UNITED STATES DISTRICT COURT
DISTRICT OF CONNECTICUT

STEPHEN C. EDBERG, ET AL	**:**	
v.	**:**	**NO. 3:98cv716 (JBA)**
CPI-THE ALTERNATIVE SUPPLIER, INC.	**:**	

RULING ON CROSS-MOTIONS FOR SUMMARY JUDGMENT
[DOC. #75, #88]

Plaintiffs Stephen Edberg, Stephen Wardlaw, and IDEXX Laboratories are the holders of various U.S. patents and the developers of a water testing product called Colilert. Plaintiffs brought suit against defendant CPI - The Alternative Supplier, Inc. ("CPI") claiming that CPI's Colitag product, a water testing product that, like Colilert, detects coliform bacteria including E. coli, infringes its U.S. Patent No. 4,925,789 ("the '789 patent"), U.S. Patent No. 5,429,933 ("the '933 patent") and U.S. Patent No. 5,780,259 ("the '259 patent"). Plaintiffs and defendant have cross-moved for summary judgment on infringement.

I. BACKGROUND

A. Factual Background

Dr. Edberg's '789 patent and the subsequently-issued '933 and '259 patents "cover[] a biological media and methods which

permit lay people to quickly and easily detect bacterial contamination in food, water or other samples in 24 hours or less by simply observing a color or florescence change." Pl. Mem. at 3. The patented invention is a medium and method for detecting target bacteria such as E. coli and other coliform bacteria, by using a chemical ("nutrient-indicator") which acts both as the primary nutrient in the media and as an indicator, and which cannot be consumed by non-target microbes, thus permitting detection of bacteria in a single step without the need for sterilization. Id. at 4-5. If target microbes are present in the sample, they will cleave the chemical bond between the nutrient and the indicator, and will consume the released nutrient component, thereby enabling rapid growth; the released indicator then will cause the solution to change color. Because other bacteria that may be present in the solution cannot cleave the chemical bond, the indicator will not be released and the color change will not occur if the target is not present.

Defendant CPI produced and sells Colitag, a coliform bacteria testing medium. Colitag, like Colilert, changes color when coliforms, including E. coli, are present. According to CPI, however, the indicators are not used as nutrients in Colitag, and abundant amino acids, including tryptophan and tryptose, serve as the primary and preferred nutrients for both target and non-target bacteria.

B. The Millipore Litigation

This is not the first time the '789 patent has been before this Court. In 1992, plaintiffs brought suit against the Millipore Corporation, Environetics, Inc. v. Millipore Corp., civ. no. 2:92cv825 (JBA), claiming that Millipore's Colisure product infringed the '789 patent. Following rulings on claim construction but prior to trial, the case settled. Plaintiffs and defendant rely heavily on the two earlier claim construction rulings interpreting the '789 patent, discussed in detail below.

In Environetics, Inc. v. Millipore Corp., 923 F. Supp. 344, 347 (D. Conn. 1996), this Court held that "what makes the invention [claimed in the '789 patent] distinct is that if the target microbes are present, they and they alone will metabolize the nutrient-indicators and hence produce a tell-tale visible change in the sample." The Court rejected the construction urged by Millipore – that the claims required that no other nutrients capable of sustaining growth of the target microbes be present in the medium – and based on the specification and the prosecution history held that the '789 patent requires "that the nutrient-indicators be not the only nutrients in the medium, but the preferred nutrients which the target microbes would, in fact, metabolize." Id.

Millipore then sought a construction of the term "specific medium" as a claim limitation. The Court first determined "that the preamble term 'specific medium' is a claim limitation

defining the invention as one tailored to a specific medium, distinguishing it from the general media used in prior art." Markman Ruling, November 24, 1997, at 4. The Court also concluded that this claim limitation applied to Claim 11 and dependent Claims 12 through 14. Finally, the Court construed the claim limitation "specific medium" to mean "a medium that will support reproductive growth of only the target microbes, in contrast to the prior art 'general medium' described in the specification and prosecution history." Id. at 10. In so holding, the Court rejected Environetics' argument that the term "specific medium" required only that the nutrient-indicator be the primary or preferred nutrient in the medium and that other viable microbes not be able to metabolize the nutrient-indicator "to the same extent that the target microbe can." Id. at 6.

