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(12) **United States Patent**
Cotton et al.(10) **Patent No.:** **US 7,411,070 B2**(45) **Date of Patent:** ***Aug. 12, 2008**(54) **FORM OF S-OMEPRAZOLE**(75) Inventors: **Hanna Cotton**, Södertälje (SE); **Anders Kronström**, Södertälje (SE); **Anders Mattson**, Södertälje (SE); **Eva Möller**, Södertälje (SE)(73) Assignee: **AstraZeneca AB**, Sodertalje (SE)

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

This patent is subject to a terminal disclaimer.

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Related U.S. Application Data

(60) Continuation of application No. 10/076,711, filed on Feb. 14, 2002, now Pat. No. 6,677,455, which is a division of application No. 09/077,719, filed as application No. PCT/SE98/00974 on May 25, 1998, now Pat. No. 6,369,085.

(30) **Foreign Application Priority Data**

May 30, 1997 (SE) 9702065

(51) **Int. Cl.****C07D 401/12** (2006.01)**A61K 31/4439** (2006.01)(52) **U.S. Cl.** **546/273.7**; 514/338(58) **Field of Classification Search** 514/338;
546/273.7

See application file for complete search history.

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X-ray powder diffraction pattern of Mg-salt of S-omeprazole trihydrate depicted by Torrent obtained by method of WO 94/27988. NDA 21-153/S-020 for Nexium® (esomeprazole magnesium) Delayed Release Capsule.

NDA 21-153/21-154 entitled "Medical Review(s)".

Statement with Exhibits A-C on Behalf of the Applicant, AstraZeneca AB, to the Opposition filed by Ranbaxy Laboratories Limited against Indian Patent Application No. 1344/DEL/98.

Statement with Exhibits A-D on Behalf of the Applicant, AstraZeneca AB, to the Opposition filed by Torrent Pharmaceuticals Limited against Indian Patent Application No. 1344/DEL/98.

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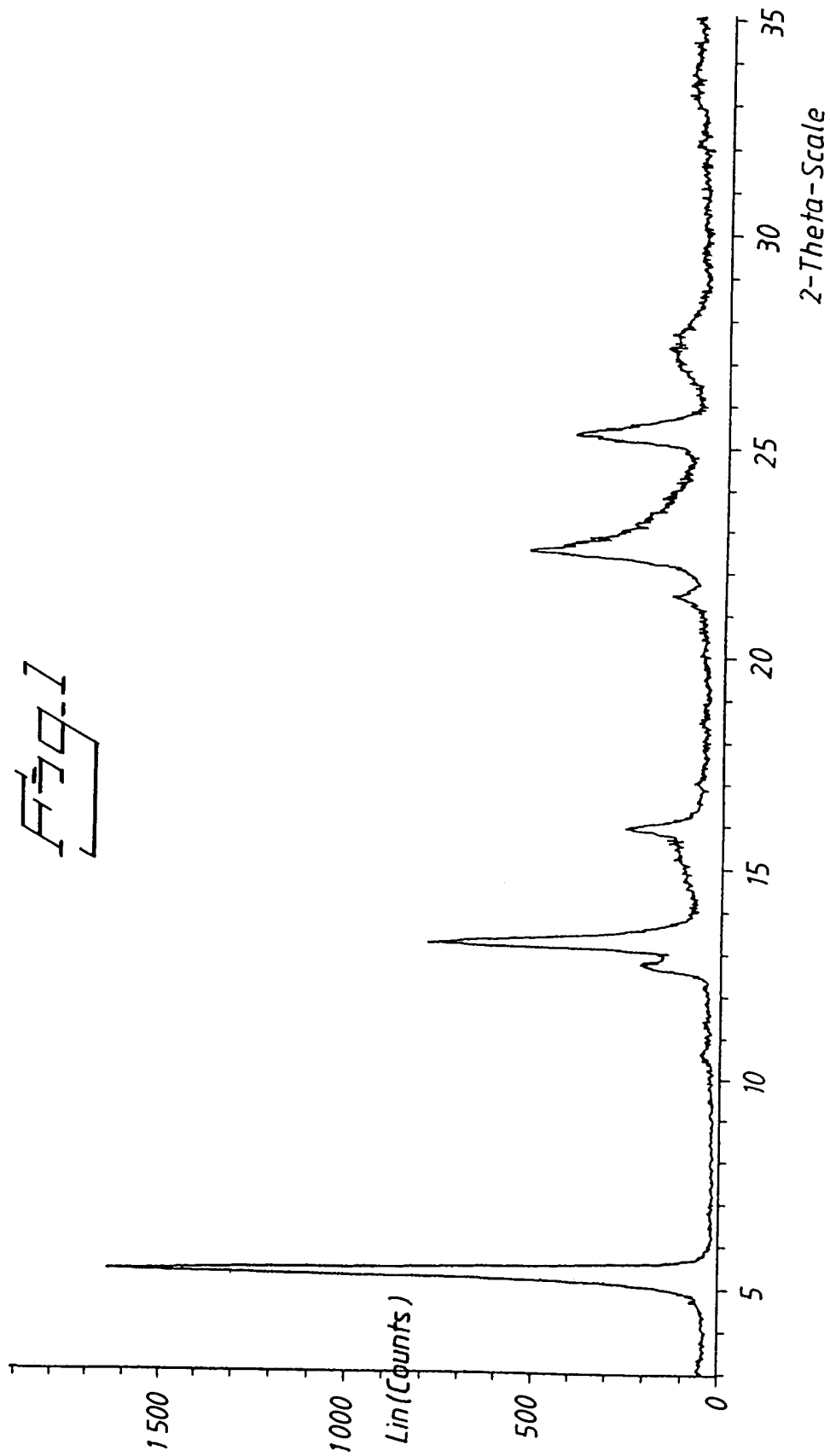
Notice of Allegation, dated Nov. 13, 2007, pursuant to the *Patented Medicines (Notice of Compliance) Regulations* with respect to Canadian Letters Patent No. 2,290,963.

