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Pravda

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(54) **MATERIALS AND METHODS FOR TREATMENT AND DIAGNOSIS OF DISORDERS ASSOCIATED WITH OXIDATIVE STRESS**

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(58) **Field of Classification Search**

CPC *A61K 31/385*; *A61K 31/606*; *A61K 9/0053*; *A61K 31/352*; *A61K 31/58*; *A61K 31/19*; *A61K 9/10*; *A61K 9/0031*; *A61K 45/06*; *A61K 31/616*; *A61K 9/48*

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See application file for complete search history.

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(56) **References Cited**

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 46 days.

This patent is subject to a terminal disclaimer.

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(65) **Prior Publication Data**

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Related U.S. Application Data

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(63) Continuation of application No. 13/298,106, filed on Nov. 16, 2011, now Pat. No. 8,916,546, which is a continuation-in-part of application No. 12/664,237, filed as application No. PCT/US2008/007401 on Jun. 13, 2008, now Pat. No. 8,476,233, and a continuation-in-part of application No. 11/540,864, filed on Sep. 28, 2006, now abandoned, and a continuation-in-part of application No. 11/107,179, filed on Apr. 15, 2005, now abandoned, and a continuation of application No. 10/927,742, filed on Aug. 27, 2004, now Pat. No. 7,312,243.

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(60) Provisional application No. 60/499,152, filed on Aug. 29, 2003, provisional application No. 61/414,047, filed on Nov. 16, 2010, provisional application No. 61/063,745, filed on Feb. 6, 2008, provisional application No. 60/934,505, filed on Jun. 13, 2007.

(57) **ABSTRACT**

The subject invention pertains to materials and methods for the prevention and treatment of disease conditions associated with oxidative stress or a compromised reducing environment, including inflammatory bowel diseases such as Crohn's disease and ulcerative colitis. Another aspect of the subject invention concerns compositions formulated for administration as an enema. In one embodiment, a composition suitable for administration as an enema comprises an effective amount of 5-ASA and a steroid such as budesonide or hydrocortisone. The subject invention also concerns compositions formulated for oral administration. In one embodiment, a composition comprises alpha-lipoic acid, and/or N-acetyl-L-cysteine (N-A-C), and/or L-glutamine. The alpha-lipoic acid can be racemic alpha-lipoic acid, R-lipoic acid, or R-dihydro-lipoic acid. Methods of the invention include administration of compounds or compositions of the invention. In one embodiment, compounds or compositions of the invention are rectally instilled in a patient. In another embodiment, compounds or compositions are orally administered. The subject invention also concerns methods for screening for, assessing risk of developing, and/or diagnosing conditions associated with oxidative stress, such as ulcerative colitis and other inflammatory bowel disorders.

(51) **Int. Cl.**

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(52) **U.S. Cl.**

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