II. SUMMARY JUDGMENT

Summary judgment will be granted when "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the and affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c); Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 247 (1986). The moving party carries the initial burden of demonstrating an absence of a genuine issue of material fact. Fed. R. Civ. P. 56; Celotex Corp. v. Catrett , 477 U.S. 317, 323 (1986). Facts,

inferences therefrom, and ambiguities must be viewed in a light most favorable to the non-moving party. Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 586 (1986); Ametex Fabrics, Inc. v. Just In Materials, Inc., 140 F.3d 101, 107 (2d Cir. 1998).

Although infringement is a factual issue, summary judgment is appropriate in a patent case when it is apparent that only one conclusion as to infringement could be reached by a reasonable jury. ATD Corp. v. Lydall, Inc., 159 F.3d 534, 540 (Fed. Cir. 1998). "The purpose of summary judgment is not to deprive a litigant of a trial, but to avoid an unnecessary trial when only one outcome can ensue. The court's construction of the claims may lead to summary disposition of the issue of infringement when no material facts remain in dispute, or when the nonmovant can not prevail on its view of the facts." Vivid Tech., Inc. v. American Science & Engineering, Inc., 200 F.3d 795, 806 (Fed. Cir. 1999) (citing Voice Techs. Group, Inc. v. VMC Sys., Inc., 164 F.3d 605, 612 (Fed. Cir. 1999)).

On cross-motions for summary judgment, "[e]ach party carries the burden on its own motion to show entitlement to judgment as a matter of law after demonstrating the absence of any genuine disputes over material facts." Massey v. Del Labs., Inc., 118 F.3d 1568, 1573 (Fed. Cir. 1997). "On an issue for which the moving party does not have the burden of proof at trial, the moving party may meet its initial burden on the motion either by

providing evidence that negates an essential element of the opposing party's case, or by showing that the evidence on file (such as pleadings, depositions, and admissions) establishes no material issue of fact and that the opposer will not be able to prove an essential element of its case." Vivid Tech., 200 F.3d at 807.

The burden then shifts to the nonmovant to show that a material factual dispute exists, i.e., a dispute upon which a reasonable jury could resolve infringement in the nonmovant's favor after a review of the entire record. See Sweats Fashions, Inc. v. Pannill Knitting Co., 833 F.2d 1560, 1562 (Fed. Cir. 1987). Where the evidence submitted in opposition to summary judgment is merely colorable, or is not significantly probative, summary judgment may be granted. Anderson, 477 U.S. at 249-50 (citations omitted). The court may not simply accept a party's statement that a fact is challenged to show that there is a genuine issue of material fact. Union Carbide Corp. v. American Can Co., 724 F.2d at 1571 (Fed. Cir. 1984). In addition, broad conclusory statements by the non-moving party or its experts are insufficient to defeat summary judgment. Arthur A. Collins, Inc. v. Northern Telecom, Ltd., 216 F.3d 1042, 1046 (Fed. Cir. 2000); see also Zelinski v. Brunswick Corp., 185 F.3d 1311, 1317 (Fed. Cir. 1999) (affirming district court's grant of summary judgment where only evidence on infringement under doctrine of equivalents was conclusory statement of plaintiff's expert); W.L. Gore &

Assocs. v. Garlock, Inc., 842 F.2d 1275, 1280 (Fed. Cir. 1988) ("Where the evidence of infringement consists merely of one expert's opinion, without supporting tests or data, the district court is under no obligation to accept it.").

III. DISCUSSION

Plaintiffs claim that Colitag literally infringes Claims 1, 3, 11, 16 and 17 and infringes Claims 2 and 14 under the doctrine of equivalents, and that the sale and offering for sale of Colitag are acts of inducement and contributory infringement of claims 11 and 14, all in violation of 35 U.S.C. § 271.

Defendant, in turn, seeks summary judgment on non-infringement of the '789 patent and the '933 and '259 patents, citing expert testing allegedly demonstrating that Colitag is not a "specific medium" and that the indicators used in Colitag – ortho nitro phenyl-ß-galactoside ("ONPG") and 4-methylumbelliferyl-ß-D-glucuronide ("MUG") -- are not the primary or preferred nutrients in Colitag.