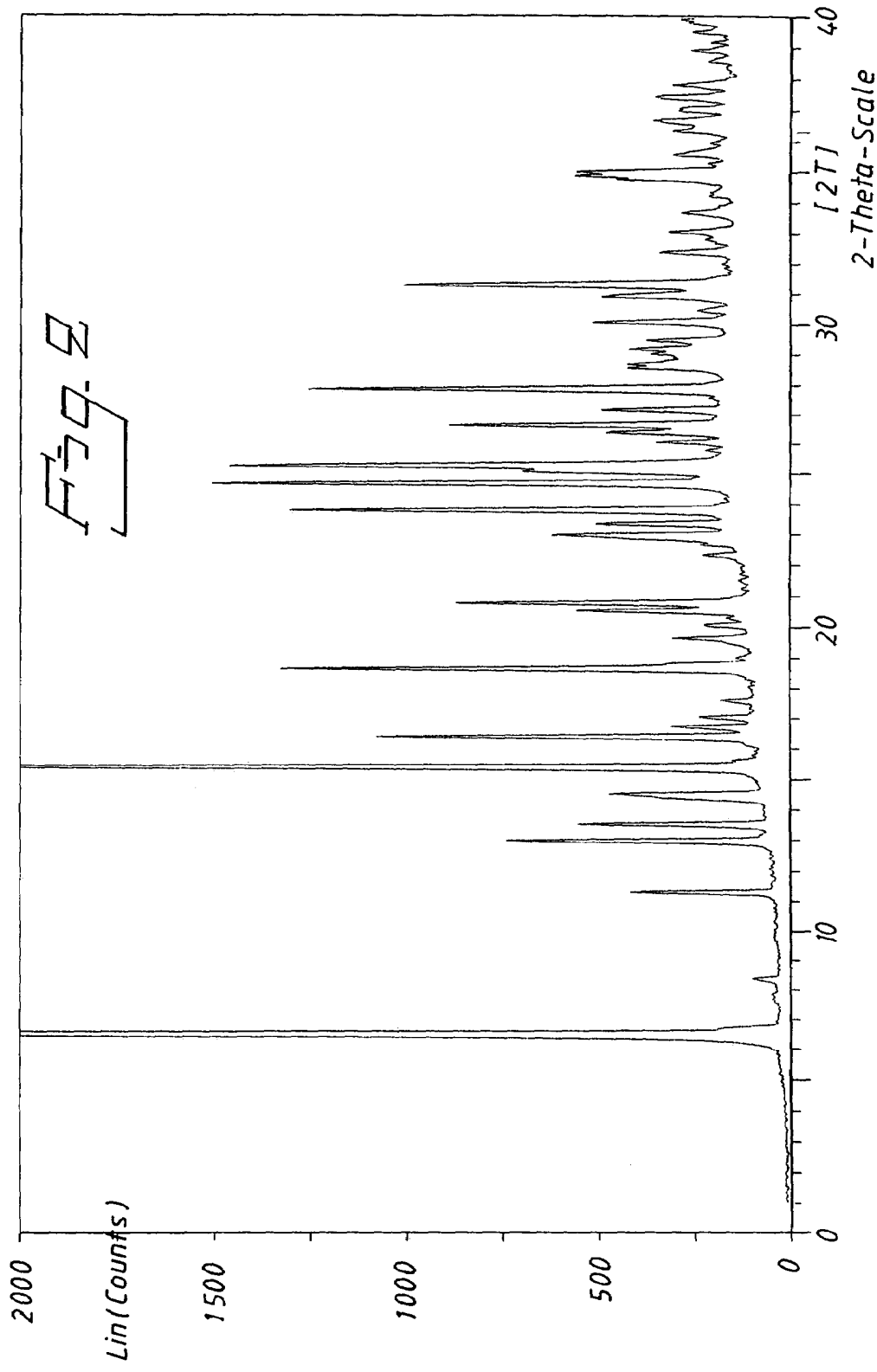
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Primary Examiner—Charanjit S Aulakh(74) *Attorney, Agent, or Firm*—White & Case LLP(57) **ABSTRACT**

