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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/962,055	10/07/2022	MAHLA POUDINEH	21846	9353

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EXAMINER	
JANG, CHRISTIAN Y	

ART UNIT	PAPER NUMBER
3791	

NOTIFICATION DATE	DELIVERY MODE
08/21/2026	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. 17/962,055	Applicant(s) POUDINEH et al.	
	Examiner CHRISTIAN JANG	Art Unit 3791	AIA (First Inventor to File) Status 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 _____.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☐ This action is **FINAL.** 2b) ☑ 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 *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5) ☑ Claim(s) 1-4,6-17,26-27 and 32 is/are pending in the application.

5a) Of the above claim(s) 18-25 and 28-31 is/are withdrawn from consideration.

6) ☐ Claim(s) _____ is/are allowed.

7) ☑ Claim(s) 1-4,6-17,26-27 and 32 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 allowable, 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 is required if the drawing(s) is objected to. See 37 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 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) ☑ Notice of References Cited (PTO-892)

2) ☑ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date _____.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.

4) ☐ Other: _____.

DETAILED ACTION

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 8/10/26 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112(a):

> (a) IN GENERAL.—The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention.

The following is a quotation of the first paragraph of pre-AIA 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4, 6-17, 26-27, and 32 are rejected under 35 U.S.C. 112(a) or 35 U.S.C. 112 (pre-AIA), first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor or a joint inventor, or for applications subject to pre-AIA 35 U.S.C. 112, the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1 recites "a probe coupled to and **embedded throughout** the hydrogel body". The specification does not describe a probe embedded throughout the hydrogel body. To the contrary, the specification describes a deliberately two-layer construction in which the probe is confined to the needle region, and supplies a rationale for why that would be desirable: "Consecutive adding of MeHA solution and aptamer-quencher complex solution rather than adding a mixture of MeHA and aptamer solution at once reduces the background signal since the aptamer-quancher complex is added only to the needle area i.e., the base of the patch does not fluoresce" ([0393] of the printed publication). Fig. 1 likewise depicts a single probe (3) at a discrete location within hydrogel (2). While the specifications does state that the probe may be coupled to an electroactive species such as metal nanoparticles ([0151]), and that the nanoparticles or graphene may be embedded within the hydrogel's 3D network ([0154]), that the probe may be coupled to an electroactive species that also happens to be embedded throughout the hydrogel body is not the same as having the probe itself also embedded throughout the hydrogel body. Applicant is required to point to support in the originally filed disclosure for a probe embedded throughout the hydrogel body, or to amend the claim to be consistent with the two-layer construction as actually described.

The following is a quotation of 35 U.S.C. 112(b):
(b) CONCLUSION.—The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.

The following is a quotation of 35 U.S.C. 112 (pre-AIA), second paragraph:
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.

Claims 1-4, 6-17, 26-27, and 32 are rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor (or for applications subject to pre-AIA 35 U.S.C. 112, the applicant), regards as the invention.

As to claim 1, the term “throughout” is a relative term of degree. As the specification provides no standard for ascertaining the requisite degree, and, as noted above, expressly describes a hydrogel article in which a portion (the base layer) contains no probe at all. Accordingly, one of ordinary skill would not be apprised of the metes and bounds of a probe “embedded throughout the hydrogel body”.

Claim 1 recites the limitation "the signal" in line 5. There is insufficient antecedent basis for this limitation in the claim. For purposes of examination, it will be understood as “the measurable signal”.

Claim Rejections - 35 USC § 103

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.

Claim(s) 1-2, 4, 6, 8-10, 12-16, 26-27, and 32 is/are rejected under 35 U.S.C. 103 as being unpatentable over Irvine (US 2020/0377929) in view of Li (US 2017/0131298).

As to claim 1, Irvine teaches a microneedle for detecting a target ([0033] – Hydrogel-coated MN patches enable detection in situ), the microneedle comprising: a hydrogel body

([0017]); a probe coupled to and embedded throughout the hydrogel body, the probe for generating a measurable signal in the presence of the target ([0017] – PNA probes are covalently bound to the alginate hydrogel matrix; [0035] – small oligonucleotides could easily diffuse within such materials and hybridize to **pre-embedded** PNAs; [0045] – provided by probe-heads already incorporated into the hydrogel structure), the probe comprising a nucleic acid that binds to the target for generating the signal ([0017] – PNA:DNA complex that is measured), and wherein the microneedle detects the target in-situ ([0033]).

