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EXAMINER
RAILEY, JOHNNY F

ART UNIT PAPER NUMBER
3991

MAIL DATE DELIVERY MODE
12/29/2015 PAPER
UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PRESENS PRECISION SENSING GMBH
Requester and Respondent

v.

UNIVERSITY OF MARYLAND BIOTECHNOLOGY INSTITUTE
Patent Owner and Appellant

 Appeal 2015-006297
Reexamination Control 95/000,615
 Patent 6,673,532 B2
 Technology Center 3900


Opinion for the Board filed by LEBOVITZ, Administrative Patent Judge.

Opinion Concurring filed by GUEST, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on the appeal by the Patent Owner from the Patent Examiner’s decision to finally reject claims 1, 3–6, 9–11, 13–16, 19, and 20 in the above-identified inter partes reexamination of US 6,673,532 B2. The Board’s jurisdiction for this appeal is under 35 U.S.C. §§ 6(b), 134, and 315. We affirm.
BACKGROUND

The patent in dispute in this appeal is 6,673,532 B2 ("the '532 patent") which was issued on January 6, 2004. The Patent Owner and Appellant is University of Maryland Biotechnology Institute ("Patent Owner") (Reel/Frame 13689-454). Appeal Brief ("Appeal Br.") 1 (dated November 18, 2014).

A request for *inter partes* reexamination of the '532 patent under 35 U.S.C. §§ 311–318 and 37 C.F.R. §§ 1.902–1.997 was filed on January 13, 2011 ("Request"). The Requester is PreSens Precision Sensing GmbH ("Requester"), who is also the Respondent in this appeal. Respondent Brief ("Resp’t Br.") 1 (dated December 16, 2014). *Inter partes* reexamination was ordered on March 16, 2011.

An oral hearing took place on November 13, 2015. A written transcript of the hearing will be entered into the records in due course.

REJECTIONS

The Examiner finally rejected of all the pending claims. Patent Owner appeals from the final rejection. The rejections are as follows:

1. Claims 1, 3–6, 9–11, 13–16, 19, and 20 stand rejected under 35 U.S.C. § 314(a) as enlarging the scope of the claims of the patent being reexamined. RAN^1^ 33.

2. Claims 1, 3–6, 9–11, 13–16, 19, and 20 stand 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. RAN 35.

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^1^ Right of Appeal Notice filed June 16, 2014.
3. Claims 1, 3–6, 9–11, 13–16, 19, and 20 stand rejected under 35 U.S.C. § 112(a) or 35 U.S.C. § 112 (pre-AIA), first paragraph, because the specification, while being enabling for processes using bioreactors, does not reasonably provide enablement for using a cultivation vessel comprising a single continuous volume. RAN 39.

4. Claims 1, 3–6, 9–11, 13–16, 19, and 20 stand rejected under 35 U.S.C. § 112(b) or 35 U.S.C. § 112 (pre-AIA), second paragraph, as indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor regards as the invention. RAN 41.

5. Claims 1, 3, and 4 stand rejected under pre-AIA 35 U.S.C. § 102(b) as anticipated by Weigl. RAN 13.


8. Claims 5, 6, 9–11, 13–16, 19, and 20 stand rejection under pre-AIA 35 U.S.C. § 103(a) as obvious in view of Weigl and EP ’253 as applied to claims 1, 3, and 4, further in view of Bambot. RAN 29.

We have not reached prior art rejections 7 and 8 because rejection 6, which is affirmed, covers all the pending claims.

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CLAIM

Claim 1 is representative and reads as follow (underlining showing additions and brackets showing deletions relative to the original claims):  

1. A method of measuring at least two cultivation parameters in a cell culture, comprising:
   (a) providing a cultivation vessel, wherein the cultivation vessel comprises,
      walls that define a single continuous volume or a non-planar surface that defines a single continuous volume, and
      at least two types of optical chemical sensors positioned within the single continuous volume;
   (b) placing a continuous culture medium within the single continuous volume of the cultivation vessel such that the continuous culture medium is in contact with at least one of the walls that define the single continuous volume of the cultivation vessel or the non-planar surface that defines the single continuous volume of the cultivation vessel, wherein the optical chemical sensors are positioned such that they are in contact with the continuous culture medium;
   [(a)] (c) establishing [at least one] a cell culture in the continuous culture medium [at least one bioreactor, wherein each bioreactor comprises at least two optical sensors];
   [(b)] (d) exciting the [at least two] optical chemical sensors to generate emission and/or light absorption, wherein the optical chemical sensors are excited using at least one excitation source per optical chemical sensor;
   [(c)] (e) detecting the emission and/or absorption generated by the [at least two] optical chemical sensors in [(b)] (d) by at least one detector for each type of optical chemical sensor used; and
   [(d)] (f) analyzing the detected emission and/or absorption detected in [(c)] (e) to assess the at least two cultivation parameters measured.

