United States District Court,
N.D. Florida.

UNIVERSITY OF FLORIDA RESEARCH FOUNDATION, INC., U.S. Biomaterials Corporation, and Block Drug Corporation,
Plaintiffs.
v.
ORTHOVITA, INC., and Paul Ducheyne,
Defendants.

No. 1:96-CV-82-MMP

April 20, 1998.

ORDER

PAUL**, Senior J.**

This matter came before the Court for a hearing on the various pending motions for summary judgment in this case on Friday, February 6, 1998. At the hearing, the parties indicated that the Court's resolution of Plaintiffs' motion for summary judgment for patent infringement (doc. 88) and Defendants' motion for summary judgment with respect to Count I of the supplemental complaint (doc. 93), both of which address the proper construction of the patent involved herein and whether there was infringement by Defendants, would assist them in shaping the issues for trial and preparing the pre-trial stipulation. Only those two motions, and the cross-motions related to Defendants' inequitable conduct and unclean hands defenses were argued at the hearing. The following motions for summary judgment are also pending before the Court: Defendant Paul Ducheyne's motion for summary judgment (doc. 92); Plaintiffs' motion for summary judgment on their false advertising, unfair competition, and trade disparagement claims and their motion for summary judgment on Defendants' counterclaims (doc. 89); Plaintiffs' motion for summary judgment on Defendants' inequitable conduct and unclean hands defenses (doc. 90) and Defendants' cross-motion for summary judgment on the same (doc. 107); as well as Plaintiffs' motion for summary judgment on Defendants' equitable estoppel defense (doc. 91).

As is set forth in greater detail below, and based upon the motions, the memoranda filed in support thereof and in opposition thereto, and upon the argument received at the February 6, 1998 hearing, the Court is of the opinion that Plaintiffs' motion for summary judgment for literal patent infringement (doc. 88) should be and the same is hereby DENIED, and Defendants' motion for summary judgment with respect to Count I of the supplemental complaint (doc. 93) should be and the same is hereby GRANTED. The remaining summary judgment motions are addressed below.

BACKGROUND:

In the mid-1980s, researchers at the University of Florida ("UF") began experimenting with different

compositions of glass particles for use in the repair of periodontal osseous defects. FN1 The researchers discovered that glass particles of a particular composition and within a particular range of particle sizes, when placed in a periodontal pocket would actually promote new bone growth, and that the glass filler would inhibit the invasion of soft tissue into the pocket, as well as help to control bleeding in the area. Additional benefits, such as increased ease of manipulability over prior applications FN2 of such bioactive glass particles, also resulted from their research.

FN1. When the bone structure supporting a tooth is destroyed by periodontal disease, a pocket, known as the periodontal osseous defect, becomes subject to invasion by the surrounding soft tissue, resulting in a loss of support for the tooth, and ultimately resulting in tooth loss.

FN2. *See* Hench, et al., *J. Biomed. Mater. Res.,* 5:117-141 (1971)(initially establishing the composition of the preferred glass particles, i.e. 45S5 glass particles, involved in the '046 patent.)

In 1985, the UF researchers applied for a patent for the resultant composition of glass particles which they determined was best suited for the repair of periodontal osseous defects, which patent was ultimately issued on July 25, 1989, as United States Patent No. 4,851,046 to Low, et al. (" '046 patent" or "Low patent"). Plaintiff University of Florida Research Foundation, Inc. ("UFRF") is the assigned owner of the '046 Patent, while Plaintiff U.S. Biomaterials, Inc. ("Biomaterials") is the exclusive licensee under the patent, and Plaintiff Block Drug Corporation ("Block") FN3 is the exclusive distributor of the commercial embodiment of the patent which is marketed and sold under the trademark PerioGlas(TM).

FN3. Plaintiffs UFRF, Biomaterials, and Block may be referred to collectively as "Plaintiffs."

The '046 patent contains a total of nine claims, all of which, excluding claims five and nine, are being asserted by Plaintiffs in this action. The relevant claims, as asserted by Plaintiffs, are as follows:

1. A composition adapted for the repair of periodontal osseous defects consisting essentially of particulate bioactive and biocompatible glass, said particulate glass having a particle size in the range of from about 355 to about 710 mum [microns] and the following weight percentage composition:

Composition	Weight Percentage
SiO_2	40-52
CaO	10-50
Na_2O	10-35
P_2O_5	2-8
CaF_2	0-25
B_2O_3	0-10

2. The composition of claim 1 wherein said particulate glass has a particle size in the range of from about 355 to about 500 mum.
3. The composition of claim 1 wherein said particulate glass has a particle size in the range of from about

500 to 710 mum.

4. The composition of claim 1 consisting essentially of a mixture of (1) said particulate glass having a particle size in the range of from about 90 to 350 mum, (2) said particulate glass having a particle size in the range of from about 355 to 500 mum, and (3) said particulate glass having a particle size in the range of from about 500 to 710 mum.

6. The composition of claim 1 additionally containing a liquid in admixture with said particulate glass in an amount sufficient to wet the particles of said glass.

