UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

SKINMEDICA, INC., Plaintiff, vs. HISTOGEN INC.; HISTOGEN AESTHETICS LLC; GAIL K. NAUGHTON, Defendants. AND RELATED COUNTERCLAIMS	CASE NO. 09-CV-122 JLS (NLS) **ORDER: GRANTING DEFENDANTS' MOTION FOR PARTIAL SUMMARY JUDGMENT OF NONINFRINGEMENT** (ECF No. 153)

Presently before the Court is Defendant's motion for partial summary judgment of noninfringement. (ECF No. 153.) Plaintiff opposes the motion. Having considered the parties' arguments and the law, the Court **GRANTS** Defendant's motion for partial summary judgment.

BACKGROUND

I. Factual History

Plaintiff SkinMedica, Inc. ("SkinMedica") brought this patent infringement action against Defendants Histogen, Inc., Histogen Aesthetics LLC, and Gail K. Naughton (collectively, "Histogen"). SkinMedica and Histogen both develop and sell products for treating dermatologic conditions and diseases affecting skin appearance. The patents in suit are United States Patent Nos. 6,372, 494 (the '494 patent) and 7,188,746 (the '746 patent).

SkinMedica is a privately held company that sells its products primarily to dermatologists and plastic surgeons. Among SkinMedica's products is its TNS® (for Tissue Nutrient System) line of anti-aging products. The main ingredient in the TNS line of products is NouriCel®. NouriCel was originally developed by Advanced Tissue Science, Inc. ("ATS"). In 2002, ATS filed for bankruptcy. In 2003, through the ATS bankruptcy proceedings, SkinMedica claims to have acquired all of the assets, "including the trade secrets and know-how," related to NouriCel through an Asset Purchase Agreement ("APA"). SkinMedica contends that the APA included both the '494 and the '746 patents asserted in this lawsuit.

Defendant Gail Naughton was the co-founder, President, Chief Operating Officer, and Chief Scientific Officer at ATS. She was also the lead named inventor on the '494 and '746 patents. Naughton left ATS shortly after it filed for bankruptcy, and is now the Chief Executive Officer and Chairman of the Board of Directors for Histogen.

During her tenure at ATS, Naughton and her colleagues experimented with NouriCel, ultimately discovering that NouriCel could possibly stimulate hair growth. By September 2002, Naughton presented a confidential report on NouriCel's hair growth potential to ATS's Scientific Advisory Board ("the SAB Report"). In her official capacity as Vice Chairman of ATS, Naughton claims to have been authorized to discuss the contents of the SAB Report with outside parties, including a former ATS employee no longer under a confidentiality agreement, and competing pharmaceutical companies.

Beginning in 2004, Naughton and Histogen began filing patent applications for "conditioned medium" research similar to the NouriCel research Naughton performed at ATS. However, as of January 2009, the U.S. Patent and Trademark Office and the European Patent Office had rejected all of these claims in light of prior art.

II. The Patents in Suit

Generally, the '494 and '746 patents describe and encompass "novel conditioned cell culture medium compositions" derived from cells cultured in three-dimensions. *See* '494 Patent col. 4 ll.40-44; '746 Patent col.40 ll.7-18. Cell culture medium is the liquid solution used to 'culture,' or, 'grow' cells *in vitro*, and typically includes various raw materials—*e.g.*, amino acids,

vitamins, sugars, etc.—that the cells need to grow and expand in number." '494 Patent col.1 ll.21–26. "Once the culture medium is incubated with cells, it becomes a 'spent' or 'conditioned' medium." '494 Patent col.1 ll.30–32.

