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(71) Applicant: GENNOVA BIOPHARMACEUTICALS LIMITED [IN/IN]; P-1, IT-BT Park, Phase-II, M.I.D.C., Hinjwadi, Pune 411057 (IN).

(72) Inventors: **RAGHUWANSHI, Arjun**; Gennova Vaccine Formulation Centre and Research Laboratory, BTS-2 Building, Chrysalis Enclave, Block-2, Plot-2, International Biotech Park, Phase II, MIDC, Hinjwadi, Pune 411057 (IN). **SINGH, Shrawan Kumar**; Gennova Vaccine Formulation Centre and Research Laboratory, BTS-2 Building, Chrysalis Enclave, Block-2, Plot-2, International Biotech Park, Phase II, MIDC, Hinjwadi, Pune 411057 (IN). **THAKER, Nidhiben**; Gennova Vaccine Formulation Centre and Research Laboratory, BTS-2 Building, Chrysalis Enclave, Block-2, Plot-2, International Biotech Park, Phase II, MIDC, Hinjwadi, Pune 411057 (IN). **SHANKAR, Shagun**; Gennova Vaccine Formulation Centre and

Research Laboratory, BTS-2 Building, Chrysalis Enclave, Block-2, Plot-2, International Biotech Park, Phase II, MIDC, Hinjwadi, Pune 411057 (IN). **KARDILE, Pavan**; Gennova Vaccine Formulation Centre and Research Laboratory, BTS-2 Building, Chrysalis Enclave, Block-2, Plot-2, International Biotech Park, Phase II, MIDC, Hinjwadi, Pune 411057 (IN). **SINGH, Sanjay**; Gennova Vaccine Formulation Centre and Research Laboratory, BTS-2 Building, Chrysalis Enclave, Block-2, Plot-2, International Biotech Park, Phase II, MIDC, Hinjwadi, Pune 411057 (IN).

(74) Agent: **ARVIND, Chitra**; Rajeshwari & Associates, Amsoft Business Centre, Unitech Trade Centre, Sector-43, Gurgaon 122002 (IN).

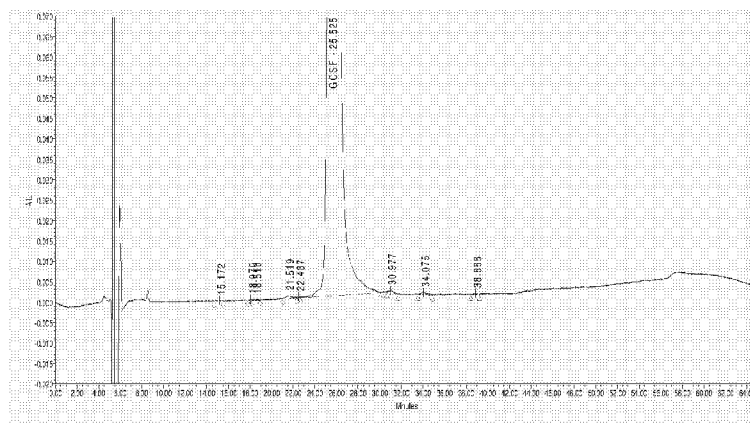
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[Continued on next page]

(54) Title: A NOVEL PROCESS FOR PURIFICATION OF RHU-GCSF

Figure 7



(57) Abstract: The present invention provides a novel, scalable and industrially viable downstream process for purification of recombinant human G-CSF.



TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/IN2015/050066

A. CLASSIFICATION OF SUBJECT MATTER
C07K1/14, C07K14/535, C12P21/00 Version=2016.01

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)

C07K, C12P

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)

PATSEER, IPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP2341061 B1 (AHMET TOKSÖZ) (31 Jul 2013) Para [0018], Para [0053], Claims	1, 11-13
Y	EP2341061 B1 (AHMET TOKSÖZ) (31 Jul 2013) Para [0018], Para [0053], Claims	1, 5-10
Y	VANZ AL et al., "Human granulocyte colony stimulating factor (hG-CSF): cloning, overexpression, purification and characterization." Microbial Cell Factories (2008); 7:13. Methods	1, 5
Y	WO2008096370 A2 (VENKATA KRISHNA RAO DASARI) (14 Aug 2008) Detailed description of invention and Claims	1, 5-8
Y	WO2012057529 A2 (SUNG CHUL CHOI) (3 May 2012) Claims	1, 8
Y	WO2012021088 A1 (TATYANA VENIAMINOVNA CHERNOVSKAYA) (16 Feb 2012) Examples 1-3	1, 9-10



Further documents are listed in the continuation of Box C.



See patent family 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 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

"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

"&" document member of the same patent family

Date of the actual completion of the international search

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Indian Patent Office
Plot No.32, Sector 14, Dwarka, New Delhi-110075
Facsimile No.

Authorized officer

Anushri Kamble

Telephone No. +91-1125300200

INTERNATIONAL SEARCH REPORT

International application No.

PCT/IN2015/050066

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	HERMAN AC et al., "Characterization, Formulation, and Stability of Neupogen® (Filgrastim), a Recombinant Human Granulocyte- Colony Stimulating Factor" Formulation, Characterization, and Stability of Protein Drugs: Case Histories, Volume 9 of the series Pharmaceutical Biotechnology (2002) pp 303-328 Full text	1-13

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IN2015/050066

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.: 2-4
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 extra sheet

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 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.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/IN2015/050066

Continuation of Claims found unsearchable (Box II)

There is no clarity in the scope of the claims as the claims 2-4 are based solely on result to be achieved. The claims fail to recite any steps of the claimed process on the basis of which the scope of the claim can be determined.

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/IN2015/050066

Citation	Pub.Date	Family	Pub.Date
EP 2341061 B1	31-07-2013	DK 2341061 T3	03-11-2013
WO 2008096370 A2	14-08-2008	IN 255/CHE/2007 A	28-11-2008
WO 2012057529 A2	28-06-2012	KR 20120045451 A	09-05-2012
		JP 2013540809 A	07-11-2013
		EP 2632944 A4	08-07-2015
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		CN 103140499 A	05-06-2013