UNITED STATES DISTRICT COURT DISTRICT OF CONNECTICUT

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JENERIC/PENTRON, INC.	:		
Plaintiff	:		
	:		
v.	:	No.	3:98cv818(EBB) - Lead
	:	No.	3:99cv1775 (EBB)
DILLON COMPANY, INC.,	:		
CHEMICHL INC., and	:		
CHEMICHL AG.,	:		
Defendants	:		

Ruling on Cross Motions for Summary Judgment

Plaintiff Jeneric/Pentron, Inc. ("Jeneric") brought this patent infringement action against Defendants Dillon Company, Inc. ("Dillon"), Chemichl, Inc. ("Chemichl"), and Chemichl AG ("Chemichl AG"), pursuant to 35 U.S.C. § 271 (1998), alleging that Defendants sell two products that infringe United States Patent No. 5,653,791 entitled "Two-Phase Dental Porcelain Composition" ("'791 Patent") and United States Patent No. 5,944,884 entitled "Dental Porcelain Composition" ("'884 Patent"). Jeneric seeks an injunction, damages, and attorney's fees as remedies. In turn, Dillon and Chemichl have asserted federal and state counterclaims against Jeneric. This ruling addresses Defendants' Combined Motions for Summary Judgment [doc. no. 84], and Plaintiff's Cross Motion for Partial Summary Judgment [doc. no. 92]. For the reasons that follow, Defendants' combined motions are granted in part and denied in part, and Plaintiff's cross motion is denied.

I. BACKGROUND

A. <u>Parties and Competing Products</u>

Plaintiff manufactures dental materials and related oven equipment, which it markets to dentists and dental technicians for the construction of dental restorations such as inlays, crowns, and bridges. Plaintiff is the owner by assignment of the '791 and '884 patents. Inventors Carlino Panzera and Lisa Kaiser filed the '791 Patent application on March 12, 1996, and the '884 Patent application on May 28, 1998. The United States Patent and Trademark Office (PTO) issued the '791 Patent on August 5, 1997 and issued the '884 Patent on August 31, 1999.

Both patents relate to dental porcelain compositions, which have specified ingredients and which exhibit certain properties. Porcelain is a type of ceramic material, which has a crystalline phase and a glass phase. Ceramics prove useful in dental restorations because they can be colored to resemble teeth and they resist degradation inside the oral cavity. The '791 and '884 patents both teach a two-phase porcelain composition, which comprises a leucite crystallite phase disbursed in a glass phase. According to Plaintiff, the critical feature of both patents is that they direct a composition where the leucite crystals in a completed dental restoration must all be smaller than 10 microns. Indeed, both patents provide that "[i]t is essential to the practice of the present invention that the leucite crystallites present in the two-phase porcelain composition herein possess

diameters not exceeding about 10 microns." ('791 Patent, col. 2, lines 48-50; '884 Patent, col. 2, lines 54-57.) This has the effect of reducing abrasive wear against natural teeth and discomfort inside the mouth. (Id.)

Defendants Dillon, based in Rhode Island, and Chemichl, based in Washington, sell two dental porcelain products used in conjunction with each other that Plaintiff accuses of infringing both the '791 and the '884 patents. The first product, known as Cerpress SL ("Cerpress"), constitutes a ceramic pellet used as a core or base material in a dental restoration. The second product, known as Sensation SL ("Sensation"), is applied over the Cerpress core to form a complete dental implant. Dillon and Chemichl import Cerpress and Sensation into the United States from Chemichl's parent company, Chemichl AG of the Country of Liechtenstein. Dillon then resells the two products to dental technicians and dentists for the construction of dental restorations.

B. <u>Procedural Background</u>

Plaintiff's first action charges Defendants with infringement of the '791 Patent, asserting that Sensation literally infringes claims 1 and 2, and that Cerpress infringes claim 1 under the doctrine of equivalents. [Doc. 3:98cv818(EBB)] As relief, Plaintiff seeks an injunction pursuant to 35 U.S.C. § 283, treble damages pursuant to 35 U.S.C. § 284, and reasonable attorney's fees and costs under 35 U.S.C. § 285. Defendants

respond with the affirmative defenses that Sensation and Cerpress do not infringe any claim of the '791 Patent, that each claim of the '791 Patent is invalid and void, and that the '791 Patent is unenforceable.

In addition, Dillon has asserted the following counterclaims against Jeneric: (1) tortious interference with contractual relations; (2) tortious interference with business relations; (3) violation of the Connecticut Unfair Trade Practices Act, Conn. Gen. Stat. §§ 42-110a et seq.; and (4) wrongful attempt to monopolize in violation of Section 2 of the Sherman Antitrust Act, 15 U.S.C. § 2 (1998). To this end, Dillon seeks a declaratory judgment of noninfringement, a declaratory judgment that the '791 Patent is invalid, treble damages, punitive damages, and attorney's fees and costs. Jeneric responds to the counterclaims by arguing that Dillon failed to state a claim upon which relief can be granted, that the counterclaims are unduly vague, and that Dillon is guilty of unclean hands.

On June 26, 1998, Plaintiff moved for a preliminary injunction, seeking to enjoin Defendants from making, using, selling, offering to sell, or importing the two accused products into the United States. Pursuant to this motion, the Court held a three-day hearing where the parties presented oral testimony and over 500 exhibits. On February 3, 1999, the Court denied Plaintiff's preliminary injunction motion on the ground that it failed to demonstrate a reasonable likelihood of success in

proving that either Sensation or Cerpress infringed the '791
Patent. See Jeneric/Pentron, Inc. v. Dillon Co., No.
3:98cv818(EBB), 1999 WL 66537 (D. Conn. Feb. 3, 1999). On March
20, 2000, the Federal Circuit affirmed this Court's decision.
See Jeneric/Pentron, Inc. v. Dillon Co., 205 F.3d 1377 (Fed. Cir.
2000).

During the pendency of the preliminary injunction proceedings and its appeal, Plaintiff prosecuted the application that ultimately issued as the '884 Patent. This application was filed on May 28, 1998, four weeks after Plaintiff initiated the '791 Patent infringement action. The PTO issued the '884 Patent on August 31, 1999, and on September 9, 1999, Plaintiff filed a second action against Defendants for infringement of the '884 Patent. [Doc. No. 3:99cv1775(EBB)] Defendants deny the allegations and filed counterclaims against Plaintiff for 1) a declatory judgment regarding the relative rights of the parties with respect to infringement of the '884 Patent; 2) fraudulent procurement of the '884 Patent; 3)"attempt to monopolize," in violation of the Sherman Act, 15 U.S.C. § 2; 4) unfair competition under Connecticut Common law; and 5) unfair practices in violation of CUTPA.

Under the first action, Defendants had filed two motions for partial summary judgment. On April 7, 2000, following a conference in Chambers, this Court consolidated the two actions. Defendants then withdrew their pending motions for summary

judgment without prejudice in order to refile the motions directed at both the '791 and the '884 Patents. In a letter dated May 2, 2000, Plaintiff identified its asserted claims. Plaintiff now asserts claim 1 of the '791 Patent against Cerpress under the doctrine of equivalents, and asserts claims 1-8, 13-15 and 18 of the '884 Patent against both Cerpress and Sensation. Defendants' Combined Motions for Summary Judgment and Plaintiff's Cross Motion for Summary Judgment are before the Court.

II. SUMMARY JUDGMENT

A motion for summary judgment will be granted when "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the 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); <u>see also Anderson v. Liberty Lobby</u>, 477 U.S. 242, 256 (1986). The moving party carries the burden of showing the absence of any genuine issue of material fact. Fed. R. Civ. P. 56. The court must "resolve all ambiguities and draw all inferences in favor of the nonmoving party. . . ." <u>Aldrich</u> v. Randolph Cent. Sch. Dist., 963 F.2d. 520, 523 (2d Cir.).

"[T]he mere existence of <u>some</u> alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment; the requirement is that there be no <u>genuine</u> issue of <u>material</u> fact. As to materiality, the substantive law will identify which facts are material. Only

disputes over facts that might affect the outcome of the suit under the governing law will properly preclude the entry of summary judgment. Factual disputes that are irrelevant or unnecessary will not be counted." <u>Anderson</u>, 477 U.S. at 247-48 (emphasis in original).

In addition, if the nonmoving party has failed to make a sufficient showing on an essential element of his case with respect to which he has the burden of proof at trial, then summary judgment is appropriate. <u>Celotex Corp. v. Catrett</u>, 477 U.S. 317, 322 (1986). "In such a situation, there can be 'no genuine issue as to any material fact,' since a complete failure of proof concerning an essential element of the nonmoving party's case necessarily renders all other facts immaterial." <u>Id</u>. at 322-23; <u>accord Goenaga v. March of Dimes Birth Defects Found.</u>, 51 F.3d 14, 18 (2d. Cir. 1995)(movant's burden satisfied if it can point to an absence of evidence to support an essential element of nonmoving party's claim).

In a patent infringement case, summary judgment is appropriate when it is apparent that only one conclusion as to infringement could be reached by a reasonable jury. <u>ATD Corp. v.</u> <u>Lydall, Inc.</u>, 159 F.3d 534, 540 (Fed. Cir. 1998). Summary judgment of noninfringement is appropriate where the patent owner's proof is deficient in meeting an essential part of the legal standard for infringement, since such failure will render

all other facts immaterial. <u>See London v. Carson Pirie Scott &</u> <u>Co.</u>, 946 F.2d 1534, 1537 (Fed. Cir. 1991). "The purpose of summary judgment is not to deprive a litigant of 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 own view of the facts." <u>Vivid Tech., Inc. v. American Science &</u> <u>Eng'g, Inc.</u>, 200 F.3d 795, 806 (Fed. Cir. 1999) (citing <u>Voive</u> <u>Techs. Groups, Inc. v. VMC Sys., Inc</u>. 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." <u>Massey v. Del Labs., Inc.</u> 118 F.3d 1568, 1573 (Fed. Cir. 1997). The party seeking summary judgment always bears the initial burden of establishing the absence of a genuine issue of material fact and that it is entitled to judgment as a matter of law. <u>See Celotex Corp. v.</u> <u>Catrett</u>, 477 U.S. 317, 323 (1986). The burden then shifts, and "the nonmoving party [must] go beyond the pleading and by her own affidavits, or by the 'depositions, answers to interrogatories, and admissions on file,' designate 'specific facts showing that there is a genuine issue for trial.'" <u>Glaverbel Societe Anonyme</u> & Fosbel, Inc. v. Northlake Mktg. & Supply, Inc., 45 F.3d 1550,

1560-61 (Fed. Cir. 1995) (quoting <u>Celotex</u>, 477 U.S. at 324)). Broad conclusory statements by the nonmoving party and/or its experts on the ultimate issue of infringement, however, are insufficient to create a genuine issue of material fact and defeat summary judgment. <u>See Arther A. Collins, Inc. v. Northern</u> <u>Telecom, Ltd.</u>, 216 F.3d 1042, 1046 (2000); <u>Capital Imaging v.</u> <u>Mohawk Valley Medical Assoc.</u>, 996 F.2d 537, 542 (2d Cir. 1993) ("Non-moving party [must] produce probative evidence [and] must do more than simply show that there is some metaphysical doubt as to the material facts." (quotations omitted)); <u>W.L. Gore & Assoc.</u> <u>v. Garlock , Inc.</u>, 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. STATEMENT OF FACTS

The following undisputed facts are culled from the parties' Local Rule 9(c) Statements, and the exhibits attached to their respective motions. The Court sets forth only those facts deemed necessary to an understanding of the issues raised in, and decision rendered on, these motions.

