UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

Corning Incorporated,

Plaintiff,

v.

Wilson Wolf Manufacturing Corporation, and John R. Wilson,

Defendants.

Civil No. 20-700 (DWF/TNL)

MEMORANDUM OPINION AND ORDER

Ivan Poullaos, Esq., and Kimball R. Anderson, Esq., Winston & Strawn LLP; Jeff M. Barron, Esq., Barnes & Thornburg LLP; and Lora Mitchell Friedemann, Esq., Fredrickson & Byron, PA, counsel for Plaintiff.

Britta S. Loftus, Esq., Devan V. Padmanabhan, Esq., Erin O. Dungan, Esq., Mariah L. Reynolds, Esq., Michelle E. Dawson, Esq., Paul J. Robbennolt, Esq., and Sri K. Sankaran, Esq., Padmanabhan & Dawson, P.L.L.C., counsel for Defendants.

INTRODUCTION

This matter is before the Court on the issue of patent claim construction pursuant to *Markman v. Westview Instruments, Inc*., 517 U.S. 370 (1996). The Court considers the claim construction issues below.

BACKGROUND

This case is closely related to another case pending before the Court involving the same parties and similar technology. *See John R. Wilson et. al. v. Corning, Inc.*, Civ. No. 13-210 (D. Minn.) (the "2013 Lawsuit"). In the 2013 Lawsuit, Wilson Wolf alleged, among other things, that Corning's HYPERStack device—the same product at issue here—infringed two patents that are from the same family as two patents at issue here.

Specifically, in the 2013 Lawsuit, Wilson Wolf alleged that Corning infringed U.S. Patent No. 8,158,426 (the "'426 Patent") and U.S. Patent No. 8,158,427 (the "'427 Patent"), both entitled "Cell Culture Methods and Devices Utilizing Gas Permeable Materials." (ECF 13-210, Doc. No. 1 ("Compl.") ¶¶ 164-71.) Before patent claims were construed in that case, the Court dismissed Wilson Wolf's patent infringement claims. (ECF 13-210, Doc. No. 299.) At issue here are U.S. Patent Nos. 9,441,192, entitled "Cell Culture Methods and Devices Utilizing Gas Permeable Materials" (the "'192 Patent"); 8,697,443, entitled "Cell Culture Methods and Devices Utilizing Gas Permeable Materials" (the "'443 Patent"); and 9,732,317, entitled "Highly Efficient Gas Permeable Devices and Methods for Culturing Cells" (the "'317 Patent") (together, the "patents-in-suit").[1]

Like in the 2013 Lawsuit, this action involves technologies for cell culture, which is the process by which cells are grown in a laboratory environment. The Court summarizes the technology below.

Cells, referred to as the "building blocks of life," contain genetic material and are the smallest biological unit of life that can replicate independently. In order to survive, grow, and replicate, cells require oxygen and nutrients that are obtained from their surroundings. Cells multiply by copying their own genetic material and dividing into two

[1] The patents-in-suit are attached as Corning's Exhibits submitted in support of its claim construction brief. (Doc. No. 115 ("Poullaos Decl.").) The '192 Patent is attached as Exhibit 1, the '443 Patent is attached as Exhibit 2, and the '317 Patent is attached as Exhibit 3. Corning has challenged the validity of the patents-in-suit in pending reexamination proceedings. (Doc. No. 114 at 2.)

cells. "Cell culture" refers to the growth of cells outside of their normal environment, such as in a laboratory in specially designed containers and under precise conditions. The techniques of cell culture allow scientists to use cell cultures for experimental studies and biological testing. Cells being cultured are placed in a nutrient liquid called "medium," which contains substances required for cell growth. There must also be a means for allowing oxygen to reach the cells.

Various types of vessels may be used to culture cells, such as bags, petri dishes, flasks, and roller bottles. Some of these devices are capable of operating in whole or part under static conditions, and there are two broad categories of such "static devices." First, in a traditional flask, cells are grown in a thin layer of liquid medium at the bottom of the flask: the medium provides the nutrients and the gas above the medium provides oxygen. When a vessel is only partially filled with medium, the area that is occupied by gas is referred to as the "head space." The surface at which the air meets the medium is referred to as a "gas-liquid interface." In these types of vessels, the oxygen from the headspace must travel down through the liquid medium to reach the cells on the bottom of the flask. Thus, the greater the depth of the medium, the farther the oxygen must travel. The use of space in a cell culture flask is inefficient, using only a small fraction of the flask volume for media and large portion for gas. These types of flasks are further limited by the fact that the cells are normally cultured in an incubator and the incubator space is also limited. Second, another type of static cell culture device uses "gas permeable" membranes. Gas permeable membranes allow oxygen and other gases to pass through, but are impermeable to liquids and larger molecules, thus allowing gas to

enter the device while preventing the liquid medium from escaping. The use of a gas permeable membrane in a cell culture device has several benefits: it eliminates the need to store gas above the medium (thus freeing up space in the flask for the use of more medium); it allows multiple cell culture cells to breathe through gas permeable material; and it allows multiple cell culture shelves to be stacked on top of each other (thus allowing more cells to be grown simultaneously).

