

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
3 April 2003 (03.04.2003)

PCT

(10) International Publication Number
WO 03/026628 A3

(51) International Patent Classification⁷: **A61K 9/28**

(21) International Application Number: PCT/US02/31063

(22) International Filing Date:
28 September 2002 (28.09.2002)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
09/966,939 28 September 2001 (28.09.2001) US
09/966,509 28 September 2001 (28.09.2001) US
09/966,497 28 September 2001 (28.09.2001) US
09/967,414 28 September 2001 (28.09.2001) US
09/966,450 28 September 2001 (28.09.2001) US

(71) Applicant (*for all designated States except US*): **MC-NEIL-PPC, INC.** [US/US]; Grandview Road, Skillman, NJ 08558 (US).

(72) Inventors; and

(75) Inventors/Applicants (*for US only*): **LEE, Der-Yang**

[US/US]; 10 Kentworth Court, Flemington, NJ 08822 (US). **SOWDEN, Harry, S.** [US/US]; 209 Woods Road, Glenside, PA 19038 (US). **THOMAS, Martin** [US/GB]; 7401 Trescott Drive, Lake Worth, FL 33467 (US).

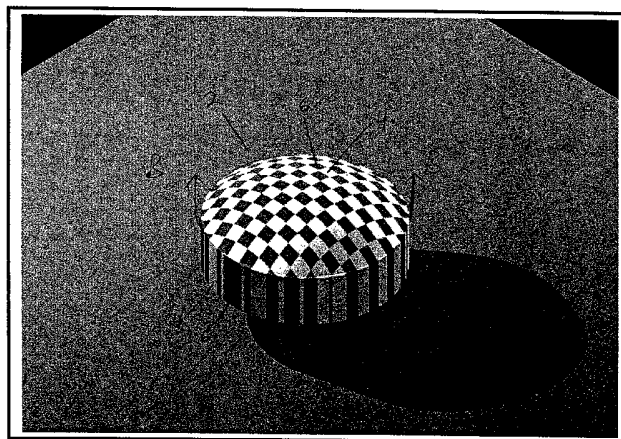
(74) Agents: **JOHNSON, Philip, S.** et al.; Johnson & Johnson, One Johnson & Johnson Plaza, New Brunswick, NJ 08903 (US).

(81) Designated States (*national*): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, OM, PH, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States (*regional*): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

[Continued on next page]

(54) Title: COMPOSITE DOSAGE FORMS HAVING AN INLAID PORTION



(57) Abstract: A dosage form comprises at least one active ingredient, a first portion which comprises an exterior surface and one or more cavities defining at least one interior surface having indentations and an exterior surface, and a second molded portion which is inlaid into the cavities of the first portion and has an exterior surface. The first and second portions are in contact at an interface, the second portion comprises a solidified thermoplastic material, and the second portion resides substantially conformally upon the indentations of the first portion. In another embodiment, a dosage form comprises at least one active ingredient, a core having an outer surface and a shell residing on at least a portion of the core outer surface, wherein the shell comprises a first shell portion and a second molded shell portion which is inlaid into the first shell portion. In another embodiment, a dosage form comprises at least one active ingredient, a core, and a shell having a first molded shell portion which is discontinuous, and a second molded shell portion which is continuous, such that the discontinuities of the first shell portion are due to the presence of the second molded shell portion, and the first and second shell portions are compositionally different.



WO 03/026628 A3



Published:

- with international search report
- before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments

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.

(88) Date of publication of the international search report:

1 May 2003

INTERNATIONAL SEARCH REPORT

Internal application No
PCT/US 02/31063

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61K9/28

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 3 146 169 A (JOHN SPENCE ET AL) 25 August 1964 (1964-08-25) figures	1, 18, 38
X	US 6 149 939 A (HARTMAN JUDY S ET AL) 21 November 2000 (2000-11-21) figures 1-4	1, 18, 38
X	GB 2 197 778 A (FASSIN KATJES GMBH & CO KG) 2 June 1988 (1988-06-02) figures 3-5	1, 18, 38
X	GB 888 038 A (WILLIAM WARREN TRIGGS C B E) 24 January 1962 (1962-01-24) figures	1
	--- -/--	

