))

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(54) Title: METHODS AND COMPOSITIONS FOR PREVENTING AND TREATING A DISEASE RELATED TO GLYCAN DYSREGULATION

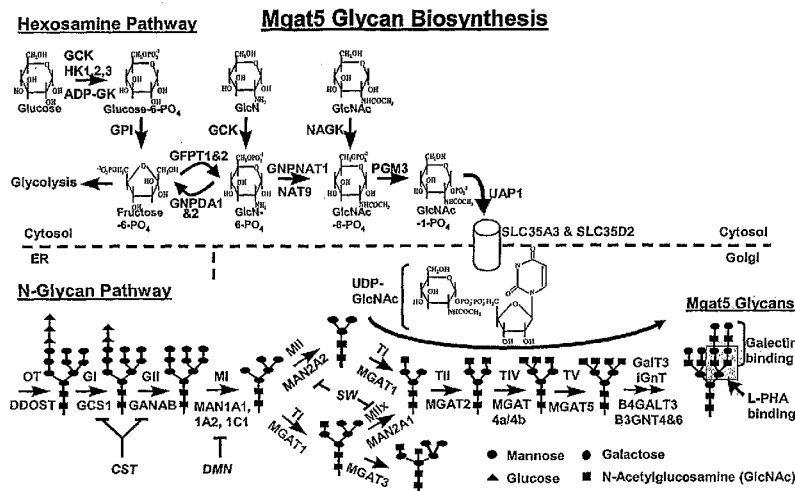


FIG. 7A

(57) Abstract: Contemplated compositions and methods are directed to prevent and/or treat various autoimmune diseases that are typically associated with glycan dysregulation, and especially autoimmune demyelinating diseases. Further especially contemplated aspects include animal models and systems for screening compounds to treat and/or prevent such diseases.

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INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 06/01337

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - C12Q 1/48 (2009.01)

USPC - 435/15

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 - 435/15

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

USPC - 435/4

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

PubWEST(PGPB,USPT,USOC,EPAB,JPAB), Google Scholar: Mgat5, autoimmune disease, acetylglucosaminyltransferase V

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2004/0082009 A1 (DENNIS et al.) 29 April 2004 (29.04.2004); para [0004], [0020], [0127], [0141], [0151]	1-6
A	DEMETRIOU et al. Negative regulation of T-cell activation and autoimmunity by Mgat5 N-glycosylation. Nature 8 February 2001; 409:733-739	1, 5
A	US 5,501,957 A (DENNIS et al.) 26 March 1996 (26.03.1996); Abstract, col 3, ln 61-64	1, 5

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

28 November 2009 (28.11.2009)

Date of mailing of the international search report

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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  
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INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 06/01337

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.

Group I: claims 1-6, drawn to a method comprising measuring a quantity of Mgat5 or derivatives thereof.

Group II, claims 7-12, drawn to a method comprising identifying a mutation in a gene in at least one of an N-glycan pathway or hexosamine pathway.

Group III, claims 13-26, drawn to a pharmaceutical composition comprising GlcNAc or an analogue thereof, and a method of using said composition.

\*\*\*\*\* See Supplemental 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. [X] 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.: 1-6

- 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**  
Information on patent family members

International application No.  
PCT/US 06/01337

..... Supplemental sheet .....

Continuation of Box No. III

Group IV, claims 27-30, drawn to a nonhuman animal displaying pathology of an autoimmune disease, and comprising at least one defective Mgat5 gene allele or by lacking at least one Mgat5 gene allele at least in its somatic cells.

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-III do not include the inventive concept of a nonhuman animal displaying pathology of an autoimmune disease, as required by Group IV.

Groups I-II and IV do not include the inventive concept of a pharmaceutical composition comprising GlcNAc or an analogue thereof, as required by Group III.

Groups I and III-IV do not include the inventive concept of identifying a mutation in a gene in at least one of an N-glycan pathway or hexosamine pathway, as required by Group II.

Groups II-IV do not include the inventive concept of measuring in the sample a quantity of Mgat5 or derivatives thereof, as required by Group I.

The inventions of Groups I-IV share the technical feature of Mgat5 gene and its product. However, this shared technical feature does not represent a contribution over the prior art of WO 2002/055728 A2 to DENNIS, et al. that discloses Mgat5 modified glycan (abstract). As said Mgat5 gene and its product were known at the time of the invention, this cannot be considered a special technical feature that would otherwise unify the groups.

Groups I-IV therefore lack unity under PCT Rule 13 because they do not share a same or corresponding special technical feature.