A. Prior Claim Construction and Estoppel

Plaintiffs assert that this Court previously concluded that "a 'specific' medium is one that is tailored, through the choice of the nutrient indicator so that the target microbes greatly prefer it over any other nutrients and sufficiently metabolize it to the extent needed to cause the color or other change in the

sample. Other microbes which may be present cannot effectively compete with the target microbe to metabolize the nutrient indicator and thus to generate a signal." Pl. Br. [doc. #88] at 15. Plaintiffs also contend that "the Court construed the term 'specific medium' to mean one that 'eliminated the need for a "preliminary target microbe growth step."'" Id. at 14.

However, as defendant objects, this selective reading of the Court's previous Markman ruling ignores the fact that the Court clearly held that the "critical" distinction between a "specific medium" and a "general medium," as set forth in the '789 patent specification and the prosecution history, was that a specific medium "'will support growth of only the target microbes rather than a general medium which will also support growth of microbes other than the target microbe.'" Ruling at 8 (quoting Patent Specification, col. 1, ll. 9-18) (emphasis added). The ruling also observed, consistent with the patent specification and prosecution history, that "the medium claimed in this invention is specific because it will support growth of only the target microbes." Ruling at 9 (emphasis in original). Accordingly, plaintiffs' attempt to elide the distinction between a specific medium, in which only the target microbes will metabolize and experience substantial reproductive, or log-phase growth, and

specific nutrient-indicators, to which only the target microbes will respond, is unsupported by the Court's previous holding[1].

Plaintiffs also ask the Court to reconsider the prior ruling that the "specific medium" limitation applies to independent Claim 11 and dependent claims 12 and 14 even though those claims do not contain the "specific medium language." Pl. Br. at 16. Alternatively, plaintiffs argue that the Court should exercise its discretion to reconsider the holding that the "specific medium" limitation applies to Claims 11 and 12 through 14, and assert that this holding is erroneous under the doctrine of claim differentiation. In response, CPI claims that plaintiffs are estopped from challenging the Court's prior ruling.

Courts have held that the doctrine of issue preclusion barred re-litigation of previously constructed claims in subsequent actions involving those same claims, provided the conditions for issue preclusion were met. See TM Patents, L.P. v. IBM, 72 F. Supp.2d 370, 375-79 (S.D.N.Y. 1999); Abbott Labs v. Dey, L.P., 110 F. Supp. 2d 667, 669-71 (N.D. Ill. 2000). As the court noted in TM Patents,

> Four elements must be met for collateral estoppel to apply. First, the issues raised in both proceedings must be identical. Second, the relevant issues must have been actually litigated and decided in the prior proceeding.

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[1] In other words, a "specific medium" is not one in which only the target microbe glows, but one in which only the target microbe grows. Whether, as plaintiffs contend, the medium's false negative rate is probative of the growth of non-target microbes vel non is addressed below in the substantive discussion of the literal infringement claim.

> Third, the party to be estopped must have had a full and fair opportunity to litigate the issues in that prior proceeding. And fourth, resolution of the issues must have been necessary to support a valid and final judgment on the merits.

72 F. Supp. 2d at 375 (citing Central Hudson Gas & Elec. Corp. v. Empresa Naviera Santa, 56 F.3d 359, 368 (2d Cir. 1995)).[2] In TM Patents, as here, the prior case had settled following the Markman hearing and before trial, and the plaintiff argued in the subsequent case that the issue was not sufficiently final for collateral estoppel purposes. Id. at 375-76. The court rejected that argument, noting that because the purpose of a Markman hearing is to construe the patent claims "so that the Court can instruct the jury on the meaning of the patent . . . [and] the jury is not free to override the Court's construction of the disputed terms[,] [i]t is hard to see how much more 'final' a determination can be." Id. at 376. The court also held that the fact that the case had settled prior to review by the Federal Circuit was irrelevant: "A party who cuts off his right to review by settling a disputed matter cannot complain that the question was never reviewed on appeal. The Markman rulings were not vacated as part of the settlement. They therefore remain preclusive." Id. at 378.

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[2] Because "the application of general collateral estoppel principles, such as finality of judgment, is not a matter within the exclusive jurisdiction of [the Federal Circuit], . . . the law of the circuit in which the district court . . . sits applies." Pharmacia & Upjohn Co. v. Mylan Pharmaceuticals, Inc., 170 F.3d 1373, 1381 n.4 (Fed. Cir. 1999).