The '192 Patent and '443 Patent share identical specifications and are in the same family as the '426 and '427 Patents.[2] These patents are generally directed to cell culture devices and methods of using them to improve cell culture efficiency. ('192 Patent, 1:14-15.) The specification notes that traditional cell culture devices that relied on a gas-liquid interface were "inefficient in terms of labor, sterilization cost, shipping cost, storage cost, use of incubator space, disposal cost, and contamination risk." (*Id*., 16:36-39.) The patents note that prior gas permeable devices were also inefficient "because they have a low height of medium, use a high gas permeable surface area to medium volume, house a small volume of medium, and require a very large number of units to be maintained during scale up." (*Id*., 16:51-55.) The '192 and '443 Patents note the need for improved cell culture devices and methods to increase efficiency to scaled cell culture research. (*Id*., 16:33-35.) The inventors subsequently discovered that "it can be beneficial to

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[2] While the '192 and '443 Patents share a specification, the '192 Patent is a divisional application for an independent invention. *See Pfizer, Inc. v. Teva Pharms. USA, Inc.*, 518 F.3d 1353, 1360 (Fed. Cir. 2008) (explaining that a divisional application is defined as "[a] later application for an independent or distinct invention, carved out of a pending application and disclosing and claiming only subject matter disclosed in the earlier or parent application") (citation omitted).

increase medium height beyond that dictated by conventional wisdom or allowed in commercially available devices." (*Id*., 17:15-20.) As to the claimed invention, the specification states:

> Certain embodiments disclosed herein provide more efficient cell culture devices and methods, that overcome the limitations of prior devices and methods, by creating gas permeable devices that can integrate a variety of novel attributes. These various attributes include gas exchange without reliance upon a gas/liquid interface, increased medium height, reduced gas permeable surface area to medium volume ratios, gas exchange through the device side walls, cell support scaffolds that are comprised of traditional materials, and increased gas permeable material thickness.

(*Id*., 17:1-11.) The '192 and '443 Patents also explain that the claimed invention allows gas permeable devices to integrate "traditional scaffolds." (*Id*., 17:52-55.)

The '317 Patent is in a different family of patents and generally relates to cell culture devices having two or more gas permeable cell culture compartments with an external gas space between them:

> The present invention overcomes many of the disadvantages of existing static cell culture devices by integrating at least two gas permeable culture compartments that, at least in part, maintain a gas space between them in order to allow gas to contact the gas permeable area of the culture compartments. This allows each culture compartment to exchange gas directly with the gas space adjacent to the culture compartment, minimizing the potential for non-uniform culture conditions.

('317 Patent, 4:30-38.) In addition, the '317 Patent notes:

> It is an object of the present invention to provide improved cell culture devices and methods that minimize the potential for non-uniform culture conditions to exist throughout the device, allow space efficient culture scale up of adherent or suspension cells, are easy to use, can function without need to perfuse medium or gas, and allow the user to make effective use of the upper, lower, or sidewall surfaces of each culture compartment.

(*Id*., 4:17-24.)

In this case, Corning seeks, among other things, a declaration that its HYPERStack product,[3] as used by Sarpenta, Brammer Bio, NCH, and TRI, has not infringed and does not infringe, either directly or indirectly, any valid and enforceable claim of the patents-in-suit. Specifically, Corning asserts the following causes of action: (1) Declaration of Non-Infringement of the '192 Patent; (2) Declaration of Unenforceability of the '192 Patent; (3) Declaration of Invalidity of the '192 Patent; (4) Declaration of Non-Infringement of the '443 Patent; (5) Declaration of Unenforceability of the '443 Patent; (6) Declaration of Invalidity of the '443 Patent; (7) Declaration of Non-Infringement of the '317 Patent; (8) Declaration of Unenforceability of the '317 Patent; (9) Declaration of Invalidity of the '317 Patent; (10) Declaration of Application of Safe Harbor Under 35 U.S.C. § 271(e)(1); (11) Declaration of Claim Preclusion; (12) Declaration of Preclusion Under the Kessler Doctrine; and (13) Tortious Interference With Prospective Economic Advantage. (Doc. No. 73 ("Am. Compl.").)

DISCUSSION

I. General Principles of Claim Construction

Patent claim construction, *i.e.*, the interpretation of the patent claims that define the scope of the patent, is a matter of law for the court. *Markman*, 517 U.S. at 390. Proper claim construction requires an examination of the intrinsic evidence of record,

[3] The HYPERStack device is a cell culturing vessel designed to culture cells that adhere to a surface, as opposed to being suspended in medium. It is comprised of thin, stackable chambers (or cartridges/stackettes), each with a gas-permeable film and a thin layer of medium. (*See* Doc. No. 114 at 8-9.)

including the claim language, the specification, and the prosecution history. *Bell Atl. Network Servs., Inc. v. Covad Commc'ns Grp., Inc.*, 262 F.3d 1258, 1267 (Fed. Cir. 2001); *Vitronics Corp. v. Conceptronic, Inc*., 90 F.3d 1576, 1582 (Fed. Cir. 1996). The starting point for claim construction is a review of the words of the claims themselves. *Phillips v. AWH Corp*., 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc) (citation omitted); *see also Vitronics*, 90 F.3d at 1582 ("First, we look to the words of the claims themselves, both asserted and nonasserted, to define the scope of the patented invention."). The words of a claim generally carry "the meaning that the term would have to a person of ordinary skill in the art at the time of the invention." *Phillips*, 415 F.3d at 1313. Claims must also be read in view of the specification. *Id.* at 1315.

