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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. | |
|----------------------------|-------------------------------------|----------------------|-------------------------|-------------------|--|
| 16/982,856 | 09/21/2020 | YONG MIN CHANG | NCIP.P0072US/1001137220 | 4867 | |
| | 7590 03/17/202 SE FULBRIGHT US L | | EXAMINER | | |
| 98 SAN JACIN | 98 SAN JACINTO BOULEVARD | | | SCHLIENTZ, LEAH H | |
| SUITE 1100 AUSTIN, TX 7 | 8701-4255 | | ART UNIT | PAPER NUMBER | |
| | | | 1618 | | |
| | | | NOTIFICATION DATE | DELIVERY MODE | |
| | | | 03/17/2023 | FI ECTRONIC | |

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.

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aoipdocket@nortonrosefulbright.com



| | Application No. | Applicant(s) | | | | | |
|--|-------------------------------------|--------------|-------------------|--|--|--|--|
| Office Action Commence | 16/982,856 | CHANG et al. | | | | | |
| Office Action Summary | Examiner | Art Unit | AIA (FITF) Status | | | | |
| | LEAH H SCHLIENTZ | 1618 | Yes | | | | |
| 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 MONTHS 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 <u>2/28/2023</u> . | | | | | | | |
| A declaration(s)/affidavit(s) under 37 CFR 1.130(b) was/were filed on | | | | | | | |
| , — | ▼ This action is non-final. | | | | | | |
| 3) An election was made by the applicant in response to a restriction requirement set forth during the interview on; the restriction requirement and election have been incorporated into this action. | | | | | | | |
| 4) 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 <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. | | | | | | | |
| Disposition of Claims* | | | | | | | |
| 5) 🗹 Claim(s) 1-20 and 30-35 is/are pending in the application. | | | | | | | |
| 5a) Of the above claim(s) is/are withdrawn from consideration. | | | | | | | |
| 6) Claim(s) is/are allowed. | | | | | | | |
| 7) 🗹 Claim(s) 1-20 and 30-35 is/are rejected. | | | | | | | |
| 8) Claim(s) is/are objected to. | | | | | | | |
| 9) Claim(s) are subject to restriction and/or election requirement | | | | | | | |
| * If any claims have been determined <u>allowable</u> , you may be eligible to benefit from the Patent Prosecution Highway program at a | | | | | | | |
| participating intellectual property office for the corresponding application. For more information, please see | | | | | | | |
| http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov. | | | | | | | |
| Application Papers | | | | | | | |
| 10) The specification is objected to by the Examiner. | | | | | | | |
| 11) 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 | | | CFR 1.121(d). | | | | |
| 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). Certified copies: | | | | | | | |
| a)☑ All b)□ Some** c)□ None of the: | | | | | | | |
| 1. Certified copies of the priority docun | nents 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) | | | | | | | |
| Notice of References Cited (PTO-892) | 3) 🔲 Interview Summary | (PTO-413) | | | | | |
| 2) Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/S | B/08b) Paper No(s)/Mail D 4) Other: | ate | | | | | |



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DETAILED ACTION

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Notice of Pre-AIA or AIA Status

The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/28/2023 has been entered.

Status of Claims

Claims 1-10, 12, 14 and 16 have been amended. Claims 1-20 and 30-35 are pending and are examined herein on the merits for patentability.

Response to Arguments

Applicant's arguments have been fully considered. The rejections have been modified. The Examiner's response to Applicant's arguments are incorporated below.

Claim Rejections - 35 USC § 103



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

A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries for establishing a background for determining obviousness under 35 U.S.C. 103 are summarized as follows:

- 1. Determining the scope and contents of the prior art.
- 2. Ascertaining the differences between the prior art and the claims at issue.
- 3. Resolving the level of ordinary skill in the pertinent art.
- 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 1-14, 16-19 and 32-34 are rejected under 35 U.S.C. 103 as being unpatentable over Port *et al.* (US 2011/0092806) in view of Marnett (US 2005/0002859).

Port teaches the synthesis of a compound (B-Ch) by coupling a biovector to a linear or macrocyclic chelate; the complexation of the compound (B-Ch) with gallium Ga68 (paragraph 0024). Various biovectors, linkers and chelates are taught on pages 2-11, including a biovector for targeting a biological target associated with a pathology, in particular chosen from enzymes (metalloproteases, COX, tyrosine kinase), etc.

Exemplary compounds are shown on pages 50 and 53, including fenbufen and diflunisal conjugates:



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Port does not specifically exemplify a compound according to Formula I as claimed, including a gadolinium ion and the linker as claimed.

However, DOTA conjugates featuring the claimed linker (CH₂CONHCH₂CH₂) are taught to be suitable for conjugation between DOTA and biovector (e.g. folic acid).

Further, the teaching is not limited to gallium, a specific contrast product vectorized for PET with Ga68 and a contrast product vectorized for MRI with gadolinium may be used, the biovectors being identical or different (paragraph 0207).



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