Graco Children's Products, Inc. v. Regalo Int'l, LLC, 77 F. Supp. 2d 660, 664 (E.D. Pa. 1999), cited by plaintiffs, is distinguishable from this case. In Graco, the plaintiff had won on its claim of patent infringement following a jury trial but had lost on an issue of claim interpretation that "could not by itself be appealed." Id. The court also observed that "Graco did not lose in the previous litigation, but, instead, obtained a jury verdict in its favor based on the doctrine of equivalents, making the court's interpretation of the term within the patent claim not essential to the final judgment in that case." Id. Under those circumstances, the court held that collateral estoppel did not apply. Plaintiffs cite dicta from the Graco case observing that "granting preclusive effect to claim construction would encourage more appeals and discourage settlement" and claim that the facts of this case are similar because they would have been "forced to appeal an otherwise amicable resolution of the Millipore case in order to rectify [the] error of claim construction." Pl. Opp. to Summary Judgment [doc. #77] at 25. However, as the TM Patents court noted, the mere fact that plaintiffs settled the prior case does not give this Court's prior rulings any less preclusive effect. Even if plaintiffs were not estopped from challenging the prior construction of claims 11, 12 and 14, the Court concludes that the ruling was correct for the reasons discussed below.

Plaintiffs cite D.M.I. Inc. v. Deere & Co., 755 F.2d 1570, 1574 (Fed. Cir. 1985) for the proposition that "[w]here some claims are broad and others narrow, the narrow claim limitations cannot be read into the broad whether to avoid invalidity or to escape infringement." Pl. Br. at 16. Thus, according to plaintiffs, because the Court's November 24, 1997 ruling was premised on the view that the invention would not be patentable over prior art if non-target microbes were allowed to grow in the medium, reading the specific medium limitation into Claims 11 and 14 to sustain their validity was improper. Id. at 17.

Claims 11 and 14 of the '789 patent contain language identical to the definition of "specific medium" in Claim 1. As noted, Claim 1 claims:

> A **specific medium** for combination with a specimen sample of a material suspected to be contaminated to determine the presence or absence of a target microbe in the specimen sample, and which can detect the presence of said target microbe without the need of performing a preliminary target microbe growth step, said medium comprising operative amounts of essential vitamins and elements needed to support growth of said target microbe and a nutrient-indicator which is the primary nutrient in the medium and **which is substantially the only nutrient in said medium which can be metabolized by said target microbe to the extent needed to support continued reproductive growth thereof, and which cannot be metabolized by other viable microbes in the specimen, to that extent** . . .

Claim 11 is a method claim that describes the method of forming a specimen sample and medium mixture, and uses the same language quoted above, apart from the term "specific medium." See '789 Patent, Claim 11, column 13, lines 20-30. However, the

mere absence of the word “specific” from Claim 11 does not mean that this Court read a limitation from a narrow claim into a broader claim; indeed, the use of the identical language indicates that Claim 1 and Claim 11 have the same scope. Moreover, the Court’s Markman ruling on the applicability of the “specific medium” limitation to Claims 11 and 14 was not to sustain their validity but rather because plaintiffs had expressly represented in the patent specification that:

> this invention relates to the detection of a target microbe through the use of a not necessarily sterile testing medium which contains a nutrient which can be significantly metabolized only by the target microbe and which, once metabolized, releases a moiety which alters a characterization of the sample. **The medium is thus a ‘specific medium’ in that it will support growth of only the target microbes rather than a general medium which will also support growth of microbes other than the target microbe**.

‘789 Patent, Column 1, ll. 7-18 (emphasis added). Moreover, the specification continues:

> **Because microbes other than the target microbes are prevented from growing, metabolizing or multiplying**, the media is so specific that the invention does not have to be sterilized before use. **Competition between target microbes and other microbes for the available nutrients in the media is eliminated by the subject invention**. . . . There is no need for a minimum incubation time to ensure growth of the target microbe since no other microbes in the sample will be able to substantially metabolize the nutrient in the media.
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> As previously noted, **using the invention, there is very little or no competition for food or nutrient among the microbes in the media because the only nutrient present in the media can be metabolized to any significant extent solely by the target microbes. Accordingly, a significant number of false-negative tests which will occur with the**

> **procedures of the prior art are eliminated by this invention.** The nutrient used will be one that the target microbes greatly prefer over any other nutrients and also one to which other microbes have little or no preference.

