

PolyProtek: Platform for Delivering and Stabilizing Therapeutic Biologics, Vaccines, and Industrial Enzymes

Tech ID: 24457 / UC Case 2015-112-0

SUMMARY

UCLA researchers in the Department of Chemistry & Biochemistry have designed an improved version of trehalose-based glycopolymer as a degradable alternative to PEG for the purpose of stabilizing a protein during storage and transport.

BACKGROUND

A UCLA team led by Professor Heather Maynard has developed a family of polymers that effectively stabilizes industrial enzymes and therapeutic biologics and vaccines against thermal and mechanical stress while improving their in vivo pharmacokinetic properties. Widely-used polymers such as PEG do not effectively stabilize proteins against thermal and mechanical stress (necessitating special handling and storage conditions in supply chains).

The team has also developed a degradable polymer that is safely and effectively cleared in vivo. This may have benefits versus PEG especially in chronic use situations as PEG has been shown to induce formation of antibodies in 32–46% of patients as well as vacuolation in rodents upon injection with high molecular weight PEG. This degradable polymer may also have significant benefits in stabilizing industrial enzymes as it avoids unwanted environmental buildup and shows high stabilization of enzymes against thermal and mechanical stress.

The technology is based on a novel series of polymers that incorporate trehalose as a side chain. Trehalose is a disaccharide that is widely used by a variety of organisms to stabilize against environmental stressors such as a high temperatures, dessication, etc.

APPLICATIONS

- ▶ Drug delivery of therapeutic proteins and vaccines (benefits versus PEG in being degradable, non-immunogenic, while preserving same PK benefits as PEG).
- ▶ Thermal and mechanical stabilization of (a) industrial enzymes, (b) therapeutic proteins and vaccines, and (c) high cost additives in cosmetics and agbio applications. Eliminates the need for cold-storage supply chains for biologics and vaccines. Improves enzymatic activity in industrial applications as either a conjugate or excipient by stabilizing against thermal and mechanical stress.

ADVANTAGES

- ▶ Hydrolytical degradability potentially eliminates problems of vacuolation and accumulation of the conjugates in the body with repeated dosage
- ▶ Conjugation of a degradable polymer to a protein may enable safe storage and transport, while degrading into short molecular weights in vivo and maintaining high therapeutic activity

RELATED MATERIALS

- ▶ Lee, J., Lin, E.W., Lau, U.Y., Hedrick, J.L., Bat, E. and Maynard, H.D., 2013. Trehalose glycopolymers as excipients for protein stabilization. *Biomacromolecules*, 14(8), pp.2561-2569.
- ▶ Liu, Y., Lee, J., Mansfield, K.M., Ko, J.H., Sallam, S., Wesdemiotis, C. and Maynard, H.D., 2017. Trehalose Glycopolymer Enhances Both Solution Stability and Pharmacokinetics of a Therapeutic Protein. *Bioconjugate Chemistry*.

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INVENTORS

- ▶ Maynard, Heather D.

OTHER INFORMATION

KEYWORDS

Trehalose glycopolymer, polymer, protein-polymer conjugates, polymer-drug conjugates, bioconjugates, degradable, protein stabilization, biomedical, drug delivery, therapeutics, environmental stressors

CATEGORIZED AS

- ▶ **Agriculture & Animal Science**
 - ▶ Nutraceuticals
- ▶ **Biotechnology**
 - ▶ Food
- ▶ **Materials & Chemicals**
 - ▶ Biological
 - ▶ Chemicals
 - ▶ Polymers
- ▶ **Medical**
 - ▶ Delivery Systems
 - ▶ Therapeutics

RELATED CASES

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

► Mancini, R.J., Lee, J., and Maynard, H.D., 2012. Trehalose Glycopolymers for Stabilization of Protein Conjugates to Environmental Stressors. J Am Chem Soc, 134(20), pp.8474-9.

PATENT STATUS

| Country | Type | Number | Dated | Case |
|--------------------------|---------------|------------|------------|----------|
| United States Of America | Issued Patent | 11,951,176 | 04/09/2024 | 2012-422 |
| United States Of America | Issued Patent | 10,899,879 | 01/26/2021 | 2015-112 |
| Germany | Issued Patent | 3180023 | 02/19/2020 | 2015-112 |
| France | Issued Patent | 3180023 | 02/19/2020 | 2015-112 |
| United Kingdom | Issued Patent | 3180023 | 02/19/2020 | 2015-112 |
| Ireland | Issued Patent | 3180023 | 02/19/2020 | 2015-112 |
| United States Of America | Issued Patent | 10,543,280 | 01/28/2020 | 2012-422 |
| United States Of America | Issued Patent | 10,273,333 | 04/30/2019 | 2015-602 |
| United States Of America | Issued Patent | 9901648 | 02/27/2018 | 2012-422 |

ADDITIONAL TECHNOLOGIES BY THESE INVENTORS

- [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](#)
- [A Novel Glycopolymer to Enhance Protein Stability](#)

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