

Mr. Lais is subject to debarment based on a finding, under section 306(a)(2)(B) of the act (21 U.S.C. 355a(a)(2)(B)), that he was convicted of a felony under Federal law for conduct relating to the regulation of a drug product.

In the plea agreement entered on April 25, 2005, Mr. Lais expressly waived his right, if any, to contest any debarment that may be initiated by the Secretary of Health and Human Services under 21 U.S.C.335a. In accordance with section 306(c)(2)(B) of the act, Mr. Lais notified FDA of his acquiescence to debarment in a letter signed on October 3, 2006. A person subject to debarment is entitled to an opportunity for an agency hearing on disputed issues of material fact under section 306(i) of the act, but by acquiescing to debarment Mr. Lais waived his opportunity for a hearing and to raise any contentions concerning his debarment.

II. Findings and Order

Therefore, the Acting Director, Office of Enforcement, Office of Regulatory Affairs, under section 306(a)(2)(B) of the act, under authority delegated to the Acting Director (Staff Manual Guide 1410.35), finds that Patrick J. Lais has been convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the act.

As a result of the foregoing finding and based on his notification of acquiescence, Mr. Lais is permanently debarred from providing services in any capacity to a person with an approved or pending drug product application under sections 505, 512, or 802 of the act (21 U.S.C. 355, 360b, or 382), or under section 351 of the Public Health Service Act (42 U.S.C. 262), effective October 3, 2006, the date of notification of acquiescence (see sections 306(c)(1)(B), (c)(2)(A)(ii), and 201(dd) of the act (21 U.S.C. 321(dd))). Any person with an approved or pending drug product application who knowingly employs or retains as a consultant or contractor, or otherwise uses the services of Patrick J. Lais, in any capacity during Mr. Lais's debarment, will be subject to civil money penalties (section 307(a)(6) of the act (21 U.S.C. 335b(a)(6))). If Mr. Lais provides services in any capacity to a person with an approved or pending drug product application during his period of debarment he will be subject to civil money penalties (section 307(a)(7) of the act). In addition, FDA will not accept or review any abbreviated new drug applications submitted by or with the assistance of Mr. Lais during his period of debarment (section 306(c)(1)(B) of the act).

Any application by Mr. Lais for special termination of debarment under section 306(d)(4) of the act should be identified with Docket No. FDA-2009-N-0585 and sent to the Division of Dockets Management (see **ADDRESSES**). All such submissions are to be filed in four copies. The public availability of information in these submissions is governed by 21 CFR 10.20(j).

Publicly available submissions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 26, 2010.

Brenda Holman,

Acting Director, Office of Enforcement, Office of Regulatory Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804; telephone: 301/496-7057; fax: 301/402-0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Automated Computer-Aided Polyp Detection for Computed Tomography Colonography (Virtual Colonoscopy)

Description of Invention: This invention describes an automated method for colon registration from supine and prone scans that combines the use of Computed Tomographic Colonography (CTC) and Computer Aided Detection (CAD) software.

Currently, in order to detect colonic polyps, patients are scanned twice—once in the supine, and again in the prone positions. This approach improves CTC sensitivity by reducing the extent of non-interpretable collapsed or fluid-filled segments. In order to assist radiologists in interpreting CTC data or evaluating colonic polyp candidates detected by CAD in both scans, it is important to provide not only the locations of suspicious polyps, but also the possible matched pairs (correspondences) of polyps in these scans. To achieve this, the two scans need to be aligned. In this invention, the colon registration problem is formulated as time series matching along the centerline of the colon. Anatomically salient points on the colon are initially distinguished as they can be viewed as landmarks along the central path of the colon. Correlation optimized warping is then applied to the segments defined by the anatomical landmarks to find better global registration based on the local correlation of segments.

When CTC is performed in conjunction with CAD software, screening may become easier on patients, less time-consuming, and more accurate. The effectiveness of the method was verified in experiments in which the polyp location was used as a measure for the registration error. The algorithm was tested on a CTC dataset of 12 patients with 14 polyps. Experimental results showed that by using this method, the estimation error of polyp location could be reduced 60.4% (from 47.2mm to 18.7mm on average) compared to a traditional method based on dynamic time warping.

Colon cancer is the second leading cause of cancer-related deaths in the United States, and the method used in this invention will aid in effective early detection of the disease, which will have a significant impact on its prognosis.

Applications: Efficient and robust detection of colon cancer.

Development Status: Early stage.

Inventors: Ronald M. Summers *et al.* (NIHCC).

Related Publication: Huang A, Roy D, Franaszek M, Summers RM. Teniae coli guided navigation and registration for virtual colonoscopy. Visualization, 2005. VIS 05. IEEE, pp. 279-285, 23-28 Oct 2005; doi 10.1109/VISUAL.2005.1532806.

Patent Status: U.S. Patent Application No. 61/220,481 filed June 25, 2009 (HHS Reference No. E-135-2009/0-US-01).

Licensing Status: Available for licensing.

Licensing Contact: Jeffrey A. James, Ph.D.; 301-435-5474; jeffreyja@mail.nih.gov.

Alpha 1-3 N-Acetylgalactosaminyltransferases With Altered Donor and Acceptor Specificities, Compositions, and Methods of Use: Development of Pharmaceutical Agents and Improved Vaccines

Description of Invention: The present invention relates to the field of glycobiology, specifically to glycosyltransferases. The present invention provides structure-based design of novel glycosyltransferases and their biological applications.

