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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte JAMES H. BRAUKER,
MARK C. SHULTS, and MARK A. TAPSAK
(APPLICANT: DexCom, Inc.)

Appeal 2017-002805
Application 14/619,651[1]
Technology Center 3700

Before DONALD E. ADAMS, RICHARD M. LEBOVITZ, and JEFFREY N. FREDMAN, *Administrative Patent Judges*.

ADAMS, *Administrative Patent Judge*.

DECISION ON APPEAL

This appeal under 35 U.S.C. § 134(a) involves claims 11–19 (App. Br. 5). Examiner entered a rejection under the written description provision of 35 U.S.C. § 112, first paragraph. We have jurisdiction under 35 U.S.C. § 6(b).

We REVERSE.

STATEMENT OF THE CASE

Appellant's disclosure "relates to [] biointerface membranes, to sensors and implantable devices including these membranes, and to methods

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[1] Applicant is the real party in interest (App. Br. 3).

for monitoring glucose levels in a biological fluid sample using an implantable analyte detection device" (Spec. ¶ 2). Appellant's claim 11 is representative and reproduced below:

> 11. An implantable device for continuous measurement of a glucose concentration, comprising:
>
> a sensing region configured to continuously measure a signal indicative of a glucose concentration in a host; and
>
> a membrane system located over the sensing region, wherein the membrane comprises a sensing membrane and a biointerface membrane, wherein the sensing membrane comprises an enzyme configured to catalyze a reaction with glucose as a reactant, wherein the biointerface membrane is configured to resist cellular attachment and is impermeable to cells and cell processes.

(App. Br. 15.)

The claims stand rejected as follows:

Claims 11–19 stand rejected under the written description provision of 35 U.S.C. § 112, first paragraph.

ISSUE

Does the preponderance of evidence on this record support Examiner's finding that Appellant's Specification fails to provide written descriptive support for the claimed invention?

FACTUAL FINDINGS (FF)

FF 1. Appellant discloses that prior art "bilayer membranes . . . that have cell impermeable layers that are porous and adhesive to cells" allow "cells . . . to reach pseudopodia into the interstices of the membrane to adhere to

and flatten on the membrane . . . thereby blocking transport of molecules across the membrane-tissue interface" (Spec. ¶ 9).

FF 2. Appellant discloses that "[t]he term 'cell processes' and the like refers to pseudopodia of a cell" (Spec. ¶ 32).

FF 3. Appellant discloses

> in one aspect of the [] invention, a biointerface membrane for use with an implantable device . . . [that] includ[es]; a first domain distal to the implantable device wherein the first domain supports tissue ingrowth and interferes with barrier-cell layer formation and a second domain proximal to the implantable device wherein the second domain is resistant to cellular attachment and is impermeable to cells and cell processes.

(*Id.* ¶ 15.)

FF 4. Appellant's figure 2 is reproduced below:

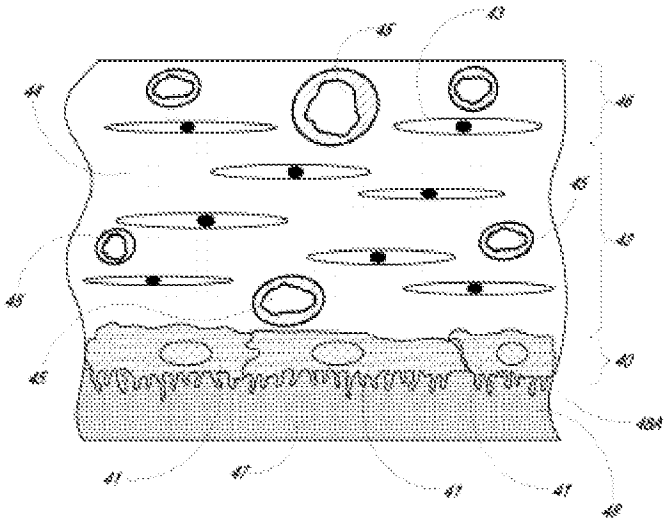

FIG. 2

Appellant's "FIG. 2 is an illustration of a device having increased neovascularization within the intermediary layer of [a] foreign body response" (Spec. ¶ 46). More specifically, Appellant's "FIG. 2 illustrates a situation in which some blood vessels 45 are brought close to an implant

membrane 48, but the primary layer 40 of cells adherent to the cell-impermeable membrane blocks glucose" (Spec. ¶ 8).