The '791 Patent issued on August 5, 1997 from an application filed on March 12, 1996. Claim 1 of the '791 Patent reads as follows:

1. A two-phase porcelain composition comprising a leucite crystallite phase dispersed in a feldspathic glass matrix, a

maturing temperature of from about 750° to about 1050 °C. and a coefficient of thermal expansion of from about 12×10^{-6} /°C. to about 17.5×10⁻⁶/°C. (room temperature to 450° C.), said porcelain composition comprising:

Component	Amount (wt.%)
SiO ₂	57-66
Al ₂ O ₃	7-15
K ₂ O	7-15
Na ₂ O	7-12
Li ₂ O	0.5-3
CaO	0-3
MgO	0-7
F	0-4
CeO ₂	0-1

wherein the leucite crystallites possess diameters not exceeding about 10 microns and represent from about 5 to about 65 weight percent of the two-phase porcelain composition.

('791 Patent, col. 6, lines 11-32.) The '884 Patent issued on

August 31, 1999 from an application filed on May 28, 1998. Claim

1 of the '884 Patent reads as follows:

1. A porcelain composition comprising a leucite crystallite phase and a glass matrix phase, the leucite crystallites possessing diameters not exceeding about 10 microns and representing from about 5 to about 65 weight percent of the porcelain composition, and wherein the porcelain composition comprises:

Component	Amount (wt.%)
SiO ₂	58-65	
Al ₂ O ₃	7-15	
K ₂ O	7-15	
Na ₂ O	7-12	
Li ₂ O	0.5-3	

('884 Patent, col. 6, lines 20-34.)

The '884 Patent application is a "child" application that is a continuation of a "parent" application which was a division of a "grandparent" application that matured into the '791 Patent. Under 35 U.S.C. § 120, patents related in these ways are entitled to the benefit of the first application date. Therefore, the '884 Patent is accorded the benefit of the '791 Patent's March 12, 1996 filing date.

Due to the abundance of facts and diversity of arguments at bar, the remaining facts will be discussed as they arise in relation to specific arguments. All facts recited herein are undisputed unless otherwise indicated.

IV. DISCUSSION

Defendants' seek summary judgment, requesting a declaration of noninfringement and a ruling that 1) the asserted claims of the '791 and '884 patents are invalid because they are "anticipated" under 35 U.S.C. § 102(b) by the issuance of United States Patent No. 4,604,366 ("'366 Patent") in 1986; 2) that the asserted claims of the '884 Patent are invalid because they are "anticipated" by Defendant Chemichl Ag's LF-1-PFM composition which was "on sale" under 35 U.S.C. § 102(b) in the United States more than one year prior to the application date of the patents at issue; 3) that Cerpress does not infringe any asserted claim; and 4) that the '884 Patent is unenforceable because Plaintiff

perpetrated a fraud on the PTO.¹ In response, Plaintiff opposes Defendants' combined motions for summary judgment, raising material issues of disputed facts, and cross moves for partial summary judgment on infringement of the '884 Patent by the Sensation product.

Any determination of patent infringement requires a two-step analysis. First, courts must construe the asserted claims of the patent to determine their proper scope and meaning. <u>See Wright</u> <u>Med. Tech., Inc. v. Osteonics Corp.</u>, 122 F.3d 1440, 1443 (Fed. Cir. 1997); <u>Carroll Touch, Inc. v. Electro Mechanical Sys., Inc.</u>, 15 F.3d 1573, 1576 (Fed. Cir. 1993). Claim construction is a question of law for the court. <u>See Markman v. Westview</u> <u>Instruments, Inc.</u>, 52 F.3d 967, 979 (Fed. Cir. 1995) (en banc), <u>aff'd</u>, 517 U.S. 370 (1996). Second, courts must determine whether the properly construed claims read onto the accused structure. <u>See General Mills, Inc. v. Hunt-Wesson, Inc.</u>, 103 F.3d 978, 981 (Fed. Cir. 1997). Whether the accused device contains an element corresponding to each claim limitation, or its equivalent, is a question of fact for trial. <u>See id</u>.

¹ Defendants' motions included a request for sanctions against Plaintiff under Rule 11. In a subsequent pleading, however, Defendants' withdrew their Rule 11 motion "without prejudice for the moment", pending resolution of a motion to compel disclosure of "pre-Complaint testing data", still before the Court at this time. (Reply Mem. in Supp. of Defs.' Combined Mots. for Summ. J., and in Opp'n to Pl.'s Cross-Mot. for Summ. J. at 34.)

A. <u>Claim Construction</u>

A patent does not protect everything it describes, but rather only the innovations set forth in its claims, which provide the metes and bounds of the invention. The claims of a patent, as distinguished from the specification and drawings, define the invention protected by the patent. <u>See Smith v. Snow</u>, 294 U.S. 1, 11 (1935); <u>Novo Nordisk v. Genentech, Inc.</u>, 77 F.3d 1364, 1369 (Fed. Cir. 1996). Courts may consult both intrinsic and extrinsic evidence as aids in construing patent claims. <u>See</u> <u>Vitronics Corp. v. Conceptronic, Inc.</u>, 90 F.3d 1576, 1582 (Fed. Cir. 1996). Intrinsic evidence consists of the patent itself, the claim or claims at issue, the specification, and the prosecution history. <u>See id</u>. Extrinsic evidence includes expert testimony, inventor testimony, dictionaries, technical treatises, and prior art not cited in the prosecution history. <u>See Markman</u>, 52 F.3d at 980.

Under established rules of claim construction, intrinsic evidence of a patent constitutes "the most significant source of the legally operative meaning of disputed claim language." <u>Vitronics</u>, 90 F.3d at 1582. The claims, specification, and prosecution history constitute the public record of a patentee's claim, upon which competitors may rely. <u>See Markman</u>, 52 F.3d at 978-79. Allowing a clearly drafted claim to be altered by extrinsic evidence would destroy the rights of competitors to rely on the public record and design around the claimed

invention. See Southwall Tech., Inc. v. Cardinal IG Co., 54 F.3d 1570, 1578 (Fed. Cir. 1995). Thus, reliance upon extrinsic evidence is improper where the intrinsic evidence unambiguously describes the scope of the patented invention. See Markman, 52 F.3d at 978-79, 986; Bell & Howell, 132 F.3d at 705-06.

In construing patent claims, a court must first consider the words of the claims themselves, both asserted and unasserted. See <u>Vitronics</u>, 90 F.3d at 1582-83. These words generally should be given their customary and ordinary meaning to one of skill in the art. See Hoechst Celanese Corp. v. BP Chems. Ltd., 78 F.3d 1575, 1578 (Fed. Cir. 1996). Next, a court must review the patent specification to determine if the inventor used any terms in a manner inconsistent with their ordinary meaning. See Vitronics, 90 F.3d at 1582. The specification contains a description of the invention, and the manner and process for making and using it in such full, clear, and exact terms as to enable any person skilled in the art to make and use it. See 35 U.S.C. § 112. In addition, the specification must explain the best mode or preferred embodiment for carrying out the invention, see id., and thus can serve as a dictionary for defining terms in the claims. See Markman, 52 F.3d at 979.

Courts also may examine the prosecution history of the patent, if in evidence. <u>See Graham v. John Deere Co.</u>, 383 U.S. 1, 33 (1966). The prosecution history includes a "complete record of all the proceedings before the Patent and Trademark Office,

including any express representations made by the applicant regarding the scope of the claims." <u>Vitronics</u>, 90 F.3d at 1582. Extrinsic evidence such as expert testimony, inventor testimony, dictionaries, technical treatises, and prior art provides a final source for claim interpretation when needed to explain scientific principles, technical terms, and terms of art. <u>See U.S. Indus.</u> <u>Chems., Inc. v. Carbide & Carbon Chems. Corp.</u>, 315 U.S. 668, 678 (1942); <u>Pall Corp. v. Micron Separations, Inc.</u>, 66 F.3d 1211, 1216 (Fed. Cir. 1995).

Claims can either be independent or dependent. An independent claim does not refer to any other claim of the patent and is read separately to determine its scope. A dependent claim refers to at least one other claim in the patent, includes all of the limitations of the claim to which it refers, and specifies a further limitation on that claim. See Wahpeton Canvas Co., Inc. v. Frontier, Inc., 870 F.2d 1546, 1553 (Fed. Cir. 1989); 35 U.S.C. 112. By definition, a dependent claim must be narrower than the independent claim upon which it relies. See Quantum, 65 F.3d at 1579. One may infringe an independent claim and not infringe a claim dependent upon that claim. The reverse is not true. One who does not infringe an independent claim cannot infringe a claim dependent on, and thus containing all the limitations of, that claim. See Wolverine World Wide, Inc. v. <u>Nike, Inc.</u>, 38 F.3d 1192, 1199 (Fed. Cir. 1994). In other words, "the dependent claim tail cannot wag the independent claim dog."

North Am. Vaccine, Inc. v. American Cyanamid Co., 7 F.3d 1571, 1577 (Fed. Cir. 1993).

1. <u>Prior Claim Construction of the '791 Patent</u>

In the context of ruling on Plaintiff's preliminary injunction motion, this Court construed claims 1 and 2 of the '791 Patent. Plaintiff argued that the elements comprising claims 1 and 2 were not limited to the weight percentage ranges set forth therein. The Court rejected Plaintiff's proposed construction and construed claim 1

as being limited to the exact weight percentage ranges for its chemical components. The proper construction of claim 1 reveals that there must be a maximum of 1% of CeO sub2 and 15% of Al sub2 O sub3 in the composition of the accused devices in order to find literal infringement.

<u>Jeneric/Pentron</u>, 1999 WL 66537 at *11. The Court also found that claim 1's precise weight percentage may not be modified by claim 2, because claim 2 is in dependent form. <u>See id.</u> at *10-*11.

Based on this construction, the Court denied Plaintiff's request for a preliminary injunction, finding that Plaintiff had

failed to demonstrate a reasonable likelihood of success in proving that Sensation literally infringes claims 1 and 2 of the '791 patent. Sensation does not literally infringe because it contains 1.61% of CeO sub2, whereas claim 1 unambiguously specifies a range of 0-1% for this element.

<u>Id.</u> at *14. In regard to infringement by Cerpress, the Court found that "Jeneric has not demonstrated a reasonable likelihood of success in proving that Cerpress infringes claim 1 of the '791 patent under the doctrine of equivalents," because while it invoked the doctrine of equivalents in regard to lithium oxide,

it did not assert the doctrine with respect to aluminum oxide, a second element whose weight percentage, tested at 15.97%, fell outside the specified range claimed in the '791 Patent. <u>Id.</u>

On appeal, the Federal Circuit agreed that, "the claim language indicates that the invention's chemical components should be limited to the precise ranges set forth therein," and upheld this Court's construction of the '791 Patent. <u>Jeneric/Pentron, Inc. v. Dillon Co., Inc.</u>, 205 F.3d 1377, 1381-82 (Fed. Cir. 2000). In regard to the application of the construed claim to the accused devices, the Federal Circuit agreed with this Court's determination that because Sensation contains 1.61% of cerium oxide (CeO₂), and claim 1 limits the range to 0-1%, Jeneric did not show a reasonable likelihood of success on literal infringement by Sensation. <u>See id.</u> at 1382-83.

In regard to whether Cerpress infringes on claim 1 of the '791 Patent under the doctrine of equivalents, the Federal Circuit upheld this Court's determination that Jeneric had not demonstrated a likelihood of success in the context of a preliminary injunction motion, but did not reach the issue of infringement because this Court had not actually performed an equivalents analysis for the lithium oxide in claim 1, and conflicting evidence in the "preliminary record disclos[ed] several issues for resolution during trial." Id. at 1384. Based upon thorough review, and in light of the Federal Circuit's ruling, this Court adheres to its prior construction of claim 1

of the '791 Patent as being limited to the exact weight percentage ranges for its chemical components.

