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[Continued on next page]

(54) Title: MOLECULES FOR DISEASE DETECTION AND TREATMENT

(57) Abstract: Various embodiments of the invention provide human molecules for diseasedetection and treatment (MDDT) and polynucleotides which identify and encode MDDT. Embodiments of the invention also provide expression vectors, host cells, antibodies, agonists, and antagonists. Other embodiments provide methods for diagnosing, treating, or preventing disorders associated with aberrant expression of MDDT.

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INTERNATIONAL SEARCH REPORT

International application No.

PCT/US02/38446

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : C12P 21/06; C12N 1/20, 15/00; C07H 21/02
US CL : 435/69.1, 252.3, 320.1; 536/23.1

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)

U.S. : 435/69.1, 252.3, 320.1; 536/23.1

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)
WEST & STN. SEQ ID NO : 1 & 70 SEARCHED IN US Patent and commercial data bases.

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 01/57276 A2 (MOLECULAR DYNAMICS, INC.) 09 August 2001 (09.08.2001). Accession No. AAM15338 is 80.3% similar to Applicants' SEQ ID NO : 1 with 101 continuous amino acid match. See the sequence search alignment (Result 3).	1, 17
X	Database GenEmbl., AC006042, 21.12.1999 (date available), 99.8% identical to Applicants' SEQ ID NO : 70 (see Result 1 of the sequence search alignment).	3, 6-9, 12-13
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A		2, 4-5, 10, 18, 56, 125

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

☐ See patent family annex.

* 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 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

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INTERNATIONAL SEARCH REPORT

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Box I Observations where certain claims were found unsearchable (Continuation of Item 1 of first sheet)

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

1. ☐ Claim Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claim 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. ☐ Claim Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of Item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:
Please 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 an additional fee, this Authority did not invite payment of any additional fee.
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.: 1-10, 12-13, 17-18, 56 & 125 (SEQ ID Nos. 1 & 70)

Remark on Protest

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☐

The additional search fees were accompanied by the applicant's protest.

No protest accompanied the payment of additional search fees.

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BOX II. 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 1, claim(s) 1-10, 12-13, 17-18, ~~56 &~~ **125**, drawn to polypeptide of SEQ ID NO : 1, the encoding DNA of SEQ ID NO : 70, vector, host cell and a recombinant method of making the polypeptide.

Group 2, claim(s) 1-10, 12-13, 17-18, ~~57 &~~ **126**, drawn to polypeptide of SEQ ID NO : 2, the encoding DNA of SEQ ID NO : 71, vector, host cell and a recombinant method of making the polypeptide.

Group 3, claim(s) 1-10, 12-13, 17-18, ~~58 &~~ **127**, drawn to polypeptide of SEQ ID NO : 3, the encoding DNA of SEQ ID NO : 72, ~~vector, host cell and a recombinant method of making the polypeptide.~~

Groups 4-69, claim(s) 1-10, 12-13, 17-18, ~~59-124 &~~ **128-193**, drawn to each do the polypeptide sequences of SEQ ID NO : 4-69, each the encoding DNA of SEQ ID NO : 73-138, vector, host cell and a recombinant method of making the polypeptide, respectively.

Group 70, claim(s) 11 & 30-45, drawn to antibody against polypeptide of SEQ ID NO : 1 and method of use.

Groups 71-138, claim(s) 11 & 30-45, drawn to each of the antibodies against polypeptides of SEQ ID NO : 2-69 and its use respectively.

Group 139, claim(s) 14-16, drawn to method of detection using the polynucleotide of SEQ ID NO : 70.

Groups 140-207, claim(s) 14-16, drawn to methods of detection using each of the polynucleotides of SEQ ID NO : 71-138, respectively.

Group 207, claim(s) 19, drawn to method of treatment using the polypeptide of SEQ ID NO : 1.

Groups 208-276, claim(s) 19, drawn to methods of treatment using each of the polypeptides of SEQ ID NO : 2-69, respectively.

Group 277, claim(s) 20-25 & 27, drawn to method of screening an agonist or antagonist of polypeptide of SEQ ID NO : 1.

Groups 278-345, claim(s) 20-25 & 27, drawn to method of screening an agonist or antagonist for each of the polypeptides of SEQ ID NO : 2-69 respectively.

Group 346, claim(s) 26, drawn to method of screening a compound that specifically binds to the polypeptide of SEQ ID NO : 1.

Groups 347-414, claim(s) 26, drawn to methods of screening a compound that specifically binds to each of the polypeptides of SEQ ID NO : 2-69.

Group 415, claim(s) 28, drawn to method of screening a compound that alters expression of a target polynucleotide of SEQ ID NO : 70.

Groups 416-483, claim(s) 28, drawn to methods of screening a compound that alters expression of each of the target polynucleotides of SEQ ID NO : 71-138, respectively.

Group 484, claim(s) 29, drawn to method of assessing toxicity using of polynucleotide of SEQ ID NO : 70.

Groups 485-552, claim(s) 29, drawn to methods of assessing toxicity using each of the polynucleotide of SEQ ID NO : 71-138.

Group 553, claim(s) 46-55, drawn to method of microarray and method of generating expression profile using the polynucleotide sequence of SEQ ID NO : 70.

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Groups 554-621, claim(s) 46-55, drawn to methods of microarray and methods of generating expression profile using each of the polynucleotide sequence of SEQ ID NO : 71-138, respectively.

The inventions listed as Groups 1-621 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:

The inventions listed as Groups 1-621 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: Group 1 has the special technical feature of the nucleotide sequence of SEQ ID NO : 70 and the encoded polypeptide of SEQ ID NO : 1, host cell and a method of making the polypeptide, which Groups 2-621 do not share. For the same reason, Group 2-69 has the special technical feature of the nucleotide sequences of SEQ ID NOS : 71-138 and the encoded polypeptides of SEQ ID NOS : 2-69, respectively, host cell and a method of making the polypeptide, which Groups 1 & groups 70-621 do not share. Each of the Groups 70-138 have a special technical in a distinct antibody pertaining to each of the polypeptide sequences of SEQ ID NOS : 1-69, which Groups 1-69 & 139-621 do not share. Each of the Groups 139-621, employ structurally distinct nucleotide sequences of SEQ ID NOS : 70-138 or the polypeptide sequences of SEQ ID NOS : 1-69 in distinct methods, however, in view of 37 CFR 1.475(b), when claims corresponding to different categories of inventions are present then only (3) and additional methods of use are deemed to lack unity. Thus the various groups discussed above show a lack of unity of invention.