The specification is always "highly relevant" to claim construction and "the single best guide to the meaning of a disputed term." *Id*. (quoting *Vitronics*, 90 F.3d at 1582.) "[T]he specification necessarily informs the proper construction of the claims." *Phillips*, 415 F.3d at 1316 (citation omitted) (explaining that the claims must be construed so as to be consistent with the specification). The specification may prescribe a special definition given to a claim term that differs from the meaning it would otherwise possess, or it may reveal a disavowal or disclaimer of claim scope by the inventor. *Id*. In such cases, the intention that is expressed by the inventor in the specification is dispositive. *Id*. The Court may not, however, import limitations from the specification into the claims. *Id*. at 1323. To avoid importing limitations from the specification into the claims, the Court considers that "the purposes of the specification are to teach and enable those of skill in the art to make and use the invention and to provide a best mode for doing so." *Id*. To

act as its own lexicographer, a patentee must "clearly set forth a definition of the disputed claim term" other than its plain and ordinary meaning. *Thorner v. Sony Comput. Ent. Am. LLC*, 669 F.3d 1362, 1365 (Fed. Cir. 2012) (citation omitted). It is not enough that patentee simply disclose a single embodiment or use a word in the same manner in all embodiments to show a clearly expressed intent to redefine a term. *Id*.

The Court "should also consider the patent's prosecution history," which "provides evidence of how the [United States Patent and Trademark Office ("USPTO")] and the inventor understood the patent." *Phillips*, 415 F.3d at 1317 (citation omitted). The prosecution history "consists of the complete record of the proceedings before the [USPTO] and includes the prior art cited during the examination of the patent." *Id*. at 1317. The prosecution history may "inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be." *Id*. (citing *Vitronics*, 90 F.3d at 1582-83).

A court may, in its discretion, consider extrinsic evidence, though such evidence is less reliable than intrinsic evidence. *Phillips*, 415 F.3d at 1317-18. In most situations, intrinsic evidence will resolve any ambiguity in a disputed term, and when it does so, the court may not rely on extrinsic evidence. *Vitronics*, 90 F.3d at 1583.

II. '192 Patent

1. "media height" limitations

Each independent claim of the '192 Patent recites the step of "adding medium and animal cells into a static cell culture device." Each claim then specifies that the distance

from "the lowermost location of said medium" to "the uppermost location of said medium" exceeds 2.0 cm.[4] Specifically, the relevant claim language requires that the "uppermost location of said medium" is "elevated," "above," or "beyond" the "lowermost location of said medium."[5] Corning submits that the "said medium" refers to the continuous height of the medium above the surface where the cells reside for culturing. Wilson Wolf argues that no construction is necessary and that the claim terms should be given their plain and ordinary meaning. Wilson Wolf further argues that Corning's proposed construction is confusing and ambiguous because the term "continuous height" is not present in the claim language itself. Instead, Wilson Wolf contends that a jury will easily and readily understand the concept of measuring the distance between the lowermost and uppermost locations of the medium.

Wilson Wolf argues that the location where the cells reside is not identical to the "lowermost location" of the medium. In support, Wilson Wolf points to Figure 6, which

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[4] Related limitations in dependent claims vary the specified distance.

[5] Claim 1: "adding medium and animal cells into a static cell culture device . . . the uppermost location of said medium is elevated beyond 2.0 cm from the lowermost location of said medium . . ."

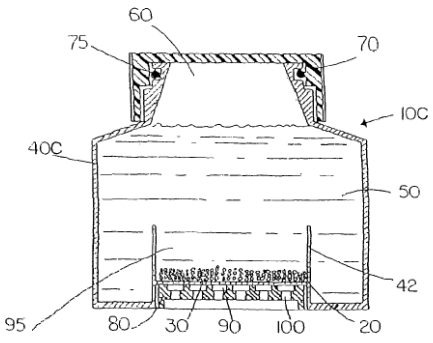
Claim 8: "adding medium and animal cells into a static cell culture device . . . the uppermost location of said medium is more than 2.0 cm above the lowermost location of said medium . . ."

Claim 18: "adding medium and animal cells into a static cell culture device . . . and the uppermost location of said medium is more than 2.0 cm above the lowermost location of said medium . . . "

Claim 25: "adding medium and animal cells into a static cell culture device . . . and the uppermost location of said medium is elevated more than 2.0 cm beyond the lowermost location of said medium . . ."

shows the "lowermost location" of the medium below the location of the cells, which are on a raised platform above the lowermost location of the medium.

FIG. 6



Wilson Wolf also argues that the specification contains embodiments in which the medium height is not continuous because the medium is maintained outside of the area directly above the cells (such as in Figure 6 above) or is interrupted by shelves and other structures. For example, Wilson Wolf submits that Figure 13 shows medium in a manifold that is in front of the cells and not above them and that Figures 10A and 13 show shelves, cells, and other structures inside the device breaking up any "continuous height" of medium.

Corning, however, correctly points out that the '192 Patent application, while sharing a specification with '443 Patent, is a divisional application for an independent invention. Corning also points out that the '192 Patent does not claim scaffolded embodiments, and thus, not all embodiments in the shared specification are *claimed* embodiments of the '192 Patent, And in particular, Figures 10A and 13 do not factor into the media height limitiations.