☒ 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.
- *G* document member of the same patent family

Date of the actual completion of the international search

3 March 2003

Date of mailing of the international search report

13/03/2003

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Friederich, M

INTERNATIONAL SEARCH REPORT

Internat Application No
PCT/US 02/31063

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 99 56730 A (ALZA CORP ; JAO FRANCISCO (US); EDGREN DAVID E (US); PUGA YOLANDA M) 11 November 1999 (1999-11-11) figures 1,2 ---	1
X	US 5 405 642 A (GILIS PAUL M V ET AL) 11 April 1995 (1995-04-11) cited in the application examples ---	1
X	EP 0 088 556 A (SUMITOMO CHEMICAL CO) 14 September 1983 (1983-09-14) cited in the application page 5, line 30 -page 6, line 21; claims 1,12-14 -----	1

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 02/31063

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:
2. ☒ Claims Nos.: 2-17, 19-37, 39-42 (not searched); 1, 18, 38 (partially)
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:
see FURTHER INFORMATION sheet PCT/ISA/210
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.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box I.2

Claims Nos.: 2-17, 19-37, 39-42 (not searched); 1, 18, 38 (partially)

Claims 2-17, 19-37 and 39-42 have been not searched and claims 1, 18 and 38 have been searched partially for the following reasons:

Present independent claims 1, 18 and 38 relate to an extremely large number of possible products ("dosage form", "active ingredient"). Support within the meaning of Article 6 PCT and/or disclosure within the meaning of Article 5 PCT is to be found, however, for only a very small proportion of the products claimed ("pharmaceutically active ingredient").

In view of the large number and also the wording of the dependent claims presently on file, which render it difficult, if not impossible, to determine the matter for which protection is sought, the present application fails to comply with the clarity and conciseness requirements of Article 6 PCT (see also Rule 6.1(a) PCT) to such an extent that a meaningful search is impossible.

Consequently, the search has been carried out for those parts of the independent claims 1, 18 and 38 which appear to be clear, supported and disclosed, namely those parts relating to the products prepared in the examples.

The applicant's attention is drawn to the fact that claims, or parts of claims, relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 02/31063

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
US 3146169	A	25-08-1964	GB 972128 A DE 1127542 B FR 1311119 A	07-10-1964 12-04-1962 07-12-1962
US 6149939	A	21-11-2000	US 6135286 A	24-10-2000
GB 2197778	A	02-06-1988	DE 3640574 A1 CH 673077 A5 DK 620387 A FR 2607365 A1 NL 8702628 A	09-06-1988 15-02-1990 28-05-1988 03-06-1988 16-06-1988
GB 888038	A	24-01-1962	US 3048526 A	07-08-1962
WO 9956730	A	11-11-1999	US 6365183 B1 AU 751429 B2 AU 3780399 A CA 2328998 A1 EP 1077680 A1 JP 2002513751 T US 2002155155 A1 WO 9956730 A1	02-04-2002 15-08-2002 23-11-1999 11-11-1999 28-02-2001 14-05-2002 24-10-2002 11-11-1999
US 5405642	A	11-04-1995	AT 143259 T AU 1260392 A DE 69214130 D1 DE 69214130 T2 DK 573462 T3 WO 9215288 A1 EP 0501553 A1 EP 0573462 A1 ES 2094902 T3 GR 3021929 T3 IE 920611 A1 JP 3237758 B2 JP 6504935 T MX 9200831 A1 NZ 241613 A ZA 9201428 A	15-10-1996 06-10-1992 31-10-1996 06-02-1997 11-11-1996 17-09-1992 02-09-1992 15-12-1993 01-02-1997 31-03-1997 09-09-1992 10-12-2001 09-06-1994 01-08-1992 25-06-1993 26-08-1993
EP 0088556	A	14-09-1983	JP 58152813 A CA 1222696 A1 DE 3380591 D1 DK 111783 A ,B, EP 0088556 A2 ES 8404181 A1 KR 8904122 B1 US 5002775 A	10-09-1983 09-06-1987 26-10-1989 09-09-1983 14-09-1983 16-07-1984 21-10-1989 26-03-1991