7. The composition of claim 6 wherein said liquid is aqueous.

8. The composition of claim 6 wherein said liquid is blood.

United States Patent No. 4,851,046, column 11, lines 36-39, column 12, lines 1-38.
In April, 1992, Defendant Paul Ducheyne ("Ducheyne"), a former doctoral fellowship mentee of Dr. Larry Hench, one of the original inventors of the '046 patent, founded Defendant Orthovita, Inc. ("Orthovita") FN4 of which he is currently the chairman of the board of directors. Defendants produce BioGran(R), which is also a composition of glass particles FN5 adapted for the repair of periodontal osseous defects. Defendants contend that BioGran(R) contains only glass particles which are smaller than 355mum when measured by conventional sieving techniques, thus placing it outside the scope of enforcement of the '046 patent. (Doc. 93, p.1).

FN4. Defendants Orthovita and Ducheyne may be referred to collectively as "Orthovita" or as "Defendants."

FN5. Like Plaintiffs' PerioGlas(TM), BioGran(R) consists wholly of particulate bioactive and biocompatible glass known in the industry as 45S5 glass.

SUMMARY JUDGMENT IN PATENT CASES:

In evaluating Plaintiffs' and Defendants' motions for summary judgment, this Court must examine whether "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits ... show that there is no genuine issue as to any material fact and the moving party is entitled to a judgment as a matter of law." Fed.R.Civ.P. 56(c). All of the evidence and reasonable factual inferences drawn from the evidence must be construed in a light most favorable to the party opposed to a motion for summary judgment. *See* Atlantic Richfield Co. v. USA Petroleum Co., 495 U.S. 328, 332, 110 S.Ct. 1884, 1888, 109 L.Ed.2d 333 (1990)(*citing* Matsushita Electric Industrial Co. v. Zenith Radio Corp., 475 U.S. 574, 587, 106 S.Ct. 1348, 1356, 89 L.Ed.2d 538 (1986)).

The fact that this case involves complex, and highly technical factual issues, does not render it unsuitable for disposition via summary judgment on the issues of infringement and claim validity. Summary judgment is as appropriate for cases involving patent law as any other civil litigation. *See* General Elec. Co. v. Nintendo Co., 983 F.Supp. 512, 518 (D.N.J.1997). Where no issue of material fact is present, district courts should not hesitate to proceed to disposition by summary judgment. *See id.* (citing Chore-Time Equip. v. Cumberland Corp., 713 F.2d 774, 778-79 (Fed.Cir.1983)). The district court should look beyond mere denials and

arguments with respect to the scope and content of prior art and other factual matters. *See id*. Where, as in this case, the parties disagree not over relevant facts regarding the allegedly infringing product, but rather disagree over the proper scope and interpretation of the claims contained within the patent at issue,FN6 the Court "may decide the issue of literal infringement as a matter of law in a motion for summary judgment." Howes v. Zircon Corporation, No. 97C5632, 1998 WL 34989 at (N.D.Ill. January 13, 1998)(citing Athletic Alternatives, Inc. v. Prince Mfg. ., 73 F.3d 1573 (Fed.Cir.1996)).

FN6. *See* Transcript of Feb. 6, 1998 hearing (Doc. 125 at p. 4, lines 19-21, p. 44, lines 7-9).

DISCUSSION:

A. *Plaintiffs' Motion for Summary Judgment for Patent Infringement (doc. 88) and Defendants' Motion for Summary Judgment for Non-Infringement or Alternatively for Patent Invalidity (doc. 93)*

Patent infringement analysis is a two-step process, with the first step being the Court's construction of the claims asserted by the plaintiff in order to establish their proper meaning and scope, and the second step being the Court's application of the construed claims to the allegedly infringing product of the defendant. *See* Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1581-82 (Fed.Cir.1996)(citing Markman v. Westview Instruments, Inc., 52 F.3d 967, 976 (Fed.Cir.1995), *aff'd* 517 U.S. 370, ----, 116 S.Ct. 1384, 1393, 134 L.Ed.2d 577, ---- (1996)). The first prong is an issue of law, reserved exclusively for the Court. *See* Markman, 52 F.3d at 977. The latter prong of the analysis may be established either by literal infringement of the patent or by infringement under the doctrine of equivalents. *See* General Electric v. Nintendo, 983 F.Supp. at 519. In this case, Plaintiffs have moved for summary judgment based only on literal infringement, reserving the issue of infringement under the doctrine of equivalents for trial should the literal infringement argument fail. Literal infringement occurs when a limitation of the patent is literally found in the accused device, i.e. the accused device contains every limitation of the asserted claim. *See id*.

1. First Prong-Claim Construction

In order to determine the proper construction and scope of patent claims, the Court should first look to the literal meaning of the words of the claims themselves, including both asserted and non-asserted terms. *See* Nova Biomedical Corp. v. i-STAT Corp., 980 F.Supp. 614, 615 (D.Mass.1997)(citing Vitronics, 90 F.3d at 1582). The proper standard to be applied in claim construction of technical terms is what one of "ordinary skill in the art" would have understood the terms of the patent claims to mean at the time of the invention. *See* Markman, 52 F.3d at 986.

