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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/463,337	08/09/2006	Shintaro KOBAYASHI	P30059	6778
7055 7590 06/16/2009 GREENBLUM & BERNSTEIN, P.L.C. 1950 ROLAND CLARKE PLACE RESTON, VA 20191			EXAMINER RUMP, RICHARD M	
			ART UNIT 1793	PAPER NUMBER
			NOTIFICATION DATE 06/16/2009	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 11/463,337	Applicant(s) KOBAYASHI ET AL.	
	Examiner Richard M. Rump	Art Unit 1793	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 April 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 13-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 and 18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Application

This action is to replace that mailed on 3 June 2009 in response to the amendment on 10 April 2009, to properly address claim 18. No new grounds of rejection for the previous pending claims has been introduced.

Claims 1-18 are pending and presented for examination. Claims 13-17 stand withdrawn and claim 18 has been newly added.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 18 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 18 recites the limitation "substrate" in line 1. There is insufficient antecedent basis for this limitation in the claim as claim 1 never mentions a substrate. For the purposes of completeness and for examination, the examiner has construed substrate to mean substance as that instantly claimed for the phosphate source.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Bouyer et al, Suspension Plasma Spraying for Hydroxyapatite Powder Preparation by RF Plasma (hereinafter referred to as Article 1; Provided by Applicant).

Regarding claims 1 and 10-12, Article 1 discloses a method of producing hydroxyapatite particles, having a particle diameter between 15 and 21 microns, via mixing phosphorus and calcium (See chemical formula 1 on page 1067) fed into a heated area and being atomized (1067 part B). The suspension is gas atomized via the RF Plasma via a 50-kW Tekna Plasma System (Though 35-45kW is also mentioned see Table 1 and Abstract). The product is then crystallized (page 1069, paragraph 3).

Regarding claims 2 and 3, the chemical formula on page 1067 is listed below:



In this formula it is inherent that the second listed reactant is a phosphorous oxide and that the first listed reactant is a calcium salt.

Regarding claims 4 & 5, given some decomposition of the HA (page 1071, chemical formula 4 (and the text immediately surrounding it)), there is a small amount of lime produced. While the amount of lime from the decomposition of HA is not expressly stated, it would be inherent that given the broadest reasonable interpretation of the term "small", that the amount of lime produced would not be enough to cause serious

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problems with the HA product. Furthermore it would be inherent that there would be some decomposition resulting in a minor level of impurities.

Regarding claim 6, the plasma is produced by ionization of Ar/O₂ and Ar/H₂ from an ambient atmosphere at a pressure of 30kPa.

Regarding claim 7, given the output quantity of 35 to 45 kW and the statement by the Applicant that at 70 kW the temperature of the plasma is 10,000 °C, it would be inherent that 35 (one-half) of 70kW would equate to approximately one-half the temperature. As such a temperature of 5000°C would be produced by Article 1.

Regarding claim 8, a cooling step is used to assist in crystalization (Article 1, page 1067, last paragraph bridging onto page 1068). Specifically it is stated that to “reduce... possible decomposition of the HA crystals... low-temperature stage (~168 °C) cooled with liquid nitrogen”. It would be inherent that this step would occur during the crystallization step to aid in reducing decomposition and production time.

Regarding claim 9, figure (a) on page 1069 shows that the particles are spherical in nature.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Article 1 in view of US PG Pub No. 20050158399 to Yu.

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Regarding claim 18, the substances required by claim 18 are not expressly stated by Article 1. However, in a process to produce a calcium-phosphate from an amorphous reaction product (Yu: abstract), Yu discloses that calcium ethoxide and triethyl phosphate can be used as the calcium and phosphate sources respectively (Yu: [0018]). As such, a skilled artisan would find it obvious to perform these in the reaction of Yu in Article 1 absent substantial evidence to the contrary, as they can control the Ca/P molar ratio to produce many different compounds (Yu: [0024]-[0025]).

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1, 6, 11 and 12 of this application conflict with claims 1, 2, 12 and 13 of US patent Application No. 11541526. 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application

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or maintain a clear line of demarcation between the applications. See MPEP § 822.

This is a provisional rejection as both applications are pending.

Response to Arguments

Applicant's arguments filed 10 April 2009 have been fully considered but they are not persuasive.

Regarding Bouyer, it is noted that while Bouyer does indeed disclose an XRD pattern it is well known that most polymers have an amorphous and crystalline nature to them as evidenced by XRD and FTIR spectra. Furthermore, Applicant is invited to the third paragraph of 1071 to Bouyer where, "Moreover, water molecules promote the transformation of amorphous HA into crystalline HA..." (emphasis added), this water as mentioned prior in Bouyer (1070 last full paragraph) is added in the plasma step, which would be the gas atomization step and as such leading to the subsequent cooling and further crystallization of the material. As such, the rejection over Bouyer is maintained as it can at a minimal be envisaged that there would be some degree of amorphous reaction product.

It is furthermore unclear how table 1 supports that the entire reaction product is 100% crystalline in nature and how the amorphous structure actually arises as Bouyer discloses that the final product is indeed crystalline in nature and no mentioning of an ethanol solution is made as the process of Bouyer does not involve ethanol. Finally, the claims require a crystalline product, so the complaint that Bouyer is crystalline is not understood.

Conclusion

The rejections of claims 1-12 are maintained and newly added claim 18 has been rejected.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard M. Rump whose telephone number is (571)270-5848. The examiner can normally be reached on Monday through Friday 7:00 AM-4:30 PM EDT.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Stanley Silverman can be reached on (571)272-1358. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/R. M. R./
Examiner, Art Unit 1793

/Stuart Hendrickson/

Primary Examiner, Art Unit 1793