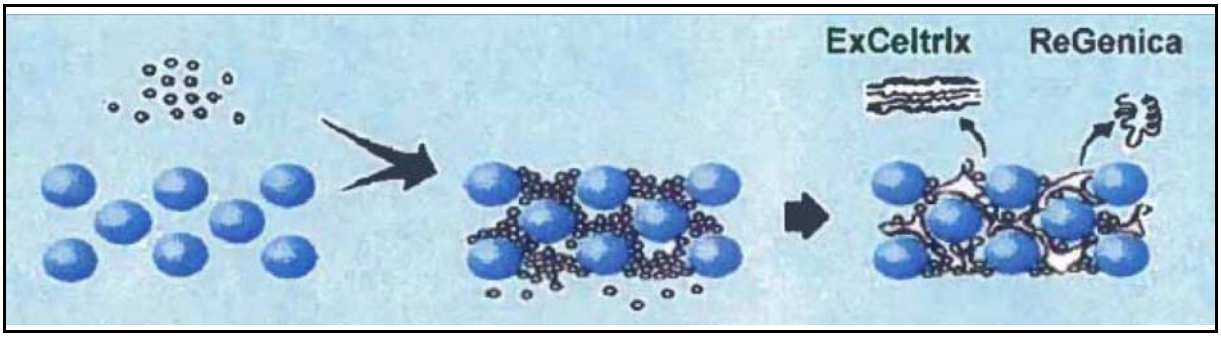
The '494 and '746 patents are specifically directed to conditioned medium derived from cells cultured in three-dimensions. Cells cultured in three dimensions "express an extracellular matrix of proteins, thus forming a living tissue." '494 Patent col.6 ll.54-56. Further, cells cultured in three dimensions secrete growth factors and other proteins in ratios higher than cells cultured in two-dimensional monolayers. '494 Patent col.5 ll.1-4, col.6 ll.9-17. Thus, conditioned medium derived from cells grown in three dimensions, such as NouriCel, is superior to conditioned medium derived from cells grown in two dimensions.

III. The Accused Products

In October 2008, SkinMedica became aware that Histogen planned to launch a line of skin care products based on a conditioned medium called ReGenica™ that sounded similar to SkinMedica's NouriCel technology. These products include the ReGenica Facial Rejuvenation Complex, Regenica Advanced Rejuvenation Day Repair, and the ReGenica Advanced Rejuvenation Overnight Repair products, in addition to other unknown products directed for use as a promoter for hair growth (collectively, "the accused products").

The parties seem to agree on the method steps Histogen uses for cell culturing, although they disagree as to which of these steps is relevant to the issue of infringement. Histogen states it manufactures the accused products "by growing cells in monolayer in smooth surface roller bottles on microcarrier beads." (Def.'s Mem. ISO Motion 1, ECF No. 153.) These microcarriers are "microscopic beads" to which cells are attached and then later "mixed in vessels to a fluidized condition to maximize, and provide control of, mass transport characteristics." (Baumgartner Decl. ISO Def.'s Motion, Ex. 10.) Known as "bioreactor vessels," these vessels contains microcarrier beads and are kept continuously stirring as cells grow on the microcarrier beads. (Baumgartner Decl. ¶ 12.) Eventually, the cells secrete "sticky" extracellular matrix ("ECM") proteins that coat the beads and the surrounding surfaces. (Pl.'s Opp'n 8, ECF No. 171 (quoting Aug. 25, 2009 Naughton Dep., at 120:5-8.)) The sticky nature of this extracellular matrix leads to

the formation of "clumps" or aggregates of beads. (*Id.*) After aggregates of beads begin to form, the cells continue to produce ECM, which forms bridges between beads, creating a three-dimensional structure. (*Id.*) Thus, SkinMedica summarizes that "cells which *start out* 'on' the beads in two dimensions then migrate into the newly forming ECM scaffold and continue to proliferate, thereby creating a three-dimensional cell culture." (*Id.* (quoting Jun. 2, 2009 Naughton Dep., at 65:25-66:6, 71:17-24.)) Histogen's illustration of this process for investors shows the formation of the three-dimensional ECM scaffold between beads, from which ReGenica is obtained.



(Pl.'s Opp'n 8 (citing Histogen Doc. H0007, Ex. G.))

IV. Relevant Procedural History

On January 22, 2009, SkinMedica filed the instant lawsuit against Naughton, Histogen, and Histogen Aesthetics alleging, *inter alia*, infringement of the '494 and '746 patents. (ECF No. 1.) SkinMedica's operative complaint asserts claims for patent infringement, misappropriation of trade secrets, unfair competition, breach of contract, and imposition of constructive trust. (ECF No. 31.) Histogen has filed counterclaims for a declaration of patent non-infringement and unfair competition. (ECF No. 35.) And each side asserts various affirmative defenses to the other's claims. (*Id.*; ECF No. 40.)