The Court should next evaluate the claim specification, which is a written description of the invention that functions as a dictionary of sorts, explaining the invention and often times defining terms used therein. *See* General Elec. v. Nintendo, 983 F.Supp. at 519. The specification is highly relevant to the analysis of claim construction and it is often dispositive; it has been described as "the single best guide to the meaning of a disputed term." Vitronics, 90 F.3d at 1582.

As a final source of intrinsic evidence regarding the proper construction of a claim, the Court should evaluate the claim's prosecution history or "file wrapper," which gives insight into the proceedings before the United States Patent and Trademark Office. *See id*. The prosecution history can limit the terms of claims to exclude any interpretation which was disclaimed or surrendered by the patentee during the patent's prosecution. *See* Howes, 992 F.Supp. 957, 1998 WL 34989 at *2. As with the specification, the prosecution

history may not be used to " 'enlarge, diminish, or vary' the limitations in the claims." Markman, 52 F.3d at 980 (quoting Goodyear Dental Vulcanite Co. v. Davis, 102 U.S. 222, 227, 26 L.Ed. 149 (1880)).

The claims, specification, and prosecution history of a patent constitute the "public record" upon which the public may rely, thus it is generally inappropriate for a court to consider extrinsic evidence beyond that available to the public, such as expert testimony, when defining the scope of the patent claims. Vitronics, 90 F.3d at 1583. However, the Court may consider extrinsic evidence for the purpose of its own understanding of the meaning or scope of technical terms used in the claims, but as noted previously, not for the purpose of "varying or contradicting the terms of the claims." Markman, 52 F.3d at 981.

In this case, the parties seek the Court's interpretation of the scope of the '046 patent claims as they relate to the range of particle sizes covered therein, and of the particle size measurement technique called for and required by the '046 patent claims.

a. Construction of '046 Patent **Claims-Regarding the Exclusion or Non-Exclusion of Particles With Sizes Below 355 mum.**

Claim 1 of the '046 patent recites a composition "consisting essentially of" particulate glass, which glass has individual particle sizes in the range of "from about 355 to about 710 mum." The parties agree that in order for Claim 1 to be infringed, particles in this range must be present; however, they disagree over whether or not the existence of smaller particles in the particulate glass composition would prevent a finding of infringement. It is the Defendants' position that the proper construction of Claim 1 is that all particles must be within the cited range, while Plaintiffs contend that Claim 1 should be read in conjunction with dependant Claim 4 to permit infringement when there is the presence of particles below the cited range. This distinction is extremely important as the BioGran$^{(R)}$ product undisputedly contains particles which are smaller than 355mum regardless of whether traditional sieving or scanning electron microscopy is utilized to determine particle size. In order to determine the proper scope of the '046 patent claims, the Court will consider the language of the claims in conjunction with the patent specification and prosecution history.

i. The Claim Language and Specification

a. Does Claim 1 Exclude Particles Smaller Than 355mum?

Claim 1 of the '046 patent identifies a composition adapted for the repair of periodontal osseous defects "consisting essentially of" particulate glass, said glass having particles within a cited range of sizes. The phrase "consisting essentially of" was deliberately inserted by the patent applicants to replace the phrase "comprised of" which was used in Claim 1 of the original patent application in an effort to narrow that broader application claim. *See Application for Patent,* June 19, 1985, at p.22 (Doc. 106, Exh.5). An 'essential' ingredient is one which is indispensable or fundamental. Plaintiffs contend that this language is intended to allow the presence of items which do not materially affect the basic characteristic, or "essence" of the composition. *See* Transcript of Feb. 6, 1998 hearing (Doc. 125 at 10). The Court agrees. *See* Water Technologies v. Calco Ltd., 850 F.2d 660, 666 (Fed.Cir.1988).

With regard to the language of Claim 1, the Court concludes that in order to be infringing, a composition must, at a very minimum, contain glass particles within the cited particle size range; however, the claim language does not preclude the existence of other materials which do not materially affect the essential characteristics of the composition of Claim 1. Yet the question remains, can those "other materials" be particulate glass with particle sizes below 355mum? In other words, does the presence of particles smaller

than 355mum, materially affect the essential characteristics of the invention claimed in the '046 patent? In order to answer these questions, the Court must determine what the essential characteristics of the claimed invention are.

