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A Novel Glycopolymer to Enhance Protein Stability

Tech ID: 22526 / UC Case 2012-422-0

BACKGROUND

Proteins have found utility for numerous commercial and clinical purposes, including use in biochemical and chemical processes, and as agents for the treatment and prevention of human and veterinary disease. A major challenge associated with the use of proteins is their inherent instability. Many proteins rapidly degrade in response to "environmental stresses," such as changes in temperature, pH, light, and desiccation, which has implications for their production, transport, use and storage. Attachment of poly(ethylene glycol) to therapeutic proteins, a process commonly referred to as PEGylation, has been used successfully to increase their stability in vivo by reducing both protease degradation and renal clearance. However, PEGylation does not necessarily increase protein stability in response to environmental stresses. The development of a technology that enhances the stability of proteins to such stresses would dramatically increase the number of proteins that could be used commercially, reduce costs associated with protein production, storage and transportation, and increase protein shelf-life.

INNOVATION

Dr. Heather Maynard and colleagues at UCLA have developed a novel glycopolymer to enhance the stabilization of proteins in response to various environmental stressors, including lyophilization and heat. The glycopolymer incorporates the disaccharide trehalose, which is frequently used as a preservative in foods and is Generally Regarded As Safe. The trehalose-based polymer developed by the Maynard group is prepared in such a way to have end-groups that the polymer can, if desired, be directly attached to the biomolecule. Direct attachment of the trehalose-polymer to proteins increases protein stability using lower polymer concentrations. Moreover, the method of synthesis allows for the preparation of trehalose-based polymers with a narrow molecular weight distribution, something that has not been achievable using methodologies developed by others. Studies are underway to determine whether the attachment of the trehalose-based polymer to the biomolecule also confers properties that are similar or superior to PEGylation, such as enhanced protection from proteolytic degradation and extended in vivo circulation time

APPLICATIONS

- Increased stability of proteins (e.g. enzymes and antibodies) or other biomolecules (e.g. siRNA) against environmental stressors,
- reducing the need for controlling such factors in their production, storage, and transportation.

Туре

► A possible substitute for PEGylation.

ADVANTAGES

Glycoconjugate can be directly attached to biomolecule, allowing lower concentrations of the glycopolymer to be used to increase biomolecule stability.

Method of synthesis allows for preparation of a polymer with narrow molecular weight distribution, which is significant when seeking regulatory approval for an agent incorporating such a polymer.

STATE OF DEVELOPMENT

Ongoing work focuses on validation of protection to other stressors. Experiments are underway to determine in vivo stability of this glycoconjugate.

PATENT STATUS

Dated

Case

CONTACT

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INVENTORS

KEYWORDS

Maynard, Heather D.

OTHER INFORMATION

protein stability, protein chemistry, protein degradation, biologics, protein storage, environmental stressors, protein therapeutics, protein delivery, vaccines, protein polymers, drug delivery, antibody, nutraceuticals, food technology

CATEGORIZED AS

- Agriculture & Animal Science
 - Nutraceuticals
- Biotechnology
 - ► Food
 - Health
- Materials & Chemicals
 - Chemicals
 - Polymers
- Medical
 - Delivery Systems
 - ▶ New Chemical Entities,
 - Drug Leads
 - ► Therapeutics
 - ► Vaccines
- Research Tools
 - Antibodies
 - Protein Synthesis
 - Reagents

| United States Of America | Issued Patent | 11,951,176 | 04/09/2024 | 2012-422 |
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| United States Of America | Issued Patent | 10,543,280 | 01/28/2020 | 2012-422 |
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| France | Issued Patent | 2807177 | 11/13/2019 | 2012-422 |
| United Kingdom | Issued Patent | 2807177 | 11/13/2019 | 2012-422 |
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| Japan | Issued Patent | 6195848 | 08/25/2017 | 2012-422 |
| European Patent Office | Published Application | EP 3723814 | 10/21/2020 | 2012-422 |

RELATED MATERIALS

- Trehalose glycopolymers for stabilization of protein conjugates to environmental stressors. J Am Chem Soc. (2012)
- ▶ Trehalose Glycopolymers as Excipients for Protein Stabilization

ADDITIONAL TECHNOLOGIES BY THESE INVENTORS

- ▶ PolyProtek: Platform for Delivering and Stabilizing Therapeutic Biologics, Vaccines, and Industrial Enzymes
- Dual-Enzyme Responsive Peptides
- ► A Novel Basic Fibroblast Growth Factor Conjugate for Broad Therapeutic Application
- ► Update To Degradable Trehalose Glycopolymers
- Noncrushable/Nonabusable Pill Formulations
- ▶ Trehalose Hydrogels For Stabilization And Delivery Of Proteins

Gateway to Innovation, Research and Entrepreneurship

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RELATED CASES

2012-422-0, 2015-112-0, 2015-602-0