The claim language itself refers to adding medium and cells into a device that "is not compartmentalized by a semi-permeable membrane" and placing that device in a

location "wherein said cell culture device is oriented in a position such that at least a portion of said cells reside upon at least a portion of said gas permeable material, the uppermost location of said medium is elevated beyond 2.0 cm from the lowermost location of said medium." ('192 Patent, claim 1.) Further, the intrinsic record of the '192 Patent explains that the asserted novelty of the claimed cell culture device is that it "allow[s] an increased height of cell culture medium:"

> The technical field of the invention relates to methods and devices that improve cell culture efficiency. They utilize gas permeable materials for gas exchange, allow an increased height of cell culture medium, reduce the ratio of gas permeable device surface area to medium volume capacity, and integrate traditional cell support scaffolds.

(*Id*., 1:14-19.) The claimed novelty also allows for the increased height of medium directly above the cells (where the cells reside for culturing). For example, the Summary of the Invention explains:

> It has been discovered that for gas permeable devices comprised of a lower gas permeable material, it can be beneficial to increase medium height beyond that dictated by conventional wisdom or allowed in commercially available devices. It is contemplated by the inventors hereof that convection of substrates within a cell culture medium plays a more important role than previously recognized.

(*Id*., 17:15-19.)[6] In addition, the prosecution history demonstrates that the novelty of the

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[6] The Summary of the Invention goes on to explain that:

> It would appear that the historic reliance upon diffusion for mass transfer underestimates the contribution that convection makes. That would result in underestimating the rate of travel of substrates such as glucose and lactate in cell culture medium, and a failure to recognize that medium residing farther away from cells than traditionally allowed can be useful to the cells.

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invention is an increased continuous height of medium above the cells to be cultured. Specifically, in a Notice of Allowance, the USPTO found that the claims were patentable in part because the prior art "teaches away from media heights or chamber heights over 2.0 cm" or "fails to teach or suggest increasing medium height beyond 2.0 cm." (Doc. No. 115-9 at 3.) The use of the terms "media heights" and "chamber heights" interchangeably highlights an understanding that the distance between the "uppermost location" and "lowermost location" of "said medium" is the continuous height of medium above where the cells are cultured. Thus, it refers to the height of the medium within the cell culture compartment. This makes sense because, as recognized by Wilson Wolf, the patents arose from the alleged discovery that nutrients and oxygen can travel further through medium than originally thought.

The specification also distinguishes prior art devices that have shallow media height or limit the media height above the cells. (*See, e.g.*, '192 Patent, 4:9-11;10:15-22.) Moreover, embodiments described in the '192 Patent show the distance between the "uppermost location" and "lowermost location" of the same medium at continuous height above the cells. (*See, e.g.*, FIG. 4A & 22:31, 53-58 (explaining that this embodiment "allows medium **50** to reside at a uniform height above gas permeable material **30**" above

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('192 Patent,17:22-29.) The movement of nutrients and oxygen "farther away from cells than traditionally thought" (and thus increased media height) is relevant to the area where cells reside for culturing.

the cells (20).) While Wilson Wolf submits that the location where the cells reside is not identical to the "lowermost location" of the medium, there is no dispute that the height of the medium must be measured from the "lowermost location" and that the dispute between the parties is whether the medium height must be continuous.[7]

The Court finds that the intrinsic record demonstrates that the asserted benefit of the claimed invention is that it allows more continuous medium to reside above the cells. The Court construes each of the height limitations in the claims of the '192 Patent to mean the continuous height of medium residing above the surface where the cells reside for culturing.

2. "semi-permeable membrane"

The parties dispute the meaning of the term "semi-permeable membrane" as it appears in the '192 Patent. Each claim of the '192 Patent requires a cell culture device that is not compartmentalized by a "semi-permeable membrane." (*See* '192 Patent, claim 1: "A method of culturing cells comprising: adding medium and animal cells into a static cell culture device that is not compartmentalized by a semi-permeable membrane . . ."). Corning contends that the term "semi-permeable membrane" is

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[7] Wilson Wolf appears to argue that the media height limitations are met if there is a "manifold" and the "the volume of medium in each stackette is fluidly connected via the manifolds," such that the manifold height is greater than 2 cm. (Doc. No. 121 at 5.) However, as pointed out by Corning, the '192 Patent does not mention a manifold in the claim language or the specification, nor is the structure of a manifold present in the patent. The Court does not find support for using the manifold as a reference to measure the media height. Instead, a manifold that is used to fill a culture chamber appears to be irrelevant to measuring media height in the cell culture chamber.