5 From amendment of November 25, 2012.
1. SECTION 314 REJECTION

The claims were amended during reexamination to replace “bioreactor” with the term “culture vessel.” In response to the amendment, the Examiner rejected the amended claims, and the claims which depend from them, under 35 U.S.C. § 314(a) (pre-AIA). Under Section 314(a), “no proposed amended or new claim enlarging the scope of the claims of the patent shall be permitted” in an *inter partes* reexamination proceeding. The Examiner stated that the term “cultivation vessel” is broader than “bioreactor” and thus impermissibly broadens the scope of the claims. RAN 33–34. To support the position that “bioreactor” is narrower than “cultivation vessel,” the Examiner cited the following passage from an article:

"By definition, a bioreactor is a system in which a biological conversion is effected. . . . Quite similar to conventional chemical reactors, bioreactors differ in that they are specifically designed to influence metabolic pathways . . . Bioreactors differ from conventional chemical reactors in that they support and control biological entities. As such, bioreactor systems must be designed to provide a higher degree of control over process upsets and contaminations, since the organisms are more sensitive and less stable than chemicals."

*Id.* at 33–34.

The Examiner’s reasoning is not supported by a preponderance of the evidence. While we recognize that “bioreactor” can be defined in the art to cover embodiments that “provide a higher degree of control over process upsets and contaminations,” we do not believe that this definition is necessarily controlling. First, we must look to the specification of the ’532 patent to see whether it
provides a definition or other enlightenment as to the meaning of “bioreactor” and “cultivation vessel.”

Patentees can act as their own lexicographers if they “clearly set forth a definition of the disputed claim term’ other than its plain and ordinary meaning.” *Thorner v. Sony Computer Entm’t Am., LLC*, 669 F.3d 1362, 1365 (Fed. Cir. 2012).

In this case, the ’532 patent – consistent with the evidence provided by the Examiner – refers to controlling the growth conditions of cultured cells in a bioreactor. ’532 patent, col. 1, ll. 60–67. However, in addition, the patent contains the express statement that “The bioreactor is preferably a cultivation vessel.” *Id.* at col. 8, l. 58. The patent explains:

[The cultivation vessel] can be as large as a 1-, 3- or even 100-liter bioreactor or as small as a 100 µl well on a multi-well microtiter plate, or even as small as microchip, or anywhere in between. The size of the cultivation vessel will depend upon the experimental parameters, e.g., number of cell types, number of media, number of different conditions to test, etc. . . . For example, if the skilled artisan has twelve different sets of conditions to determine growth optimization for a particular cell line, then a 12-well plate could be employed. Other cultivation vessel possibilities include, but are not limited to, cuvettes, culture plates such as 6-well plates, 24-well plates, 48-well plates and 96-well plates, culture dishes, microchips, 1-liter or larger bioreactors, cell culture flasks, roller bottles, culture tubes, culture vials, e.g., 3, 4 or 5 ml vials, flexible bags, etc. Thus, any type of container can be used as a cultivation vessel.

“[T]he PTO applies to the verbiage of the proposed claims the broadest reasonable meaning of the words in their ordinary usage as they would be understood by one of ordinary skill in the art, taking into account whatever enlightenment by way of definitions or otherwise that may be afforded by the written description contained in applicant’s specification.” *In re Morris*, 127 F.3d 1048, 1054 (Fed. Cir. 1997).
Id. at col. 8, l. 58 – col. 9, l. 8.

Moreover, the patent teaches:

Depending upon their configuration within the well-plate, the wells on a well plate can function as microbioreactors or as receptacles, wherein a culture vessel such as a culture vial is placed in the receptacle and the culture vial becomes the bioreactor and the well plate becomes a bioreactor platform.

Id. at col. 9, ll. 9–13 (emphasis added).

In our view, these passages provide compelling evidence that a bioreactor can simply be a cultivation vessel. For example, the statement that the “culture vial becomes the bioreactor” clearly means that a bioreactor can be a vessel – such as a culture vial. This is also consistent with teachings in Bambot. See FF13 below (“In the bioprocess industry, spinner flasks, roller bottles and shaker flasks are commonly employed as bioreactors, and are currently not instrumented at all.”). In other words, while a bioreactor can contain instruments to control conditions, it can also be a narrower embodiment in which it is just a container suitable for culturing cells.

The Examiner’s point may be that bioreactor is narrower than a “cultivation vessel” because a bioreactor must include something more (e.g., instrumentation) than just a container. However, the claim recites “a cultivation vessel” which comprises “at least two types of optical chemical sensors.” Thus, the claim is not merely limited to a vessel, but to a vessel with optical chemical sensors.