The Plaintiffs' claimed invention is a powder comprised of bioactive and biocompatible glass particles within such a range of particle sizes with the following essential characteristics: that when it is combined with an aqueous solution, it not only promotes bone growth, stops the invasion of soft tissue into the periodontal osseous defect, and helps control bleeding, but it also forms a paste that is cohesive, is easily manipulable, and which resists breakdown when subjected to irrigation or suction. *See* '046 Patent, col. 4, lines 23-68 (Doc. 106, Exh. 1). These characteristics are based upon the improved performance of the claimed invention over prior art in the same field. The patent specification suggests that the most advantageous composition is one with the widest range of particle sizes, i.e. 90 to 710mum, and more specifically, the specification notes that the most superior performance resulted from testing a hypothesized formulation containing particles in equal thirds, each third having particles within the three ranges cited in Claim 4. The characteristics of three compositions of differing size ranges are summarized in column 5, table 1 of the '046 patent,FN7 the relevant portions of which provide:

FN7. This table lacks any indication of the performance characteristics which result from the use of particles either largely or solely within a range similar to that used in Defendants' product, i.e. 300 to 355mum or within the range of Claim 1, i.e. 355 to 710mum.

Materials	Particle Size (mum)	Ease of Manipulation	Cohesiveness with Blood	Appearance in Periodontal Defect
Glass 45S5 or 45S5F	500-710	good remained on instrument	good	moderately, densely packing of particles filling defect
Glass 45S5 or 45S5F	90-355	very good, easy to handle & transport	very good, easily packed	very good, dense packing, resistant to irrigation
Glass 45S5 or 45S5F *['046 patent Claim 5]*	90-710 [8]	excellent superb adhesion to instrument, superb ease of transport	excellent superior packing	very dense packing in site, translucent, appears in site as if bone resistant to irrigation and

				suction

FN8. The optimal characteristics of the composition, with particles in the range of 90 to 710mum, are predicated upon the useof glass particles within the each of the three size ranges set forth in dependant Claims 4 and 5.

Plaintiffs argue that the evidence confirms that the additional presence of particles sized below 355mum in a composition under Claim 1, does not affect the basic characteristics of the composition, but rather only affects the degree of resultant cohesiveness of the composition, i.e. its performance. However, it was the improved performance of a broader range of particle sizes cited in the '046 patent claims which served as the impetus for the patent application, and which has been cited as the distinguishing characteristic of Plaintiffs' product over the prior art. *See* United States Patent No. 4,851,046, col. 3, ll. 58-68, col. 4, ll. 1-45. The improved performance derives from the use of particles in the ranges cited in Claim 5, i.e. one which contains no more than one-third of its particles in the 90 to 355mum size range. It, therefore, seems apparent that the basic characteristics of the claimed invention are inextricably intertwined with the degree of performance associated with the use of particles within the cited ranges.

Defendants likewise contend that the presence of a greater number of the smaller glass particles does affect the characteristic of the composition, and they point to the existence of smaller particles in Plaintiffs' own product PerioGlas(TM)FN9 and the Patent Office's subsequent issuance of the Schepers patent as evidence of the same. Defendants do agree that the smaller particles which are present in the BioGran$^{(R)}$ product affect the performance of the composition, but unlike Plaintiffs, they contend that the marked difference in performance brought about by the inclusion of a greater percentage of smaller particles does materially alter the characteristics of the composition at issue. They cite to the Patent Office's issuance of a separate patent to Schepers et al., for a composition restricted solely to particles of a smaller range than that of the '046 patent,FN10 and which restricted size range and smaller particle characteristics "result[ ] in a quantitatively greater amount of bone formation than the particles as disclosed by [the '046 patent]." *See* (Doc. 126, Attach.B)(citing to Patent Office's reaffirmation of patentability of the claims in the Schepers patent). Defendants contend this is evidence that, by increasing the amount of bone formation, the presence of a greater number of smaller particles does change the basic characteristics of the composition in Claim 1 of the '046 patent.

FN9. Defendants have properly noted that there is no evidence of any composition being produced with particles solely within the range cited in Claim 1 of the '046 patent, i.e. from about 355 to 710mum. In fact, analysis using a Microtrac Particle Size Determination method ("Microtrac"), which Plaintiffs contend is equivalent to Scanning Electron Microscopy ("SEM"), reveals that Plaintiffs' own PerioGlas(TM) is composed of a percentage of particles smaller than 355mum, as high as 57.83%. *See* Corning Analysis (Doc. 88, Exh. 12 at p. 4).

FN10. Claim 1 of the Schepers patent calls for a composition in which at least 95% of the particles are within the particle size range of from between 280 and 425mum. Dependant Claim 2 requires the composition of Claim 1 wherein 2/3 of the particles are between 300 and 360mum, and dependant Claim 3 requires a composition of Claim 2 wherein at least 90% of the particles are between 300 and 360mum. *See* United States Patent No. 5,204,106, column 8, lines 56-61.

