Abstract:

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PCT/EP2010/001208

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DONALD, Bernard Francis [IE/IE]; Comaghy, Mullyash, Castleblayney, Co. Monaghan (IE).

HARRISON GODDARD FOOTE; Belgrave Hall, Belgrave Street, Leeds LS2 8DD (GB).

IMMUNOMODULATORY COMPOSITIONS COMPRISING HYDRALAZINE FOR THE TREATMENT GASTROINTESTINAL DISORDERS

Exemplary formulations comprise hydralazine as a hydroxylase inhibitor and/or cyclosporin A as an immunosuppressant.

WO 2012/069658 A3

Title: IMMUNOMODULATORY COMPOSITIONS COMPRISING HYDRALAZINE FOR THE TREATMENT GASTROINTESTINAL DISORDERS

Abstract: Immunomodulator formulations for use in the treatment of disease of the GI tract. The formulations comprise a hydroxylase inhibitor and/or an immunosuppressant. Exemplary formulations comprise hydralazine as a hydroxylase inhibitor and/or cyclosporin A as an immunosuppressant.
This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. □ Claims Nos.:
   because they relate to subject matter not required to be searched by this Authority, namely:

2. □ Claims Nos.:
   because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. □ Claims Nos.:
   because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. X As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. □ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. □ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. □ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

□ The additional search fees were accompanied by the applicant’s protest and, where applicable, the payment of a protest fee.

□ The additional search fees were accompanied by the applicant’s protest but the applicable protest fee was not paid within the time limit specified in the invitation.

□ No protest accompanied the payment of additional search fees.
A. CLASSIFICATION OF SUBJECT MATTER

INV. A61K9/00 A61K9/50 A61K31/436 A61K31/502 A61K45/06
A61P1/04 A61P37/06 A61P1/00

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61K A61P

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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<th>Category*</th>
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<td>WO 2008/122965 A2 (SIGMOID PHARMA LTD [IE]; COULTER IVAN [IE]) 16 October 2008 (2008-10-16) page 35, lines 5-8; claims 1-5, 15-24, 48-53, 55 page 24, paragraph 2</td>
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<td>WO 2008/122967 A2 (SIGMOID PHARMA LTD [IE]; COULTER IVAN [IE]) 16 October 2008 (2008-10-16) page 70, paragraph 3; claims 1, 7, 26, 28, 29, 50, 59, 63, 64, 68, 76, 77 page 70, paragraph 4 - page 71, paragraph 4</td>
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* Special categories of cited documents:

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier application or patent but published on or after the international filing date
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- "O" document referring to an oral disclosure, use, exhibition or other means
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- "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a skilled person in the art
- "A" document member of the same patent family

Date of the actual completion of the international search: 22 May 2012

Date of mailing of the international search report: 29/05/2012

Name and mailing address of the ISA/

European Patent Office, P.B. 5818 Patentlaan 2
NL-2280 HV Rijswijk
Tel. (+31-70) 340-2040.
Fax. (+31-70) 340-3016

Authorized officer

Ansaldo, M
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<td>WO 2010/005980 A1 (LIFECYCLE PHARMA AS [DK]; GORDON ROBERT D [US]; HOLM PER [DK]; LADEMAN) 14 January 2010 (2010-01-14) pages 48-50; claims 21, 48-52, 68</td>
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This International Search Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-16, 21, 22, 28-30, 43-45 (completely) ; 17-20, 23-27, 46-71 (partially)

Pharmaceutical composition comprising hydralazine and cyclosporin A for the treatment of a disorder of the gastrointestinal tract

2. claims: 46, 47 (completely) ; 17-20, 23-27 (partially)

Pharmaceutical composition comprising an immunosuppressant and a hydroxylase inhibitor for treating a fibrotic intestinal disorder

3. claims: 31-42, 48-50, 87-92

Pharmaceutical composition, such as a multiple minibead unit dosage form comprising a hydroxylase inhibitor for treating an inflammatory intestinal disorder

4. claims: 51-86

Pharmaceutical composition comprising an active ingredient selected from calcineurin inhibitors, mTor inhibitors and macrolide immunosuppressants alone or in combination with a hydroxylase inhibitor for use in treating a disorder of, or at least suspected of being associated with, a leaky intestinal epithelial barrier, where in the disorder is not irritable bowel syndrome, inflammatory bowel syndrome, Crohn’s disease, ulcerative colitis, GVHD, or GI-GVHD and process for obtaining it.