Irvine fails to expressly teach that the nucleic acid comprises an aptamer, single stranded complementary probe DNA, nucleic acid enzyme, or combinations thereof. Li teaches a nucleic acid probe biosensor comprising an aptamer that specifically binds a target that is coupled to a reporter moiety and quenching moiety ([0042]) and that the aptamers may be in the form of an oligonucleotide or peptide molecules that bind to a specific target molecule and that they could be any fluorophore-labelled DNA oligonucleotides ([0068]). It would have been obvious to modify Irvine with Li such that the nucleic acid probe embedded in the hydrogel comprises an aptamer, a single-stranded complementary DNA, or nucleic acid enzymes as an alternative to the PNA probe taught by Irvine as it would be a matter of simple substitution.

As to claim 2, Irvine teaches the hydrogel body comprises a polymer comprising at least one C=C functionality; an acrylated polymer, a methacrylated polymer, or a combination thereof; and/or methacrylated gelatin, methacrylated hyaluronic acid, methacrylated alginate, methacrylated chitosan, methacrylated collagen, methacrylated polyethylene glycol, methacrylated polyvinyl alcohol, methacrylated polylysine, or a combination thereof ([0059]).

As to claim 4, Irvine teaches the probe coupled to the hydrogel body comprises the probe being coupled to the hydrogel body by covalent bonding, intermolecular bonding, physisorption, complexation, a linker; or a combination thereof ([0017], [0060]).

As to claim 6, Irvine teaches the nucleic acid comprises a linker functional group for coupling the probe to the hydrogel ([0017] - photo-cleavable linker; [0034], [0060]).

As to claim 8, Irvine teaches the probe comprises a fluorophore; or an electroactive species, a redox active species, or a combination thereof ([0037], [0043-45], [0106-0139]).

As to claim 9, Li teaches the nucleic acid comprises a fluorophore or is linked to a fluorophore, or the nucleic acid comprises a redox reporter or is linked to a redox reporter ([0043]; [0068]).

As to claim 10, Li teaches a quencher, and the probe is optionally reversibly bound to a quencher, or is optionally tethered to the quencher via covalent bonding, intermolecular bonding, physical adsorption, conjugation, or a combination thereof ([0044] – labeled aptamer complexed with a quenching moiety forming a probe complex). It would have been obvious to further modify the above combination with further teachings of Li to allow for a low background fluorescence and improve the accuracy of the device.

As to claim 12, Li teaches the quencher comprises a graphene-based material, wherein the graphene-based material optionally comprises graphene-oxide (GO) nanosheets, graphene-oxide(GO) nanoparticles, graphene-oxide (GO) nanocomposites, or a combination thereof. As such, it would have been obvious to modify the above combination with Li to utilize a known material that can act as a quencher as an obvious substitution yielding similar and thus expected results.

As to claim 13, Irvine teaches the measurable signal is fluorescence; or an electrochemical signal ([0043-45], [0106]).

As to claim 14, Irvine teaches the target comprises a biomolecule present in interstitial fluid ([0124]).

As to claim 15, Irvine teaches the target comprises small biomolecules, proteins, or micro ribonucleic acids; or cortisol, vanomycin, gentamicin, tyrosinamide, thrombin, micro-RNA miR21, micro-RNA miR210, uric acid (UA), serotonin, insulin, adenosine triphosphate, or glucose ([0018]).

As to claim 16, Irvine teaches the microneedle has a length of about 300 pm to about 1000 pm, such as about 800 pm ([0142]).

As to claim 26, Irvine teaches an apparatus for detecting a target in a sample (Abstract), the apparatus comprising: the microneedle according to claim 1 (see above); and a detector for detecting the measurable signal (Claim 1).

As to claim 27, Irvine teaches a transdermal patch ([0017]) comprising the microneedle according to claim 1 (see above).

As to claim 32, Irvine teaches the probe being coupled to the hydrogel comprises the probe and the hydrogel being crosslinked together ([0017], claim 6).

Claim(s) 3 and 17 is/are rejected under 35 U.S.C. 103 as being unpatentable over Irvine et al. (US 2020/0377929) and Li (US 2017/0131298), and further in view of Cui et al. (US 2009/0005667).

