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Declaration under Rule 4.17:

— of inventorship (Rule 4.17(iv)) for US only

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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: PHARMACEUTICAL COMPOSITION OF IBUPROFEN

(57) Abstract: The active ingredient, ibuprofen or (s)(+)-ibuprofen as free base or as alkali metal salts or mixtures thereof, is covered by this invention in the form of soft gelatin capsule, said soft gelatin capsules have improved soft gelatin capsule gel mass composition which facilitates solubilization of active ingredient. The present invention also proposes the method of producing such a soft gelatin capsule or soft gelatin gel mass composition. One of the further aspects of the present invention is to avoid the use of polyethylene glycol or hydroxide ion species containing solvents as solubilizers for the preparation of soft gelatin capsules containing said active ingredient.



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INTERNATIONAL SEARCH REPORT

International Application No

PCT/IB 02/00534

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61K9/48 A61K31/19

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61K

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 practical, search terms used)

EPO-Internal, WPI Data, PAJ, BIOSIS, MEDLINE, CHEM ABS Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 376 688 A (MORTON FRANK S S ET AL) 27 December 1994 (1994-12-27) cited in the application	1-4, 23
Y	column 5; example 1	5-8, 16-21
X	GB 2 331 458 A (MOONGA GURSHARAN SINGH) 26 May 1999 (1999-05-26)	1-4, 23
Y	claims 1,9	5-8, 16-21
X	US 5 858 401 A (BHALANI VINAYAK T ET AL) 12 January 1999 (1999-01-12)	1, 3, 4, 23
Y	column 4; example 2	5-8, 16-21
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Further documents are listed in the continuation of box C.



Patent family members are listed in annex.

* 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 document but published on or after the international filing date

L document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

O document referring to an oral disclosure, use, exhibition or other means

P document published prior to the international filing date but later than the priority date claimed

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 person skilled in the art.

Z document member of the same patent family

Date of the actual completion of the international search

18 October 2002

Date of mailing of the international search report

29/10/2002

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INTERNATIONAL SEARCH REPORT

International Application No

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 98 38984 A (SUGEN INC ; SHENOY NARMADA (US); WAGNER GREGORY S (US)) 11 September 1998 (1998-09-11)	1, 3, 4, 23
Y	page 91 -page 92; example 4	5-8, 16-21
X	US 5 645 856 A (LACY JONATHAN ERNEST ET AL) 8 July 1997 (1997-07-08)	1, 3, 4, 23
Y	column 21; example 6	16-21
Y	US 4 834 966 A (GIANESELLO VALTER ET AL) 30 May 1989 (1989-05-30) column 1, line 34 - line 61	5-8, 16-21

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IB 02/00534

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

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:

Although claim 23 is directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the composition.
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).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

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

1. ☐ 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 fee, this Authority did not invite payment of any additional fee.
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.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/IB 02/00534

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5376688	A	27-12-1994	AU 692431 B2 11-06-1998
			AU 5851894 A 19-07-1994
			CA 2152062 A1 07-07-1994
			DE 69330353 D1 19-07-2001
			DE 69330353 T2 02-05-2002
			EP 0678019 A1 25-10-1995
			ES 2157975 T3 01-09-2001
			JP 8507494 T 13-08-1996
			WO 9414423 A1 07-07-1994
GB 2331458	A	26-05-1999	NONE
US 5858401	A	12-01-1999	NONE
WO 9838984	A	11-09-1998	AU 743024 B2 17-01-2002
			AU 6680698 A 22-09-1998
			EP 1014953 A2 05-07-2000
			JP 2001514626 T 11-09-2001
			NZ 337394 A 25-05-2001
			US 6248771 B1 19-06-2001
			WO 9838984 A2 11-09-1998
			US 2001012844 A1 09-08-2001
US 5645856	A	08-07-1997	AU 686767 B2 12-02-1998
			AU 1897495 A 03-10-1995
			CA 2185347 A1 21-09-1995
			EP 1205180 A2 15-05-2002
			EP 0750495 A1 02-01-1997
			WO 9524893 A1 21-09-1995
			JP 10503750 T 07-04-1998
			US 6096338 A 01-08-2000
US 4834966	A	30-05-1989	IT 1197038 B 25-11-1988
			AT 394945 B 27-07-1992
			AT 187887 A 15-01-1992
			AU 595342 B2 29-03-1990
			AU 7554087 A 04-02-1988
			BE 1002109 A3 10-07-1990
			BG 60832 B2 30-04-1996
			CA 1286992 A1 30-07-1991
			CH 673394 A5 15-03-1990
			DE 3725176 A1 04-02-1988
			FR 2602141 A1 05-02-1988
			GB 2193093 A , B 03-02-1988
			GR 871197 A1 04-12-1987
			IE 60276 B 29-06-1994
			JP 2585005 B2 26-02-1997
			JP 63041420 A 22-02-1988
			MX 9203167 A1 01-07-1992
			NL 8701729 A , B, 01-03-1988
			ZA 8705397 A 01-02-1988