The structural information of glycosyltransferases has revealed that the specificity of the sugar donor in these enzymes is determined by a few residues in the sugar-nucleotide binding pocket of the enzyme, which is conserved among the family members from different species. This conservation has made it possible to reengineer the existing glycosyltransferases with broader sugar donor specificities. Mutation of these residues generates novel glycosyltransferases that can transfer a sugar residue with a chemically reactive functional group to N-acetylglucosamine (GlcNAc), galactose (Gal) and xylose residues of glycoproteins, glycolipids and proteoglycans (glycoconjugates). Thus, there is potential to develop mutant glycosyltransferases to produce glycoconjugates carrying sugar moieties with reactive groups that can be used in the assembly of bio-nanoparticles to develop targeted-drug delivery systems or contrast agents for medical uses.

Accordingly, methods to synthesize N-acetylglucosamine linkages have many applications in research and medicine, including in the development of pharmaceutical agents and improved vaccines that can be used to treat disease.

This application claims compositions and methods based on the structure-based design of alpha 1-3 N-Acetylgalactosaminyltransferase (alpha 3 GalNAc-T) mutants from alpha 1-3galactosyltransferase (a3Gal-T) that can transfer 2'-modified galactose from the corresponding UDP-derivatives due to mutations that broaden the alpha 3Gal-T donor specificity and make the enzyme alpha3 GalNAc-T.

Applications: Development of pharmaceutical agents and improved vaccines.

Development Status: Enzymes have been synthesized and preclinical studies have been performed.

Inventors: Pradman Qasba, Boopathy Ramakrishnan, Elizabeth Boeggeman, Marta Pasek (NCI).

Patent Status: PCT Application No. PCT/US2007/018678 filed August 22, 2007, which published as WO 2009/025646 on February 26, 2009 (HHS Reference No. E-279-2007/0-PCT-01).

Licensing Status: Available for licensing.

Licensing Contact: John Stansberry, PhD; 301-435-5236; stansbej@mail.nih.gov.

Collaborative Research Opportunity: The National Cancer Institute's Nanobiology Program is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize structure-based design of novel glycosyltransferases. Please contact John D. Hewes, PhD at 301-435-3121 or hewesj@mail.nih.gov for more information.

Beta 1,4-Galactosyltransferases With Altered Donor and Acceptor Specificities, Compositions and Methods of Use: Development of Pharmaceuticals and Improved Vaccines

Description of Invention: The present invention relates to the field of glycobiology, specifically to glycosyltransferases. The present invention provides structure-based design of novel glycosyltransferases and their biological applications.

The structural information of glycosyltransferases has revealed that the specificity of the sugar donor in these enzymes is determined by a few residues in the sugar-nucleotide binding pocket of the enzyme, which is conserved among the family members from different species. This conservation has made it possible to reengineer the existing glycosyltransferases with broader sugar donor specificities. Mutation of these residues generates novel glycosyltransferases that can transfer a sugar residue with a chemically reactive functional group to N-acetylglucosamine (GlcNAc), galactose (Gal) and xylose residues of glycoproteins, glycolipids and proteoglycans (glycoconjugates). Thus, there is potential to develop mutant glycosyltransferases to produce glycoconjugates carrying sugar moieties with reactive groups that can be used in the assembly of bio-nanoparticles to develop targeted-drug delivery systems or contrast agents for medical uses.

Accordingly, methods to synthesize N-acetylglucosamine linkages have many applications in research and medicine, including in the development

of pharmaceutical agents and improved vaccines that can be used to treat disease.

The invention claims beta (1,4)-galactosyltransferase I mutants having altered donor and acceptor and metal ion specificities, and methods of use thereof. In addition, the invention claims methods for synthesizing oligosaccharides using the beta (1,4)-galactosyltransferase I mutants and to using the beta (1,4)-galactosyltransferase I mutants to conjugate agents, such as therapeutic agents or diagnostic agents, to acceptor molecules. More specifically, the invention claims a double mutant beta 1, 4 galactosyltransferase, human beta-1, 4-Tyr289Leu-Met344His-Gal-T1, constructed from the individual mutants, Tyr289Leu-Gal-T1 and Met344His-Gal-T1, that transfers modified galactose in the presence of magnesium ion, in contrast to the wild-type enzyme which requires manganese ion.

Application: Development of pharmaceutical agents and improved vaccines.

Development Status: Enzymes have been synthesized and preclinical studies have been performed.

Inventors: Pradman Qasba, Boopathy Ramakrishnan, Elizabeth Boeggeman (NCI).

Patent Status: PCT Application No. PCT/US2007/018656 filed August 22, 2007, which published as WO 2009/025645 on February 26, 2009 (HHS Reference No. E-280-2007/0-PCT-01).

Licensing Status: Available for licensing.

Licensing Contact: John Stansberry, PhD; 301-435-5236; stansbej@mail.nih.gov.

Collaborative Research Opportunity: The National Cancer Institute's Nanobiology Program is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize glycosyltransferases. Please contact John D. Hewes, PhD at 301-435-3121 or hewesj@mail.nih.gov for more information.

Dated: February 4, 2010.

Richard U. Rodriguez,

Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

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