Thus, Defendants argue that the "consisting essentially of" language, which Plaintiffs have argued only excludes from Claim 1 those other materials or particles which materially affect the essential characteristic of the claimed invention, does in fact exclude the smaller sized glass particles found in the BioGran(R) product from the scope of Claim 1, since BioGran's smaller particles appear in much larger quantities than those contemplated by the '046 patent claims, and because, according to the Patent Office's holding in the Schepers patent, the presence of the greater number of smaller particles changes the characteristics of the '046 claimed invention. Defendants' argument relies on the Patent Office's conclusions regarding the Schepers patent, which patent and the resultant product characteristics cited therein, are based on the presence of particles which are *solely* within a smaller particle size range, and which does not deal with smaller particles co-existing with larger sized particles, as would be required under the '046 patent claims. However, this Court agrees with Defendants, and with the Patent Office's conclusion in the Scheper's patent, that the presence of a greater number of smaller particles does affect the performance of the composition to the point that it alters its basic characteristics, especially in light of the fact that the characteristics of the claimed invention are based upon its improved performance over prior art in the field. And while the claims within, and the findings of the Patent Office with regards to the Schepers patent, do not qualify as being part of the '046 patent, its patent specification, its prosecution history, or the relevant *prior* art which this Court can properly consider when construing the meaning and scope of the terms thereof, this Court finds them to be instructive in determining what amount of smaller particles are anticipated by Claim 1 of the '046 patent. Accordingly, the Court concludes that a larger presence of particles smaller than the range cited in Claim 1, especially where the percentage thereof is greater than the one-third fraction cited in Claim 5, could easily lead to the conclusion that the basic characteristic of the claimed invention would be altered by the variance in performance brought about by their inclusion. Indeed, were a hypothetical composition to be comprised of more than two-thirds of its particles below 355mum, it would be difficult to argue that the composition consists "essentially of" particles within the range of 355 to 710mum.

This Court, therefore concludes that the basic characteristics of a composition consistent with Claim 1 of the '046 patent, i.e. a composition of particles with sizes in the range of from about 355 to 710mum, may not be altered by the inclusion of smaller particles in an potentially infringing composition. Thus, Claim 1 is amenable to infringement actions against compositions which not only contain particles within the size range of 355 to 710mum recited in Claim 1, but which also contain particles with sizes smaller than 355mum. However, the Court also concludes that the presence of substantially more than one-third of a composition's particles below the range cited in Claim 1 would very likely affect the performance in a manner sufficient to alter the basic characteristics of the composition claimed in the '046 patent, and therefore, would remove the composition from infringement of Claim 1, which, though it allows for and even anticipates the presence of smaller particles, does not anticipate the presence of smaller particles in much greater a quantity than the one-third weight percentage cited in Claim 5 thereof. The inclusion of particles smaller than 355mum in compositions alleged to infringe upon '046 patent Claim 1 must remain subject to the limitations of dependant Claims 4 and 5, which narrow the scope of Claim 1 by allowing the additional presence of up to one-third of the particles in the size range of 90 to 355mum.

b. Does Claim 4 Permit the Presence of Particles Smaller Than 355mum?

In order to determine whether the '046 patent, and specifically Claim 1, can be interpreted to allow for compositions which include other glass particles sized below 355mum, Plaintiffs suggest that the Court look to the dependant Claim 4. The fourth claim is for the composition of Claim 1, wherein that composition is defined as consisting "essentially of" a mixture of particulate glass within the following three, separately delineated particle size ranges: (1) from about 90 to 350mum, (2) from about 355 to 500mum, and (3) from

about 500 to 710mum. Under 35 U.S.C. s. 112, a dependant claim "shall be construed to incorporate by reference all the limitations of the claim to which it refers." Id. Additionally, a dependant claim shall specify a further limitation on the subject matter of the claim to which it is referenced. *See* id. Dependant Claim 4 adds a limitation to independent Claim 1, by requiring not only the presence of particles in the size range contained in Claim 1, but also the presence of particles in the 90 to 350mum range. Claim 4 further requires that the particles within the 355 to 715mum range of Claim 1 be comprised of particles from the two more specific ranges already claimed in dependant Claims 2 and 3, i.e. the 355 to 500mum and 500 to 710mum ranges. Plaintiffs contend that, by implication, Claim 1 must be sufficiently broad to accommodate the further restriction of dependant Claim 4. Indeed, the Patent Examiner specifically approved of the revised text of Claim 1 knowing that the dependant Claim 4 was based upon it. In doing so, the Examiner implicitly found that the scope of Claim 1 does not exclude the presence of particles smaller than 355mum.

It is axiomatic in patent law that all patent claims, be they independent or dependant in nature, are presumed to be valid regardless of the validity of other claims. *See* Applied Materials, Inc. v. Advanced Semiconductor Materials, 98 F.3d 1563, 1569 (Fed.Cir.1996), *cert. denied,* 520 U.S. 1230, 117 S.Ct. 1822, 137 L.Ed.2d 1030 (1997); *see also* 35 U.S.C. s. 282. Furthermore, the presumption of validity of patent claims is based upon the presumption of administrative correctness associated with the actions of an agency which is charged with patentability evaluation. *See* Applied Materials, 98 F.3d at 1569. Accordingly, this Court must give due weight to the presumption of validity of the patentabilty determinations of the United States Patent Office as manifested by its approval of dependant Claim 4 in conjunction with Claim 1 of the '046 patent. *See* id. (citing Interconnect Planning Corp. v. Feil, 774 F.2d 1132, 1139 (Fed.Cir.1985)).