2. <u>Additional Construction of the '791 Patent and</u> <u>Construction of the '884 Patent</u>

Additional construction of claim 1 of the '791 Patent and construction of the same element in claim 1 of the '884 Patent is necessary in connection with Defendants' claim of invalidity by anticipation, and Plaintiff's response thereto. A dispute exists as to whether the limitation that the leucite crystals possess "diameters not exceeding about 10 microns", ('791 Patent, Column 6, lines 29-30; '884 Patent, Column 6, lines 21-22), found in claim 1 of each patent, refers to the micron size in the raw material or in the final composition. Plaintiff urges the Court to construe this limitation as the size of leucite crystals required in the "final restoration," relying on the specification in each "Summary of the Invention Section":

It is essential to the practice of the present invention that the leucite crystallites present in the two-phase porcelain composition herein possess diameters not exceeding about 10 microns. Diameters in excess of about 10 microns will impart an undesirably rough and uneven surface to the composition when employed in its intended environment of use. Indeed, it has been determined that leucite diameters above about 10 microns may wear away <u>local dentition</u> and cause discomfort/irritation <u>inside the oral cavity</u>.

('791 Patent, col. 2, lines 49-57; '884 Patent, col. 2, lines 54-62 (emphasis added)). Plaintiff argues that these statements make clear that the leucite crystal size limitation is directed to the "final restoration." Defendants, however, argue that the plain language in both claims refers to a "porcelain composition" rather than a "final restoration." Specifically, Defendants point to claim 14 of the '884 Patent, which discloses a "dental restoration comprising a high expansion metal alloy or ceramic framework and at least one coating fused thereon of the <u>porcelain composition</u> of claim 1," ('884 Patent, col. 7, lines 54-56 (emphasis added)), as proof that claim 1 does not refer to a "final restoration." According to Defendants, this differentiation in terms shows that the "not exceeding about 10 microns" limitation refers to the leucite crystal size in the raw material rather than in the final product.

While the Court is aware that "a patent claim is not necessarily limited to a preferred embodiment disclosed in the specification," <u>see Transmatic, Inc. v. Gulton Indus., Inc.</u>, 53 F.3d 1270, 1277 (Fed. Cir. 1995), and that judges may not read into a claim a limitation that appears in the specification but not in the claim, <u>see Minnesota Mining Mfg. Co. v. Johnson &</u> <u>Johnson Orthopaedics, Inc.</u>, 976 F.2d 1559, 1566 (Fed. Cir. 1992); <u>SRI Int'l v. Matsushita Elec. Corp. of Am.</u>, 775 F.2d 1107, 1121-22 (Fed. Cir. 1985), the Federal Circuit has "repeatedly stated" that "claims must be read in view of the specification of which they are a part," that the specification is usually "dispositive," and that the specification "is the single best guide to the meaning of a disputed term." <u>Vitronics</u>, 90 F.3d at

1582.

Here, the disputed limitation in claim 1 of each patent, read in light of the specifications cited by Plaintiff, are, in the Court's view, unambiguous. Neither claims to being, in and of itself, a final dental restoration. Rather both claims disclose a "dental porcelain composition . . . useful in the preparation and repair of dental restorations such as porcelainfused-to metal restorations, all-ceramic restorations, inlays, onlays, and veneers." ('791 Patent, col. 1, lines 4-11; '884 Patent, col. 1, lines 13-20.) Therefore, Defendants' citation to claim 14 is inapposite. When Plaintiff asks the Court to construe the leucite crystal size limitation in claim 1 as the size required in the "final restoration," the Court understands this to mean the final porcelain composition taught by the claim. In other words, the limitation refers to the leucite crystal properties as they exist in the final product offered by the invention, not to the size of the leucite crystals before they are blended and heated. The fact that the invention's porcelain composition might serve as a glaze on a dental restoration, rather than embody the entire restoration, does not diminish the fact that the "porcelain composition" disclosed in claim 1 of each patent constitutes the final composition of the invention's product.

Accordingly, based on the plain language of the patents and the specifications' references to "wear" on "local dentition,"

and to "discomfort/irritation inside the oral cavity," the Court construes the leucite crystal size limitation "not exceeding about 10 microns" in claim 1 of both the '791 and the '884 patents, as directed to the size of the leucite crystallites in the "final restoration," that is, the final dental porcelain composition created by the invention.

B. <u>Anticipation</u>

Defendants' first ask for summary judgment that the asserted claims of the '791 and '884 patents are invalid because they are "anticipated" under 35 U.S.C. § 102(b) by the issuance of the '366 Patent and the disclosure embodied in Example 2. Plaintiff argues that the '791 and '884 patents are distinguishable from the '366 Patent on the size of their leucite crystals, and that the Examiner who prosecuted the '884 Patent considered Example 2 of the '366 Patent.

On December 7, 1998, in the first Office Action taken on the application that matured into the '884 Patent [hereinafter "'884 Application"], the Examiner rejected claims 1-8, 12, and 16-19² under 35 U.S.C. § 102(b) as being anticipated by, among others, the '366 Patent, stating that "['366] teach[es] the production of a porcelain composition including Leucite crystals having an exemplified crystallite size of 5 to 10 microns (see example 2)

² Plaintiff has asserted claims 1-8, 13-15, and 18 of the '884 Patent. These issued claims correspond to claims 1-8, 16-18, and 22, respectively, of the original application.

with a thermal expansion within the instant claims." The '366
Patent, issued on August 5, 1986, qualifies as an item of prior
art under 35 U.S.C. § 102(b), and was cited as a prior art
reference during the prosecution of both the '791 and the '884
patents. The '366 Patent directs various dental porcelain
compositions, which blend various combinations of a "glassy phase
matrix" and a "dispersed leucite phase." (Defs.' Ex. 6, '366
Patent.) While there is clearly dispute between the parties
about the '366 Patent's overall readability on the '791 and '884
patents, there appears to be little dispute over the readability
of Example 2 of the '366 Patent on each element of the asserted
claims, except with regard to their respective limitations on the
size of leucite crystals.

As set forth above, claim 1 of both the '791 and the '884 patents have the express limitation that the leucite crystallites "possess diameters not exceeding about 10 microns," a limitation which, based on the Court's construction of those claims above, refers to the size of the leucite crystallites in the final porcelain composition. Example 2 of the '366 Patent, teaches the blending of two "master frits", the first "doped" with 4 percent potassium nitrate and the second "doped" with 9 percent potassium nitrate, a substance that controls the amount of leucite crystals.

Both of the master frits contained leucite in a 5 to 10 micron particle size range dispersed in the residual glassy phase . . . A porcelain product was prepared from a mixture

of equal parts of the first and second master frits. The Porcelain product, which had a fusion temperature of about 955 degrees C. exhibited a coefficient of thermal expansion which was intermediate that of the respective master frits."

(Defs.' Ex. 6, '366 Patent, Example 2, col. 9, lines 22-35.) Based on Example 2, Defendants argue that the '366 Patent teaches a <u>final</u> porcelain composition containing leucite crystals in the 5 to 10 micron range. Plaintiff's, however, claim that Example 2 of the '366 Patent teaches a blending of two glass-ceramic frits, which, <u>prior to heating</u>, contain leucite crystals in a 5 to 10 micron range. Plaintiff asserts that "it is well known in the ceramic arts that the heating of such a mixture as described in Example 2 promotes growth of the leucite crystals." (Pl.'s Resp. to Defs.' Statement of Undisputed Facts & Pl.'s Statement of Additional Facts in Dispute [hereinafter "Pl.'s 9(c)(2)"] at 4-5.) The resulting porcelain composition taught by Example 2, Plaintiff contends, contains leucite crystals 2 to 50 microns in size, as taught by columns 4 and 7 of the '366 Patent.

Therefore, whether the "5 to 10 micron particle size" limitation set forth in Example 2 refers to the size of the leucite crystals in the final porcelain composition or their size prior to heating hinges on the factual question of whether the leucite crystals described in Example 2 will grow when heated to 955 degrees Celsius. Defendants' expert, Dr. Walker, opined that "at 955 degrees the leucite crystals will not grow," and that a temperature of 1150 degrees was necessary for growth. (Defs.'

Ex. 7, Walker Test. at 122.) Both of Plaintiff's experts (and inventors of the '791 and '884 patents), however, opined that the leucite crystals, as described in Example 2, will grow at temperatures as low as 500 to 700 degrees. (Pl.'s Ex. 5(A), Panzera Test. at 78-80, 162-65; Pl.'s Ex. 5(C), Kaiser Test. at 83-84.)

All patents are entitled to a presumption of validity under 35 U.S.C. § 282. A defendant must provide clear and convincing evidence of invalidity to overcome this presumption. See Amazon.com, Inc. v. Barnesandnoble.com, Inc., 239 F.3d 1343, 1358 (Fed. Cir. 2001) ("To succeed with a summary judgment motion of invalidity . . ., the movant must demonstrate a lack of genuine dispute about material facts and show that the facts not in dispute are clear and convincing in demonstrating invalidity."); Union Oil Co. v. Atlantic Richfield Co., 208 F.3d 989, 994 (Fed. Cir. 2000). "The presumption of validity under 35 U.S.C. § 282 carries with it the presumption that the Examiner did his duty and knew what claims he was allowing. Therefore, the challenger's burden is especially difficult when the prior art was before the PTO examiner during prosecution of the application." Al-Site Corp. v. VSI Int'l, Inc., 174 F.3d 1308, 1323 (Fed. Cir. 1999) (citations and quotations omitted); see also Hewlett-Packard Co. v. Bausch & Lomb Inc., 909 F.2d 1464, 1467 (Fed. Cir. 1990).

"To anticipate a claim, a prior art reference must disclose

every limitation of the claimed invention, either explicitly or inherently." Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342, 1346 (Fed. Cir. 1999) (quoting <u>In re Schreiber</u>, 128 F.3d 1473, 1477 (Fed. Cir. 1997)); Electro Med. Sys. v. Cooper Life Sciences, Inc., 34 F.3d 1048, 1052 (Fed. Cir. 1994). "Anticipation of a patent claim requires a finding that the claim at issue 'reads on' a prior art reference," Atlas, 190 F.3d at 1346, and "is a question of fact, including whether or not an element is inherent in the prior art." Id.; Union Oil Co., 208 F.3d at 994. "Specifically, when a patent claims a chemical composition in terms of ranges of elements, any single prior art reference that falls within each of the ranges anticipates the claim . . .," "regardless of whether it also covers subject matter not in the prior art." Atlas, 190 F.3d at 1346. Therefore, in the context of anticipation defenses, the district court must "assess the meaning of the of the prior art references cited to support the validity challenge." Amazon.com, 239 F.3d at 1358. What a prior art reference teaches is a question of fact; therefore, "the district court necessarily makes fact-findings, explicitly or implicitly, concerning the meaning of the asserted references." Id.

Both parties are now in agreement that the factual dispute over whether and to what extent the leucite crystals taught by Example 2 will grow when heated constitutes a material factual issue sufficient to preclude summary judgment that the asserted

claims of the '791 and '884 patents are invalid on the ground of anticipation. (Pl.'s 9(c)(2) at 9; Pl.'s Consolidated Opp'n to Defs.' Combined Mots. for Summ. J. & Cross Mot. for Partial Summ. J. for Infringement of the '884 Patent [hereinafter "Pl.'s Opp'n"] at 23; Defs.' Reply Mem. in Supp. of Defs.' Combined Mots. for Summ. J. and in Opp'n to Pl.'s Cross-Mot. for Summ. J. [hereinafter "Defs.' Reply"] at 10-11.) Accordingly, Defendants' motion for summary judgment on the claim of anticipation by the '366 patent is DENIED.