Column 3, ll. 45-51, 57-60 (emphasis added); column 4, ll. 36-46 (emphasis added).

"Where the specification makes clear that the invention does not include a particular feature, that feature is deemed to be outside the reach of the claims of the patent, even though the language of the claims, read without reference to the specification, might be considered broad enough to encompass the feature in question." Scimed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc., 242 F.3d 1337, 1340 (Fed. Cir. 2001). Because the '789 patent specification makes clear that the claimed invention will only support growth of target microbes, and at various points distinguishes prior art on the basis of the use of a general medium and points out the advantages of using a specific medium that will support growth of only the target microbe, the Court concludes that specific medium limitation necessarily applies to all claims in the patent and therefore the previous claim construction rulings were correct. See Scimed, 242 F.3d at 1343 (holding that the fact that the specification claimed a particular feature offered advantages over prior art supported the conclusion that the claims cannot be read so broadly so as to encompass the distinguished prior art).

B. Claim Construction: The ‘259 and ‘933 Patents

Citing concerns of efficiency and judicial economy, plaintiffs do not move for summary judgment on the ‘259 and ‘933 patents because they assert that they are entitled to judgment on the ‘789 patent alone. See Pl. Mem. at 2. Defendant, however, has moved for summary judgment on non-infringement under the ‘259 and ‘933 patents as well as the ‘789 patent, arguing that the “specific medium” requirement of the ‘789 patent is also a limitation of the ‘933 and ‘259 patents.[3] According to defendant, because the specifications of the ‘933 and ‘259 patents define the claimed invention as “a ‘specific medium’ in that it will support growth in log phase of only the target microbes, rather than a general medium which will also support growth in log phase of microbes other than the target microbes” and states that “the medium will only support reproductive growth of the target microbes,” Def. Br. at 17, all three patents contain the claim limitation that the medium must support log-phase, reproductive growth of only the target microbes, even though the term “specific medium” is not used in the claims in either the ‘933 patent or the ‘259 patent.

Plaintiffs assert without citation that “the subsequently issued claims in the ‘933 and ‘259 Patents foreclose the very non-infringing arguments CPI is making here” and argue that “CPI

[3] The parties agree that the ‘933 and ‘259 patent are identical for purposes of the claims at issue here.

is asking the Court to sweep all of this history under the rug without even giving plaintiffs a full and fair opportunity to be heard on matters raised in the subsequent prosecution." Pl. Opp. at 29. However, interpretation of the '933 and '259 patents is a matter of law for the Court to determine, and plaintiffs's opposition to defendant's motion for summary judgment has provided them with ample opportunity to be heard.[4] Therefore, the Court will proceed to interpret the '933 and '259 patents in the context of defendant's motion for summary judgment on non-infringement.

According to plaintiffs, the '933 and '259 specifications differ from the '789 patent specification by permitting the growth of some non-target microbes. Defendant does not dispute that there are some differences between the '789 and '933 and '259 patents, but claims that these differences are not different in any material respect with regard to the construction of the "specific medium" requirement. The Court agrees.

When construing a patent claim, the Court must first analyze "the intrinsic evidence of record -- the claims and written description of the patent itself, and, if in evidence, the prosecution history." Biovail Corp. Int'l v. Andrx

[4] Although plaintiffs claim that they would be "severely prejudiced if the claims of the '933 and '259 patents are construed on this incomplete record and/or in the context of briefing on the pending motions for summary judgment of infringement and non-infringement," there is no explanation as to the nature of any such prejudice, nor why they could not complete the record in their opposition submission. Pl. Opp. at 5.

Pharmaceuticals, Inc., 239 F.3d 1297, 1300 (Fed. Cir. 2001). As discussed above, a patentee may limit the scope of its claims through statements made in the specification. See Scimed, 242 F.3d at 1341; Cultor Corp. v. A.E. Stanley Mfg. Co., 224 F.3d 1328, 1331 (Fed. Cir. 2000) ("Claims are not correctly construed to cover what was expressly disclaimed."). As with the '789 patent, the specification of the '259 patent expressly states that the medium of the invention is a specific medium in which non-target microbes will not experience log-phase reproductive growth. Accordingly, such a limitation is properly construed as part of the claims.