The Court concludes that based upon the claim language as interpreted by the Patent Office, the presumptively valid dependant Claim 4 could not exist but for the amenability of Claim 1 to the inclusion of compositions that contain particles below 355mum, so long as the composition in question also contains those essential particle sizes in the range of 355 to 710mum. Claim 1 is sufficiently broad to include particle sizes smaller than 355mum, especially when, as required by Claim 4, the smaller particles co-exist in a mixture with particles that have sizes in the range of 355-500mum, and with particles that have sizes in the range of 500-710mum. Furthermore, as stated above, the Court agrees that the basic characteristics of the patented invention would not be altered by the presence of additional smaller particles below the range state in Claim 1, so long as those smaller particles were subject to the limitations of dependant Claims 4 and 5 which allow for the presence of up to one-third of the composition's particles in the range below 355mum.

Scope of the Term "Mixture" in Claim 4

In interpreting the meaning and scope of the claims of the '046 patent, the Court must now consider what is meant by the term "mixture" in dependant Claims 4 and 5. Of these two claims, Plaintiffs have only asserted infringement of Claim 4, which encompasses:

The composition of claim 1 consisting essentially of a mixture of (1) said particulate glass having a particle size in the range of from about 90 to about 350 mum, (2) said particulate glass having a particle size in the range of from about 355 to about 500 mum, and (3) said particulate glass having a particle size in the range of from about 500 to about 710 mum.

United States Patent No. 4,851,046, column 12, lines 18-24.

Defendants have argued Claim 4 dictates, that in order for a product containing smaller sized particles to be

infringing, it must have been created by "mixing" three separate compositions of glass, each of the three said compositions consisting only of particles in each of the three ranges cited. With regard to the language in dependant Claim 4, which claims a composition that consists 'essentially of a mixture,' Defendants state that the term "mixture" in that claim "must be interpreted to require the preparation and subsequent combination of the three compositions." FN11 (Doc. 93, p. 16 n. 12). To construe it otherwise say the Defendants, would be to resurrect the scope of application Claim 1 which was held unpatentable by the Board of Appeals, and such a construction would effectually broaden, rather than narrow the scope of independent Claim 1, all in violation of 35 U.S.C. s. 112. Defendants state that " 'the dependant claim tail cannot wag the independent claim dog." ' (Doc. 93, p.16 n.12)(quoting North American Vaccine, Inc. v. American Cyanamid Co. ., 7 F.3d 1571, 1577 (Fed.Cir.1993)).

FN11. According to Defendants, Claims 5 and 6 require that the claimed composition be "a 'mixture' of three compositions, each having a different range of particle sizes. Thus one composition [with] a particle size range of from about 90 to 350mum, a second composition [with] a particle size range of from about 355 to 500mum, and the third composition [with] a particle size range of from about 500 to 710mum ."

(Doc. 93, p.15 n. 11).
The Court cannot accept Defendants' interpretation of the term 'mixture' for several reasons. First, the plain meaning of the term 'mixture' is that which consists of different elements; it is a noun which refers to what is contained in a composition, not how a composition is created. Specifically, a mixture has been defined as "a portion of matter consisting of two or more components that do not bear a fixed proportion to one another and that however thoroughly commingled are regarded as retaining a separate existence ." *WEBSTER'S THIRD NEW INTERNATIONAL UNABRIDGED DICTIONARY* 1149 (1968). Thus, one would be able to identify the components of a mixture because each component would retain its own composition.

In this case, the resultant embodiment of the patented claims is a powder consisting of bioactive and biocompatible glass particles. If three compositions of glass particles, i.e. three powders, each falling within the three respective size ranges cited in Claim 4, were to be combined with one another, they would no longer remain recognizable in any of the three separate composition forms which they embodied prior to being mixed together, rather they would form a new powder which would only be identifiable as having particles somewhere within each of the three cited ranges. The individual glass particles would retain their original characteristics, but if three powder compositions consisting of particles within three separate ranges were mixed, those three separate powder compositions would no longer be distinguishable. FN12 For example, if Powder-A, containing only particles in the range of 90 to 350mum, were combined with Powder-B containing particles in the range of 355 to 500mum, it would not be possible to identify Powder-A within the new Powder-AB, much less to distinguish Powder-AB from another composition powder that was simply created directly from particles in the size range of 90 to 500mum. Consistent with the above-referenced definition of a mixture, if particles are mixed together to form a resultant powder by any process, each particle will retain its own size characteristics within the mixture, thus, it matters not how the resultant powder composition is formed. The relevant inquiry regarding the "mixture" cited in Claim 4, is whether the resultant mixture contains particles in each of the three cited ranges, not whether three separate compositions of glass particles were mixed to form one.

FN12. This is inconsistent with Defendants' proffered interpretation of the term 'mixture' as meaning a process of combining three separate compositions together to form the resultant product.

