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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 Claims 13-23 are withdrawn as being directed to unelected inventions.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 The previous objection with respect to claim 10 is withdrawn in view of Applicant's amendments to the claim.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 –

(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 Wikswa (US 2014/0356849).
7. With respect to claims 1, 3, 4, 6, 8, 10, and 24, Wikswa discloses a fluid delivery device (see Wikswa, paragraph [0220]) comprising an inlet portal (851, 852, 853) to allow

fluid passage into a chamber (“organ N”); an outlet portal to allow fluid passage from the chamber (see Wiksw, paragraph [0221]); a biosensor (870); an actuator, wherein the actuator unambiguously derivable from the disclosure of “selectively operable valves” (see Wiksw, paragraphs [0223] and [0227]); wherein the biosensor (870) is in fluid communication with the fluid (see Wiksw, 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 Wiksw, paragraphs [0234]-[0236] and [0285]). The valve having actuator capability may be a single unit which responds to a selected fluid parameter (see Wiksw, paragraphs [0223] and [0227]). The device may comprise a plurality of fluidic switches (i.e. valves) (see Wiksw, paragraphs [0223] and [0227]). The device may be integral to a microfluidic chip (see Wiksw, Abstract), the chip being associated with a pump for assisting fluid flow (see Wiksw, Abstract). The biosensor may detect changes in electrochemical or fluorescent signals (see Wiksw, paragraph [0103]). The biosensor may be linked to molecules detectable by light sensors (see Wiksw, paragraph [0311]). The inlet and outlet ports may include a seal (see Wiksw, paragraph [0347]). The valve may be linked to a control system capable of processing data which permits or inhibits delivery of fluid (see Wiksw, paragraph [0296]). Examiner notes that the specific limitations of claim 24 do not structurally limit the claimed device over that disclosed by Wiksw. 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.

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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