Requester contends that the term “cultivation vessel” is broader than a bioreactor because the process could read on crystal cultivation. Resp’t Br. 8. This argument is not persuasive. It’s not clear how the term “bioreactor” would change be narrower because any container, even a “bioreactor,” could be used for another purpose, whether it be for growing crystals, or for containing soda.
Moreover, both the claim language and the specification of the ’532 patent clearly state that the “cultivation vessel” must be suitable for “establishing a cell culture” in “a continuous culture medium” put inside the cultivation vessel. Because the cultivation vessel must be capable of maintaining a cell culture, the structure is distinguished from a structure that would perform other functions but would not be capable of being used to establish a cell culture, to the extent that such a distinction exists.

In sum, in view of the disclosure in the patent stating in several places that a bioreactor can be a “culture vessel,” and requirement in the claim that optical sensors are present in the vessel, we cannot sustain the Examiner’s rejection under 35 U.S.C. § 314 that the claim was impermissibly broadened.

2. WRITTEN DESCRIPTION REJECTION

The claims were amended to include the new limitation that “the cultivation vessel comprises walls that define a single continuous volume or a non-planar surface that defines a single continuous volume.” The Examiner found that the added limitation is not described in the patent in violation of the written description requirement of 35 U.S.C § 112, first paragraph. Specifically, Examiner states that “continuous” could also be defined to mean a series of repeated units attached together. Id. Under this interpretation, the Examiner stated that “it is not evident how two or more culture vials might be ‘attached together in repeated units’ to create a ‘continuous volume of the cultivation vessel.’ This concept is not described in the original patent specification.” RAN 36. The Examiner also states that “nonplanar surface” could be a “vinyl examination glove” which is not described in the patent. Id.
Requester further contends that the disputed limitation is not mentioned or disclosed in the patent specification, and raises issues as to what is covered by the limitation. Resp’t Br. 9. Requester argues: “The inventor did not clearly possess any and all vessels with walls or a non-planar surface as claimed, and did not clearly possess closed cultivation vessels, which also appear to be covered by the language, but would not work.” Id. at 10.

We shall reverse the rejection.

Legal principles

35 U.S.C. § 112 requires a patentee to provide a written description that allows a person of skill in the art to recognize that the patentee invented what is claimed. Ariad Pharms., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc). To that end, to satisfy the written description requirement, the inventor “must . . . convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention.” Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1563-64 (Fed. Cir. 1991). There is no requirement that the wording in the claim be identical to that used in the specification as long as there is sufficient disclosure to show one of skill in the art that the inventor “invented what is claimed.” Union Oil Co. of Cal. v. Atlantic Richfield Co., 208 F.3d 989, 997 (Fed. Cir. 2000). The written description “need not recite the claimed invention in haec verba but [it] must do more than merely disclose that which would render the claimed invention obvious.” ICU Med., Inc. v. Alaris Med. Sys., Inc., 558 F.3d 1368, 1377 (Fed. Cir. 2009). Thus, so long as a person “of ordinary skill in the art would have understood the inventor to have been in possession of the claimed invention at the time of filing, even if every
nuance of the claims is not explicitly described in the specification, then the adequate written description requirement is met.” In re Alton, 76 F.3d 1168, 1175 (Fed. Cir. 1996). “[H]ow the specification accomplishes this is not material.” In re Wertheim, 541 F.2d 257, 262 (CCPA 1976). A drawing alone may provide adequate description for a claim. Vas-Cath, 935 F.2d at 1560.

Discussion

There is no dispute that the words “walls that define a single continuous volume or a non-planar surface that defines a single continuous volume” do not appear in the patent. However, it is not necessary that the identical words appear in the patent specification as long as one of ordinary skill in the art would have recognized that the inventors invented what is being claimed. Union Oil Co., 208 F.3d at 997; ICU Med., 558 F.3d at 1377. The question is whether the concept of “walls” or a “non-planar surface” that “define a single continuous volume” was possessed by the inventors, despite the absence of the explicit words. Ariad Pharms., 598 F.3d at 1351.

First, we begin with the words in the claim. The phrase “single continuous volume” is not defined in the patent. Consequently, we look for a conventional meaning of “continuous” that is consistent with the written description of the ’532 patent. Morris, 127 F.3d at 1054. “Continuous” is defined in a general purpose dictionary as “marked by uninterrupted extension in space, time, or sequence.”7 This meaning is consistent with Figs. 1 and 6 of the patent which show open containers comprising a single continuous volume of liquid culture media in which there is no interruption, such as no partitioning wall or partitioning valve in the

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7 http://www.merriam-webster.com/dictionary/continuous
container to interrupt a continuous volume of liquid. A drawing alone may provide adequate description for a claim. *Vas-Cath*, 935 F.2d at 1560.