The Court concludes that the term 'mixture' as used in dependant Claim 4 of the '046 patent means a composition of particulate glass which contains a mixture of glass particles, said particles having sizes within each of the three size ranges cited in Claim 4, and that the term does not mean a mixture comprised of three separately composed compositions of glass particles mixed with one another to form a compound composition as argued by Defendants. The Court's interpretation of the term 'mixture' as used in the context of Claim 4 of the '046 patent is consistent with the definition cited above. As construed, Claim 4 deals with a mixture of glass particles of various sizes, which particles would each retain their own identity within the mixture; it does not deal with a mixture of three separately composed compositions of particles, which compositions' individual identities would be lost in, or subsumed by, the resultant mixture comprised thereof.

Citing to the '046 patent specification at column 4, lines 48-57, Defendants contend that the specification refers to a process of blending three different particle size range components to obtain the 'mixture' referred to in Claim 4. (Doc. 106, pp.9-10). However, the reference in the specification is an explanation of the patentee's hypothesis that a composition of glass particles with a broader range of particle sizes, i.e. within each of the three cited ranges, yields the most effective osseous defect repair mechanism. The reference is included as support for the proposition that powders containing glass particles over a wider range of particle sizes would improve the cohesiveness and workability of the resultant product. The Court must reject Defendants interpretation of the term 'mixture' on these grounds because it is legally improper to read from the specification and into the patent, a process limitation which is simply not there. Additionally, a patent claim cannot be limited by the examples listed within the patent specification. *See* Modine Mfg. Co. v. United States Int'l Trade Comm'n, 75 F.3d 1545, 1551 (Fed.Cir.), *cert. denied,* 518 U.S. 1005, 116 S.Ct. 2523, 135 L.Ed.2d 1048 (1996)(citing Specialty Composites v. Cabot Corp., 845 F.2d 981, 987 (Fed.Cir.1988)).

Defendants' argument that construction of the term mixture to mean anything other than the process of mixing three separate compositions would improperly resurrect the application claim rejected by the Board of Appeals and impermissibly broaden, rather than limit the scope of independent Claim 1, is also wrong. Defendants mistakenly assume that if the term mixture is construed to mean the resultant particulate glass composition, regardless of how it is formed, that such a construction would transform Claim 4 into the equivalent of application Claim 1 which cited a range of particles sizes from about 90 to 710mum. Application Claim 1 was refused because it was too broad and could be construed to encompass a composition containing glass particles only in the size range below 355mum, without a requirement that larger particles be present as well. Claim 4, by construing the term 'mixture' to mean the resultant composition, regardless of the process by which it was formed, encompasses those compositions in which the smaller particles *co-exist* with particles in the 355 to 500mum range and with particles in the 500 to 710mum range. Thus, the scope of the '046 patent Claim 4 is substantially different than application Claim 1. The Court must also reject Defendants' argument that this interpretation of Claim 4 broadens rather than narrows the scope of independent Claim 1, in violation of 35 U.S.C. s. 112. Claim 1 involves a composition containing glass particles within the size range of 355 to 710mum. Claim 4 further restricts this claim by also requiring the additional presence of particles within the range of about 90 to 350mum, thus narrowing the scope of Claim 1.

Having considered the patent claims themselves and the specification provided therefor, the Court concludes that the proper interpretation of the scope of the '046 patent, and specifically Claim 1, is that it not only

allows for, but anticipates *via* Claims 4 and 5, the presence of glass particles with sizes smaller than 355mum, however, it excludes from Claim 1 the presence of those smaller particles when they occur in a number sufficient to affect the performance in such a manner that they also alter the basic characteristics of the claimed invention. Additionally, the presence of smaller particles allowable under Claim 1 remains subject to the further limitations of dependant Claims 4 and 5, which narrow the scope of Claim 1 by allowing the additional presence of up to one-third of the particles in the size range of 90 to 355mum. Thus, where a composition contains *substantially* more than one-third of its particles in the smaller range (e.g. two-thirds or more), it will not be within the scope of Claim 1.

ii. The Prosecution History

The prosecution history of the patent is also relevant to the proper construction of the claims therein. As will be discussed below, the prosecution history of the '046 patent also reveals that it encompasses not only those compositions of particulate glass which consist *only* of particles sized within the range of from 355 to 710mum, but that it also encompasses compositions with particles in the range of 355 to 710mum that also include particles sized smaller than 355mum.

Claim 1, which originally cited a particle size range of from about 90 to about 710mum, was rejected by the Patent Examiner under 35 U.S.C. s. 103 as unpatentable over prior art, the Gross et al. Patent No. 4,239,113 ("Gross patent"). The examiner concluded that Claim 1 was too broad and could theoretically encompass the prior art Gross patent which required the presence of much smaller particles (those in the range of 10 to 200mum). On appeal of the examiner's rejection of Claim 1, the Patent Office Board of Patent Appeals and Interferences ("Board of Appeals") held that any of the claims which could be construed as requiring only smaller particles were not patentable, but it noted that those claims which required the presence of larger particles were indeed patentable. The original Claim 5, which was re-numbered as Claim 4 in the '046 patent, was found to be patentable by the Board of Appeals because it cited and required the presence of particles within size ranges substantially larger than anything disclosed in the Gross patent. *See* Opinion on Appeal, No.88-0461 at p.3 (Doc. 88, Exh. 10 at OVIT 00368).