The '259 patent specification states that:

> [T]his invention relates to the detection of a target microbe through the use of a testing medium which medium contains a nutrient which can be significantly metabolized only by the target microbe during log phase of growth in the medium . . . . **The medium is thus a 'specific medium' in that it will support growth in log phase of only the target microbes**, rather than a general medium which will also support growth in log phase of microbes other than the target microbes. . . . **The nutrient-indicator actively participates in the growth of the target microbes by serving as the preferred or primary nutrient source**. The target microbes can grow, metabolize and multiply into log phase because they, and substantially only they, can use the indicator as their primary nutrient. . . . Because **microbes other than the target microbes are prevented from growing, metabolizing or multiplying substantially into log phase**, the medium is so specific that it does not have to be sterilized before use.
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> The testing medium also includes a **minor** amount of a growth accelerant which will boost the target microbes and all of the other viable microbes in the sample through lag phase

> and toward log phase growth in the testing procedure. . . . **The accelerant is present in a small amount so as to be dissipated by the time the microbes enter log phase of growth.**
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> As previously noted, using the invention, **there is very little or no competition for food or nutrients among the microbes in the medium because the only nutrient present in the medium which can be metabolized to any significant extent can be metabolized solely by the target microbes**. . . The nutrient used will be one that the target microbes greatly prefer over any other nutrients, and also, one for which other microbes in the sample have little or no preference, and cannot significantly assimilate.

'259 Patent, Column 1, ll. 20-29; Column 2, ll. 39-42, 62-64; Column 3, ll. 20-25, 28-31.

The patent specification further states:

> In general, with respect to this invention, after the specific medium has been added to the sample, **during the lag phase** while the microbes are adjusting to the presence of the medium **no substantial microbial metabolism will occur with either the target or non-target microbes**. At the beginning of the log phase, all of the microbes will begin to metabolite [sic] the vitamin and mineral components of the medium, **but only the target microbes will also metabolize the specific nutrient component of the medium. This specific nutrient is the only ingredient in the medium which will allow substantial growth**, i.e., growth which will allow microbial reproduction at logarithmic rates (log phase), of any microbes in the sample. **Thus, the medium will only support reproductive growth of the target microbes.** For this reason the population of non-target microbes in the sample will not substantially increase, and will actually begin to decline during the log phase.

Column 7, ll. 13-29.

Claim 1 of the '259 patent claims "a target microbe-specific medium . . . comprising . . . b) an effective amount of a nutrient-indicator which is provided in an amount sufficient to

support log phase growth of said target microbe . . . said nutrient-indicator being incapable of supporting continued logarithmic growth of any viable non-target microbes in the medium/sample mixture to produce a detectable characteristic signal . . . ."

In light of this Claim language and the specification, the Court concludes that the invention claimed by the '259 and '933 patents is limited to those media in which only the target microbes can metabolize and experience log phase, reproductive growth. This construction does not differ markedly from the Court's prior construction of the '789 patent ("the claim limitation which discloses a 'specific medium' means a medium that will support reproductive growth of only the target microbes").

This interpretation of the '259 and '933 patent language is further supported by claims made during the prosecution history of these patents. "[P]rosecution history serves as a limit on the scope of claims by excluding any interpretation for the claim language that would permit the patentee to assert a meaning of the claim that was disclaimed or disavowed during prosecution in order to obtain claim allowance." Zenith Lab., Inc. v. Bristol-Meyers Squibb Co., 19 F.3d 1418, 1421 (Fed. Cir. 1994).

Rejections based upon prior art, including Feng et al. and Trepeta et al., were withdrawn following an amendment, because:

> Applicants appear to claim an invention whereby in a balance of growth rates and media constituents target organisms and non-target organisms are initially boosted from lag to log phase with a limited amount of an 'accelerant.' **Subsequently, the selective and differential nature of the other constituents allows target organisms to thrive while other organisms do not. Such a concept is not taught by the prior art of record.**

Examiner's Office Action, dated May 31, 1991, in application No. 07/349,653 (emphasis added); see also Amendment and Request for Reconsideration dated May 21, 1991, in application No. 07/349,653. Plaintiffs thus expressly represented, and the patent examiner expressly relied on the fact that the claimed invention would permit log-phase reproductive growth of only the target microbe. Accordingly, plaintiffs cannot now "obtain, through litigation, coverage of subject matter relinquished during prosecution." Haynes Int'l, Inc. v. Jessop Steel Co., 8 F.3d 1573, 1577 (Fed. Cir. 1993).