C. <u>On-Sale Bar</u>

Defendants next ask for summary judgment that the invention defined in the asserted claims of the '884 Patent is invalid under 35 U.S.C. § 102(b) because the subject matter disclosed therein was "on sale" in the United States more that one year prior to March 12, 1996, the effective filing date for the patent at issue. Plaintiff responds by arguing that 1) the alleged product was not "on-sale" prior to March 12, 1995, and 2) that the product, as allegedly offered in 1995, was different than the product on sale today.

Under 35 U.S.C. § 102(b) "A person shall be entitled to a patent unless - . . (b) the invention was . . . on sale in this country, more than one year prior to the date of the application for patent in the United States." To challenge a presumptively valid patent, an accused infringer must demonstrate by clear and convincing evidence that 1) there was a sale or offer to sell

more than one year before the application for the subject patent, and 2) that the subject matter of the sale or offer to sell fully anticipated the claimed invention. <u>Group One, LTD. v. Hallmark</u> <u>Cards, Inc.</u>, 2001 WL 668549, No. 00-1014, at *4 (Fed. Cir. June 15, 2001); <u>UMC Elecs. Co. v. United States</u>, 816 F.2d 647, 656 (Fed. Cir. 1987).

1. <u>Sale or Offer to Sell</u>

Currently, Defendant Chemichl provides Defendant Dillon with a product called "LF-1-PFM", which Dillon repackages into smaller containers and resells under its trademark, Sensation, one of the two allegedly infringing products. There is no dispute that Sensation and LF-1-PFM are the same, and that the instructions for use of Sensation and the instructions for use of LF-1-PFM are the same.

In October of 1994, Chemichl shipped "LF-PFM" (later renamed "LF-1-PFM") samples, with instructions on its use, to J.F. Jelenko Co. ("Jelenko") in Armonk, NY. On October 10, 1994, in a telefax from Dan Johnson of Chemichl, to Rudy Michl of Chemichl AG, Johnson summarized a meeting he had had with Jelenko representatives regarding Jelenko's concerns with the "PFM system":

The most significant concern they have is with our pricing structure. They indicated to us that after a more thorough look at the current U.S. market . . . [,] [t]hey feel that we would have to come down at least \$5-\$6 per ounce in order for them to feel comfortable selling our PFM product. * * * This discussion led us into the LF-PFM product. They wanted

to know more about this ceramic and how it performed on the alloys they sent us in August. . . They felt that if the product worked on their Prospector alloy . . . then they could re-define the porcelain market and the price objection would be non-existent. The following morning, Rolf and I discovered from Egbert that our present LF-PFM ceramic worked on both metals they sent . . . After hearing this information, . . [t]hey gave us five ounces of Prospector . . for our technical department to do testing and wanted samples immediately for evaluation. They said they would begin a full blown marketing effort immediately upon confirmation of the product's performance.

(Pl.'s Ex. 30, Letter dated October 10, 1994, at 2.) On January

4, 1995, Johnson sent Dave Kasza of Jelenko a letter stating:

After more extensive experimentation, our developers believe it is possible to lower the firing temperature of our Low-Fusing ceramic and extend the hold time in order to fuse it to Prospector. . . . Since the hold time is substantially increased, I would like to know if the this project is still of interest and if you would like us to do additional testing.

(Pl.'s Ex. 13, Letter dated January 4, 1995.) Thereafter, on

February 6, 1995, in another telefax from Johnson to Michl,

Johnson summarized another conversation he had had with Jelenko

representatives.

After a fairly lengthy conversation with both Dave Kasza and his ceramist, Frank Munzenmayer, they concluded that both our PFM opaque paste and our LF-PFM are not yet marketable in the US for the following reasons: * * * LF-PFM This they believe needs the most work. The handling characteristics as far as stacking is good, however, they experienced severe tearing. This is not checking, this is tearing (large crevices in the fired ceramic). They have had consistent tearing . . . using our ceramic in conjunction with both Albacast and Suncast DFK. They have tried several techniques to overcome this problem, but have given up due to the sensitivity of the product. They are definitely interested in seeing if our LF-PFM could be used in conjunction with Prospector despite the long hold time

required. This would be the product of primary interest. COMMENTS

Jelenko is not interested in creating a new market with our existing ceramic system. Their intention with our ceramic would be to go after the Ceraco users and cut into their opaque market share. If they can piggy-back our opaque paste with their top selling alloys, they would have a winner. . . .

(Pl.'s Ex. 14, Letter dated February 6, 1995.)

In December of 1994, Chemichl also shipped LF-PFM samples and instructions to Dillon in North Attleboro, MA. On December

8, 1994, Johnson wrote to Kevin Dillon:

I enjoyed our phone conversation and am looking forward to the possibility of doing business in the future. Enclosed are samples of our two latest versions of porcelain-fusedto-metal-ceramic for your testing and evaluation. . . .

(Defs.' Ex. 9, Letter dated December 8, 1994.) In January of

1995, Johnson wrote to Michl:

I enjoyed talking with you the other day. Sounds like some interesting things came out of your meeting with Kevin [Dillon]. . . I've thought of a few incidental items that we should stick to during our negotiations with him:

- 1. I think he should immediately give us a Non-Disclosure agreement.
- 2. A firm, ironclad contract based on a volume commitment, discounts (by way of free product) would only apply if the volumes are met.
- 3. The 50% margin should be a gross margin prior to any give away programs or other miscellaneous expenses.
- 4. The audit should be done by our accountants. . . .

(Pl.'s Ex. 31, Letter dated 1/23/95.) Also in January of 1995, Mr. Johnson requested that Michl give him the formulation for the LF-PFM product so that he could file the formula with the Food and Drug Administration under the pre-market notification guidelines to obtain approval for sale of the product. Johnson did not receive the formulation at this time.

In February of 1995, Chemichl distributed its "1995 Wholesale Price List", which included listings on its LF-PFM product, to various companies in the United States. For example, on February 6, 1995, Johnson wrote to Mark DeTorre of 3M:

Enclosed is our new 1995 Whole Sale Price List. This new price list includes the complete CHEMICHL product line and is designed to make it easier for you to order. . . I want to point out our latest development in low-fusing ceramics shown on pages 14-18. We believe, with time, low fusing ceramics will ultimately replace existing traditional ceramics (see attached Argumentation - LF-PFM). . . .

(Defs.' Ex. 8, Letter dated February 6, 1995.)

Also in February of 1995, a "Secrecy and Non-disclosure Agreement" was executed by Chemichl and Dillon, whereby both parties agreed to protect each other's product and trade information. (Pl.'s Ex. 11, Michl Cross at 131; Pl.'s Ex. 53, Johnson Cross at 172; Pl.'s Ex. 58, Copy of unsigned Secrecy and Non-Disclosure Agreement.) In April of 1995, Chemichl sent additional LF-PFM samples to Dillon. (Defs.' Ex. 8, Proforma Invoice for Samples dated April 20, 1995.) In August of 1996, Johnson received the formula for the LF-1-PFM (formerly LF-PFM) product for filing with the FDA. The attached cover letter read:

Enclosed you will find a description of our "new" ceramic products and the composition of the basic glasses. The composition is confidential and only for the FDA. . . .

(Pl.'s Ex. 35, Letter and Formula.) The first completed sale of the LF-1-PFM product occurred in August of 1996 between Chameleon Dental Products Inc. and Chemichl. (Pl.'s Ex. 38, Purchase Agreement.) In the fall of 1997, Dillon ordered commercial quantities of the LF-1-PFM product from Chemichl, and continues to do so today.

"Whether a particular activity raises the on-sale bar is a question of law, based on underlying factual considerations." <u>Intel Corp. v. International Trade Comm.</u>, 946 F.2d 821, 829 (Fed. Cir. 1991). The Supreme Court recently rejected the "totality of the circumstances" approach, previously employed by the Federal Circuit, for determining whether the on-sale bar applies, and replaced it with a two-prong test: "First, the product must be the subject of a commercial offer for sale. . . . Second, the invention must be ready for patenting." <u>Pfaff v. Wells Elecs.,</u> <u>Inc.</u>, 525 U.S. 55, 67 (1998) (finding proof of acceptance of a purchase order prior to the critical date, and proof that inventor's drawings sent to manufacturer prior to the critical date fully disclosed the invention, sufficient to raise the onsale bar); <u>see also Brasseler v. Stryker Sales Corp.</u>, 182 F.3d 888, 890 (Fed. Cir. 1999) (quoting <u>Pfaff</u>, 525 U.S. at 67)).

In regard to the first prong, it is well established that "a single sale or offer to sell is enough to bar patentability," <u>In</u> <u>re Caveney</u>, 761 F.2d 671, 676 (Fed. Cir. 1985). Moreover, "[i]t is not necessary that the sale be consummated for the bar to operate . . . no more than a firm offer to sell may be sufficient." <u>Buildex Inc. v. Kason Indus., Inc.</u>, 849 F.2d 1461, 1464 (Fed. Cir. 1988). However, "[u]nder longstanding judicial

interpretation, a product embodying the patented invention, which is sold or offered for sale more than a year before the application's filing date, may escape the statutory bar where such sale was primarily for a bona fide experimental purpose to perfect the invention, rather than for commercial exploitation." <u>Paragon Podiatry Lab., Inc. v. KLM Lab., Inc.</u>, 984 F.2d 1182, 1185 (Fed. Cir. 1993).

Although the Supreme Court in <u>Pfaff</u> did not elaborate on what it meant by a "commercial offer for sale", the Federal Circuit has since determined that "[a]pplying established concepts of contract law, rather than some more amorphous test, implements the broad goal of Pfaff, which, in replacing this court's 'totality of the circumstances' test with more precise requirements, was to bring greater certainty to the analysis of the on-sale bar." Group One, 2001 WL 668549, at *5. Based upon this determination, the Federal Circuit held that "the question of whether an invention is the subject of a commercial offer for sale is a matter of Federal Circuit law," and that it will "look to the Uniform Commercial Code ("UCC") to define whether . . . a communication or series of communications rises to the level of a commercial offer for sale." Id. at *5-*6. While the Group One court did not offer any specific guidance on what constitutes a commercial offer for sale, it did note that only an offer "which the other party could make into a binding contract by simple acceptance (assuming consideration), constitutes an offer for

sale under § 102(b)," and that "contract law traditionally recognizes that mere advertising and promoting of a product may be nothing more than an invitation for offers, while responding to such an invitation may itself be an offer." <u>Id.</u> at *6 (citing <u>Restatement (Second) of Contracts</u> § 26 (1981)).

In regard to the second prong, the Supreme Court clearly held that the "ready for patenting" condition could be satisfied by "proof of reduction to practice before the critical date; or by proof that prior to the critical date, the inventor had prepared drawings or other descriptions of the invention that were sufficiently specific to enable a person skilled in the art to practice the invention." <u>Pfaff</u>, 525 U.S. at 67. In so holding, the Court disposed of the "substantially complete" standard previously employed by the Federal Circuit, and determined that although the invention must be fully complete. <u>See Pfaff</u>, 525 U.S. at 66; <u>Robotic Vision Sys.</u>, Inc. v. View <u>Eng'g</u>, Inc., 249 F.3d 1307, 1312 (Fed. Cir. 2001) (interpreting <u>Pfaff</u>).

a. <u>Commercial Offer for Sale</u>

Here, the critical date under 35 U.S.C. § 102(b) is March 12, 1995, one year prior to the application filing date. There is no dispute that no actual sale was completed prior to the critical date. The activity that transpired prior to March 12, 1995, included the sending of samples and instructions to Jelenko

and Dillon, and the distribution of price lists a few months later. The fact that the above activity transpired is not in dispute. The legal issue of whether the combination of these activities constituted a commercial offer for sale of a product ready for patenting, however, is contested and is dispositive here.

