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(54) Title: METHODS OF MAKING AND USING BIOCOMPOSITE COMPOSITIONS

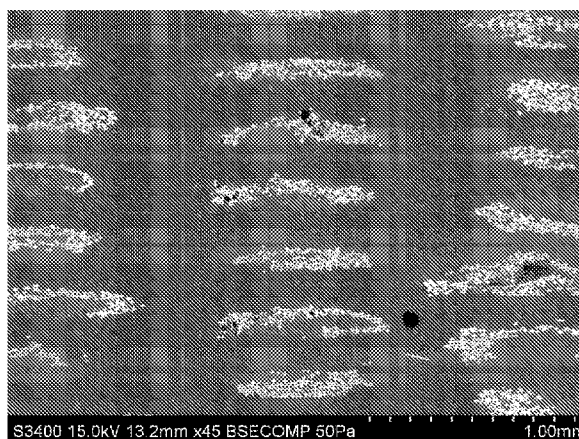


FIG. 1

(57) Abstract: Disclosed herein are methods of making and using biocomposite compositions comprising at least a polymeric component and a fiber component.



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:

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Group I: Claims 1-44, directed to a biocompatible biodegradable biocomposite.

Group II: Claims 45-46, directed to a method of additive manufacture of a biocomposite article.

The groups of inventions listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Special Technical Features:

Group II requires a method of additive manufacture of a biocomposite article, comprising, a) providing a fiber comprising a biocomposite to a fiber deposition additive manufacturing device, and b) depositing the fiber comprising the biocomposite on a surface to form a biocomposite article; not required by group I.

Common Technical Features:

Groups I and II share the technical feature of a biocompatible biodegradable biocomposite, comprising, a. a continuous thermoplastic matrix, the matrix comprising an absorbable segmented block copolymer comprising at least a majority repeat unit derived from cyclic monomers selected from glycolide, lactide, caprolactone or dioxanone, b. a plurality of microfibrinous degradable mineral-containing fibers, wherein the mineral-containing fibers exhibit tensile elongation of less than 5%. However, these shared technical features do not represent a contribution over prior art, because the shared technical feature is obvious over US 2022/0296866 A1 to POLY-MED, INC. (hereinafter "POLY-MED"). POLY-MED teaches a biocompatible biodegradable biocomposite (abstract, "Disclosed herein are methods, devices and compositions for degradable medical devices and/or compositions"), comprising, a. a continuous thermoplastic matrix (para [0030], "In an aspect, a medical device and/or composition is formed, at least in part, from one or more of a thermoplastic or thermoset or elastomeric polymer"), the matrix comprising an absorbable segmented block copolymer comprising at least a majority repeat unit derived from cyclic monomers selected from glycolide, lactide, caprolactone or dioxanone (para [0086], "In an aspect, the polymer comprises an absorbable, low crystallinity, segmented block copolymer, wherein the copolymer is a polyaxial copolyester made from trimethylene carbonate and at least one cyclic monomer selected from the group consisting of p-dioxanone, 1,5-dioxapan-2-one, glycolide, l-lactide, .epsilon.-caprolactone"; para [0059], "A nonwoven polymeric matrix comprising an active agent may be coated with a polymeric composition that aids in control of at least one active agent. Such a coating may be continuous or may be interrupted, e.g., a coating applied in stripes on the matrix"), b. a plurality of microfibrinous degradable mineral-containing fibers (para [0059], "polymeric compositions comprising at least one active agent into fibers that are assembled to form a nonwoven polymeric matrix"; para [0073], "The linear block copolymers may also be comprised of semicrystalline blocks in all cases, with no amorphous blocks, resulting in polymers that can be oriented after fiber formation to create alternating patterns of different crystalline structure and percentage in the fiber, such that there is slight differences in degradation profile of the alternating blocks forming the fiber"; para [0067], "The plurality of microparticles may all comprise one active agent, or may comprise more than one active agent by having each microparticle comprise more than one active agent, or having multiple types of microparticles, each of which comprises a different active agent. High modulus microparticles may comprise channels for penetration of one or more active agents, and may comprise glass, ceramics, and/or absorbable glass"), wherein the mineral-containing fibers exhibit tensile elongation of less than 5% (para [0278], "melt extrusion and oriented to create a fiber... The longitudinal slit reduced the initial tensile strength by a small amount, e.g., about 5%. The tensile strength was measured by upwrapping the monofilament from the cord and then placing a segment of monofilament into a tensile strength tester"; para [0286], "After this time, degradation primarily within the glycolide containing monofilament coil reduced the tensile strength, approximately to less than about 20% of the initial strength"; para [0198], "an intravesical degradable medical device and/or composition comprises an elongate"); but does not explicitly teach said biocomposite in a single embodiment. However, it would have been obvious to one of ordinary skill in the art to provide said combination of components by routine experimentation to meet the end-use needs of the material (abstract, "Disclosed herein are methods, devices and compositions for degradable medical devices and/or compositions that provide local and/or systemic delivery of at least one active agent").

INTERNATIONAL SEARCH REPORT

International application No.

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

Accordingly, the inventions listed as Groups above lack unity of invention under PCT Rule 13 because they do not share a same or corresponding special technical feature providing contribution over prior art.

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.: **1-44**

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/US2024/041737

A. CLASSIFICATION OF SUBJECT MATTERIPC: **C08J 5/04** (2024.01); **A61L 27/48** (2024.01); **C08J 5/24** (2024.01); **A61L 27/26** (2024.01); **C04B 35/80** (2024.01)CPC: **C08J 5/04**; **A61L 27/48**; **C08J 5/24**; **A61L 27/26**; **C04B 35/80**

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)

See Search History Document

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

See Search History Document

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

See Search History Document

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2022/0296866 A1 (POLY-MED, INC.) 22 September 2022 (22.09.2022) abstract, [0030], [0059], [0067], [0072], [0073], [0086], [0198], [0278], [0286]	1-32, 35-44
A	US 2022/0296866 A1 (POLY-MED, INC.) 22 September 2022 (22.09.2022) abstract, [0030], [0059], [0067], [0072], [0073], [0086], [0198], [0278], [0286],	33-34
A	US 6,231,970 B1 (Andersen et al.) 15 May 2001 (15.05.2001) entire document	1-44
A	US 2005/0043585 A1 (Datta et al.) 24 February 2005 (24.02.2005) entire document	1-44
A	US 5,763,075 A (Benjamin et al.) 09 June 1998 (09.06.1998) entire document	1-44
A	US 2019/0168420 A1 (Arris Composites Inc.) 06 June 2019 (06.06.2019) entire document	1-44

☐ 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

“D” document cited by the applicant in the international application

“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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Name and mailing address of the ISA/US

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