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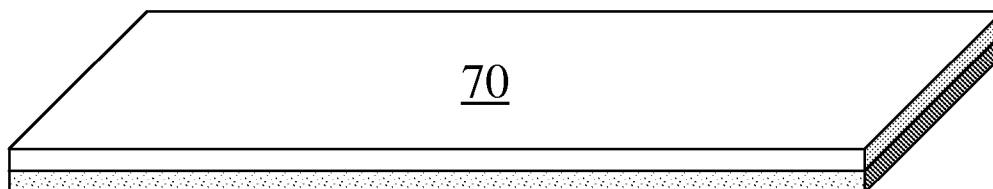
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(54) Title: PROCESS FOR THE PREPARATION OF A HOT-MELT EXTRUDED LAMINATE



(57) Abstract: A process for the preparation of a bioadhesive laminate comprising a hot-melt extruded reservoir layer and a hot-melt extruded backing layer is provided. The reservoir layer comprises a thermoplastic bioadhesive composition containing an active agent. An active agent-containing thermoplastic bioadhesive hydrophilic composition is hot-melt coextruded with a hydrophobic composition to form at least a bi-layered laminate. The hydrophilic composition and the hydrophobic composition have at least one polymer in common. In addition, the melt flow index of the hydrophobic composition is within 50% of the melt flow index of the hydrophilic composition. As a result, the laminate has a uniform transverse cross-section and/or a uniform longitudinal cross-section throughout a major of the length of the laminate. Moreover, when the laminate is divided into unit doses of approximately the same size, they have a high degree of content uniformity with respect to the active agent(s) present therein.

WO 2007/112285 A3

# INTERNATIONAL SEARCH REPORT

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## A. CLASSIFICATION OF SUBJECT MATTER

IPC: **B29C 47/06**( 2006.01),**47/00**( 2006.01);**A61F 13/00**( 2006.01);**A61K 9/58**( 2006.01),**9/32**( 2006.01),**9/14**( 2006.01)

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Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US RE33,093 (SCHIRALDI et al.) 17 October 1989 (17.10.1989), Abstract; col. 2, lines 35-62; col. 3, lines 16-68; col. 4, lines 1-49; Example 1; Example 5; claim 8	1-9, 15, 17-21,23-37, 42-44, 46-53, 55-62, and 69-73 ----- 10-14, 16, 22, 38-41, 45, 54, 63-68
Y	US 3,017,304 (BURGENI) 16 January 1962 (16.01.1962), Figure 16; col. 9, lines 15-27	16
Y	US 6,375,963 (REPKA et al.) 23 April 2002 (23.04.2002), col. 8, lines 26-30	10-14, 38-41, 63-67
Y	APICELLA et al. Poly(ethylene oxide) (PEO) and Different Molecular Weight PEO Blends Monolithic Devices for Drug Release, Biomaterials 1993, 14(2): 83-90; pg. 86 paragraph 4	10-14, 38-41, 63-67
Y	US 2005/0169977 (KANIOS et al.) 04 August 2005 (04.08.2005); Figure 2	22, 45, 54, 68

☒ Further documents are listed in the continuation of Box C.



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