According to Defendants, these samples were sent with the intent of procuring commercial orders, and they, in combination with the distribution of the 1995 Wholesale Price List in February, 1995, constituted a firm offer for sale before the critical date. Jelenko ultimately declined to do business with Chemichl due to problems it perceived with the product, but Dillon, in the fall of 1997, ultimately placed orders with Chemichl for commercial quantities of the LF-PFM product, samples of which, according to defendants, had been sent to Dillon in 1994 and 1995.

In contrast, Plaintiff argues that the samples sent in 1994 and 1995 were for experimental purposes and did not constitute commercial offers for sale. Specifically, Plaintiff argues that Johnson's letter to Dillon stating "enclosed are samples . . . for your testing and evaluation," Michl's Declaration stating that in February of 1995 he met with Jelenko representatives "to discuss the results of their testing and evaluation of the samples of the LF-PFM," Johnson's letter to Michl stating that according to Jelenko, the product was "unmarketable" and "needs

more work," and the year and a half delay between Johnson's request for the formulation to file with the FDA and Chemichl AG's provision of such formula in August of 1996, establish the experimental nature of the 1994 and 1995 activity. Plaintiff asserts that these facts make clear that the samples sent to Jelenko and Dillon were for the purpose of determining the product's utility with respect to various methods and alloys, not for the purpose of a specific commercial sale.

Applying the standards set forth above, the Court finds that, under the stricter standards set forth in <u>Pfaff</u> and its progeny, the activity that transpired prior to March 12, 1995 did not constitute a commercial offer for sale. The UCC does not define "offer," and, therefore, does not displace pre-code law as to what constitutes an offer. Accordingly, courts must look to the common law for the definition. <u>See</u> Ronald A. Anderson, 2 <u>Anderson on the Uniform Commercial Code</u> § 2-206:12 (3d ed. 1997) (footnotes omitted). However, although neither <u>Pfaff</u> nor the UCC provide a clear definition of what constitutes a commercial offer, the authorities appear to be in agreement on certain business activities that do not constitute offers, but rather constitute invitations to make an offer.

Frequently, negotiations for a contract are begun between parties by general expressions of a willingness to enter into a bargain upon stated terms, and yet the natural construction of the words and the conduct of the parties is that they are inviting offers, or suggesting the terms of a possible future bargain, rather than making positive offers. This is especially likely to be true where the words in

question are in the form of an advertisement , circular, catalog or the like. Thus, if goods are advertised at a certain price, it is generally not an offer, and no contract is formed by the statement of an intending purchaser that he will take a specified quantity of the goods at that price. Rather, the courts routinely hold that such advertisements or other expressions of intention are invitations to solicit offers or to enter into a bargain rather than offers themselves. Similarly, <u>a published price list is not an</u> offer to sell the goods listed at the published prices . .

The cases are legion on this point; and though they are grounded on various bases, including the absence of quantity terms, the absence of apparent intent to form a contract, or potentially unlimited liability of the offeror if an offer is held to exist, they all share two other common characteristics: first, in virtually all of the cases there is <u>the absence of a promissory undertaking</u>; and second, in all the cases a reasonable person receiving the communication has reason to know, from the circumstances under which the manifestation is made, that no offer exists.

Richard A. Lord, 1 <u>Williston on Contracts</u> § 4.7, at 285-290 (4th ed. 1990) (footnotes omitted) (emphasis added); <u>see also</u> Anderson, <u>supra</u>, § 2-206:15, at 20-21 ("An expression of intention that does not manifest a willingness to enter into a binding agreement on stated terms is, by definition, not an offer. Consequently, it is ordinarily held that an advertisement, a price quotation, or other invitation to negotiate, is not an offer." (footnotes omitted)).

Here, none of the letters contained quantity terms, price quotations, or delivery terms, and the wholesale price list essentially amounted to a catalogue form of advertising. Moreover, no order form or other contractual instrument was contained in either the letters accompanying the samples or the price lists. Defendants' only evidence to the contrary is

Michl's testimony that he distributed the samples "with the hope of procuring commercial sales." (Defs.' Ex. 8, Michl Decl. ¶ 8; Defs.' Ex. 9, Dillon Decl. ¶ 6). An inventor's attempted exploitation, however, "must be objectively manifested as a definite sale or offer to sell the invention. The subjective, uncommunicated, and ultimate intention of the offeror, however clear, is not alone sufficient." <u>Envirotech Corp. v. Westech</u> <u>Enq'q Inc.</u>, 904 F.2d 1571, 1575 (2d Cir. 1990). Additionally, Plaintiff raises serious issues about Michl's credibility, elicited on cross-examination during the preliminary injunction hearing. (Pl.'s Ex. 5(D), Michl Cross at 43-47.)

Therefore, the Court finds that the combination of the samples, their accompanying letters, and distribution of the price lists constitutes invitations to offer or otherwise negotiate, specifically invitations to make offers to purchase a certain porcelain product at the prices listed; offers which Chemichl could then accept or reject. Accordingly, the Court concludes that Defendants have failed to show by clear and convincing evidence that, prior to March 12, 1995, a commercial offer for sale was made.

Because the Court finds that Defendants' activity falls short of a commercial offer for sale, the Court does not reach the second prong under <u>Pfaff</u> of whether the product was ready for patenting. Furthermore, because the Court finds that no offer for sale was made, the Court does not reach the issue of whether

the LF-PFM product as offered in 1995 actually anticipated the '884 Patent. Defendants' motion for summary judment under the on-sale bar is DENIED.

D. <u>Infringement by Cerpress</u>

Defendants' third request asks for summary judgment that Cerpress does not infringe any of the asserted claims. Specifically, Defendants claim that Cerpress does not literally infringe either of the patents because it does not contain lithium oxide (Li₂0), and that under the doctrine of prosecution history estoppel, Plaintiffs are precluded from establishing infringement under the doctrine of equivalents. In response, Plaintiff claims that the lithium oxide was added as a flux modifier to make the porcelain composition "operable," not as a limitation to distinguish claim 1 over prior art.

1. Literal Infringement

Direct infringement occurs when a party "without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent." 35 U.S.C. § 271(a). To establish direct infringement, the patentee must prove by a preponderance of evidence that every element of the asserted claim, as properly construed by the Court, is found in the accused device or process, either literally or under the doctrine of equivalents. <u>See Wolverine World Wide</u>, 38 F.3d at 1196; <u>Laitram Corp. v. Rexnord, Inc.</u>, 939 F.2d 1533, 1535 (Fed.

Cir. 1991). In this regard, each and every clause of a claimed invention is considered material and essential. <u>See</u> <u>Warner-Jenkinson Co., Inc. v. Hilton Davis Chem. Co.</u>, 520 U.S. 17, 29 (1997). Therefore, the absence of even one element or its equivalent of a claimed invention places the accused device outside the coverage of the claims.

There is no dispute that although Cerpress contains all of the physical parameters specified in claim 1 of both patents, i.e. the leucite crystal size, the amount of leucite crystals, the maturing temperature, and the coefficient of thermal expansion, Cerpress does not literally infringe either the '791 or the '884 patent because its chemical composition does not contain the Li₂0 specified in claim 1 of both patents. The following chart shows a comparison of the chemical compositions:

Compound	<u>'884(wt.%)</u> <u>Claim 1</u>	<u>'791(wt.%)</u> <u>Claim 1</u>	<u>Cerpress(wt.%)</u>
SiO_2	58-65	57-66	59.2
Al ₂ O ₃	7-15	7-15	15.97 ³

³ The amount of aluminum oxide contained in Cerpress, according to Plaintiff's expert, also falls outside the claimed range. The record, however, reveals conflicting evidence on the amount it contains. In fact, as the Federal Circuit noted on appeal, "each party's evidence undercuts its own infringement position." <u>Jeneric/Pentron</u>, 205 F.3d at 1383. Plaintiff's expert, as listed in the above chart, found 15.97% of aluminum oxide, an amount outside the 7-15 weight percentage range specified by the claim. Defendants' testing, on the other hand, found 14.98% of aluminum oxide, bringing the element inside the specified range. Therefore, the parties' position, on the relevance of this element and the discrepancy over the amount present in Cerpress, remains unclear.

K ₂ O	7-15	7-15	10.22
Na ₂ O	7-12	7-12	9.31
Li ₂ O	0.5-3	0.5-3	.041
CaO		0-3	1.62
MgO		0-7	.020
F		0-4	.005
CeO ₂		0-1	.45
B_2O_3			1.93
BaO			1.02

('791 Patent; '884 Patent; Pl.'s Ex. 6(c), Sisson Decl.) Based on Sisson's testing, Plaintiff's own expert, Cerpress does not contain sufficient lithium oxide, an ingredient specifically required by every asserted claim of both patents. Accordingly, the Court finds that Cerpress does not literally infringe either the '791 or the '884 patent.

2. <u>Doctrine of Equivalents</u>

Plaintiff asserts that, despite the absence of literal infringement, Cerpress infringes the asserted claims under the doctrine of equivalents. Defendants respond that based on amendments made during the prosecution of the '884 Patent, prosecution history estoppel applies to bar Plaintiff's use of the doctrine of equivalents to establish infringement.

a. <u>Prosecution History of the '791 Patent</u>

In an Office Action dated November 1, 1996, made in response to the '791 Application, the Examiner entered certain restrictions, and rejected claims 1-10 as being unpatentable over a prior art, U.S. Patent No. 4,101,330. (Pl.'s Ex. 1, '791 Patent

File Wrapper.) On March 21, 1997, in a statement to the Examiner, Plaintiff/Applicant distinguished its invention from the prior art on the ground that the prior art employed a "mepheline syenite" glass matrix phase, as opposed to a feldspar glass matrix phase, making the prior art unsuitable for coating dental restorations, and on the ground that the leucite crystals in the prior art possessed diameters not exceeding about 37 microns, whereas Plaintiff/Applicant's invention required leucite crystallites "not exceeding about 10 microns." ('791 Patent File Wrapper.) On March 27, 1997, the PTO issued a notice of allowability. No amendments were added, and more importantly, the element at issue was neither amended nor argued during prosecution of the patent.

b. <u>Prosecution History of the '884 Patent</u>

In addition to originally rejecting the '884 Application as anticipated by the '366 Patent discussed above, the Examiner also rejected claims 1-7 and 16-19 as being anticipated by U.S. Patent No. 4,798,536 (Katz), claims 1-10 and 16-19 as being anticipated by U.S. Patent No. 5,698,019 (Frank et al.), claims 2-20 under 35 U.S.C. § 112 as being indefinite for failing to particularly point out and distinctly claim the subject matter regarded as the invention, and claims 1-19 for "obvious-type" double patenting in view of the '791 Patent. (Defs.' Ex. 13, '884 File Wrapper.)

On March 4, 1999, Plaintiff's attorneys, Leah Reimer and Michael Cantor, had a personal interview with the Examiner. The

Examiner's Interview Summary indicates (via check mark) that all claims were discussed, that all identifications of prior art were discussed, and adds:

Applicants [sic] representative suggested incorporating claims [sic] 9 and silica amount of claim 13 which appears to put case in condition for allowance. All arguments will be reconsidered. 112, second paragraph in reference to 1 and 20 will be overcome with composition limitations.

