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(71) Applicant: **STEER ENGINEERING PRIVATE LIMITED** [IN/IN]; 290, 4th main, 4th Phase, Peenya Industrial Area, Bangalore 560058 (IN).

(72) Inventors: **PADMANABHAN, Bahu**; A 205, Mantri Greens, Malleswaram, Bangalore 56000 (IN). **PRODDUTURI, Suneela**; 265, avenue 17, SA Palm meadows, Kompally 500100, Hyderabad (IN). **SEN, Himadri**; Elite Embassy, Ramnagar Colony, Bavdhan, NDA Pashan Road, Pune 411021 (IN).

(74) Agent: **AGARWAL, Sneha**; Obhan & Associates, 501/7, Lane W-21A, Western Avenue, Sainik Farms, New Delhi 110062 (IN).

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(54) Title: A HOT MELT FRAGMENTATION EXTRUDER AND PROCESS

(57) Abstract: A co-rotating twin screw extruder for forming fragments is disclosed. The extruder comprises of an intake zone for receiving one or more excipient(s) suitable for oral dosage or one or more excipient(s) suitable for oral dosage along with one or more active pharmaceutical ingredient, a melt zone for softening at least one excipient to form a viscous mass or melt and a fragmenting zone for fragmenting and cooling the viscous mass into cooled fragments and an extruder outlet for recovering the cooled fragments from the extruder.



WO 2014/192026 A3

INTERNATIONAL SEARCH REPORT

International application No.

PCT/IN 14/00358

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61K 9/30, B29B 9/12, B29C 47/48, B29C 47/90 (2015.01)

CPC - A61K 9/2833, B29B 9/12, B29C 47/48, B29C 47/88, B29C 47/90

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(8)- A61K 9/30, B29B 9/12, B29C 47/48, B29C 47/90 (2015.01);

CPC- A61K 9/2833, B29B 9/12, B29C 47/48, B29C 47/88, B29C 47/90

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

USPC- 264/7, 264/211.11, 264/211.21, 424/451, 424/464;

Patents and NPL (classification, keyword; search terms below)

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

Pub West (US EP JP WO), Pat Base (AU BE BR CA CH CN DE DK EP ES FI FR GB IN JP KR SE TH TW US WO), Google Patent, Google Scholar, Free Patents Online; search terms: extrude, screw, coextrude, barrel, rotate, fragment, granula, tablet, particle, oral, dosage, mill, fracture, crush, break, pulverize, cool, quench, dry ice, nitrogen, stearic, acid

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X — Y	WO 2013/074951 A1 (VERDU et al.) 23 May 2003 (23.05.2003), Fig. 3; para [0033], [0038], [0044]-[0048], [0053]-[0060]	1, 2, 7/(1, 2), 9-12, 15, 17 3-6, 7/(3-6), 13, 14, 16
Y	US 5,048,971 A (WALL et al.) 17 September 1991 (17.09.1991), Figs. 1, 6a; col 1, ln 6-23; col 2, ln 17-31; col 3; ln 26-30; col 5, ln 54 to col 6, ln 2	3, 4, 7/(3, 4), 16
Y	US 2007/0259070 A1 (SONG et al.) 08 November 2007 (08.11.2007), para [0039], [0053]	5, 6, 7/(5, 6), 13, 14
A	US 2011/0063940 A1 (PADMANABHAN) 17 March 2011 (17.03.2011), para [0010]-[0015]	1-7, 9-17
A	US 5,693,342 A (CERVOS et al.) 02 December 1997 (02.12.1997), col 1, ln 25 to col 9, ln 59	1-7, 9-17

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

* 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

"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

"I" 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

"&" document member of the same patent family

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Authorized officer:

Lee W. Young

PCT Helpdesk: 571-272-4300

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INTERNATIONAL SEARCH REPORT

International application No.

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Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 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.:
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.: 8
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 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 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.