The Examiner adopted a broader definition to mean “a series of repeated units attached together.” RAN 36. Under this interpretation, the Examiner appeared to interpret the claim to encompass multiple vials attached to each other and flexible tubing, neither of which the Examiner found to be described in the patent specification. *Id.*

The claims require the “continuous volume” to be part of a “cultivation vessel.” It is a strained reading of the claim to interpret the “vessel” to be multiple vessels attached together. The Examiner did not adequately support interpreting the recited “cultivation vessel” to mean anything more than a single vessel. On the other hand, Patent Owner provided a reasonable definition of “vessel” to mean a container, such as a cup, bowl, or bottle. *Id.* at 35.

With regard to the Examiner’s example of flexible tubing as a culture vessel, a patent specification does not have to disclose every single species of a genus (“cultivation vessels”) to have described it. *Bilstad v. Wakalopulos*, 386 F.3d 1116, 1124–25 (Fed. Cir. 2004). Consequently, we do not consider the failure to disclose this species to contravene the written description requirement.

Requester further contends that “walls that define a single continuous volume or a non-planar surface that defines a single continuous volume” is ambiguous because it is not clear whether outlets can be present on the wall and whether the container must be closed in order for it to satisfy the limitation of being “continuous.” Resp’t Br. 9–10.

The disputed phrase does not require the walls to be “continuous,” but rather the “volume” contained within it must be “continuous,” i.e., “walls that define a
single continuous volume or a non-planar surface that defines a single continuous volume.” The plain meaning of the words in the claim is that walls or a surface define “a continuous volume,” not that walls, themselves, are continuous. In other words, when the culture media of step (b) of claim 1 is placed in the cultivation vessel, it must be uninterrupted. This condition would be satisfied if there were inlet/outlet openings in the walls and if the container were a well that is either open or closed at the top. The ’532 patent supports this interpretation because the drawings show open vessels (see Figs. 1, 2, 6), and the patent discloses these and other types of vessels as well, such as microchips, roller bottles, culture tubes, and culture bags. Moreover, Requester’s reading of the claim is overly broad and did not take into account that a “cultivation vessel” is claimed which must be suitable for culturing cells.

The Examiner’s statement that a “cultivation vessel” could be an examination glove is not persuasive. The claims require a “cultivation vessel” with at least two optical sensors. In context of the patent’s written description, a “cultivation vessel” would reasonably be understood to be a vessel suitable for culturing cells. ’532 patent, col. 9, ll. 1–30; see also Section 314 Rejection. Moreover, the claims require optical sensors positioned in the vessel, a configuration that would unreasonable to impose on a glove.

In sum, we conclude that the ’532 patent adequately describes walls that define a single continuous volume or a non-planar surface that defines a single continuous volume.” The written description rejection is reversed.
3. ENABLEMENT REJECTION

The Examiner contends that the newly added limitation “walls that define a single continuous volume or a non-planar surface that defines a single continuous volume” is not enabled. The Examiner’s reasoning is the same as that discussed above for the written description rejection. RAN 39–41. Because we have interpreted this phrase to mean that there must be a continuous volume in the cultivation vessel, and reject the contention that it requires uninterrupted walls or a closed vessel, we cannot sustain the Examiner’s rejection of the claims based on his reading of the claim.

ADDITIONAL CLAIM INTERPRETATION ISSUES

In addition to the claim interpretation issues discussed under the Section 314 and Section 112 written description and enablement rejections, it is also asserted that the claimed “cultivation vessel” with “walls that define a single continuous volume or a non-planar surface that defines a single continuous volume” is reasonably interpreted to encompass “any and all tubing exiting a culture vessel and connecting to any flow-through cell unit.” RAN 8. In reaching the conclusion that it does, the Examiner relied on statements by Patent Owner said to be admissions. Id. at 11. The issue is whether the claimed “cultivation vessel” includes tubing extensions from it.

During reexamination of an unexpired patent, claims are given their broadest reasonable interpretation consistent with the patent specification. In re Suitco Surface, Inc., 603 F.3d 1255, 1259 (Fed. Cir. 2010); In re Abbott Diabetes Care Inc., 696 F.3d 1142, 1148 (Fed. Cir. 2012).
In this case, the claims are directed to a “cultivation vessel.” The term “vessel” is not defined in the patent. Accordingly, we adopt its ordinary definition to mean a “container (as a cask, bottle, kettle, cup, or bowl) for holding something.” This definition is consistent with the patent which describes “cuvettes, culture plates . . ., culture dishes, microchips, 1-liter or larger bioreactors, cell culture flasks, roller bottles, culture tubes, culture vials, . . . flexible bags” as containers. ’532 patent, col. 9, ll. 3–7. Based on the ordinary meaning of “vessel” and the disclosure in the ’532 patent, we do not find sufficient evidence to support the more expansive interpretation that it would include “any and all tubing exiting” the vessel because tubing that is connected to a cultivation vessel, for example, for adding reagents, etc, is not volume that is used for culturing cells. RAN 8.