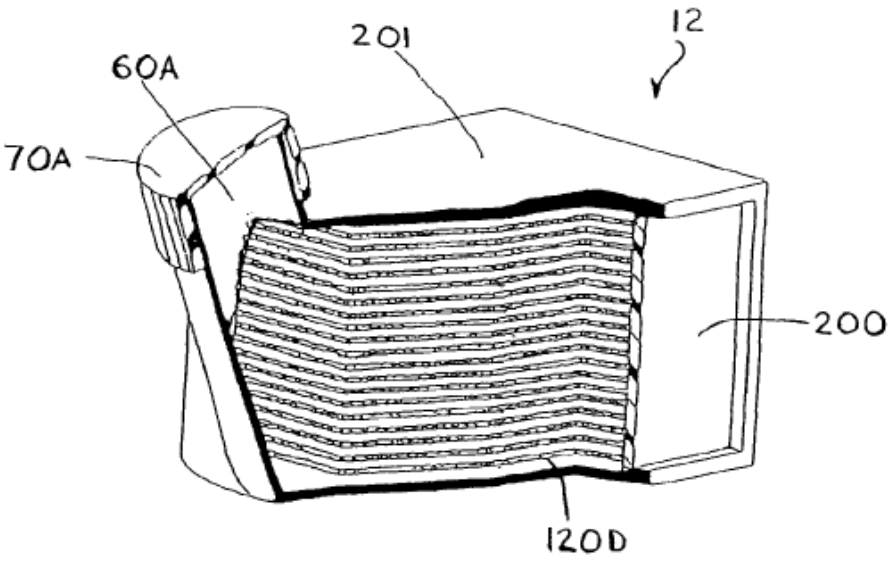
properly construed using its plain and ordinary meaning as "a membrane that allows the passage of certain molecules but prevents the passage of other molecules." Corning's construction of semi-permeable membrane encompasses membranes that are gas-permeable. Wilson Wolf does not dispute the plain meaning of the term but argues that the '192 Patent repeatedly and consistently uses "semi-permeable" in a specific way that is different than the plain and ordinary meaning. Specifically, Wilson Wolf asserts that "semi-permeable membrane" should be construed more narrowly as "a membrane that allows some solutes or substances in a liquid to pass through, but not all." Wilson Wolf's construction would exclude membranes that are only gas permeable.

Corning argues that its proposed construction is supported by the plain language of the claims, the specification, prosecution history, and extrinsic evidence. In particular, Corning stresses that the prefix "semi" has the meaning of "half" or "partially," and that "semi-permeable" therefore means partially permeable, including a membrane that is partially permeable to gas. (Doc. No. 116 ("Chalmers Decl.") ¶ 68.) Corning further submits that the specification and prosecution history do not provide any explicit definition of the term that would warrant deviating from the ordinary meaning, and that nothing in prior art disclosures contradict the concept that a gas-permeable membrane is a type of semi-permeable membrane.

Corning also submits that the patent's figures support the concept that a gas permeable material is a subset of the broader group of semi-permeable materials. For example, Corning points out that Figure 13 depicts an embodiment that includes "[s]caffolds **120**D [that] are oriented parallel to each other" ('192 Patent, 31:25-28) and

where "at least one wall of the device provides gas transfer" (*id*., 31:5-7).

FIG. 13



Corning submits that a person of ordinary skill in the art ("POSA") would understand that the gas-permeable material is on the wall (and not compartmentalizing), so as to permit the gas transfer. In addition, Corning points out that Figures 10 and 11 show embodiments with internal "scaffolds" (120) and a separate gas-permeable wall (40F & 40G), thus demonstrating that the claimed invention is not "compartmentalized" by any semi-permeable (or gas-permeable) membrane.

FIG. 10A

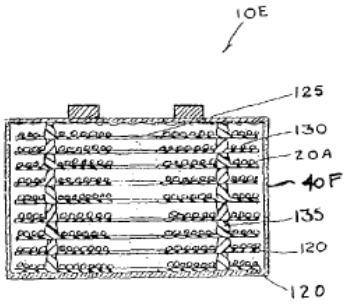


FIG. 10B

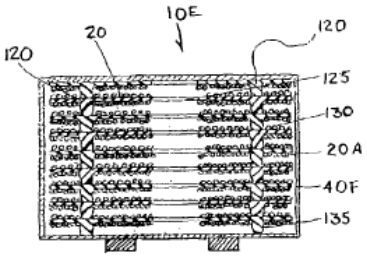
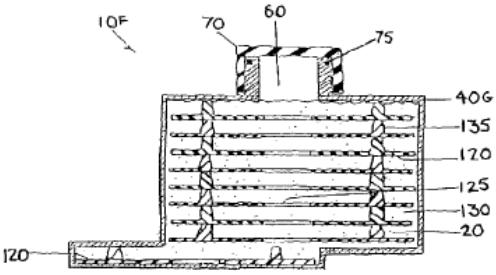


FIG. 11



Wilson Wolf submits that the term "semi permeable," as used by the patentee, does not include only gas-permeable materials. Wilson Wolf argues that "semi-permeable membranes" in the '192 Patent allow some solutes or substances in a liquid to pass through, but not all. Wilson Wolf further submits that gas-permeable materials would allow gas molecules to pass through, but not solutes or other materials. Wilson Wolf argues that the '192 Patent distinguishes gas-permeable materials from semi-permeable membranes and treats gas-permeable materials as distinct from semi-

permeable membranes. In addition, Wilson Wolf argues that the term "semi-permeable" must be a porous material. In support, Wilson Wolf points to the use of the term "semi-permeable" in the '192 Patent's discussion of prior art. Wilson Wolf argues that the term "semi-permeable" is only used a few times and each time only to include porous materials. (*See* '192 Patent, 9:20-10:42 (discussing prior art device that is compartmentalized by a semi-permeable dialysis membrane).) Wilson Wolf submits that in the discussion of a prior art patent, the '192 Patent makes clear that the term "semi-permeable" does not include membranes that are only gas permeable and that other uses of the term "semi-permeable" in the '192 Patent are consistent with how the term is used in the discussion of prior art. Because, as Wilson Wolf asserts, the patentee consistently used a single meaning of "semi-permeable" throughout the entire patent, Wilson Wolf argues that the term has been defined as such by implication. *See Bell Atl. Network Servs., Inc. v. Covad Commc'ns Grp., Inc.*, 262 F.3d 1258, 1268 (Fed. Cir. 2001).