Having construed the claims, the Court now turns to plaintiffs' claims of infringement. Infringement, unlike claim construction, is a question of fact. See Uniroyal, Inc. v. Rudkin-Wiley Corp., 837 F.2d 1044, 1054 (Fed. Cir. 1988).

C. Literal Infringement

"Literal infringement requires the patentee to prove that the accused device contains each limitation of the asserted claim(s)." Bayer AG v. Elan Pharmaceutical Research Corp., 212 F.3d 1241, 1248 (Fed. Cir. 2000); accord Mas-Hamilton Group v.

LaGard, Inc., 156 F.3d 1206, 1211 (Fed. Cir. 1998). If any claim limitation is absent from the accused device, as a matter of law there is no literal infringement. See id.

To summarize the Court's claim construction rulings, the '789, '933 and '259 patents claim an invention in which only target microbes (i.e., E. coli and other coliform bacteria) will reproduce in log-phase growth. This limitation applies to all claims in these three patents, including the method claims 11-14. Thus, to prevail on their motion for summary judgment, plaintiffs must prove that non-target microbes will not reproduce in log phase growth in Colitag; similarly, to prevail on the cross-motion, defendant must prove that non-target microbes do reproduce in Colitag.

According to defendant, Colitag is not a specific medium but rather a "nutrient-rich, general medium" in which multiple non-target microbes will experience substantial, log-phase reproductive growth. Plaintiffs, in turn, contend that Colitag's undisputedly low false-negative rate demonstrates that Colitag is a specific medium as previously construed by this Court.

Plaintiffs claim that the existence vel non of false negatives is a way to determine whether there is reproductive growth of non-target microbes, because where there is significant non-target microbe growth in the medium, there is competition between the targets and the non-targets for necessary nutrients and vitamins and therefore there is a possibility that target

microbes might not be able to reproduce in great enough numbers to cause the color change. At oral argument, plaintiffs' counsel also argued that with significant non-target microbe growth, the medium may become turbid, or cloudy, and thus it might be difficult to determine whether the color change had occurred, which would also lead to an increased false negative rate. Thus, in support of their motion for summary judgment (and in opposition to defendant's motion), plaintiffs rely on EPA field testing which revealed very low false negative rates for Colitag,[5] and claim that this data shows that "a trivial amount of non-target growth has occurred." Pl. Reply Br. at 10.

However, as defendant's expert Dr. Matin notes, even if the reproductive growth of large numbers of non-target microbes under certain circumstances may increase the false negative rate, plaintiffs have not provided any evidence that the inverse is necessarily true. See Matin Supp. Dec. at ¶ 8(b). In other words, the fact that the false negative rate is low in Colitag is not evidence that there is not reproductive growth of non-target microbes. According to Dr. Matin, two factors unrelated to mininal non-target microbe growth account for the low false negative rate in Colitag: the fact that E. coli is able to metabolize efficiently even when other microbes are present and

[5] EPA testing showed a 0% false negative rate for total coliforms and a 1.4% false negative rate for E. coli. Halvorson Decl. ¶ 35. Defendant does not dispute these figures.

the fact that almost all E. coli bacteria are capable of hydrolyzing the indicator (MUG) and thus causing the color-change reaction. Id.

Plaintiffs characterize the '789 patent specification as "contemplat[ing] the use of the false negative test to determine whether a medium is specific." Pl. Opp. at 7. While the specification does assert that "a significant number of false-negative tests which will occur with the procedures of the prior art are eliminated by this invention," it does not refer to the false negative test as part of the definition of a specific medium. Instead, the specification simply claims that fewer false negatives will be experienced through the use of a specific medium -- one in which non-target microbes will not reproduce -- than the prior art general medium.