('884 File Wrapper, 3/4/99 Summary Interview.) Further, the box indicating that "[i]t is not necessary for applicant to provide a separate record of the substance of the interview" was not checked. The notice under the box reads:

Unless the paragraph above has been checked to indicate to the contrary. A FORMAL WRITTEN RESPONSE TO THE LAST OFFICE ACTION IS NOT WAIVED AND MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. If a response to the last Office Action has already been filed, APPLICANT IS GIVEN ONE MONTH FROM THIS INTERVIEW DATE TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW.

('884 File Wrapper, 3/4/99 Interview Summary (emphasis in original)).

On March 5, 1999, Plaintiff/Applicant filed an Amendment to the '884 Application, which amended certain claims, canceled certain claims, and added new claims. Significant here is the change to Claim 1:

<u>Claim 1(original)</u>

A porcelain composition comprising a leucite crystallite phase and a glass matrix phase, the improvement comprising:

the leucite crystallites possessing diameters not exceeding about 10 microns and representing from about 5 to about 65 weight percent of the porcelain composition.

<u>Claim 1(amended)</u> A porcelain composition comprising a leucite crystallite phase and a glass matrix phase,[the improvement comprising:] the leucite crystallites possessing diameters not exceeding about 10 microns and representing from about 5 to about 65 weight percent of the porcelain composition, and wherein the fused(subsequently deleted) porcelain composition comprises:

Compound	<u>Weight % Amount</u>
SiO ₂	58-65
Al ₂ O ₃	7–15
K ₂ O	7–15
Na ₂ O	7-12
Li ₂ O	0.5-3

('884 File Wrapper, Amendment A.) The explanation and argument accompanying this amendment stated that Plaintiff/Applicants:

believe that the amendments presented herein are in accord with the agreement reached at that interview. Applicant's [sic] have accordingly re-written claim 1 to incorporate certain of the limitations of claims 9 and 13, and added new dependent claims 21 and 22 in order to further define the invention. Claim 1 as amended is therefore allowable, as well as claims 2-8, 11, and 21-22, which are dependent thereon.

('884 File Wrapper, Amend. A.) On May 11, 1999 an additional telephone interview transpired between the Examiner and Plaintiff's counsel, resulting in a few additional changes. The application was formally allowed on May 12, 1999, and the '884 Patent issued on August 31, 1999. ('884 File Wrapper.)

On these facts, Plaintiff asserts under the doctrine of equivalents that the lithium oxide in the dental porcelain functions as a flux modifier, which works to regulate the viscosity of the porcelain and lower the fusion temperature and maturing temperature, thereby altering the amount of leucite crystals and affecting the coefficient of thermal expansion. Both Sisson, Plaintiff's expert, and Panzera, one of the

inventors, opined that baron oxide (B_2O_3) , barium oxide (BaO), and sodium oxide (Na_2O) are common substitutions for lithium oxide, and that the B_2O_3 , BaO, and Na_2O contained in Cerpress were present in sufficient amounts to achieve the effect of lithium oxide, that is, the right viscosity, maturing temperature, and fusion temperature to achieve porcelain having leucite crystals less than ten microns in size. (Pl.'s Ex. 6, Sisson Decl. ¶¶ 24-28.)

c. <u>Doctrine of Equivalents and Prosecution History</u> <u>Estoppel</u>

When literal infringement cannot be established, infringement may be proven under the doctrine of equivalents. The Supreme Court recently made clear that infringement under the doctrine of equivalents must be established on an element by element basis, not by comparing the accused product or process to the invention as a whole. See Warner-Jenkinson, 520 U.S. at 29, 40; Litton Sys., Inc. v. Honeywell, Inc., 140 F.3d 1449, 1454 (Fed. Cir. 1998). Infringement under the doctrine of equivalents is a question of fact. Warner-Jenkinson, 520 U.S. at 38. Under the "all elements" rule, the operative question concerns whether "the accused product or process contains elements identical or equivalent to each claimed element of the patented invention." Id. at 29; accord Digital Biometrics, Inc. v. Identix, Inc., 149 F.3d 1335, 1349 (Fed. Cir. 1998). To prove infringement under the doctrine of equivalents, the accused product or process "must

be shown to include an equivalent for each literally absent claim limitation." <u>See Dawn Equip. Co. v. Kentucky Farms Inc.</u>, 140 F.3d 1009, 1015 (Fed. Cir. 1998); <u>Hughes Aircraft Co. v. United</u> <u>States</u>, 140 F.3d 1470, 1474 (Fed. Cir. 1998). To determine equivalency, "the role played by each element in the context of the claim will [] inform the inquiry as to whether a substitute element matches the function, way, and result of the claimed element, or whether the substitute element plays a role substantially different from the claimed element." Warner-Jenkinson, 520 U.S. at 40.

"Application of the doctrine of equivalents is the exception, however, not the rule." London v. Carson Pirie Scott & <u>Co.</u>, 946 F.2d 1534, 1538 (Fed. Cir. 1991). The doctrine is not a license to ignore structural and functional limitations on which the public is entitled to rely in avoiding infringement. See Athletic Alternatives, Inc. v. Prince Mfg., Inc., 73 F.3d 1573, 1582 (Fed. Cir. 1996). Relevant here is the limitation called prosecution history estoppel, which "limits undue expansion of a claim's scope through the doctrine of equivalents." Augustine Medical, Inc. v. Gaymar Indus., Inc., 181 F.3d 1291, 1298 (Fed. Cir. 1999). Specifically, "prosecution history estoppel prevents a patentee from recapturing subject matter surrendered during prosecution of the patent," id.; see also Athletic Alternatives, 73 F.3d at 1582, and it arises most frequently in the context of amendments added during the prosecution of a claim which narrow

the scope of a claim. The application of prosecution history estoppel is a question of law for the court to decide. <u>See</u> Augustine Medical, 181 F.3d at 1298.

In Warner-Jenkinson, the Supreme Court held that prosecution history estoppel "continues to be available as a defense to infringement," and that its application to bar the doctrine of equivalents depended on the reason disclosed in the prosecution history for the amendment to the claims. Warner-Jenkinson, 520 U.S. at 40-41; see also Sextant Avionique v. Analog Devices, Inc., 172 F.3d 817, 827-28 (Fed. Cir. 1999). In that case, an amendment was added to a claim limiting the range of pH level to between 6.0 and 9.0 in a purification process involving the ultrafiltration of dye. Based on the prosecution history, it was clear that the upper limit was added to distinguish the claim from a prior art operating at a pH level above 9.0. The reason for adding the lower limitation, however, was unclear from the prosecution history, and the patentee on appeal did not proffer a reason for the inclusion of a lower limit. Accordingly, the Supreme Court held that prosecution history estoppel applied and precluded the use of the doctrine of equivalents to establish that the accused product, operating at a pH level of 5.0, infringed the patent at issue. See Warner-Jenkinson, 520 U.S. at 32-34; see also Sextant Avionique, 172 F.3d at 827-28 (finding that despite fact that added limitation was not necessary to overcome the specified prior art rejection, because the

prosecution history did not disclose a reason for the added term, the rebuttable presumption that the limitation was added for a reason related to patentability must apply thereby invoking prosecution history estoppel, and holding that patentee failed to rebut the presumption because his asserted reason for the added term was unsupported by and contrary to the prosecution history record).

In so holding, the Court established several guidelines for determining whether prosecution history estoppel applies. First, the Court found that if the amendments to the claim were "related to patentability," prosecution history estoppel applies. Specifically, the Court stated that, in its prior rulings, prosecution history estoppel had primarily been "tied to amendments made to avoid the prior art, or otherwise to address a specific concern--such as obviousness--that arguably would have rendered the claimed subject matter unpatentable." <u>Warner-Jenkinson</u>, 520 U.S. at 30-31. If the claims were amended for a reason "unrelated to patentability", however, the Court determined that prosecution history estoppel generally does not apply. <u>Id.</u> at 30-33; <u>see also Sextant Avionique</u>, 172 F.3d at 827-28.

To establish the reason for an amendment required during the prosecution of a patent, the Supreme Court placed the burden on the patent holder. <u>See Warner-Jenkinson</u>, 520 U.S. at 33. If the prosecution history record does not reveal the reason behind the

amendment, and the patent holder is unable to otherwise establish a purpose unrelated to patentability, courts "should presume that the patent applicant had a substantial reason related to patentability for including the limiting element added by amendment," such that "prosecution history estoppel would bar the application of the doctrine of equivalents as to that element." <u>Id.</u> In support of this holding, the Court explained that the presumption "gives proper deference to the role of claims in defining an invention and providing public notice." <u>Id.</u>

Recently, in <u>Festo Corp. v. Shoketsu Kinzoku Koqyo</u> <u>Kabushiki, Co.</u>, 234 F.3d 558 (Fed. Cir. 2000), <u>cert</u>. <u>granted</u>, 121 S. Ct. 2519 (2001), the Federal Circuit, set forth a process for analyzing the application of prosecution history estoppel in light of the Supreme Court's holding in <u>Warner-Jenkinson</u>:

The first step in a prosecution history estoppel analysis is to determine which claim elements are alleged to be met by equivalents. Then, the court must determine whether the elements at issue were amended during prosecution of the patent. If they were not, amendment-based estoppel will not bar the application of the doctrine of equivalents. However, the court still may need to consider whether statements made during prosecution give rise to argument-based estoppel.

If the claim elements at issue were amended, the court first must determine whether the amendment narrowed the literal scope of the claim. If so, prosecution history estoppel will apply unless the patent holder establishes that the amendment was made for a purpose unrelated to patentability. If the patent holder fails to do so, prosecution history estoppel will bar the application of the doctrine of equivalents to that claim element. . .

In order to give due deference to public notice considerations under the <u>Warner-Jenkinson</u> framework, a patent holder seeking to establish the reason for an amendment must base his arguments solely upon the public record of the patent's prosecution, i.e., the patent's prosecution history. To hold otherwise--that is, to allow a patent holder to rely on evidence not in the public record to establish a reason for an amendment--would undermine the public notice function of the patent record. If the reasons for the amendment do not appear in the public record of the patent's prosecution, the reasons in most cases will be known only to the patent holder. We therefore hold that a narrowing amendment will give rise to prosecution history estoppel unless the prosecution history of the patent reveals that the amendment was made for a purpose unrelated to patentability concerns.

Festo, 234 F.3d at 586.

The facts in <u>Festo</u> are similar to ones at issue here. There, in response to the first Office Action, the patentee replaced claim 1 with a claim reciting a "magnetizable sleeve" element, and canceled another claim. Although the amendment was included in the submissions filed in response to the First Office action, the court determined that the addition of the "magnetizable sleeve" element was not itself responsive to the rejections set forth therein. Further, no statement in the prosecution history explained why the element was included. The patentee argued that the amendment was made to "clarify" the claim, but the court found the assertion "inadequate to escape the <u>Warner-Jenkinson</u> presumption [] because nothing in the prosecution history of the [patent at issue] indicates that the magnetizable sleeve element was merely added for purposes of clarification unrelated to patentability concerns." Festo, 234 F.3d at 588. Accordingly, the court concluded that the patentee had failed to meet its burden, and, therefore, that prosecution

history estoppel applied, baring the application of the doctrine of equivalents to that claimed element. <u>See id.</u>

In the context of this ruling, the <u>Festo</u> Court made several interpretive holdings in light of <u>Warner-Jenkinson</u>, one of which is relevant here.

For the purposes of determining whether an amendment gives rise to prosecution history estoppel, a "substantial reason related to patentability" is not limited to overcoming or avoiding prior art, but instead includes any reason which relates to the statutory requirements for a patent. Therefore, a narrowing amendment made for any reason related to the statutory requirements for a patent will give rise to prosecution history estoppel with respect to the amended claim element.