The Court concludes that the plain and ordinary meaning of the term "semi-permeable membrane" could encompass membranes that are gas-permeable. In short, the Court concludes that Wilson Wolf has not adequately demonstrated that the inventors clearly defined the term semi-permeable differently than its plain and ordinary meaning. Moreover, Wilson Wolf has not made a showing that the patentees defined the term by implication. Instead, the '192 Patent specification does not contradict the concept that a gas-permeable membrane is a type of semi-permeable membrane. Therefore, the Court construes the term "semi-permeable membrane" as "a membrane that allows the passage of certain molecules but prevents the passage of other molecules."

3. "static cell culture device"

The parties dispute the meaning of the term "static cell culture device" as it appears in the '192 Patent. The claims of the '192 Patent require, directly or indirectly, a "static cell culture device." Corning proposes that the term be construed using the plain and ordinary meaning as "cell culture device that is capable of functioning in a static mode." Wilson Wolf asserts that the term should be construed as a device "without mixing or perfusion [pumping] equipment."[8]

Wilson Wolf argues that the patent explicitly defines "static device." In support, Wilson Wolf points to the specification, which states that static devices "do not require ancillary equipment to mix or perfuse the cell culture medium." ('192 Patent, l:47-51.) Further, Wilson Wolf submits that the '192 Patent explains that static devices do not have equipment to mix or perfuse (pump) the gas:

> Static devices can be subdivided into two broad categories, 1) those that are not gas permeable and oxygenate the cells by way of a gas/liquid interface and 2) those that are gas permeable and oxygenate the cells by way of gas transfer through the device housing.

(*Id*., l:51-55.) Corning, however, argues that Wilson Wolf's construction improperly reads limitations in the plain claim language that are contrary to the specification. Specifically, Corning maintains that the specification describes a static device as one that does not *require* perfusion equipment but also does not *require* that the device be free of such equipment.

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[8] Perfusion means to cause a liquid to flow, spread, or pass through something, such as by pumping.

Claim 1 recites "[a] method for culturing cells comprising: adding medium and animal cells into a static cell culture device . . . and said device is in a state of static cell culture." The claim language itself supports the conclusion that a static cell device need only be capable of functioning in a static mode. If the term "static cell culture device" required the claimed device to be free of perfusion equipment, the device would always be in a "state of static cell culture" and there would be no need to specify that the device be in such a state. In addition, claim 8 recites adding medium and cells into a "static cell culture device" wherein "said device is not subjected to mixing or perfusion." Again, if the device was required to be free of any mixing or perfusion equipment, claim 8 would be superfluous. In addition, the specification states that "[d]evices that minimize complexity *do not require* ancillary equipment to mix or perfuse the cell culture medium" and that such devices "are often referred to as static devices." ('192 Patent, l:48-51 (emphasis added).) The description of a static device as one that does not *require* perfusion equipment is consistent with a construction that a claimed cell culture device need only be capable of functioning in a static mode.

The Court concludes that this term is properly construed as "cell culture device that is capable of functioning in a static mode."

4. "ambient gas"

The parties dispute the meaning of the term "ambient gas" as it appears in the '192 Patent. The claims require that the device be placed "in a cell culture location that includes ambient gas at a composition suitable for animal cell culture." The '192 Patent recites that "ambient gas is in contact with at least a portion of gas permeable material"

(claim 1) or that "at least a portion of said gas permeable material is in contact with ambient gas" (claims 8, 18, 25).

Corning contends that the term "ambient gas" is properly construed as "gas of the environment surrounding and external to the multi-shelf apparatus." Wilson Wolf asserts that no construction of the term "ambient gas" is necessary and that the term should be given its plain and ordinary meaning as "a gas that encompasses and contacts the external surfaces of the cell culture device and has a particular set of characteristics."

Corning argues that its proposed construction is supported by the ordinary meaning of the term "ambient," the plain language of the claims, and that its definition has been adopted by the USPTO. Wilson Wolf submits that its definition of "ambient gas" correctly reflects the requirement that every claim requires that the device be placed "in a cell culture location that includes ambient gas" at a composition suitable for animal cell culture and that the "ambient gas" be "in contact with" "gas permeable material" that is a component of the device. Wilson Wolf further submits that Corning's proposed construction is confusing and unclear, as the definition does not require that the "ambient gas" contact the device and improperly requires a multi-shelf apparatus.[9]

Here, the Court agrees that the plain and ordinary meaning of "ambient" is "surrounding; encircling." (Doc. No. 115-14 (American Heritage Dictionary).) In addition, the USPTO has adopted the definition of "ambient gas" as "gas of the

[9] Corning does not dispute that the definition can be edited to refer simply to an "apparatus" for purposes of the '192 Patent.

environment surrounding and external to the cell culture device." (Doc. No. 115-13 at 3.) The Court concludes that the term "ambient gas" is properly construed as "gas of the environment surrounding and external to the apparatus."[10]

III. '443 Patent

1. "scaffolds/scaffold"

The parties dispute the meaning of the term "scaffolds/scaffold" as it appears in the '443 Patent. Each claim of the '433 Patent requires, directly or indirectly, a cell culture device including at least two "scaffolds."