The Examiner relied on statements by Patent Owner said to be an admission that “within an embodiment of the invention, the presence of tubing can constitute part of the ‘single continuous volume’ of the cultivation vessel.” RAN 11. We have reviewed this statement by Patent Owner on page 43 of the Response filed Dec. 19, 2013. The Examiner’s characterization of Patent Owner’s response is accurate. Patent Owner states:

If one were to connect two culture vials such that their individual volumes were connected in an uninterrupted fashion (such as connecting them with uninterrupted tubing), thereby combining the two volumes, then this would satisfy the claim limitation “. . . the cultivation vessel comprises walls that define a single continuous volume or a non-planar surface that defines a single continuous volume . . .”

Id.

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8 http://www.merriam-webster.com/dictionary/vessel
However, it is not reasonable to construe two connected culture vials as a “cultivation vessel” because doing so essentially eviscerates the meaning of vessel as a container. To construe a “vessel” to be two vessels connected together by tubing, or a container with tubing exiting from it, would be like calling any configuration a “vessel” which contains a continuous volume, such as the entirety of a sink with the drain pipes, drain pipes connecting to the sewer, and the sewer.

The Examiner refers to Patent Owner’s argument about two vials connected by tubing as being continuous, and finds it contradictory to Patent Owner’s narrower arguments at other places in their response that tubing is excluded. Id. at 42. While we understand the Examiner’s frustration with Patent Owner’s remarks, nonetheless it is the language of the claim which is controlling and how that it is interpreted in the context of the patent’s written description. Morris, 127 F.3d at 1054. In this case, there is no persuasive support for the interpretation that a vessel would include the tubing which projects from it, other than Patent Owner’s own confusing statements.

Optical sensors inside vessel

According to the claim, the continuous volume is defined by the walls or a surface of the cultivation vessel (“wherein the cultivation vessel comprises, walls”). Step (a) of the claim recites that “at least two types of optical chemical sensors positioned within the single continuous volume.” Because the walls or surface of the vessel define the “continuous volume,” we interpret the claim to require that the optical sensors are within the cultivation vessel. Step (b) of the claim recites that “continuous culture medium” is placed within the continuous
volume. The culture medium is therefore also required to be in the cultivation vessel.

4. INDEFINITENESS REJECTION

The Examiner found that the claims are not in compliance with Section 112, second paragraph, because the term “continuous volume” is indefinite. RAN 41. The Examiner contends that construing the term “continuous” as meaning “uninterrupted” as defined by Patent Owner would require the vessel to be completely closed without inlet or outlet ports, and therefore could not function as a cultivation vessel. *Id.*

We do not find this argument to be persuasive since the claims require the vessel to be suitable for cultivation, i.e., a “cultivation vessel” is claimed. Consequently, we cannot agree with the Examiner’s argument. The rejection is reversed.

5. ANTICIPATION BY WEIGLE

The Examiner found that claims 1, 3, and 4 are anticipated by Weigl. RAN 13. The following findings of fact (“FF”) are pertinent to this determination:


FF2. Each of the parameters is measured by a sensor which is a “flow-through cell.” *Id.* at 128.

FF3. “The electronic system consists of three independent opto-electronic units (one for each chemical species), each controlled by one micro-controller, and built into one housing.” *Id.*
FF4. “The flow through cells comprise stainless steel sensor heads mounted together on a steel support” to form “a flow through unit.” *Id.*

FF5. Weigl depicts a flow through cell for measuring pH and carbon dioxide in Fig. 2 reproduced below:

![Flow through cell diagram](image)

Fig. 2 shows a flow through cell for measuring pH or carbon dioxide. RAN 18 (“In view of . . . the description of Figure 2 on page 129 and the text on page 132, the flow-through cell shown in Figure 2 is a configuration that may contain either the pH optoelectronic unit or the CO₂ optoelectronic unit.”). The cell contains an inlet for introducing “sample” into the cell and an outlet for “waste.”

FF6. Weigl states that “we are presently testing and using the sensors in bioreactors in an ongoing project.” *Id.* at 137.

FF7. The Examiner found claim 1 is anticipated by Weigl for the following reason:

the broad definition of a “cultivation vessel” as provided at columns 8 and 9 of the ’532 patent includes any and all tubing connecting the culture vessel to any flow-through cell unit. Thus there is a
“continuous culture medium” that is part of the “single continuous volume of the cultivation vessel.” The triple sensor unit of Figure 1 has independent optoelectronic units for each parameter being measured, yet because the triple sensor is considered part of the continuous volume of the cultivation medium along with the cultivation vessel, the entirety of the bioreactor, tubing, and triple-sensor unit together anticipates the claimed invention.