The present invention relates to a novel form of the (-)-enantiomer of 5-methoxy-2[[[(4-methoxy-3,5-dimethyl-2-pyridinyl)-methyl]sulfinyl]-1H-benzimidazole, i.e. S-omeprazole. More specifically, it relates to a novel form of the magnesium salt of the S-enantiomer of omeprazole trihydrate. The present invention also relates to processes for preparing such a form of the magnesium salt of S-omeprazole and pharmaceutical compositions containing it. Furthermore, the present invention also relates to new intermediates used in the process.

4 Claims, 5 Drawing Sheets





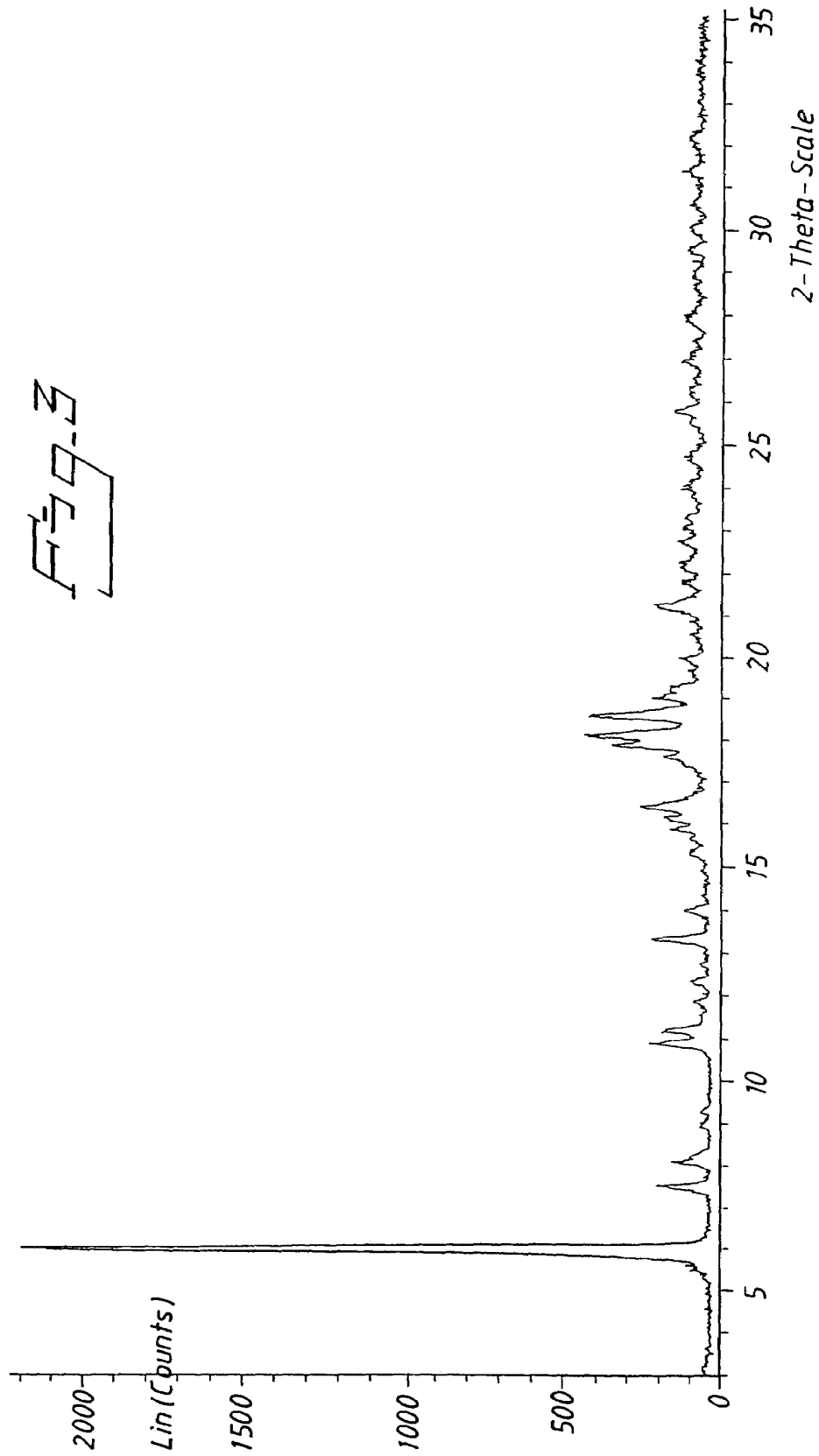
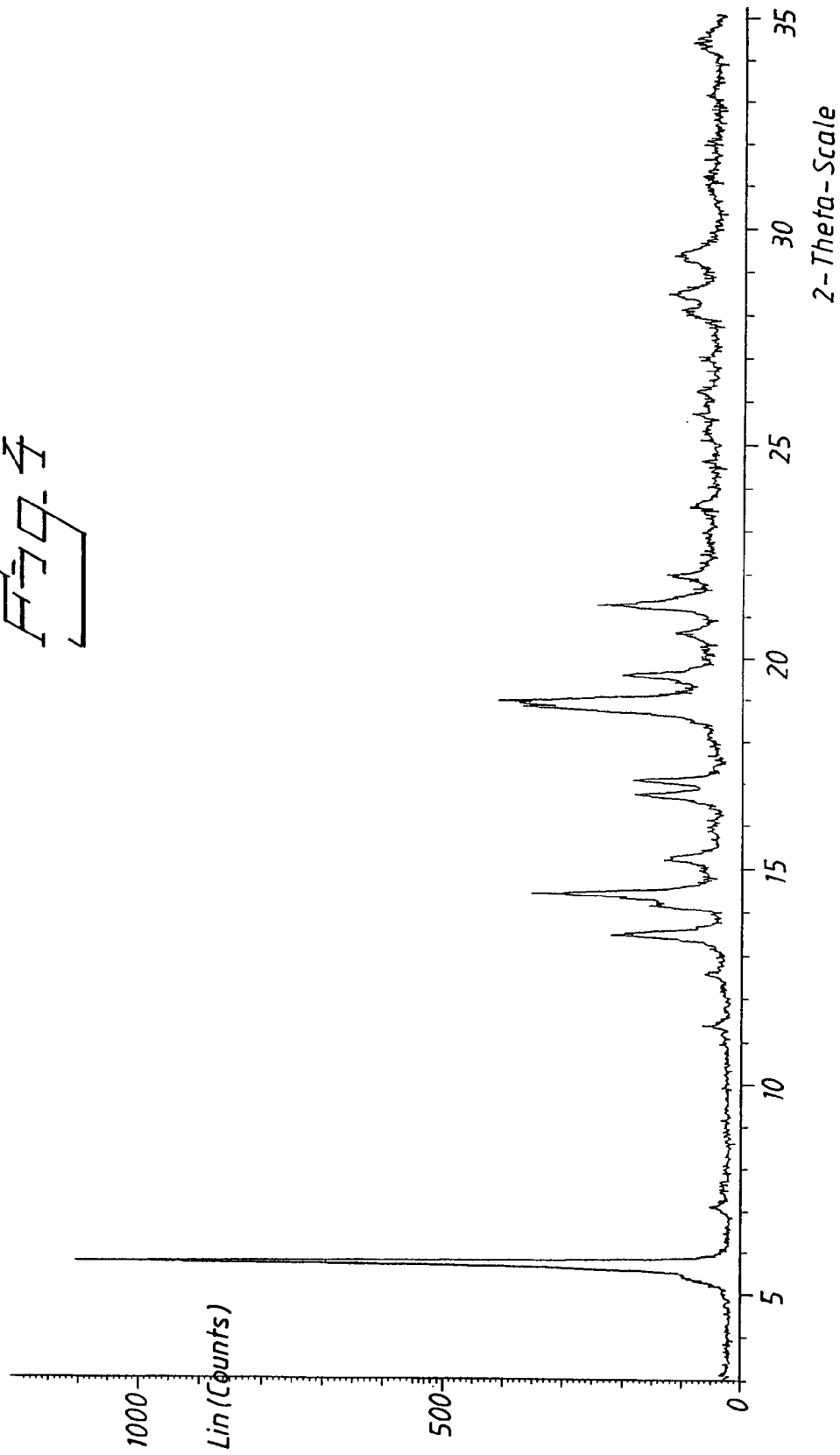


Fig. 4



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