> A method of culturing cells in a cell culture device comprised at least in part of a gas permeable material and including at least one access port and including at least two scaffolds, the method comprising
> a) adding cells and a volume of liquid medium into said cell culture device;
> b) orienting said cell culture device into an inoculation position such that said scaffolds reside at different elevations within said cell culture device;
> c) allowing cells to settle upon said scaffolds; . . .

('443 Patent, claim 1 (emphasis added).)

Corning submits that the plain and ordinary meaning of "scaffold" as used in the claims throughout the specification, is "a platform for cells to reside upon that is separate from the gas-permeable material." Wilson Wolf asserts that no construction is needed and that the plain and ordinary meaning of "scaffold" is "a platform for cells to reside on the top surface of."

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[10] The Court notes that Wilson Wolf's construction requiring that the gas "encompass and contact' the device is duplicative of the claim language that requires that ambient gas "contact" the device.

Corning argues that its construction is supported by the plain language of the claims and the specification. In particular, Corning points out that the claims themselves distinguish between the "scaffolds" and "gas-permeable material," which suggests that the terms have separate meanings. Corning also points out that claim 1 of the '192 Patent requires that "at least a portion of said cells reside upon at least a portion of said gas permeable material," while the claims of the '443 Patent do not. Corning submits that the gas-permeable material described in the '192 Patent for providing a surface for cells to reside is different from the "scaffolds" required in the '443 Patent. Corning further argues that the specification indicates that the claims' "scaffolds" are separate from gas-permeable material. For example, the Summary of the Invention reads in part: "This eliminates the need for excess device size that results from the presence of gas in traditional devices, and allows gas permeable devices to integrate traditional scaffolds." ('443 Patent, 17:24-27.) The specification also explains that a drawback of prior art devices was that "traditional scaffolds [had the] effect of inhibiting gas exchange at the cell location" and that "[g]as permeable materials should be located in a manner in which the attachment scaffold does not prevent adequate gas transfer." (*Id*., 14:10-16.) This language suggests that the scaffolds themselves are not gas permeable. And the claimed invention provides gas permeable material on a structure other than the scaffolds:

> The inventive apparatus and methods herein demonstrate that the gas/liquid interface is not necessary for adequate gas exchange when a wall of a device is gas permeable, scaffolds are present, and the device is operated in a static mode.

(*Id*., 17:21-24.) Moreover, the specification consistently explains that novel aspects of

the claimed invention include gas transfer through other structures, such as the side walls:

> Certain embodiments disclosed herein provide more efficient cell culture devices and methods, that overcome the limitations of prior devices and methods, by creating gas permeable devices that can integrate a variety of novel attributes. These various attributes include gas exchanges without reliance upon a gas/liquid interface, increased medium height, reduced gas permeable surface areas to medium volume ratios, gas exchange through the device side walls, cell support scaffolds that are comprised of traditional materials, and increased gas permeable material thickness.

(*Id*., 16:41-50.)[11]

Wilson Wolf argues that the ordinary meaning of the term scaffold is a structure or platform that holds something above it or allows something to rest on its surface. Wilson Wolf points to the claim language stating that the cell culture device contains multiple scaffolds, that the device is placed in an inoculation position such that the scaffolds reside at different elevations, and that cells are allowed to settle upon the scaffolds. Thus, Wilson Wolf maintains that the construction must specify that the cells reside on the top of the surface of the scaffolds. Wilson Wolf further argues that Corning's construction improperly introduces a limitation not found in the claims—that the scaffolds "are separate from gas permeable material." In particular, Wilson Wolf maintains that the claims do not limit the material that scaffolds are made of and, therefore, may be comprised partially, entirely, or not at all of gas permeable material. Wilson Wolf also argues that the specification discloses embodiments with cell growth surfaces that are gas

[11] Both Figure 10 and 11 depict embodiments where sidewalls are comprised of gas permeable materials with internal scaffolds.

permeable. (*See* '443 Patent, 26:17-38 & FIG. 6.)

Here, the Court concludes Corning correctly points out that the gas-permeable material described in the '192 Patent for providing a surface for cells to reside upon is different from the "scaffolds" required by the '443 Patent. The '443 patent distinguishes between the "scaffolds" within the cell culture device and the gas permeable material that is in contact with the ambient air on the exterior of the devices. Importantly, the '443 Patent is directed at allowing gas permeable devices to integrate scaffolds that have the effect of inhibiting gas exchange. Even accepting Wilson Wolf's argument that the patent does not limit what type of material of a scaffold, the patent is clear that the scaffolds and gas-permeable material are distinct structures. Accordingly, the Court construes the term as "a platform for cells to reside upon that is separate from the gas-permeable material."