RAN 18.

Discussion

Claim 1 requires “at least two types of optical chemical sensors positioned within the single continuous volume.” We have interpreted this language to require that the sensors are inside the cultivation vessel whose walls define the continuous volume. The issue in this rejection is whether two optical sensors of Weigl, namely the flow through cells, are positioned within Weigl’s cultivation vessel.

The Examiner contends that the flow through cells are within the bioreactor in Weigl because they are connected to it by tubing and the tubing is part of the vessel. FF7. Requester, relying on statements in Weigl that it is testing and using sensors “in bioreactors” (FF6), argues that claim limitations are satisfied because Weigl expressly teaches the triple sensor is inside the bioreactor. Resp’t Br. 6.

These arguments are not supported by a preponderance of the evidence.

First, the Examiner’s interpretation of the claimed “cultivation vessel” to include the tubing and flow through cells outside it is not the broadest reasonable interpretation of the claim as discussed in the Section 112 rejections and “Claim Interpretation” section above. Consequently, the rejection cannot be sustained based on the Examiner’s reasoning.
Second, Requester’s alternative basis that the flow through cells described by Weigl are inside the bioreactor is not supported by a preponderance of the evidence. While Weigl mentions “testing and using the sensors in bioreactors” (FF6), the only configuration of the triple sensor unit described in Weigl is of a housing containing three separate units, with an inlet for a sample and outlet for waste for each unit. FF1, FF3, FF5. The disclosure provides no explanation as to how this configuration would be positioned with respect to a cultivation vessel as required by the claim. Weigl does not explain with sufficient specificity to find that the sample inlet and waste outlet for each flow through cell would be configured with respect to the vessel container so as to form a continuous volume. Moreover, Weigl does not enables placing the housing comprising all three triple sensor units inside a single cultivation vessel as required by the claims. *In re Samour*, 571 F.2d 559 (CCPA 1978); *Schering Corp. v. Geneva Pharm.*, 339 F.3d 1373, 1381 (Fed. Cir. 2003) (prior art reference must be enabling).

6. OBVIOUSNESS IN VIEW OF WEIGL AND BAMBOT

The Examiner found that claims 1, 3–6, 9–11, 13–16, 19, and 20 are obvious in view of Weigl and Bambot. RAN 19. The Examiner found that Weigl teaches measuring three parameters, pH, carbon dioxide, and oxygen. *Id.* at 19–20. Weigl does not describe the sensors positioned inside the cultivation vessel. However, the Examiner found that “Bambot teaches that these sensors do not have to be placed outside of the bioreactor, but may be in the bioreactor itself, positioned on the bioreactor wall and in contact with the continuous culture medium.” *Id.* at 21–22. The Examiner concluded in a well-reasoned statement of the rejection:

Given the teachings of Weigl taken in combination with Bambot, it would have been obvious to measure various bioreactor
culture parameters by utilizing any number of optical chemical sensors positioned inside the bioreactor, attached to the interior of the bioreactor. Each optical chemical sensor is excited using at least one excitation source per optical chemical sensor, and there is at least one detector for each type of optical chemical sensor. Weigl teaches the concept of using a separate detector and light source for each separate optical chemical sensor for the purpose of simultaneously monitoring different cultural parameters.

*Id.* at 21.

Findings of Fact

The following findings of fact summarize the pertinence of Bambot to the rejection:

FF8.

The availability of sensors that can be integrated on-line into the bioreactor, require minimal maintenance and calibration, have high sensitivity and are readily sterilized, would dramatically improve bioprocess management. . . . The technology we describe here, lifetime-based phase-modulation fluorimetry, is particularly applicable to making optical measurements in biological media since it is relatively insensitive to interference. . . . although our discussion focuses on application to bioprocess monitoring . . .

Bambot 107.

FF9. Bambot describes an oxygen sensor (*id.* at 109; *id.* at 111 (“The sensor performed satisfactorily in a bioreactor environment”)), a pH sensor (*id.*), pCO₂ sensor (*id.*), and a glucose sensor (*id.* at 112). Each sensor can have its own excitation source (*id.* at 109 (blue LED), 111 (red laser diode, etc.).

FF10. “The sensor element can be mounted on a glass window and glucose can be optically monitored with a fiber bundle from outside the bioreactor.” *Id.* at 112.
FF11.
Spinner flasks used for hybridoma growth were set up with oxygen-sensitive Ru complex-containing patches (orange squares) stuck inside prior to sterilization. Both headspace- and medium-oxygen tensions can be monitored. Monitoring is accomplished by holding the fiber bundle flush against the glass door of the CO2 incubator and directly illuminating the sensor patch.