<u>Festo</u>, 234 F.3d at 566. The court found that although in <u>Warner-Jenkinson</u> the Supreme Court focused on claim amendments made to overcome prior art, "there are a number of statutory requirements that must be satisfied before a valid patent can issue and that thus relate to patentability," such as the novelty and non-obviousness requirements of 35 U.S.C. §§ 102 and 103, the patentable subject matter and usefulness requirements set forth in 35 U.S.C. § 101, and the specification, description, enablement, and particularity requirements set forth in the first and second paragraphs of 35 U.S.C. § 112. Because the Patent Office will reject a patent application that fails to satisfy any one of these statutory requirements, the Federal Circuit held that "an amendment related to anyone of these statutory requirements is an amendment made for 'a substantial reason

related to patentability.'" Festo, 234 F.3d at 566-67.

d. <u>Prosecution History Estoppel and the '884 Patent</u>

The reason behind the addition of lithium oxide in the amendment to claim 1 during the prosecution of the '884 Patent is the dispositive issue here. It is undisputed that lithium oxide was one of five chemical components added with precise ranges in response to the Examiner's rejections. Plaintiff claims, however, that although the lithium oxide component was included in the amendment, it was not necessary to distinguish the claim over prior art. According to Plaintiff, the '884 Patent was distinguished over the '366 Patent on the leucite crystal size, and was distinguished over the '536 and '019 patents on silica (SiO_2) and alumina (Al_2O_3) liminations. Plaintiff asserts that the fact that the 0.5-3% weight range of lithium oxide specified in the '884 Patent overlaps with the ranges in the prior art, at 0-2.5% in the '019 Patent and 1-5% in the '536 Patent, proves that the lithium oxide was not a distinguishing component in relation to prior art. The lithium oxide, according to Plaintiff, was added "to meet the requirement that the porcelain have a flux modifier to be operable," and thereby satisfy the "operative requirement of 35 U.S.C. § 112." (Pl.'s Opp'n at 38-39.) Plaintiff asserts that by adding the lithium oxide component, it only surrendered porcelain compositions without flux modifiers, it did not surrender porcelain compositions employing any flux modifiers other than lithium oxide.

Plaintiff's arguments were made based on its interpretation of the Supreme Court's ruling in <u>Warner-Kenkinson</u>, prior to the Federal Circuit's ruling in <u>Festo</u>. Although there may have been a debate under <u>Warner-Jenkinson</u> over whether Plaintiff's stated reason was related to patentability in such a way as to raise the prosecution history estoppel bar, the Federal Circuit's opinion in <u>Festo</u> makes clear that any reason related to patentability is sufficient to raise the bar, and specifically included § 112 as an example. <u>See Festo</u>, 234 F.3d at 566-67. Under these standards, the Court finds that prosecution history estoppel applies to bar Plaintiff's use of the doctrine of equivalents against the lithium oxide element in the '884 Patent.

The prosecution history record does not state any specific reason for the addition of the lithium oxide. As set forth above, the Examiner's 3/4/99 Interview Summary states that Plaintiff/Applicant suggested "incorporating claims [sic] 9 and the silica amount of claim 13" to "put the case in condition for allowance", and indicates that § 112, second paragraph, in relation to claim 1 will "be overcome with composition limitations." ('884 File Wrapper, 3/4/99 Interview Summary.) Plaintiff's statement accompanying the amendment is no more specific in regard to the lithium oxide, and merely states that the amendments "are in accord with the agreement reached at the interview," and that "certain of the limitations of claims 9 and

13" were incorporated, thereby making claim 1 "allowable."⁴
('884 File Wrapper, Amendment A.)

Under <u>Warner-Jenkinson</u>, it is Plaintiff's burden to establish the reason behind the amendment. Here, the prosecution history record does not make clear the specific reason for the addition of lithium oxide. Lithium oxide, at the level ultimately disclosed, was one of the ingredients in the original

⁴ Plaintiff also relies on the declarations of Reimer and Cantor regarding the substance of the 3/4/99 interview with the Examiner to support its claim that the amendment is in accord with the "agreement reached at the interview," including the fact that the lithium oxide was simply added as a representative flux modifier, and, therefore, that during prosecution of the patent, Plaintiff only surrendered like dental porcelaim compositions without flux modifiers. The written prosecution history record, is devoid of any memorialization of such "agreement," however, and the Court agrees with Defendants that its assessment must primarily be based on the written record. The Code of Federal Regulations makes clear that "action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation or understanding in relation to which there is disagreement or doubt." 37 C.F.R. § 1.2. Moreover, section 1.133(b) provides that "in every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant." 37 C.F.R. § 1.133(b). These regulations are consistent with the Federal Circuit's holding that "to give due deference to public notice considerations under the Warner-Jenkinson framework, a patent holder seeking to establish the reason for an amendment must base his arguments solely upon the public record of the patent's prosecution, i.e., the patent's prosecution history. . . We therefore hold that a narrowing amendment will give rise to prosecution history estoppel unless the prosecution history of the patent reveals that the amendment was made for a purpose unrelated to patentability concerns." <u>Festo</u>, 234 F.3d at 586. Accordingly, the Court finds that the declarations of Reimer and Cantor regarding the substance of the 3/4/99 interview are an improper source of evidence to establish the reason behind the amendment because they are not part of the public record.

claim 9. Therefore, based on the written record, we only know, based on Plaintiff's explanation, that it was added, like the rest of the ingredients, to make claim 1 "allowable," and, based on the Examiner's summary, that it was possibly added as a compositional limitation "to overcome § 112". While it appears clear, based on its overlap with the '536 and '019 patents' ranges, that the lithium oxide was not necessary to distinguish claim 1 over prior art, it is by no means clear that the element was "unrelated to patentability." Based on the record alone, therefore, the presumption of relatedness would apply because nothing in the prosecution history record itself indicates that the lithium oxide was added for anything other than patentability. Moreover, Plaintiff's explanation that it was added "to meet the operability requirement," rather than supporting Plaintiff's position, actually undercuts its argument and reinforces the component's relatedness to patentability under Festo.

In sum, although it appears that the lithium oxide was not necessary to distinguish the patent over prior art, the specific reason for its addition remains unclear. Therefore, the presumption that the addition of lithium oxide was related to patentability applies, barring Plaintiff's use of the doctrine of equivalents against the lithium oxide element to establish infringement. Accordingly, because the accused product does not contain elements identical to each claimed element of the '884

Patent, the Court finds as a matter of law that Cerpress does not infringe claim 1 of the '884 patent or any other asserted claim dependent thereon. Defendants' motion for summary judgment that Cerpress does not infringe the '884 Patent is GRANTED.

e. <u>Prosecution History Estoppel and the '791 Patent</u>

In contrast to the '884 Patent, the lithium oxide present in the '791 Patent was an original part of the claimed invention in the '791 Application, and no amendments were ultimately necessary to allow issuance of the '791 Patent. In these circumstances, "amendment-based estoppel will not bar the application of the doctrine of equivalents," <u>Festo</u>, 234 F.3d at 586, and the Court finds that none of the statements made during prosecution of the '791 Patent surrendered subject matter related to the lithium oxide element that would give rise to argument-based estoppel.

Defendants, however, claim that because the '791 and '884 patent are related under 35 U.S.C. § 120, any estoppel affecting the '884 Patent also affects the '791 Patent. Defendants base their argument on a Federal Circuit case indicating that "the prosecution history of a <u>parent</u> application may limit the scope of a <u>later</u> application using the same claim term." <u>Augustine</u> <u>Med., Inc. v. Gaymar Indus., Inc.</u>, 181 F.3d 1291, 1300 (Fed. Cir. 1999) (emphasis added) (finding that claim amendments regarding the "self-erecting" limitation made during prosecution of the parent application restricted the scope of the claims in each of the later issued child patents containing that term); <u>see also</u>

Jonsson v. Stanley Works, 903 F.2d 812, 818 (Fed. Cir. 1990) (finding that because the patent at issue was the result of a "continuation-in-part" application from a prior application and patent, the prosecution history of the earlier patent regarding the construction of a certain term was relevant to an understanding of that same term in the later patent). Defendants also cite to a district court case which, relying on Augustine Medical, found that, despite the fact that the patent at issue was unrelated (i.e. independent) to the prior patent, because plaintiff used "the claimed element to distinguish over the prior art and that claim term is common to the claims of both patents, prosecution history may disavow structures in the scope of the claims in both patents." Depuy Orthopaedics Inc. v. Androphy, U.S.P.Q.2d 1941, 1950 (N.D. Ill. 2000). In both Augustine Medical and Depuy Othepedics, the respective courts determined that the prosecution history of a prior application may limit a later application using the same claim term.

Here, however, the situation is reverse. Defendants ask the Court to impose claim limitations arising in the prosecution history of a "child" (i.e later) patent to an element in the "grandparent" (i.e. prior) patent. The original claim 1 of the '884 Application was very broad and did not contain any specific chemical components and ranges. Upon the Examiner's rejection, Plaintiff amended the claim by introducing certain ingredients within precise ranges--ingredients and ranges which are common to

both patents. Therefore, according to Defendants, the principal that the prosecution histories of related patents may affect each other is the same, regardless of the converse positions of the patents here.

Defendants, however, cite to no authority, and the Court finds none, for the proposition that just as the prosecution history of an earlier patent may limit a claim using the same term in a later related patent, so may the prosecution history of a later patent reach back and limit a claim using the same element in an earlier related patent. The Court finds this proposition implausible, especially where a defendant is attempting to use this principal as a vehicle to apply prosecution history estoppel to an element that was an original part of a prior patent and that was never amended or argued. Accordingly, the Court finds that prosecution history estoppel does not apply to the lithium oxide component in the '791 Patent, and, therefore, Plaintiff is not precluded from using the doctrine of equivalents to establish infringment.

In regard to infringement by Cerpress of the '791 Patent under the doctrine of equivalents, this Court, in its preliminary injunction ruling, "avoided" the equivalency analysis on the ground that because Plaintiff had only asserted equivalency in regard to one of the two elements in Cerpress whose weight percentage fell outside the specified range in the '791 Patent, the <u>Warner-Jenkinson</u> "all-elements" test precluded a finding of

infringment. On appeal, although the Federal Circuit upheld the Court's denial of a preliminary injunction, it found that "[t]his analysis does not resolve infringement by equivalents" because 1) "the record reveals conflicting evidence on the amount of aluminum oxide that Cerpress contains" with each parties' evidence undercutting its own infringement position,⁵ and 2) in regard to the factual issue of the substitution of flux modifiers for lithium oxide, the "preliminary record discloses several issues for resolution during trial."⁶ <u>Jeneric/Pentron</u>, 205 F.3d at 1383-84. Upon thorough review, the Court agrees that material factual issues exist regarding the elements of aluminum oxide and lithium oxide, sufficient to preclude summary judgment. Accordingly, Defendants' request for summary judgment that

⁵ "A comparison table . . . prepared by Jeneric's expert . . . states that Cerpress contains 15.97% of aluminum oxide . . . However, . . . Dillon's own technical expert and owner of Chemichl AG admitted that Cerpress contains 15.1% of aluminum oxide with a tolerance of +/- 0.1%. . . Moreover, [Dillon's] testing results . . . show that Cerpress contains 14.98% of aluminum oxide. Therefore, the record facts do not resolve the question of Cerpress's literal infringement of the aluminum oxide limitation." Jeneric/Pentron, 205 F.3d at 1383-84.

⁶ "For instance, the Sisson Table [Plaintiff's testing] shows that Cerpress contains 0.041% of lithium oxide, outside the claimed 0.5-3%. A full record will show whether this difference is insubstantial. Also, Jeneric argues that the district court must consider evidence that barium oxide . . ., boron oxide . . ., and sodium oxide . . . can act as fluxes and substitutes for lithium oxide. Dillon does not dispute that these compounds were known to function as fluxes. However, questions on the quantities necessary to substitute for lithium oxide require further factual development." Jeneric/Pentron, 205 F.3d at 1384.