In support of its cross motion for summary judgment, CPI cites testing by Dr. Rosalind Tung which shows that eleven different microbes were found to grow in Colitag during early field testing and additional tests with the commercial formulation of Colitag showing that salmonella bacteria experienced substantial log phase growth. Defendant also points to additional testing described in the supplemental declaration of Ms. Tung of the commercial formulation of Colitag which showed substantial log phase growth of seven non-target microbes, including salmonella.

Plaintiffs raise several objections to the original Tung testing cited by defendant which they claim preclude entry of summary judgment on defendant's behalf. Plaintiffs argue that the test results showing eleven different microbes capable of reproductive growth in the Colitag medium were conducted on an experimental formulation of Colitag ten years ago, that there were procedural inadequacies to the testing and that the notes describing the testing are too unspecific to permit review. However, plaintiffs have not set forth any explanation as to how the procedural deficiencies had an impact on the outcome of the testing. Moreover, plaintiffs have not raised any methodological or procedural challenge to defendant's more recent testing showing very substantial, log-phase reproductive growth of seven non-target microbes when incubated in small numbers in the commercial formulation of Colitag. See Supp. Decl. of Rosalind Tung [doc. #97], Table 1. Most notably, plaintiffs have not submitted any testing showing that non-target microbes do not grow in Colitag.

In light of the evidence submitted by defendant showing substantial growth of non-target microbes in Colitag, particularly the unchallenged supplemental testing by Dr. Tung of the commercial Colitag, and the absence of any testing from plaintiffs showing that non-target microbes do not grow in Colitag or any evidence showing that the testing performed by defendant was inadequate in some way that would have made a

difference in the outcome, there simply is not any genuine dispute of material facts as to whether Colitag is a specific medium, and defendant is entitled to summary judgment on literal infringement.[6]

D. Doctrine of Equivalents

Plaintiffs also claim that defendant's product infringes claims 2 and 14 of the '789 patent under the doctrine of equivalents. According to plaintiffs, because Colitag contains sodium lauryl sulfate, which operates similarly to an antibiotic to inhibit microbial growth, Colitag infringes these claims by performing the same function to achieve the same result. Pl. Br. at 23. Because the Court has already found that Colitag is not a specific medium, and Claims 2 and 14 both incorporate the specific medium requirement, plaintiffs' motion for summary judgment on infringement of Claims 2 and 14 of the '789 patent is denied.[7]

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[6] Because the conclusion that Colitag is not a specific medium necessarily requires the grant of summary judgment in defendant's favor on literal infringement of the '789, '259 and '933 patents, the Court need not reach defendant's additional claim that Colitag does not read onto the plaintiffs' patents because the nutrient-indicators MUG and ONPG are not primary or preferred nutrients in Colitag.

[7] Plaintiffs do not, and could not, argue that Colitag infringed under the doctrine of equivalents even though it was not a specific medium because plaintiffs expressly disclaimed general media during the prosecution history of the patents at issue. See Biovail Corp. Int'l v. Andrx Pharmaceuticals, Inc., 239 F.3d 1297, 1303-04 (Fed. Cir. 2001) ("'When a claim amendment creates prosecution history estoppel with regard to a claim element, there is no range of equivalents available for the amended claim element.'") (quoting Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd, 234 F.3d 558, 569 (Fed. Cir. 2000) (en banc)).

E. Acts of Inducement and Contributory Infringement

Finally, plaintiffs' motion for summary judgment based on acts of inducement and contributory infringement arising out of the sale and marketing of Colitag is denied because summary judgment has been granted in defendant's favor on non-infringement. See Joy Tech., Inc. v. Flakt, Inc., 6 F.3d 770, 774 (Fed. Cir. 1993) ("Liability for either active inducement of infringement or for contributory infringement is dependent upon the existence of direct infringement.").

IV. CONCLUSION

For the foregoing reasons, the undisputed facts demonstrate that Colitag is not a "specific medium" as previously construed by this Court's ruling.

Accordingly, Plaintiffs' Motion for Summary Judgment [doc. #88] is DENIED and Defendant's Motion for Summary Judgment on the '789, '933 and '259 patents [doc. #75] is GRANTED.

IT IS SO ORDERED.

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Janet Bond Arterton, U.S.D.J.

Dated at New Haven, Connecticut: June 04, 2001