

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

To:

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Philadelphia, Pennsylvania 19103 USA**

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Applicant's or agent's file reference L1240-20101		Date of mailing (day/month/year) 31 March 2023
FOR FURTHER ACTION See paragraph 2 below		
International application No. PCT/US2022/049490	International filing date (day/month/year) 10 November 2022	Priority date (day/month/year) 10 November 2021
International Patent Classification (IPC) or both national classification and IPC A61F 2/10(2006.01)i; A61F 2/00(2006.01)i		
Applicant LORIA PRODUCTS LLC		

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)(i) 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/KR Korean Intellectual Property Office 189 Cheongsa-ro, Seo-gu, Daejeon, 35208	Date of completion of this opinion 30 March 2023	Authorized officer HEO, Joo Hyung
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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/US2022/049490

Box No. I

Basis of the 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 43bis.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.
 - b. ☐ furnished subsequent to the international filing date for the purposes of international search (Rule 13ter.1(a)),
☐ accompanied by a statement to the effect that the sequence listing does not go beyond the disclosure in the international application as filed.
4. ☐ With regard to any nucleotide and/or amino acid sequence disclosed in the international application, this opinion has been established to the extent that a meaningful opinion could be formed without a WIPO Standard ST.26 compliant sequence listing.
5. Additional comments:

**WRITTEN OPINION OF THE
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Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application.

☒ claims Nos. 18

because:

☒ the said international application, or the said claims Nos. 18 relate to the following subject matter which does not require an international search (*specify*):

The subject-matter of claim 18 does not require an opinion, as it is directed to a method for treatment of the human body by surgery (PCT Rules 43 bis.1(b) and 67.1(iv)).

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. _____ are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed (*specify*):

☒ no international search report has been established for said claims Nos. 18

☐ a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:
☐ furnish a sequence listing complying with WIPO Standard ST.26, and such listing was not available to the International Searching Authority in the form, language and manner acceptable to it.

☐ pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rule 13*ter*.1(a).

☐ See Supplemental Box for further details.

**WRITTEN OPINION OF THE
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International application No.

PCT/US2022/049490

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	1-17,19-23	YES
	Claims	NONE	NO
Inventive step (IS)	Claims	12-17	YES
	Claims	1-11,19-23	NO
Industrial applicability (IA)	Claims	1-17,19-23	YES
	Claims	NONE	NO

2. Citations and explanations:

Reference is made to the following documents:

D1: US 10561490 B2 (LORIA PRODUCTS LLC) 18 February 2020
D2: CN 102665579 B (HAIRSTETICS LTD) 08 July 2015
D3: US 2003-0195625 A1 (GARCIA, C. M. A. et al.) 16 October 2003
D4: US 2007-0067033 A1 (BONATI, A. O.) 22 March 2007
D5: US 2004-0149301 A1 (ARROYO, M. S. et al.) 05 August 2004

I. Novelty and Inventive Step (PCT Article 33(2) and (3))

1. Claims 1-11

D1, which is considered to be the closest prior art to the subject matter of claim 1, discloses a hair implant suitable for subcutaneous implantation, comprising: (a) an anchor comprising: (i) an anchor body having a cylindrical portion and a tapered portion, one end of said cylindrical portion forming a proximal end of said anchor body and one end of said tapered portion forming a distal end of said anchor body; and (ii) at least one collagen receiving structure consisting of at least one tunnel disposed through the anchor body (see claim 1), wherein the at least one collagen receiving structure selected from the group consisting of a tunnel disposed through the anchor body and an external surface feature of the anchor body; and (b) at least one hair strand projecting from a distal end of the anchor body, wherein the at least one collagen receiving structure is configured to support collagen ligature growth after subcutaneous implantation of the hair implant so as to anchor the anchor to a hair implant recipient (see column 9, lines 1-9); and (b) at least one hair strand projecting from said distal end of the anchor body (see claim 1). The subject-matter of claim 1 differs from the D1 in the said at least one hair strand comprising a primary hair element and an emerging hair element that emanates off of said primary hair element. However, the different feature would be easily derived by a person skilled in the art from the disclosure of D1 ("Emerging" hair elements originate off of the primary hair elements at a predetermined distance above the distal end and these emerging hair elements terminate at the same distance as the primary hair elements (see column 33, lines 40-53; figure 38)).

Therefore, claim 1 lacks an inventive step as being obvious over D1.

The additional features of claim 2-3 would be merely design options or optional matters easily added by a person skilled in the art from the disclosure of D1 (variations of the external surface within the scope of the invention include but are not limited to a vertical component distal upward then downward slope or only a downward slope (undulation), a vertical component mid-section concavity, a vertical component widening from distal to proximal, a vertical component proximal bulbous shape 54, and rounded edges on all aspects of the anchor. (see column 27, lines 5-16)).

The additional feature of claim 4 would be easily derived by a person skilled in the art from the disclosure of D1 (the fracture line runs vertically between the closed tunnels, from the proximal end to the distal end of the anchor body (see column 13, lines 5-17)).

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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

The additional feature of claim 5 would be easily derived by a person skilled in the art from the disclosure of D1 (the placement of hair strands in the mold cavities can be varied to provide implants with hair exit angles ranging from 1-90° (see column 41, lines 20-31)).

The additional features of claims 6-11 are merely matters of design option when the general knowledge in the relevant field of the art is used.

Therefore, claims 2-11 lack an inventive step as being obvious over D1.

2. Claims 12-17

None of the cited documents discloses the features of claim 12: “at least one hair stem, said at least one hair stem projecting away from a distal end of said anchor body”. And it is not obvious to a person skilled in the art from the cited documents, when taken individually or in any combination.

Claims 13-17 are dependent on claim 12.

Therefore, claims 12-17 are novel and involve an inventive step.

3. Claims 19-22

D1, which is considered to be the closest prior art to the subject matter of claim 19, discloses a hair implant suitable for subcutaneous implantation, comprising: (a) an anchor comprising: (i) an anchor body having a cylindrical portion and a tapered portion, one end of said cylindrical portion forming a proximal end of said anchor body and one end of said tapered portion forming a distal end of said anchor body; and (ii) at least one collagen receiving structure consisting of at least one tunnel disposed through the anchor body; and (b) at least one hair strand projecting from said distal end of the anchor body (see claim 1). The subject-matter of claim 19 differs from the D1 in the said at least one hair strand comprising a primary hair element and an emerging hair element that emanates off of said primary hair element. However, the different feature would be easily derived by a person skilled in the art from the disclosure of D1 (“Emerging” hair elements originate off of the primary hair elements at a predetermined distance above the distal end and these emerging hair elements terminate at the same distance as the primary hair elements (see column 33, lines 40-53; figure 38)).

Therefore, claim 19 lacks an inventive step as being obvious over D1.

The additional features of claim 20-21 would be merely design options or optional matters easily added by a person skilled in the art from the disclosure of D1 (the anchor has at least one open tunnel, at least one closed tunnel and at least one bridge between two vertical components (see column 5, lines 1-6)).

The additional feature of claim 22 would be easily derived by a person skilled in the art from the disclosure of D1 (the fracture line runs vertically between the closed tunnels, from the proximal end to the distal end of the anchor body (see column 13, lines 5-17)).

The additional feature of claim 23 would be easily derived by a person skilled in the art from the disclosure of D1 (the placement of hair strands in the mold cavities can be varied to provide implants with hair exit angles ranging from 1-90° (see column 41, lines 20-31)).

Therefore, claims 20-23 lack an inventive step as being obvious over D1.

II. Industrial Applicability (PCT Article 33(4))

Claims 1-17, 19-23 are industrially applicable.