As to claim 3, Irvine does not explicitly teach that the hydrogel further comprises a conductive polymer, an ionomer, or a combination thereof; or poly(3,4-ethylenedioxythiophene) polystyrene sulfonate; polyacetylene; polypyrrole; polyindole; polyaniline; a copolymer thereof; or a combination thereof. Cui teaches a hydrogel to be used in combination with an electrode system ([0099]) in which the hydrogel comprises polymers such as polypyrrole and PEDOT (i.e. poly(3,4-ethylenedioxythiophene)) to improve the electrical characteristics of the hydrogel, as well as incorporating conductive polymer within the hydrogel ([0106]). Accordingly, it would have been obvious to modify Irvine with Cui to utilize the recited materials as part of the overall hydrogel structure to improve any electrical characteristics of the hydrogel as desired.

As to claim 17, Irvine does not explicitly teach a conductive material, wherein the conductive material optionally comprises a metal nanoparticle, graphene-based material, conductive polymer, or an ionomer, or a combination thereof. Cui teaches a hydrogel to be used in combination with an electrode system ([0099]) in which the hydrogel comprises polymers such as polypyrrole and PEDOT (i.e. poly(3,4-ethylenedioxythiophene)) to improve the electrical characteristics of the hydrogel, as well as incorporating conductive polymer within the hydrogel ([0106]). Accordingly, it would have been obvious to modify Irvine with Cui to utilize the recited materials as part of the overall hydrogel structure to improve any electrical characteristics of the hydrogel as desired.

Claim(s) 7 is/are rejected under 35 U.S.C. 103 as being unpatentable over Irvine et al. (US 2020/0377929) and Li (US 2017/0131298), and further in view of Woodbury et al. (US 2020/0016567).

As to claim 7, Irvine does not explicitly teach that the linker functional group comprises a phosphoramidite functional group; or an acrydite functional group. However, Woodbury teaches that a peptide can be physically tethered via a linker molecule such as a phosphramidite functional group ([0040]). Accordingly, it would have been obvious to utilize a known material that can perform the function as it would be an obvious substitution that yields similar, and thus expected, results.

Claim(s) 11 is/are rejected under 35 U.S.C. 103 as being unpatentable over Irvine et al. (US 2020/0377929) and Bradbury et al. (US 2021/0145985) in view of Steelman (US 2020/0181710).

As to claim 11, the above combination fails to expressly teach the quencher comprises a sequence partially or fully complimentary to at least a portion of the nucleic acid sequence. Steelman teaches a nucleic acid detection scheme in which the quencher moiety is carried on an oligonucleotide that hybridizes to the probe sequence ([0207]). It would have been obvious to modify the above combination with Steelman as a complementary quencher strand is a known means of holding the fluorophore and quencher in proximity in the absence of target to produce a low background signal.

Response to Arguments

Applicant's arguments have been fully considered but they are not persuasive.

In particular, applicant characterizes Irvine as teaching only a microneedle that is coated with a composition and not a microneedle comprising a hydrogel body and a probe coupled to and embedded throughout the hydrogel body. This is not persuasive. Irvine repeatedly describes the PNA as being distributed within the three-dimensional hydrogel network:

- [0035] – target oligonucleotides "could easily diffuse with such porous materials and hybridize to pre-embedded PNAs"
- [0045] – probe heads are "already incorporated into the hydrogel structure through covalent attachment at the end of the PNA oligomers"
- [0048] – device works by "attaching PNA oligomers to the hydrogel's fibers"

Moreover, the applicant appears to conflate the microneedle body with the hydrogel body. The Irvine's microneedle comprises the hydrogel as well as the core PLLA array. The claims do not recite that the microneedle consists of the hydrogel body, that the hydrogel body constitutes the entire needle, or that no other structural material is present.

Applicant's other arguments have been considered but are moot because the new ground of rejection does not rely on any reference applied in the prior rejection of record for any teaching or matter specifically challenged in the argument.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Chang et al. ("A Swellable Microneedle Patch to Rapidly Extract Skin Interstitial Fluid

for Timely Metabolic Analysis") teaches a microneedle body comprising crosslinked MeHA which allows for the extraction of interstitial fluids for analysis. Khademhosseini et al. (USP #12,544,547) teaches microneedles formed from a crosslinked gelatin-based material which allows for the detection and/or analysis of analytes (col. 3 lines 1-14). Jin (USP #9,320,878) teaches a microneedle patch formed of hydrophilic polymeric materials and are water-swellable (Abstract; claim 1) in which agents can be loaded into the matrix of the needles (col. 2 lines 49-59). Woolfson et al. (WO 2009/040548) teaches microneedles made of crosslinked hydrogels (p6).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTIAN JANG whose telephone number is (571)270-3820. The examiner can normally be reached Monday-Friday (7-3:30 EST).

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Chen can be reached at 571-272-3672. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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