On May 24, 2011, the Court issued an order construing the disputed claim terms of the '494 and '746 patents. (Claim Construction Order (CCO), ECF No. 150.) Subsequently, Histogen filed the instant motion for partial summary judgment of noninfringement. (ECF No. 153.) SkinMedica filed an opposition, and Histogen replied. (ECF Nos. 171, 177.) SkinMedica then filed an *ex parte* motion for leave to file a sur-reply to Histogen's reply, and Histogen

opposed. (ECF Nos. 185, 187.) On October 11, 2011, the Court denied SkinMedica's motion for leave to file a sur-reply. (ECF No. 189.) The Court held oral argument on November 4, 2011, and took the matter under submission.

LEGAL STANDARD

Federal Rule of Civil Procedure 56 permits a court to grant summary judgment where (1) the moving party demonstrates the absence of a genuine issue of material fact and (2) entitlement to judgment as a matter of law. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). "Material," for purposes of Rule 56, means that the fact, under governing substantive law, could affect the outcome of the case. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986); *Freeman v. Arpaio*, 125 F.3d 732, 735 (9th Cir. 1997). For a dispute to be "genuine," a reasonable jury must be able to return a verdict for the nonmoving party. *Anderson*, 477 U.S. at 248.

The initial burden of establishing the absence of a genuine issue of material fact falls on the moving party. *Celotex*, 477 U.S. at 323. The movant can carry his burden in two ways: (1) by presenting evidence that negates an essential element of the nonmoving party's case; or (2) by demonstrating that the nonmoving party "failed to make a sufficient showing on an essential element of her case with respect to which she has the burden of proof." *Id*. at 322–23. "Disputes over irrelevant or unnecessary facts will not preclude a grant of summary judgment." *T.W. Elec. Serv., Inc. v. Pac. Elec. Contractors Ass'n*, 809 F.2d 626, 630 (9th Cir. 1987).

Once the moving party establishes the absence of genuine issues of material fact, the burden shifts to the nonmoving party to set forth facts showing that a genuine issue of disputed fact remains. *Celotex*, 477 U.S. at 324. The nonmoving party cannot oppose a properly supported summary judgment motion by "rest[ing] on mere allegations or denials of his pleadings." *Anderson*, 477 U.S. at 256. When ruling on a summary judgment motion, the court must view all inferences drawn from the underlying facts in the light most favorable to the nonmoving party. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986).

In the context of patent litigation, "[i]nfringement is assessed by comparing the accused device to the claims; the accused device infringes if it incorporates every limitation of a claim, either literally or under the doctrine of equivalents. If, however, even one claim limitation is

missing or not met, there is no literal infringement." *MicroStrategy, Inc. v. Bus. Objects, S.A.*, 429 F.3d 1344, 1352 (Fed. Cir. 2005). Where there is a factual dispute as to whether the allegedly infringing device includes a claim limitation, summary judgment is not appropriate. *Int'l Rectifier Corp. v. IXYS Corp.*, 361 F.3d 1363, 1375 (Fed. Cir. 2004). However, where parties do not dispute any fact regarding the accused product, but instead disagree over interpretations of the court's claim construction, summary judgment is appropriate. *Gen. Mills, Inc. v. Hunt-Wesson, Inc.*, 103 F.3d 978, 983 (Fed. Cir. 1997).

ANALYSIS

Infringement analysis involves a two-step process: first, the court must determine the meaning of disputed claim terms, and second, the court must compare the accused device to the claims as construed. *Wavetronix v. EIS Electronic Integrated Sys.*, 573 F.3d 1343, 1354 (Fed. Cir. 2009) (citing *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995)). Here, the Court has already determined the meaning of the disputed claim term in its May 24 Claim Construction Order. Thus, the single task before the Court for the resolution of the present motion is to compare the accused products to the claims as construed. The parties contest the proper interpretation of the Court's construction of a single claim element, "culturing . . . cells in three-dimensions," which is repeated in substantially the same form in claims 1 and 8 of the '494 patent, and claims 1 and 11 of the '746 patent. The parties also contest the correct comparison of the accused products with this disputed claim element. If the accused products do not incorporate this claim limitation as construed, the products do not infringe. Thus, the Court will address in turn the interpretation of the claim construction and a comparison of the accused products to the disputed claim element as construed.

