CORRECTED VERSION* | CORRECTED VERSION**

PCT

WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 :
C12N 15/31, 15/70, 1/20, C07K 14/205, C12Q 1/68, G01N 33/569, 33/68, A61K 39/106

A3

(11) International Publication Number: WO 96/10639

(43) International Publication Date: 11 April 1996 (11.04.96)

(21) International Application Number: PCT/US95/12669

(22) International Filing Date: 29 September 1995 (29.09.95)

(30) Priority Data:
08/316,397 30 September 1994 (30.09.94) US

(71) Applicant: VANDERBILT UNIVERSITY [US/US]; 405 Kirkland Hall, Nashville, TN 37240 (US). ORAVAX, INCORPORATED [US/US]; 230 Albany Street, Cambridge, MA 02139 (US).

(72) Inventors: COVER, Timothy, L. [US/US]; 2804 West Linden Avenue, Nashville, TN 37212 (US). BLASER, Martin, J. [US/US]; 733 Darden Place, Nashville, TN 37205-2308 (US). KLEANTHOUS, Harry [US/US]; 230 Albany Street, Cambridge, MA 02139 (US). TUMMURU, Murali, K., R. [US/US]; 212 Fairfax Avenue, Nashville, TN 37212 (US).

(74) Agents: NEEDLE, William, H. et al.; Needle & Rosenberg, Suite 1200, 127 Peachtree Street, N.E., Atlanta, GA 30303-1811 (US).

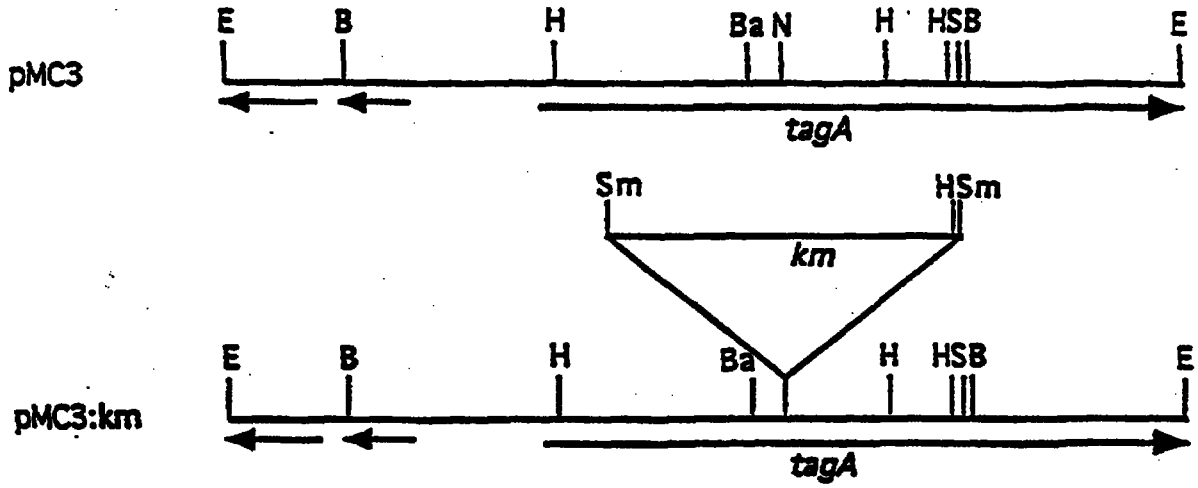
(81) Designated States: AM, AT, AU, BB, BG, BR, BY, CA, CH, CN, CZ, DE, DK, EE, ES, FI, GB, GE, HU, IS, JP, KE, KG, KP, KR, KZ, LK, LR, LT, LU, LV, MD, MG, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, TJ, TM, TT, UA, UG, UZ, VN, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG), ARIPO patent (KE, MW, SD, SZ, UG).

Published
With international search report.
Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

(88) Date of publication of the international search report:
17 May 1996 (17.05.96)

SG 9701526-7 ① PCT + ISR ② = PCT + Annexes.

(54) Title: THE tagA GENE AND METHODS FOR DETECTING PREDISPOSITION TO PEPTIC ULCERATION AND GASTRIC CARCINOMA



(57) Abstract

The present invention provides an isolated nucleic acid encoding an approximately 120-128 kilodalton antigen of *Helicobacter pylori*, or an antigenic fragment thereof, wherein the antigen is associated with peptic ulceration. The present invention also provides methods of detecting the presence of a *Helicobacter pylori* strain possessing the 120-128 kilodalton antigen in a subject, comprising the steps of contacting an antibody-containing sample from the subject with a detectable amount of the tagA antigen or antigenic polypeptide of the present invention and detecting the binding of the antigen or fragment and the antibody. The detection of a strain expressing the TagA antigen is an indication of predisposition to peptic ulceration and gastric carcinoma. A mutant *H. pylori* not expressing a functional TagA antigen is also provided.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	GB	United Kingdom	MR	Mauritania
AU	Australia	GE	Georgia	MW	Malawi
BB	Barbados	GN	Guinea	NE	Niger
BE	Belgium	GR	Greece	NL	Netherlands
BF	Burkina Faso	HU	Hungary	NO	Norway
BG	Bulgaria	IE	Ireland	NZ	New Zealand
BJ	Benin	IT	Italy	PL	Poland
BR	Brazil	JP	Japan	PT	Portugal
BY	Belarus	KE	Kenya	RO	Romania
CA	Canada	KG	Kyrgystan	RU	Russian Federation
CF	Central African Republic	KP	Democratic People's Republic of Korea	SD	Sudan
CG	Congo			SE	Sweden
CH	Switzerland	KR	Republic of Korea	SI	Slovenia
CI	Côte d'Ivoire	KZ	Kazakhstan	SK	Slovakia
CM	Cameroon	LI	Liechtenstein	SN	Senegal
CN	China	LK	Sri Lanka	TD	Chad
CS	Czechoslovakia	LU	Luxembourg	TG	Togo
CZ	Czech Republic	LV	Latvia	TJ	Tajikistan
DE	Germany	MC	Monaco	TT	Trinidad and Tobago
DK	Denmark	MD	Republic of Moldova	UA	Ukraine
ES	Spain	MG	Madagascar	US	United States of America
FI	Finland	ML	Mali	UZ	Uzbekistan
FR	France	MN	Mongolia	VN	Viet Nam
GA	Gabon				

9701526-7