Garti et al. (45) **Date of Patent:** Mar. 1, 2005 CRYSTAL FORMS OF LAMOTRIGINE AND (58) **Field of Search** 544/182; 514/242 PROCESSES FOR THEIR PREPARATIONS References Cited (56)(75) Inventors: Nissim Garti, Ramot (IL); Yana U.S. PATENT DOCUMENTS Berkovich, Jerusalem (IL); Ben-Zion Dolitzky, Petach Tiqva (IL); Judith 4,560,687 A 12/1985 Baxter et al. 544/182 Aronhime, Rehovot (IL); Claude 6,124,308 A 9/2000 Nobbs et al. 544/182 Singer, Kfar Saba (IL); Anita OTHER PUBLICATIONS Liebermann, Tel-Aviv (IL); Neomi Gershon, Rosh Ha-Ain (IL) Janes et al., "Structure of Lamotrigine Methanol Solvate: 3,5-Diamino-6-(2,3-dichlorophenyl)-1,2,4-triaz-(73) Assignee: Teva Pharmaceutical Industries Ltd., ine-Methanol, a Novel Anticonvulsant Drug," Acta Cryst., Petah Tiqva (IL) 1989, C45, 129-132. Pharmacopeial Forum, vol. 24, No. 1, (Jan.-Feb. 1998) p. Subject to any disclaimer, the term of this (*) Notice: 5438-5440. patent is extended or adjusted under 35 E. Schmitt et al "Moisture-Dependent Crystallization of U.S.C. 154(b) by 0 days. Amorphous Lamotrigine Mesylate" Journal of Pharmaceutical Sciences vol. 85, No. 11, Nov. 1996, pp. 1215-1219. (21) Appl. No.: 10/086,157 Primary Examiner—Richard L. Raymond (22) Filed: Feb. 27, 2002 (74) Attorney, Agent, or Firm-Kenyon & Kenyon (57)**ABSTRACT** (65)**Prior Publication Data** US 2003/0018030 A1 Jan. 23, 2003 The present invention relates to lamotrigine, a useful agent for anti-epilepsia. New crystal forms of lamotrigine con-Related U.S. Application Data

100 Claims, 18 Drawing Sheets

preparing the new crystal forms of lamotrigine.