Histogen argues that the Court's construction of the disputed claim element excludes the growth of cells using beads. (Def.'s Mem. ISO Motion 2.) Histogen claims the cell culture method steps for the accused products involve growing cells "in monolayer . . . or by using microcarrier beads," which was excluded by the Court's construction of that claim element. (*Id.* at 2.) Thus, its process for manufacturing the accused products does not infringe this necessary claim element of both the '494 and '746 patents. (*Id.* at 1.) Because this claim limitation is

missing from the accused products, Histogen argues summary judgment of noninfringement is appropriate.

SkinMedica counters that three-dimensional growth *between* beads is not excluded by the Court's claim construction, which excludes growing cells "*on* beads." (Pl.'s Opp'n 1-2.) According to SkinMedica, the accused products are derived from a three-dimensional cell culture that eventually grows on ECM formed between beads, which infringes the disputed claim element. Histogen opposes this interpretation, and also objects on the basis that this "ECM theory" was not contained in SkinMedica's Final Infringement Contentions, as required by the patent local rules of the Southern District of California, as well as the Court's scheduling order. (Def.'s Reply 2.)

Both parties agree that Histogen's process for manufacturing the accused devices involves the use of beads. (Def.'s Mem. ISO Motion 1; Pl's Opp'n 1.) The key question is whether the Court construed the disputed claim element to exclude *all types* of growth using beads, or merely the growth of cells *on* beads. The Court agrees with Histogen that the use of microcarrier beads was excluded from the construction of "culturing . . . cells in three-dimensions," and that as a result the accused products do not infringe this claim element, rendering summary judgment of noninfringement appropriate.

I. Claim Construction

The Court construed the term "culturing . . . cells in three-dimensions" to mean "growing . . . cells in three dimensions (excluding growing . . . cells in monolayers or on microcarrier beads)." (CCO 13.) The Court's claim construction order specifically addresses the use of beads at length in the context of construing this term, eventually deciding to exclude beads from the disputed claim element based on the patent record. (CCO 6-11, 13.)

SkinMedica argues that the claim construction order left open "the prospect that Defendants may still infringe if they use beads in the formation of a 'three-dimensional framework' on which a three-dimensional cell culture might subsist to any extent, and at any stage of their cell culture process." (Pl.'s Opp'n 1.) SkinMedica emphasizes that the claim construction language only excludes two-dimensional cell growth "*on* beads." (Pl.'s Opp'n 3.) SkinMedica implores the Court to "carefully scrutinize the Defendants' erroneous and deceptive argument that

culturing cells in ***any*** way 'using beads' is equivalent to culturing cells '***on*** beads.'" (Pl.'s Opp'n 4.) After carefully scrutinizing both parties' arguments, the Court cannot agree with SkinMedica.

SkinMedica's argument places too much emphasis on the importance of the single word "on," and overlooks the substance of the Court's analysis in which it construes the disputed claim element to exclude beads. Because this analysis is vital to properly interpreting the construction of the disputed claim element, the Court briefly summarizes the claim construction's reasoning below.

The Court arrived at the construction of the disputed claim element after examining the patent record, which showed "that the inventors acted as their own lexicographers, defining 'culturing . . . cells in three-dimensions' away from its ordinary meaning. . . . By consistently distinguishing culturing on beads from culturing in three dimensions, the inventors defined 'culturing . . . cells in three dimensions' by implication to exclude culturing on beads." (CCO 9-10.) The inventors did this "despite that culturing cells in three dimensions on beads was known in the art at the time the patent was filed." (*Id.* at 10.) Thus, it was based on the inventor's own exclusion of three-dimensional culturing on beads that the Court excluded beads from the claim. Crucially, the Court found that the inventor had excluded culturing on beads from the claimed invention in spite of the fact that three-dimensional culturing on (or using) beads was already known in the art at that time.