FF 5. Appellant discloses that "[a] disadvantage of cell-impermeable membranes is that they often stimulate a local inflammatory response, called the foreign body response (FBR) that has long been recognized as limiting the function of implanted devices that require solute transport" (Spec. ¶ 6).

FF 6. Appellant discloses that

> [t]he FBR . . . is composed of three main layers . . . . The innermost FBR layer 40, adjacent to the device [48], is composed generally of macrophages and foreign body giant cells 41 (herein referred to as the barrier cell layer). These cells form a monolayer 40 of closely opposed cells over the entire surface 48[A] of a smooth or microporous . . . membrane 48. The intermediate FBR layer 42 (herein referred to as the fibrious zone), lying distal to the first layer with respect to the device, is a wide zone . . . composed primarily of fibroblasts 43 and fibrous matrix 44. The outermost FBR layer 46 is loose connective granular tissue containing new blood vessels 45 (herein referred to as the vascular zone 46).

(Spec. ¶ 6–7)

FF 7. Appellant discloses that "[b]ecause the cell impenetrable layers [48, illustrated in Appellant's FIG. 2,] are porous, cells are able to reach pseudopodia into the interstices of the membrane to adhere to and flatten on the membrane . . . thereby blocking transport of molecules across the membrane-tissue interface" (Spec. ¶ 9).

FF 8. Appellant's figure 3 is reproduced below:

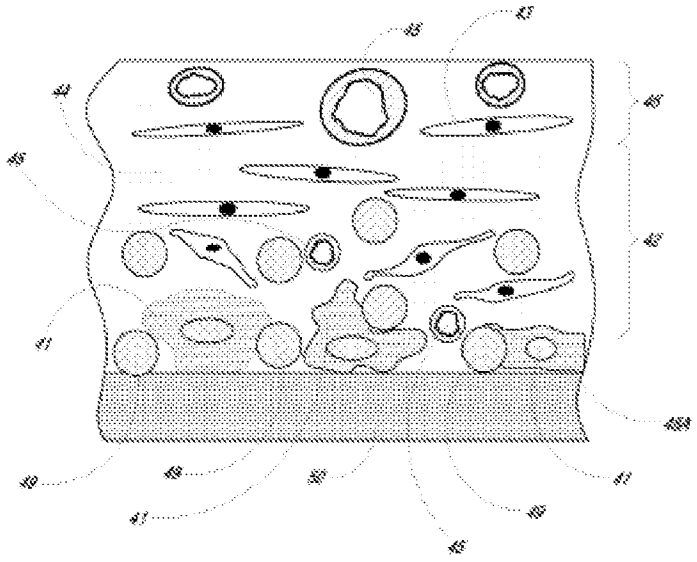

FIG. 3

Appellant's "FIG. 3 is an illustration of membrane of [Appellant's] . . . invention including a barrier-cell disruptive domain composed of fibers and a cell impermeable domain" (Spec. ¶ 47). More specifically, Appellant's "FIG. 3 illustrates how the non-woven fibers 49 serve to disrupt the continuity of cells, such that they are not able to form a classical foreign body response. . . . [Because,] they are unable to form an ordered closely opposed cellular monolayer parallel to the surface of the device as in a typical foreign body response to a smooth surface" (*id.* ¶ 69).

FF 9. Appellant's

> biointerface membrane is constructed of two or more domains . . ., preferably, the membrane includes a cell impermeable domain 50 proximal to an implantable device, also referred to as the second domain; and a cell disruptive domain, which in the embodiment illustrated[, in Appellant's FIG. 3,] includes

> non-woven fibers 49 distal to an implantable device, also referred to as the first domain.