Cerpress does not infringe the '791 Patent under the doctrine of equivalents is DENIED.

E. <u>Fraud</u>

Defendants' fourth and final ground for summary judgment claims that the '884 Patent should be found invalid because Plaintiff engaged in inequitable conduct during the prosecution of the '884 Patent and thereby perpetrated a fraud on the PTO. Defendants' claim centers on Plaintiff's admitted failure to disclose the "Final Product" calculations in connection to Example 2 of the '366 Patent, and Plaintiff's alleged misrepresentations regarding the properties of the LF-1-PFM product allegedly on-sale prior to the critical date. Plaintiff vigorously denies these allegations of deceit, calling Defendants' assertions frivolous.

On March 5, 1999, during the prosecution of the '884 Patent, Leah Reimer, Plaintiff's counsel, filed an "Information Disclosure Statement" (IDS) pursuant to 37 C.F.R. §§ 1.56, 1.97, and 1.98, and attached a "Declaration" of Dr. Richard D. Sisson, (the same expert who had submitted a declaration and testified during the original litigation over the '791 Patent), dated February 23, 1999 [hereinafter "Sisson Declaration"], pursuant to 37 C.F.R. § 1.132. The IDS disclosed that Plaintiff/Applicant was party to litigation against Defendants in a patent infringement action concerning the '791 Patent, and that during the course of that litigation, Defendant Chemichl asserted that

more than one year prior to the filing date of the '884 Application, it distributed a dental porcelain product in the United States called LF-1-PFM which has a chemical composition within the weight ranges of the '884 Patent, and has leucite crystals with diameters of less than 10 microns. ('884 Patent File Wrapper, 2/23/99 IDS at 1-2.) Plaintiff/Applicant's IDS included a copy of Defendant Chemichl's 1995 Wholesale Price List of Dental Ceramics and Related Laboratory Products, and specifically directed the Examiner to the page and paragraph in the materials where Chemichl described its ceramic systems as having "an average leucite crystal dimension of 3 microns." (Id. The IDS then disclosed that Plaintiff/Applicant had at 2.) retained Dr. Sisson to evaluate the LF-1-PFM product as it existed in 1995, and reported that Dr. Sisson had determined that the product, as distributed in 1995, did not exhibit crystallites with diameters not exceeding about 10 microns. (Id.)

The Sisson Declaration disclosed that he had been retained by Plaintiff/Applicant in connection with the litigation over the '791 Patent, and that he had "studied" and "compared" the 1995 micrographs of the LF-1-PFM product with micrographs of Plaintiff's invention. The Sisson Declaration opined that "the LF-1-PFM product of Chemichl, Inc., as distributed in 1995, does not exhibit leucite crystals wherein the leucite crystallites possess diameters not exceeding about ten microns." ('884 Patent File Wrapper, Sisson Declaration at ¶ 9.)

Under 37 C.F.R. § 1.56(d), "[a]pplicants have a duty to prosecute patent applications in the PTO with candor, good faith, and honesty." Li Second Family, Ltd. v. Toshiba Corp., 231 F.3d 1373, 1378 (Fed. Cir. 2001); see also Molins, PLC v. Textron, Inc., 48 F.3d 1172, 1178 (Fed. Cir. 1995). "Inequitable conduct includes affirmative misrepresentations of material facts, failure to disclose material information, or submission of false material information, coupled with an intent to deceive." Baxter Int'l, Inc. v. McGaw, Inc., 149 F.3d 1321, 1327 (Fed. Cir. 1998); see also Molins, 48 F.3d at 1178. A party asserting an inequitable conduct defense must show by clear and convincing evidence that the alleged misrepresentation or nondisclosure occurred, that the misrepresentation or nondisclosure was material, and that the patent applicant acted with the intent to deceive the PTO. See Li Second Family, 231 F.3d at 1378. Determination of inequitable conduct requires a two step analysis by the court about whether the alleged conduct meets the threshold levels of materiality and intent. <u>See Baxter Int'l</u>, 149 F.3d at 1327. "The more material the omission or misrepresentation, the lower the level of intent required to establish inequitable conduct, and vice versa." See Critikon, Inc. v. Becton Dickinson Vascular Access, 120 F.3d 1253, 1256 (Fed. Cir. 1997).

Materiality of information is measured by whether "'there is a substantial likelihood that a reasonable examiner would have

considered the information important in deciding whether to allow the application to issue as a patent'." Li Second Family, 231 F.3d at 1379 (quoting Halliburton Co. v. Schlumberger Tech. Corp., 925 F.2d 1435, 1440 (Fed. Cir. 1991)). "Direct evidence of intent or proof of deliberate scheming is rarely available in instances of inequitable conduct, but intent may be inferred from the surrounding circumstances." Critikon, Inc., 120 F.3d at 1256 (finding that failure to disclose a prior art, which applicant should have known was material, and failure to disclose related ongoing litigation sufficient to infer an intent to mislead where no good faith explanation was offered); see also Paragon Podiatry Lab., Inc. v. KLM Lab., Inc., 984 F.2d 1182, 1193 (Fed. Cir. 1993) (holding that "[a]bsent explanation, the evidence of a knowing failure to disclose sales that bear all the earmarks of commercialization reasonably supports an inference that the inventor's attorney intended to mislead the PTO"). The Federal Circuit has instructed, however, that it "will not hold unenforceable a patent once granted in the absence of an intent to mislead, although the nondisclosure of facts of which the applicant should have known the materiality may justify an inference of intent to mislead in appropriate cases." Burlington Indus., Inc. v. Dayco Corp., 849 F.2d 1418, 1421 (Fed. Cir. 1988).

Here, Defendants' allegations of inequitable conduct rely primarily on Plaintiff's failure to provide the Examiner with the

"Final Product" calculations from Example 2 of the '366 Patent that Defendants generated in connection with the '791 Patent litigation ongoing at the time, and on Plaintiff's allegedly inconsistent statements and submissions regarding the LF-1-PFM product and its alleged sale. Although many courts have found inequitable conduct for failure to disclose material prior art, see e.g., Elk Corp. v. GAF Bldg. Materials Corp., 168 F.3d 28, 32 (Fed. Cir. 1999); Critikon, Inc., 120 F.3d at 1256, the facts here are clearly distinguishable. Plaintiff disclosed the '366 Patent to the Examiner as prior art; it is only calculations inherent in Example 2 of the '366 Patent that went "undisclosed." On this point, the Federal Circuit is clear that, when a disclosure of prior art has been made, the content of such patent is presumed to be before the examiner. See In re Portola <u>Packaging, Inc.</u>, 110 F.3d 786, 790 (Fed. Cir. 1997). The calculations embodied in the '366 Patent, therefore, were presumed to be before the Examiner. Furthermore, the Examiner's initial rejection over the '366 Patent was due to the overlapping size of the leucite crystals, not the relative weight percentages of specific components. Based upon this rejection, and on the facts detailed above under Defendants' anticipation claim, Plaintiff asserts that it believed the leucite crystal size to be the distinguishing element between the '366 Patent and its own invention, and, therefore, did not believe that disclosure of the chemical composition inherent in Example 2 constituted material

information.

In sum, it is undisputed that Plaintiff disclosed the '366 Patent to the Examiner, that it disclosed the ongoing litigation regarding the '791 Patent, that it disclosed the literature regarding the alleged prior sale, and that it directed the Examiner to the place in the materials indicating an overlap of invention. The Federal Circuit has set a relatively high standard for proof of inequitable conduct, and cautioned attorneys not to abuse the use of this defense when representing their clients.

[T]he habit of charging inequitable conduct in almost every major patent case has become an absolute plaque. Reputable lawyers seem to feel compelled to make the charge against other reputable lawyers on the slenderest grounds, to represent their client's interests adequately, perhaps. They get anywhere with the accusation in but a small percentage of the cases, but such charges are not inconsequential on that account. They destroy the respect for one another's integrity, for being fellow members of an honorable profession, that used to make the bar a valuable help to the courts in making a sound disposition of their cases, and to sustain the good name of the bar itself. A patent litigant should be made to feel, therefore, that an unsupported charge of "inequitable conduct in the Patent Office" is a negative contribution to the rightful administration of justice. The charge was formerly known as "fraud on the Patent Office," a more pejorative term, but the change of name does not make the thing itself smell any sweeter. Even after complete testimony the court should find inequitable conduct only if shown by clear and convincing evidence. A summary judgment that a reputable attorney has been guilty of inequitable conduct, over his denials, ought to be, and can properly be, rare indeed.

Burlington Industries, Inc. v. Dayco Corp., 849 F.2d 1418, 1422

(Fed. Cir. 1988).

Reading the evidence in the light most favorable to

Plaintiff, Defendants have failed to meet this standard. This undisputed evidence does not support an inference of intent to deceive sufficient to eliminate any triable issue of fact. The evidence on the motion is, in the Court's view, consistent with the innocent assumption of knowledge and a genuine belief by Plaintiff that its product did not overlap with prior art. A determination of whether Plaintiff's attorneys actually withheld information in bad faith will require a careful and thorough examination which is only appropriate for trial. Accordingly, Defendants' motion for summary judgment that the '884 Patent is invalid due to inequitable conduct is DENIED.

F. <u>Plaintiff's Motion for Partial Summary Judgment</u>

In response to Defendants' combined motions for summary judgment, Plaintiff cross moves for partial summary judgment that Sensation infringes claim 1 of the '884 Patent. Although the Court has denied each of Defendants' motions for summary judgment as they pertain to Sensation and the '884 Patent, material factual issues exist with regard to at least Defendants' anticipation and inequitable conduct defenses. If resolved in Defendants' favor at trial, either of these defenses could defeat Plaintiff's claim of infringement. Therefore, material factual disputes in connection with at least two of Defendants' affirmative defenses make summary judgment on Plaintiff's claim of infringement inappropriate at this time. Accordingly,

Plaintiff's cross motion for partial summary judgment that Sensation infringes the '884 Patent is DENIED.

V. CONCLUSION

In sum, the Court adheres to its prior construction of claim 1 of the '791 Patent as being limited to the exact weight percentage ranges for its chemical components; the Court construes the leucite crystal size limitation "not exceeding about 10 microns" in claim 1 of both the '791 and the '884 patents as directed to the size of the leucite crystallites in the "final restoration," that is, the final dental porcelain composition created by the invention; the Court denies Defendants' motion for summary judgment on the ground of anticipation by the '366 patent based on factual disputes; the Court denies Defendants' motion for summary judgment under the on-sale bar as a matter of law; the Court grants in part and denies in part Defendants' request for summary judgment that Cerpress does not infringe any asserted claim (finding that Cerpress does not literally infringe either the '791 or the '884 patent, and that Cerpress does not infringe the '884 Patent under the doctrine of equivalents, but that factual issues exist regarding whether Cerpress infringes the '791 Patent under the doctrine of equivalents); the Court denies Defendants' motion for summary judgment that the '884 Patent is invalid due to inequitable conduct based on material factual issues; and the Court denies Plaintiff's cross motion for partial summary

judgment that Sensation infringes the '884 Patent based on material factual issues surrounding Defendants' defenses to that claim.

Accordingly, Defendants' combined motions for summary judgment [doc. no. 84] are GRANTED IN PART AND DENIED IN PART, and Plaintiff's cross-motion for partial summary judgment [doc. no. 92] is DENIED.

SO ORDERED

ELLEN BREE BURNS, SENIOR JUDGE UNITED STATES DISTRICT COURTS

Dated at New Haven, Connecticut, this ____ day of August, 2001.