At the *Markman* hearing, SkinMedica attempted to avoid this result by incorporating into the intrinsic patent record *Cell & Tissue Culture: Laboratory Procedures*, which describes "how beads may *be used* to culture cells in three dimensions":

> A common occurrence in microcarrier culture is the formation of large microcarrier aggregates *in which the microcarriers are joined by cellular bridges*. Microcarrier aggregates made up of as many as 10 or more microcarriers are not uncommon. . . . In certain cases, such as *to promote bead-to-bead transfer of cells* to bare microcarriers, low agitation rates would be desirable during the culture growth phase.

(emphasis added). A. DOYLE ET AL., CELL & TISSUE CULTURE: LABORATORY PROCEDURES 8D:2.7 (1996), *available at* SkinMedica's CCB Ex. 7; *see also* (CCO 9.) Although SkinMedica argued that Doyle et al.'s "discussion of beads as a three-dimensional culture method" was incorporated

by reference and thus the use of beads comported with intrinsic patent record, the Court rejected this argument. (CCO 10-11.) After examining the patent record, the Court held that "because Doyle et al.'s discussion of beads as a three-dimensional culture method is not incorporated into the patents by reference, the intrinsic patent record does not compel a broader construction of 'culturing . . . cells in three-dimensions.'" (*Id.* at 11.) Even though three-dimensional growth of cells using beads already existed at the time of the '494 and '746 patents, the patent record did not disclose even a single instance of such methods. The Court explicitly stated in its analysis of the disputed claim element that culturing cells in three dimensions was being construed "away from its ordinary meaning" to exclude the use of beads and that, because the inventor "disclosed [not even] a single reference to culturing cells in three dimensions *using* beads," this method could not be incorporated into the patent's claim. (emphasis added) (CCO 9-10.) Thus, the Court's analysis of the disputed claim element makes clear that the patent record did not disclose three-dimensional cell culturing using beads, which is why the Court excluded beads in the claim construction.

However, SkinMedica appears to ignore this analysis and argues that, because all of the references in the patent specification equated the phrase "on beads" to a two-dimensional cell culture method, the Court's construction imports this limitation. (Pl.'s Opp'n 5.) SkinMedica is correct in that the Court found, through an examination of the patent record, that the inventors had defined "beads" as a two-dimensional culture method. (CCO 10.) As previously discussed, the Court found the intrinsic record did not contain any reference to culturing cells in three dimensions using beads, even though such methods existed in the prior art. However, SkinMedica attempts to distort the significance of this fact. Although the inventor equated culturing "on beads" with culturing in two dimensions, the Court did not. In fact, the Court explicitly rejected the inventor's definition as contrary to the prior art. In declining to incorporate the Doyle reference into the intrinsic record, the Court made clear that even three-dimensional culture methods on beads were excluded by the inventor. Thus, the Court finds that SkinMedica's attempt to narrow the claim construction based on the inventor's equation of beads with a two-dimensional culture method is unfounded and misleading.

//

In fact, there is no indication at all in the claim construction order that the Court's use of the preposition "on" as opposed to the preposition "between" or the gerund "using" carries the meaning that SkinMedica seeks to have attached to it. To the contrary, the Court's claim construction analysis switches interchangeably between "on" and "using" throughout, without attempting to differentiate the two words. This switching between "on" and "using" depends sometimes on the word used in the patent record, and sometimes on nothing more than the Court's dictional preference. The Doyle reference, which the Court declined to incorporate into the intrinsic patent record, does not emphasize the growth must be "*on* beads." Instead, it describes "the formation of large microcarrier aggregates in which the microcarriers are joined by cellular bridges" and discusses "bead-to-bead transfer of cells to bare microcarriers." (CCO 9-10.) It was the inventor's failure to disclose any references to culturing cells in three dimensions using beads, not any distinction between whether the cells were growing *on* the beads or *between* the beads, that dominated the Court's analysis of the claim limitation.