2. "inoculation position"

The parties dispute the meaning of the term "inoculation position" as it appears in the '443 Patent. The claims of the '433 Patent require, in part, the steps of orienting the device into an "inoculation position" and "adding enough liquid medium to prevent a unique-gas liquid interface from forming directly above at least one scaffold." Specifically, claim 1 reads:

> A method of culturing cells in a cell culture device comprised at least in part of a gas permeable material and including at least one access port and including at least two scaffolds, the method comprising
> a) adding cells and a volume of liquid medium into said cell culture device;
> b) orienting said cell culture device into an inoculation position such that said scaffolds reside at different elevations within said cell culture

device;
c) allowing cells to settle upon said scaffolds;
d) adding enough liquid medium to prevent a unique-gas liquid interface from forming directly above at least one scaffold when the device is oriented in the inoculation position and to have at least a portion of the liquid medium in contact with at least a portion of said gas permeable material;
e) placing cell culture device in a cell culture location that includes ambient gas at a composition suitable for cell culture, said ambient gas making contact with said gas permeable material; and
f) not perfusing said liquid medium when said device is in the cell culture location.[12]

('443 Patent, claim 1 (emphasis added).)

Corning submits that "inoculation position" means "the position in which the device is placed when being filled with medium and cells." Wilson Wolf asserts that no construction is needed and that Corning's construction is improper at least because it impermissibly combines separate steps of the claims, and that the step of "adding cells" does not require the device to be in any particular position.

Corning argues that its construction is supported by the plain language of the claims, the specification, the prosecution history, and extrinsic evidence. In particular, Corning highlights that the claims require "adding enough liquid medium . . . when the device is oriented in the inoculation position." Corning submits that this language alone would lead a POSA to understand that "adding" or "filling" the liquid medium occurs in the "inoculation position." (*See* Chalmers Decl. ¶ 99.) Moreover, Corning argues that the specification supports its construction and indicates that the device is filled with media and cells in the inoculation position. In addition, Corning maintains that during

[12] *See also* Claim 26.

reexamination of the ’443 Patent, the USPTO understood the inoculation position to be the “filling” position when it found claims obvious over the prior art. (Doc. No. 115-15 at 3; Doc. No. 116-16 at 18.)

Wilson Wolf argues that the claim language itself defines the term “inoculation position”—that it is a position such that the scaffolds reside at different elevations within the device— and that no construction is necessary. Wilson Wolf argues that Corning’s proposed construction improperly imposes a requirement that the step of “orienting said cell culture device into an inoculation position” occur before the step of “adding cells and a volume of liquid medium.” Wilson Wolf further argues that nothing in the claims or the specification supports a requirement that those steps occur in that order and, in fact, that the claims themselves recite those steps in the reverse order.

The Court agrees with Wilson Wolf that the steps of the claim are not required to occur in any particular order and otherwise finds that the term need not be construed as a juror will understand it as written within the context of the plain claim language.

IV. ’317 Patent

1. “static cell growth apparatus”

The parties dispute the meaning of the term “static cell growth apparatus” as it appears in the ’317 Patent. Corning submits that this term is not materially different from the term “static cell culture device” in the ’192 Patent and urges the Court to adopt its proposed construction for the reasons discussed with respect to the ’192 Patent. Similarly, Wilson Wolf proposes the same construction as “static cell culture device.” Wilson Wolf acknowledges that this dispute mirrors that of “static cell growth device” in

the ’192 Patent but submits that additional evidence here supports its construction. Specifically, Wilson Wolf argues that the prosecution history shows that the ’317 Patent distinguishes a prior art reference because it requires perfusion of gas and/or liquid and that the term “static” was added to distinguish that perfused system. However, Corning points out that the Examiner found that the reference discloses a “static cell growth apparatus” even though the device had structures that could be used to perfuse the medium. (Doc. No. 115-19 at 9.)

Similar to the ’192 Patent, the ’317 Patent provides that the claimed apparatus “can function in a static mode without need for equipment to perfuse medium.” (’317 Patent, 1:60-62.) This description of a static device as one that does not *require* perfusion equipment is consistent with a construction that a claimed static cell growth apparatus need only be capable of functioning in a static mode. In addition, the reexamination of the ’317 Patent supports a definition of “static” that does not require the absence of mixing equipment. (Doc. No. 115-18 at 3 (“The ’317 patent specification defines “static” as “without the need for equipment to perfuse medium.”).)

The Court concludes that this term is properly construed as a “cell growth apparatus that is capable of functioning in a static mode.”

2. “a liquid impermeable housing”

The parties dispute the meaning of the term “a liquid impermeable housing” as it appears in the ’317 Patent. Claim 6 recites in part: “A static cell growth apparatus comprising: a liquid impermeable housing, the inside of which is able to contain cells and medium and the outside of which is in contact with ambient gas.” (’317 Patent, claim 6.)

Corning contends that the term "liquid impermeable housing" is properly construed using its plain and ordinary meaning as "a liquid impermeable casing that encloses the device." Wilson Wolf asserts that "a liquid impermeable housing" does not require construction and that Corning's construction does not reflect the plain meaning because the "housing" is part of the device and Corning's definition separates the "housing" or "casing" from the device.

The Court finds that the term need not be construed as it is a non-technical term which the Court believes a lay juror will understand as written within the context of the plain claim language.

3. "ambient gas"

The parties dispute the meaning of the term "ambient gas" as it appears in the '317 Patent and submit that it should be construed in the same way as the '192 Patent. Accordingly, the Court construes the term as "gas of the environment surrounding and external to the apparatus."

ORDER

Based upon the foregoing, and the files, records, and proceedings herein, **IT IS HEREBY ORDERED** that the disputed claims are construed as set forth in this Memorandum Opinion and Order.

Dated: May 27, 2022

s/Donovan W. Frank
DONOVAN W. FRANK
United States District Judge