taining molecules of the solvent in stoichiometric ratios are

disclosed. The present invention also provides processes for

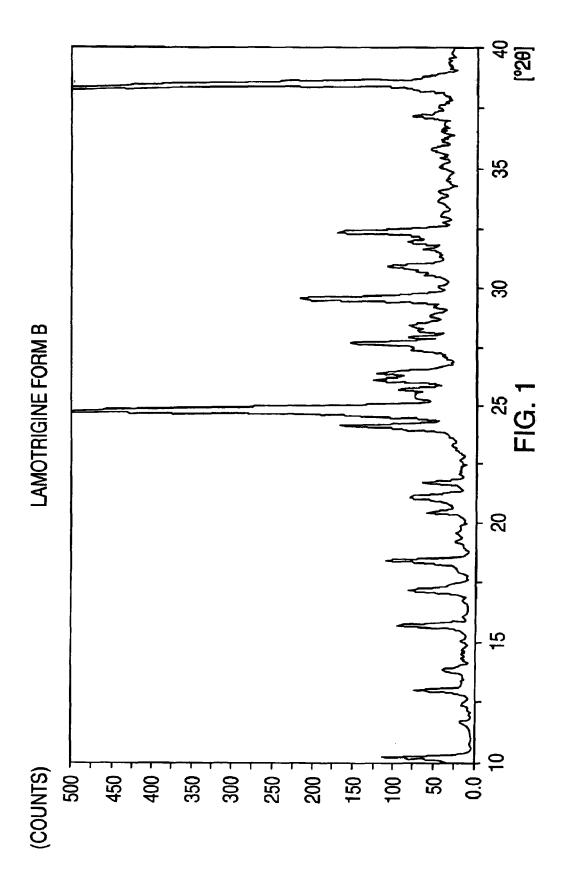


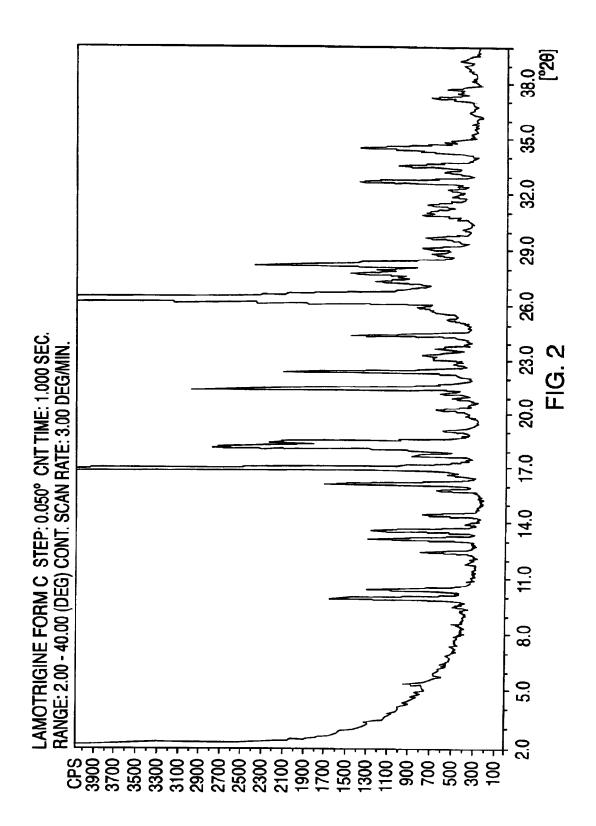
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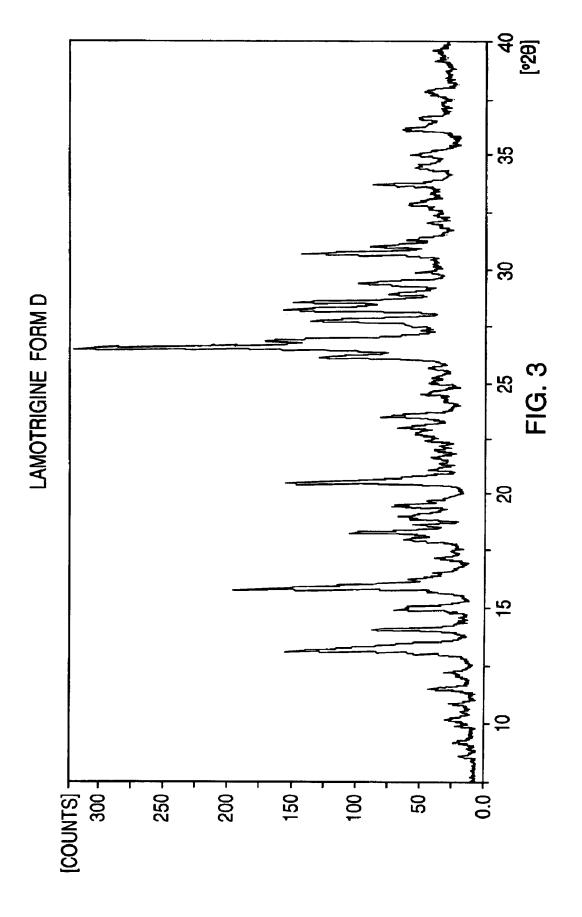
Provisional application No. 60/271,688, filed on Feb. 27,

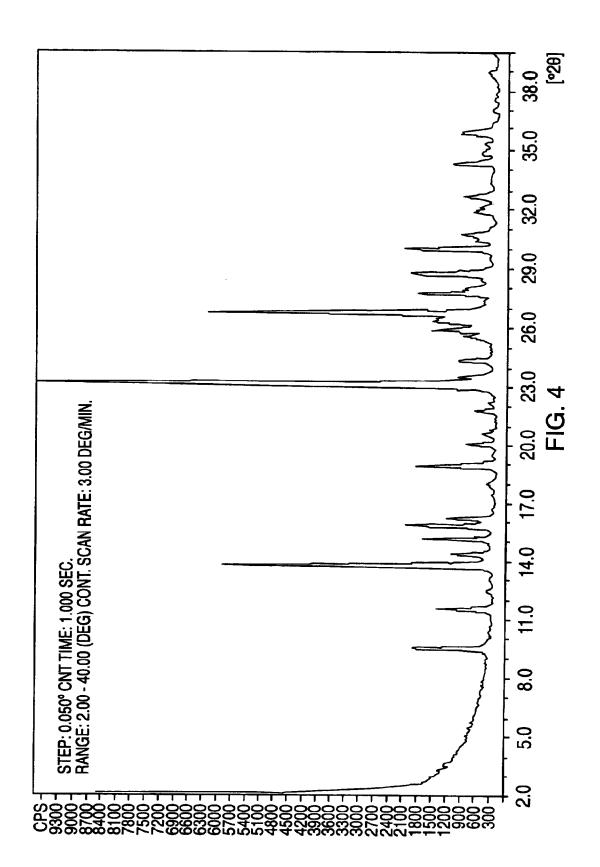
(51) Int. Cl.⁷ A61K 31/35; C07D 253/075 (52) **U.S. Cl.** 514/242; 544/182

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