Nor does the Court's rejection of Histogen's proposed claim construction language indicate that the word "on" leaves open the possibility of infringement by three-dimensional growth using beads, as SkinMedica argues. (Pl.'s Opp'n 1.) For the claim "culturing . . . cells in three-dimensions," Histogen proposed the following construction: "growing . . . cells on a structure forming a porous framework (as opposed to monolayers or beads) wherein the cells proliferate both on the surface of and into the pores of the framework, forming a three dimensional tissue." (CCO 6.) The Court divided its analysis of Histogen's proposed construction into two parts. The Court discussed first "as opposed to monolayers or beads," and second "a structure forming a porous framework . . . wherein the cells proliferate both on the surface of and into the pores of the framework, forming a three dimensional tissue." The Court agreed with Histogen's proposed construction as to the first part, excluding beads from the disputed claim element (CCO 9, 11), and rejected Histogen's proposed construction as to the second part, declining to limit the disputed claim element to growth on mesh or porous frameworks (CCO 12-13). Because these two parts were both elements of the same claim and were intertwined in Histogen's proposed construction, the Court necessarily could not adopt either party's proposed construction in its entirety. However,

in construing the disputed claim element, the Court did not state any important distinction between Histogen's proposed language, "as opposed to monolayers or beads," and the language adopted in the claim construction, "excluding growing . . . cells in monolayers or on microcarrier beads." SkinMedica ignores that it was necessary to edit Histogen's proposed language because the Court rejected Histogen's proposed (and intertwined) porous framework limitation. Instead of accepting this logical and obvious explanation, SkinMedica argues that the Court suddenly attached significant meaning to the word "on" in the language construing the disputed term, and that the use of the word "on" was meant to import the important limitation that solely two-dimensional growth on beads was excluded, without any explicit clarification of this meaning. The Court finds that SkinMedica's proposed distinction between "on" and "using" is simply not supported by the claim construction analysis.

Finally, SkinMedica asserts that the Court's decision not to exclude beads from serving as part of a "framework . . . formed into a three-dimensional structures," which is a different, non-disputed claim element, somehow "embraces the presence of beads in the three-dimensional cell structure – at least for the portions of the culture where cells are not growing 'on' the beads themselves." (Pl.'s Opp'n 5-6.) However, this argument erroneously implies that a broad interpretation of one claim element should impact a different claim element. In order to infringe the patents in question, the accused devices must incorporate *every* limitation of a claim. *MicroStrategy, Inc. v. Bus. Objects, S.A.*, 429 F.3d 1344, 1352 (Fed. Cir. 2005.) That one element of the claim incorporates the use of beads does not negate the explicit exclusion of beads by another element of the claim. Nor does the Court's decision not to constrain the disputed element to porous frameworks, as Histogen suggested, embrace the presence of beads, which are specifically excluded by the claim construction language. Thus, the Court finds that SkinMedia's attempts to import convenient language from other claim elements into the disputed claim element fail.

In sum, the Court rejects SkinMedica's argument that the Court's construction of the disputed claim element excludes only two-dimensional growth on beads, not three-dimensional growth using beads. SkinMedica cannot reargue the Court's construction of the disputed claim element in opposing the instant motion. The Court finds that the disputed claim element as

construed, "excluding growing . . . cells in monolayers or on microcarrier beads," is not limited to two-dimensional culture methods on beads.

II. Infringement

Having resolved the proper interpretation of the construction of the disputed claim element, the Court now turns to the issue of whether Histogen's accused products infringe this element.[1] The Court finds that they do not.

There is no dispute that Histogen's process for the accused products starts with cells growing on beads as part of the "seeding" process. At oral argument, both parties also admitted that this process, which starts as one- or two-dimensional growth, evolves into a three-dimensional growth phase in which the cells crawl off the beads and grow on three-dimensional ECM, consistent with the Doyle reference.

In spite of admitting, for the purposes of this motion, that its process for the accused products involves three-dimensional cell growth between beads on ECM, Histogen argued for the first time at oral argument that the Court need not consider any stages of the cell growth process beyond the initial one- or two-dimensional growth stage on beads. Histogen apparently now proposes the only relevant fact to the instant motion is the fact that the cells grow *on* beads initially. According to Histogen, what happens after (namely, three-dimensional growth between beads as explained in the Doyle reference) is immaterial.