*Id.* at 112 (legend to Fig. 3).

FF12.
As an example of its versatility, in Fig. 3 we show an application where oxygen levels are being monitored in spinner flasks that have a silicon oxygen sensor patch attached to the interior. Oxygen readings are taken by simply interrogating the patch from outside with a fiber bundle that provides blue excitation light and carries back the emission to a photomultiplier tube (see Fig. 1b).

*Id.* at 114.

FF13.
In the bioprocess industry, spinner flasks, roller bottles and shaker flasks are commonly employed as bioreactors, and are currently not instrumented at all. In principle, it should be possible to monitor oxygen levels (and other analytes) economically in all these bioreactors using a similar approach …

*Id.*

FF14. “An example would be an instrument such as the combination O2, CO2, and pH sensors for blood-gas monitoring . . . . Similar concepts are applicable to bioreactor monitoring.” *Id.*

Discussion
As found by the Examiner, Bambot describes positioning a sensor inside a bioreactor, where the bioreactor can be a spinner flask, roller bottle, or shaker
flask. FF8–13. Bambot, like Weigl, teaches measuring multiple analytes using different optical sensors. FF1, FF13, FF14. Accordingly, a preponderance of the evidence support the Examiner’s determination that it would have been obvious to one of ordinary skill in the art to provide a “cultivation vessel” that comprises “walls that define a single continuous volume or a non-planar surface that defines a single continuous volume, and at least two types of optical chemical sensors positioned within the single continuous volume” as recited in the claims.

Patent Owner argues in the Rebuttal Brief (“Rebuttal Br.”) that, based on Weigl’s teaching that CO2 sensor has a poor chemical and mechanical stability, “a person of ordinary skill in the art would have been led to not insert a pH membrane and a CO2 membrane in a common cultivation vessel, because the performance of the sensors collectively would be limited by the weakest component, in this case the CO2 sensor.” Rebuttal Br. 13. This argument is not persuasive since the rejection is based on using Bambot’s sensor CO2 sensor, which operates independently of the other sensors. FF9. Patent Owner’s arguments focus on Weigl alone, when the rejection is based on Weigl and Bambot.

Patent Owner also contends that “Bambot provides very little teaching, if any, with regards to the simultaneous monitoring of parameters in a continuous culture medium that resides within the single continuous volume of the cultivation vessel.” Appeal Br. 32.

The claims do not require simultaneous monitoring. The claims only require positioning at least two types of optical sensors in the cultivation vessel’s continuous volume. Weigl teaches sensors for separately measuring O2, CO2, and pH for use with a bioreactor. In addition to positioning sensors within a cultivation vessel (FF10 and FF12), Bambot suggests measuring multiple analytes (FF13 (“it
should be possible to monitor oxygen levels (and other analytes) economically in all these bioreactors”); FF14 (“An example would be an instrument such as the combination O₂, CO₂, and pH sensors for blood-gas monitoring . . . . Similar concepts are applicable to bioreactor monitoring.”). Bambot also describes including more than one oxygen sensor (measuring two different oxygen levels) in a single cultivation vessel. Because each of Bambot’s sensors operate independently, it would have been obvious to arrange more than one sensor inside a cultivation vessel and using the light excitation and detection means described in Bambot for each one. FF9–FF12.

For the reasons described above, we affirm the rejection of claim 1 as obvious in view of Weigl and Bambot. Independent claims 6, 11, and 16 have similar limitations and are affirmed for the same reason as claim 1 and those of the Examiner. Dependent claims 3–6, 9, 10, 13–15, 19, and 20 fall with the independent claims because separate reasons for their patentability were not provided. See 37 C.F.R. § 41.67(c)(vii).

TIME PERIOD FOR RESPONSE

In accordance with 37 C.F.R. § 41.79(a)(1), the “[p]arties to the appeal may file a request for rehearing of the decision within one month of the date of . . . [t]he original decision of the Board under § 41.77(a).” A request for rehearing must be in compliance with 37 C.F.R. § 41.79(b). Comments in opposition to the request and additional requests for rehearing must be in accordance with 37 C.F.R. § 41.79(c)-(d), respectively. Under 37 C.F.R. § 41.79(e), the times for requesting rehearing under paragraph (a) of this section, for requesting further rehearing under
paragraph (d) of this section, and for submitting comments under paragraph (c) of this section may not be extended.

An appeal to the United States Court of Appeals for the Federal Circuit under 35 U.S.C. §§ 141-144 and 315 and 37 C.F.R. § 1.983 for an *inter partes* reexamination proceeding “commenced” on or after November 2, 2002 may not be taken “until all parties’ rights to request rehearing have been exhausted, at which time the decision of the Board is final and appealable by any party to the appeal to the Board.” 37 C.F.R. § 41.81. See also MPEP § 2682 (8th ed., Rev. 7, July 2008).

