

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

To: SHARMA, ISHAE 17, MASJID MITH, GK-3, NEW DELHI , DELHI-110048 INDIA
--

Date of mailing (day/month/year) 29-06-2018
--

Applicant's or agent's file reference 201741030659	FOR FURTHER ACTION See paragraph 2 below
---	--

International application No. PCT/IN2018/050170	International filing date (day/month/year) 26-03-2018	Priority date (day/month/year) 30-08-2017
--	--	--

International Patent Classification (IPC) or both national classification and IPC A61K36/00, A61K9/10, A61K31/355, A61K47/10 Version=2018.01

Applicant DUTTA, TATHAGATA

<p>1. This opinion contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the opinion</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input checked="" type="checkbox"/> Box No. VIII Certain observations on the international application</p> <p>2. FURTHER ACTION</p> <p>If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.</p> <p>If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.</p> <p>For further options, see Form PCT/ISA/220.</p>
--

Name and mailing address of the ISA/ Indian Patent Office Plot No. 32, Sector 14, Dwarka, New Delhi-110075 Facsimile No.	Date of completion of this opinion 29-06-2018	Authorized officer Ravi S Telephone No. +91-1125300200
--	--	--

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/IN2018/050170

Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of:
 - the international application in the language in which it was filed.
 - a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).
2. This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43*bis*.1(a)).
3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of a sequence listing:
 - a. forming part of the international application as filed:
 - in the form of an Annex C/ST.25 text file.
 - on paper or in the form of an image file.
 - b. furnished together with the international application under PCT Rule 13*ter*.1(a) for the purposes of international search only in the form of an Annex C/ST.25 text file.
 - c. furnished subsequent to the international filing date for the purposes of international search only:
 - in the form of an Annex C/ST.25 text file (Rule 13*ter*.1(a)).
 - on paper or in the form of an image file (Rule 13*ter*.1(b) and Administrative Instructions, Section 713).
4. In addition, in the case that more than one version or copy of a sequence listing has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that forming part of the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
5. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/IN2018/050170

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	_____	YES
	Claims	1-12	NO
Inventive step (IS)	Claims	_____	YES
	Claims	1-12	NO
Industrial applicability (IA)	Claims	1-12	YES
	Claims	_____	NO

2. Citations and explanations:

The present invention relates to a stable oil-in-water ophthalmic emulsion for ocular delivery of antioxidants comprising one or more antioxidants as active ingredients, at least one oil of vegetable, mineral or animal or a combination thereof, at least one surfactant and at least one pharmaceutically acceptable excipient, wherein the pH is in the range of about 4 to 8.

1. Reference is made to the following documents:

D1: US20130108674 A1 (MEDIVIS S.R.L., 02 MAY, 2013)

D2: US5496811 A (PHARMOS CORP, 5 MARCH, 1996)

D3: US20130253070 A1 (GUPRON GMBH, 26 SEPTEMBER, 2013)

D4: US20140170247 A1 (GUARDION HEALTH SCIENCES LLC, 19 JUNE, 2014)

2. Novelty under Article 33(2) PCT:

The present application fails to comply with the requirements of PCT Article 33(2) with respect to novelty because the subject matter of claims 1-12 is not novel.

D1 discloses an oil-in-water ophthalmic emulsion formulation for ocular delivery, comprising one or more liposoluble active ingredients, an emulsifying agent wherein the oily component contains medium chain triglycerides and the liposoluble active ingredient is selected from the group consisting of steroidal anti-inflammatory drugs, non-steroidal anti-inflammatory drugs, prostaglandin derivatives, calcineurin inhibitors or immunosuppressants, antioxidants, active ingredients of a biotechnological origin (see abstract, example 5, claims 1, 5-10). D1 also discloses that the antioxidant is selected from beta-carotene, lutein, zeaxanthin, lycopene, the compounds derived from vitamin E and their derivatives. Further discloses the concentration of antioxidant in the formulation is about 0.005-2%

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/IN2018/050170

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

1. The wording "at least one" in claims 1, 9-12 has not been considered for examination because it encompasses a non-limited number of chemical compounds so that the scope of this claim is not clear (Article 6 PCT).
2. The use of the word "about", especially in connection with numerical ranges, is generally regarded as rendering the determination of the exact scope of the range difficult. Therefore, claims 4 and 5, as well as the description, should not have been drafted using this word.

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/IN2018/050170

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of:

Continuation of Citation and Explanation(Box5)

(which is within the claimed range of instant application) and the pH of the formulation is in the range of about 5.5 to 7.2.

The topical formulation of D1 further comprises surfactants, buffering agents, osmotizing agents and one or more antimicrobial agents.

Therefore the subject-matter of claims 1-12 is not novel in view of D1.

D2 discloses an oil-in-water formulation for ocular drug delivery comprising antioxidant (alpha-tocopherol), surfactant, preservatives, osmotic agents and pH adjustment agents wherein the pH of the formulation is 6.47 and the concentration of antioxidant is 1.0% (within the claimed range of instant application) (see example 1, claims 1,3-5, 7-10, 19). Therefore the subject-matter of claims 1-12 is not novel in view of D2.

3. Inventive step under Article 33(3) PCT:

As described in paragraph 2 concerning novelty, the subject matter of claims 1-12 is not novel, and therefore also not inventive (PCT Article 33(1) and (3)).

4. Industrial Applicability under Article 33(4) PCT:

The subject matter of claims 1-12 is considered to be industrially applicable under PCT Article 33(4).