SkinMedica counters that the later stages of cell growth are vital to the issue currently before the Court. Although Histogen's method begins with cells growing in one- or two-dimensions on beads, it evolves and changes until the cells are growing in three-dimensions on ECM formed between beads. "While Defendants may *begin* their conditioned media production process by growing cells 'on beads,' that process creates a three-dimensional framework comprised of extracellular matrix ("ECM") formed in the interstices *between* multiple beads that aggregate or 'clump' together while stirred in a solution of liquid media." (Pl.'s Opp'n 1-2.) Thus, according to SkinMedica, "Defendants not only grow cells 'on beads' <u>*but also within a three-dimensional*</u>

[1]The Court notes that SkinMedica has not argued that the accused products infringe under the doctrine of equivalents or any other theory of infringement other than direct infringment in opposition to the present motion. (*See* Pl.'s Opp'n.)

extracellular matrix framework." (emphasis in original) (*Id.* at 2.)[2] It is this cell growth within the three-dimensional ECM, which eventually grows between beads in the manufacture of the accused products, that SkinMedica reasons infringes the disputed claim element.

The Court agrees with SkinMedica that the later stages of Histogen's cell growth on the ECM formed between beads is relevant to the issue of infringement, but ultimately finds that even this later stage cannot not infringe the patents in suit because the disputed claim element is not incorporated in the accused products.

First, the Court finds that the claim element "growing . . . cells in three-dimensions" is not limited to the initial "seeding" stage of growth. There is nothing in the claim construction order to indicate such a limitation, and Histogen points to no facts or legal arguments to support its contention that the Court should ignore the later stages of cell growth. Thus, the Court will consider all stages of Histogen's process for manufacturing the accused products which involve "growing . . . cells."

However, even considering all stages of Histogen's cell growth process, the Court finds Histogen's accused products do not infringe the disputed claim element. The parties agree that Histogen's process uses beads at all stages. Even when some of the cells are growing on ECM, this ECM is formed on and around beads. All of SkinMedica's arguments in opposition to partial summary judgment of noninfringement rely upon its premise that the claim limitation "excluding growing . . . cells in monolayers or on microcarrier beads" applies only to the two-dimensional growth of cells on beads, and that the use of beads to grow cells in three dimensions is not

---

[2]The Court rejects Histogen's argument that the Court should not consider SkinMedica's opposition because SkinMedica failed to present its "ECM theory" in its Final Infringement Contentions. (Def.'s Reply 2.) The Court agrees that patent local rules require parties to state with specificity the theories upon which they plan to rely early in the litigation. These rules are important because they "require parties to crystallize their theories" so as to "prevent the 'shifting sands' approach to claim construction." *O2 Micro Int'l Ltd. v. Monolithic Power Sys.*, 467 F.3d 1355 (Fed. Cir. 2006) (quoting *Atmel Corp. v. Info. Storage Devices, Inc.*, 1998 WL 775115 at *2 (N.D. Cal. 1998)). However, here it is not clear that SkinMedica failed to adequately disclose its current infringement theory. *See, e.g.*, SkinMedica's Final Infringement Contentions, Ex. A at 4 ("ReGenica is produced by culturing cells in three dimensions using dextran microcarrier beads and extracellular matrix formed between those beads.") Histogen itself points out that SkinMedica's current ECM theory is similar to what it argued at the Markman hearing. (Def.'s Reply 7.) As a result, the Court finds Histogen had adequate warning of the ECM theory presented in SkinMedica's opposition and will consider it in ruling on this motion.

excluded. However, as discussed above, the Court rejects these arguments. SkinMedica's premise is contrary to the patent history and contrary to the Court's claim construction analysis. Thus, Histogen's cell growth process, which uses beads, cannot infringe the disputed claim element as construed.

CONCLUSION

For the foregoing reasons, the Court **GRANTS** Histogen's motion for summary judgment of noninfringement of both the '494 and the '746 patents.

IT IS SO ORDERED.

DATED: November 21, 2011

Janis L. Sammartino

Honorable Janis L. Sammartino
United States District Judge