

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

To: CUMBERBATCH Guy L. SoCal IP Law Group LLP 310 N. Westlake Blvd., Suite 120 Westlake Village, California 91362 United States of America		Date of mailing <i>(day/month/year)</i>		17 Aug 2020
Applicant's or agent's file reference P200-P20778		FOR FURTHER ACTION See paragraph 2 below		
International application No. PCT/US2020/030847	International filing date <i>(day/month/year)</i> 30 Apr 2020	Priority date <i>(day/month/year)</i> 30 Apr 2019		
International Patent Classification (IPC) or both national classification and IPC IPC (20200101) C12M 1/00 C12N 5/00 C12M 1/12 C12M 3/00 CPC (20130101) C12M 23/02 C12N 2535/10 C12N 5/0068 C12M 25/06 C12M 21/08				
Applicant PBS BIOTECH, INC.				

1. This opinion contains indications relating to the following items:

- Box No. I Basis of the opinion
- Box No. II Priority
- Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- Box No. IV Lack of unity of invention
- Box No. V Reasoned statement under Rule 43bis.1(a)(1) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement
- Box No. VI Certain documents cited
- Box No. VII Certain defects in the international application
- Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

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.

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.

For further options, see Form PCT/ISA/220.

Name and mailing address of the ISA: Israel Patent Office Technology Park, Bldg.5, Malcha, Jerusalem, 9695101, Israel Email address: pctoffice@justice.gov.il	Date of completion of this opinion 17 Aug 2020	Authorized officer ORENSHTEIN-VILENSKY Liya Telephone No. 972-73-3927241
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WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US2020/030847

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(b))
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:

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 4-7,11-22	YES
	Claims 1-3,8-10	NO
Inventive step (IS)	Claims	YES
	Claims 1-22	NO
Industrial applicability (IA)	Claims 1-22	YES
	Claims	NO

2. Citations and explanations:

2.1 Reference is made to the following document:

D1: WO2012080475A1 GE HEALTHCARE UK LIMITED; GENERAL ELECTRIC COMPANY; MILLER, SCOTT, MICHAEL; RUBINSZTAJN, SLAWOMIR; SMITH, REGINALD DONOVAN; SUSARLA, PRAMEELA; YOON, YOSANG 2012-06-21

D2: WO2014037862A1 PLURISTEM LTD. 2014-03-13

2.2 Novelty

The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claims 1-3, 8-10 does not fulfill the requirements of Article 33(2) PCT.

D1 is considered to represent the most relevant state of the art concerning the subject-matter of claims 1-22.

Regarding claim 1, D1 discloses a macrocarrier (§29 regarding a carrier having a length of 5mm) for a cell culture growth process, comprising: a molded plate-like body (§38 regarding planar disc-like carrier) having opposed faces separated by a peripheral edge, the body having a thickness T that is between about 0.4 to 10% of the minimum dimension from one side of the peripheral edge to the other (§29 regarding 0.2 mm length and 0.012mm height), the body defining a vertical axis perpendicular to the thickness and further including a vertical bump (§33 regarding a domed protrusion), projecting from each face to prevent two macrocarriers from contacting one another across entire adjacent faces (§52 regarding relief features).

Regarding claims 2 and 3, D1 further discloses that the body may be in a shape of a disc or square (§38) having a minimum dimension from one side of the peripheral edge to the other of greater than 0.2 mm and a thickness of greater than 0.02 mm (§29), the bumps may be hemispherical (§35).

Regarding claims 8- 10, D1 further discloses that the surface treatment may comprise gas plasma treatment, corona discharge treatment or collagen coating (§45).

2.3. Inventive step

The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claims 1-22 does not fulfill the requirements of Article 33(3) PCT.

The subject matter of claims 1-3, 8-10 is not new and therefore does not involve an inventive step.

Regarding claims 4-6, 11-12, 15 and 20, D1 does not describe the specific configurations of the wings protruding from opposite sides of the of the disc or a wave-like curves surrounding the peripheral edge of the disc. However by teaching that the carrier may have a curved wall which may separately surround the top and the bottom of the base (§40), skilled in the art person would consider using alternative designs as defined in claims 4-6. D1 further teaches that the

body may have a substantially rounded square shape in top plan view (§38). Therefore, the subject matter of claims 4-6, 11-12, 15 and 20 does not involve inventive step over D1.

Regarding claims 7, 13, 14, 19, D1 does not describe that the body may have a constantly curved (hyperbolic paraboloid or saddle) shape without any planar areas. D1 teaches that the carrier may have several surfaces and walls surrounding those surfaces, forming a cylindrical carrier or a cup shaped carrier (§40). In addition, D1 teaches that the carriers provide high surface area (§44). It is known that curved surfaces can increase the surface area, as compared to flat surfaces, thereby providing additional area for cell attachment, as taught for example in D2 (§55) which also refers to cell culture carriers. Skilled in the art person, starting from D1 is likely to be motivated to design the carrier body constantly curved, without any planar areas. Therefore, the subject matter of claims 7, 13, 14, 19 does not involve inventive step over D1 in light of D2.

The objections raised with respect to claims 1-3, 9, 10 apply, *mutatis mutandis*, to the subject-matter of the corresponding claims 16-18, 21, 22 (dependent on claim 11) which therefore are considered not inventive over D1.

2.4 Industrial Applicability

The invention defined in the claims 1-22 is considered to meet the requirements of industrial applicability under Article 33(4) of the PCT.