(Spec. ¶ 63; *see also id.* ¶¶ 64–77 (providing a description of the first and second domains of Appellant's biointerface membrane); *id.* ¶ 73 (Appellant's cell impermeable domain "is permeable to oxygen and may or may not be permeable to glucose and is constructed of biodurable materials . . . that are impermeable by host cells (e.g., macrophages) such as, for example, polymer blends of polycarbonate based polyurethane and PVP"); *id.* ¶ 75 (Appellant's cell impermeable domain "is resistant to cellular attachment and is impermeable to cells and preferably composted of a biostable material"); *id.* ¶ 77 (Appellant's cell impermeable domain "prevents cell entry or contact with device elements underlying the membrane, and prevents the adherence of cells, and thereby prevents the formation of a barrier cell layer").)

ANALYSIS

Examiner finds that Appellant's disclosure fails to establish "that Appellant was in possession, at the time of filing, of a device including a second layer [the "biointerface membrane" of claim 11] that is impermeable to cells 'and cell processes'" (Ans. 2–3). In support of this finding, Examiner directs attention to paragraphs 75–77 of Appellant's Specification, finding that these paragraphs are

> [t]he most relevant portion of the specification [and] . . . focuses almost exclusively on cell ingrowth, thus there is no teaching or inherent disclosure that a cell process (which is understood to be one or several orders of magnitude smaller in scale than a cell) would have been inhibited from growth relative to the disclosed layer composed of the listed materials.

(*Id.* at 3). Examiner recognizes, however, that Appellant discloses a "second domain [that] is resistant to cellular attachment and cell processes" (*id.* at 6). Nevertheless, Examiner finds that this disclosure "is not sufficiently detailed to constitute a teaching to one of skill in the art of the actual structure of such a membrane" and "[t]hus, the sentence cannot serve to establish that Appellant was in possession of the structure of the claimed invention, without additional teachings elsewhere in the specification" (*id.*). In this regard, Examiner finds that Appellant's Specification provides "no recognition or assertion that impermeability to cell processes has occurred in the tested arrangement nor is there analysis presented to indicate that impermeability to cell processes has influenced the observed results" (*id.*). Examiner, therefore, finds that "[a]bsent a teaching of impermeability to 'cell processes', there is no evidence/basis for one of skill in the art to reasonably conclude that Appellant was in possession of the claimed subject matter at the time of filing" (*id.* at 5; *see also id.* at 7).

We are not persuaded.

As Examiner recognizes, Appellant discloses a device that comprises a "biointerface member" as claimed, which comprises a "second domain [that] is resistant to cellular attachment and cell processes" (*see* Ans. 6; FF 3). In addition, Appellant's Specification provides details regarding this domain's composition (*see* FF 9; *see generally* FF 1–8). *See generally* App. Br. 11–13; Reply Br. 5–6. Therefore, we find that Appellant satisfied the requirements of the written description provision of 35 U.S.C. § 112, first paragraph.

It may be that Examiner is concerned that Appellant's Specification fails to provide an enabling description of the subject matter set forth in

Appellant's claims. The enablement provision of 35 U.S.C. § 112, first paragraph, however, is not the same as the written description provision of this Section. *See Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1561 (CAFC 1991) ("With respect to the first paragraph of §112 the severability of its 'written description' provision from its enablement ('make and use') provision was recognized by this court's predecessor, the Court of Customs and Patent Appeals, as early as *In re Ruschig*, 379 F.2d 990, 154 USPQ 118 (CCPA 1967)"). The factual analysis required to address enablement is set forth in, *inter alia*, *In re Wands*, 858 F.2d 731, 735, 736-37 (Fed. Cir. 1988). We find no fact-based reasoned analysis of this record in the context of an enablement rejection. Therefore, we decline to consider whether Appellant's Specification provides an enabling disclosure of Appellant's claimed invention.

CONCLUSION OF LAW

The preponderance of evidence on this record fails to support Examiner's finding that Appellant's Specification fails to provide written descriptive support for the claimed invention. The rejection of claims 11–19 under the written description provision of 35 U.S.C. § 112, first paragraph is reversed.

REVERSED