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|---|-------------|----------------------|---|------------------|
| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
| 17/052,990 | 11/04/2020 | Emre Ozer | P00497US.family | 1047 |
| 134423 7590 08/23/2024 Leveque Intellectual Property Law, P.C. 241 E. 4th Street, #102 Frederick, MD 21701 | | | EXAMINER BOYER, RANDY | |
| Frederick, MD | 21701 | | ART UNIT | PAPER NUMBER |
| | | | 1771 | |
| | | | NOTIFICATION DATE | DELIVERY MODE |
| | | | 08/23/2024 | 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.

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| Office Action Summary | | 17/052,990 | Ozer et al | Applicant(s) Ozer et al. | |
|--|---|--|--|---------------------------------------|--|
| | | Examiner | Art Unit | AIA (FITF) Status | |
| | | Randy Boyer | 1771 | Yes | |
| The MA | AILING DATE of this communication app | l bears on the cover sheet wi | ith the corresponder | nce address | |
| Period for Reply | | | | | |
| DATE OF THIS C - Extensions of tim | ED STATUTORY PERIOD FOR REPL COMMUNICATION. re may be available under the provisions of 37 CFR 1.1 | - | | | |
| Failure to reply w | eply is specified above, the maximum statutory period rithin the set or extended period for reply will, by statute of by the Office later than three months after the mailing | , cause the application to become Al | BANDONED (35 U.S.C. § 13 | 33). | |
| Status | | | | | |
| 1) 🗹 Respon | sive to communication(s) filed on 5 F | ebruary 2024. | | | |
| 🗆 A decl | aration(s)/affidavit(s) under 37 CFR | 1.130(b) was/were filed o | on | | |
| 2a) 🗹 This act | , | This action is non-final | | | |
| on | tion was made by the applicant in res _; the restriction requirement and ele | ction have been incorpo | rated into this actio | on. | |
| | nis application is in condition for allow n accordance with the practice under | | | | |
| Disposition of Cla | aims* | | | | |
| 5) 🗹 Clain | n(s) <u>1,3-4,6,8,10 and 13-24</u> is/are | pending in the application | n. | | |
| 5a) Of t | he above claim(s) <u>13-23</u> is/are withd | rawn from consideration. | | | |
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DETAILED ACTION

Response to Amendment

1. Examiner acknowledges Applicant's response filed 5 February 2024 containing amendments to the claims and remarks.

2. Claims 1, 3, 4, 6, 8, 10, and 13-24 are pending. Claims 13-23 are withdrawn as being directed to unelected inventions. Consequently, only claims 1, 3, 4, 6, 8, 10, and 24 are pending for examination.

3. The previous objection with respect to claim 10 is withdrawn in view of Applicant's amendments to the claim.

4. The previous rejection of claims 1, 3, 4, 6, 8, 10, and 24 under 35 U.S.C. 102(a)(1) is maintained. The rejection follows.

Claim Rejections - 35 USC § 102

5. 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:

A person shall be entitled to a patent unless -

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(a)(1) the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention.

6. Claims 1, 3, 4, 6, 8, 10, and 24 are rejected under 35 U.S.C. 102(a)(1) as being anticipated by Wikswo (US 2014/0356849).

7. With respect to claims 1, 3, 4, 6, 8, 10, and 24, Wikswo discloses a fluid delivery

device (see Wikswo, paragraph [0220]) comprising an inlet portal (851, 852, 853) to allow

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fluid passage into a chamber ("organ N"); an outlet portal to allow fluid passage from the chamber (see Wikswo, paragraph [0221]); a biosensor (870); an actuator, wherein the actuator unambiguously derivable from the disclosure of "selectively operable valves" (see Wikswo, paragraphs [0223] and [0227]); wherein the biosensor (870) is in fluid communication with the fluid (see Wikswo, paragraph [0224]) and is associated with a valve having actuator capability, the valve being in communication with the sensor measured conditions upon which the valve permits or inhibits delivery of fluid from the chamber (see Wikswo, paragraphs [0234]-[0236] and [0285]). The valve having actuator capability may be a single unit which responds to a selected fluid parameter (see Wikswo, paragraphs [0223] and [0227]). The device may comprise a plurality of fluidic switches (i.e. valves) (see Wikswo, paragraphs [0223] and [0227]). The device may be integral to a microfluidic chip (see Wikswo, Abstract), the chip being associated with a pump for assisting fluid flow (see Wikswo, Abstract). The biosensor may detect changes in electrochemical or fluorescent signals (see Wikswo, paragraph [0103]). The biosensor may be linked to molecules detectable by light sensors (see Wikswo, paragraph [0311]). The inlet and outlet ports may include a seal (see Wikswo, paragraph [0347]). The valve may be linked to a control system capable of processing data which permits or inhibits delivery of fluid (see Wikswo, paragraph [0296]). Examiner notes that the specific limitations of claim 24 do not structurally limit the claimed device over that disclosed by Wikswo. Claims directed to an *apparatus* must be distinguished from the prior art on the basis of structural differences. Hewlett-Packard Co. v. Bausch & Lomb Inc., 909 F.2d 1464, 1469 (Fed. Cir. 1990) ("[A]pparatus claims cover what a device is, not what a device does.") (emphasis in original).

Response to Arguments

8. Applicant's arguments filed 5 February 2024 have been fully considered but they

are not persuasive.

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- 9. Examiner understands Applicant's arguments to be:
 - I. Wikswo relates to synthetic organs on chips, for the purpose of investigating organ interactions and drug responses. As such, Wikswo does not disclose any implantable device. The presently claimed devices and methods are directed to devices implantable into mammalian, bird, amphibian, arthropod, fish, or reptile body either directly or within a biocompatible implant device, and to methods which are carried out in vivo with implantable devices.
 - II. Wikswo is directed towards non-implantable devices for the purpose of investigating organ interactions and drug responses without the need for animal testing.
 - III. Wikswo does not disclose or imply a biosensor to sense and detect fluid properties to generate one or more sensor measured conditions and to output the one or more sensor measured conditions to the control unit wherein the biosensor detects one of a variety of signals.
 - IV. Wikswo's sensor is not one as presently claimed, linked to the controlled release (or prevention of release) of fluid from a chamber, i.e. drug delivery.
 - V. Any sensor disclosed in Wikswo is used to measure a pressure drop of the fluid or to detect properties of the effluent outputted by the bio-object responsive to the perfusion, and is totally different from the biosensor for detecting properties of the fluid within the chamber for biosafety as defined in claim 1.
- 10. With respect to Applicant's first and second arguments, Examiner notes (1) the claims at issue are all directed to an apparatus *per se* and (2) that the subject limitation "implantable" simply means "capable of being implanted." In this regard, Applicant points

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