In the event neither party files a request for rehearing within the time provided in 37 C.F.R. § 41.79, and this decision becomes final and appealable under 37 C.F.R. § 41.81, a party seeking judicial review must timely serve notice on the Director of the United States Patent and Trademark Office. See 37 C.F.R. §§ 90.1 and 1.983.

**AFFIRMED**

GUEST, *concurring*.


While I agree that a cultivation vessel as understood by one of ordinary skill in the art as informed by the specification of the ’532 Patent would be a vessel
suitable for culturing cells, the claims do not appear to be limited to vessels of any regular shape. To the contrary, the ’532 Patent describes cultivation tubes and bags that would not necessarily have a regular shape. ’532 Patent, col. col. 8, l. 58 – col. 9, l. 8. Thus, a vessel that includes more than one regularly shaped vessel connected by tubing, which is capable of containing a continuous culture medium and a cell culture in a continuous irregular shaped volume within the entire structure, would read on the claimed cultivation vessel, as the irregular shaped volume would nonetheless constitute a single cultivation vessel. Similarly, I find that the ’532 Patent’s disclosure of microchips and culture tubes (id.) reasonably provide written descriptive support for continuous reactors or plug-flow reactors, which were well-known at the time of the invention, in which the defined “single continuous volume” is where the reaction occurs but, may nonetheless be moving through a system.

I agree that not every container necessarily would fall within the scope of the term “cultivation vessel,” only those already suitable for culturing cells – i.e., already bioreactors. Yet, if cells could be cultured in a glove, though there is no evidence of record to support that this would be the case, it is reasonable to conclude that sensors of the type described in Bambot could be positioned therein.

Further, I can easily reconcile Patent Owner’s arguments with respect to distinguishing “any and all tubing exiting” the vessel. More than one type of tubing could be extending from a cultivation vessel. A tube could be there to add air or reagents or to eliminate waste or remove a culture sample for testing, etc. Such tubing would not be considered part of the cultivation vessel or the “single continuous volume” because the cells are not cultured in this tubing. Yet, I understand that any tubing that is part of the volume in which cells are cultured
constitutes part of a continuous volume of the cell culture. Again, neither the claim language nor the ’532 Patent requires the vessel or the volume have a regular shape. It is my understanding that the Patent Owner, in limiting the “bioreactor” to a “cultivation vessel” by amendment, attempted to distinguish the location where the cells are being cultured from any other portion, tubing, equipment, etc. that might otherwise be part of a “bioreactor,” which could be interpreted to include not only a collection vessel, but also any other included equipment in a reactor structure. Thus, the sensors recited in the claim must be positioned within a certain location in a bioreactor, namely within the cultivation vessel. To the extent that cells are cultured in a tubular vessel and sensors are put within the tubes, I would think it would read on the claim and would be consistent with the disclosed invention.

Thus, I agree with the majority that Weigl does not anticipate the claimed invention. Weigl mentions “testing and using the sensors in bioreactors.” FF6. However, there is no disclosure that Weigl’s sensors are even connected to a cultivation vessel, let alone that the sensors are positioned within a cultivation vessel that contains an active cell culture. All testing described in Weigl is for calibration purposes, and does not described samples provided from an actual bioreactor. Accordingly, it is unclear how a “sample” would be obtained from a bioreactor or if even connected thereto. Weigl merely discloses providing samples of material in a tubing for testing. These may be samples completely removed from a cultivation vessel. Moreover, even if each set of tubing contains a cell culture, which is not supported by a fair reading of Weigl, and thus would constitute a “cultivation vessel,” there is only one sensor in each set of tubing acting on each sample. Neither the Examiner nor the Requester direct us to
evidence to support a finding that the three separate units are configured in any way with respect to a single cultivation vessel, and in particular to not teach two or more sensors in a single cultivation vessel. The invention must have been known to the art in the detail of the claim; that is, all of the elements and limitations of the claim must be shown in a single prior reference, arranged as in the claim. *Karsten Mfg. Corp. v. Cleveland Golf Co.*, 242 F.3d 1376, 1383 (Fed. Cir. 2001); *Verve, LLC v. Crane Cams, Inc.*, 311 F.3d 1116, 1120 (Fed. Cir. 2002) (“A single reference must describe the claimed invention with sufficient precision and detail to establish that the subject matter existed in the prior art.”).

This broader claim interpretation does not affect the majority’s determination with respect to the Examiner’s obviousness rejection. I agree that Weigl and Bambot teach the desire to include sensors for more than one analyte in a cell culture, and Bambot describe that positioning sensors within a cultivation vessel was a practice known in the art with improved versatility.
Appeal 2015-006297
Reexamination Control 95/000,615
Patent 6,673,532 B2

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