



(12) **United States Patent**
Alliger et al.

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(54) **PRODUCTION OF BORRELIA
BURGDORFERI VACCINE, PRODUCT
PRODUCED THEREBY AND METHOD OF
USE**

FOREIGN PATENT DOCUMENTS

90/04411 * 5/1990 (WO) .

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Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

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This patent is subject to a terminal disclaimer.

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(21) Appl. No.: **08/475,542**

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Related U.S. Application Data

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(51) **Int. Cl.**⁷ **A61K 39/02**; A61K 39/38;
C12N 13/00; C12N 1/00

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(52) **U.S. Cl.** **424/234.1**; 435/173.1;
435/173.4; 435/173.7; 435/243

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(58) **Field of Search** 424/234.1; 435/173.1,
435/173.4, 173.7, 243

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(57) **ABSTRACT**

A process for the preparation of a vaccine from substantially viable spirochetal bacteria of *Borrelia*, preferably *Borrelia burgdorferi* having immunogenic or therapeutic properties and capable of inducing an immune or therapeutic response against Lyme Disease when administered to a patient is described. The product for use against Lyme Disease is produced by ultrasound treatment of substantially viable spirochetal bacteria of *Borrelia burgdorferi*. The invention produces a product and a method of treatment that can be used for the immunization and/or therapy of a patient against Lyme Disease to minimize or prevent the contraction of the disease or to treat the disease.

26 Claims, 7 Drawing Sheets