Defendants have argued under their fourth defense, that the additional subject matter of Claim 4, i.e. the range of particles from 90 to 350mum, was "ceded" to the public domain when the Patent Examiner rejected the original broad Claim 1 in favor of the more restrictive Claim 1 that cited particle sizes in the range of about 355 to 710mum. *See* Transcript of Feb. 6, 1998 hearing (Doc. 125, p.27, lines 2-5); *see also* (Doc. 106, p.4). Defendants argue that "the purported scope of claim 1, as now advanced by [Plaintiffs], was 'disclaimed during prosecution,' and, cannot be adopted now." *Id*. (quoting Southwall Tech., Inc. v. Cardinal IG Co., 54 F.3d 1570, 1576 (Fed.Cir.1995)). However, *Southwall* and the other cases cited by Defendants, deal with situations where the patentee construed a term one way in order to obtain its allowance in the patent, and then sought to construe it the opposite way against accused infringers. *See* Southwall, 54 F.3d at 1576. In this case, what was originally claimed was a range of particle sizes which could be construed to include *only* smaller particles to the exclusion of larger ones, thus violating a prior art patent regarding the smaller particles. What is now claimed is a composition which includes particles within the lower range of particle sizes, but only where the co-presence of larger particles is explicitly required as well. This construction is not inconsistent with the position previously taken by Plaintiffs, and all that was ceded to the public domain, or that was "disclaimed" during the prosecution of the original patent application, that can now limit the interpretation of dependant Claim 4, was any claim which permitted the presence of *only* the smaller particles to the exclusion of any larger particles. No portion of the original Claim 5, re-numbered as Claim 4, was ever disclaimed or rejected by the Board of Appeals such that Plaintiffs are now forbidden

from advancing an interpretation of its current patent claims consistent therewith. Thus Defendants' fourth defense of prosecution history estoppel must fail.

Plaintiffs had wanted to patent the original broader range because their testing indicated that those compositions with the broadest range, i.e. with particles in the range of from 90 to 710mum, created the most adhesive and manipulable resultant product; this was a clear advantage over the prior art Gross patent material, and this advantage served as the impetus for the original application to patent the range of 90 to 710mum. *See* '046 Patent, col. 4, lines 23-68 (Doc. 106, Exh. 1). However, since the originally requested open range was denied because it was so open and broad as to potentially encompass the Gross patent, Claim 1 was cut back to provide Plaintiffs with an open range from 355 to 710mum. Claims 2 and 3 concern two separate ranges within the broader initial range of Claim 1, and Claims 4 and 5 allow Plaintiffs to claim rights to a composition consisting of a mixture which is subject to Claim 1 and which also contains particles in the lower range. This allowed the Plaintiffs to have a patent over a composition with particles in the most desirable range of 90 to 710mum, but only so long as the composition consists of a mixture of glass particles across the entire range of particle sizes, so as to avoid the problem of the original claim 1 which would have overlapped the Gross patent.FN13 The revised versions of the '046 patent claims allowed the Plaintiffs to take as full advantage as possible of the benefits which flow from the use of the broadest range of particle sizes, and to prevent potential infringers from duplicating or mimicking the composition of PerioGlas(TM) only to avoid an infringement claim by simply adding in some smaller sized particles.

FN13. The only way the Gross patent ever falls within the '046 patent is in compositions under Claim 4, but even then, the '046 patent is distinct because it requires the co-presence of particles from two separate size ranges larger than those cited in the Gross patent.

In this case, the prosecution history only serves to bolster this Court's conclusion that the '046 patent claims do not exclude the presence of smaller particles, and it is consistent with this Court's determination that the claims of the '046 patent, while requiring the presence of particles within the size range of from 355 to 710mum, do not exclude the possible presence of particles with sizes smaller than 355mum.

Thus, having considered the patent claims themselves, the patent specification, and the prosecution history thereof, this Court concludes that as a matter of law, the '046 patent, and more specifically, Claim 1, is not restricted to an interpretation that all particles be between 355 and 710mum, as suggested by Defendants. It is sufficient for a finding of infringement of the '046 patent claims, that a composition contain either particles solely within the range cited in Claim 1, from about 355 to 710mum, or that the composition contain additional smaller particles in such quantities that do not affect the basic characteristic of the claimed composition or which occur in a manner consistent with the additional limitations of dependant Claims 4 and 5. However, while infringement of Claim 1 cannot be avoided by the mere additional presence of particles smaller than 355mum when those smaller particles either do not affect the material characteristics of the composition, or appear in a manner consistent with Claims 4 and 5, a composition which contains a substantially greater number of its particles in the smaller range than is explicitly referred to in Claim 5, can only be found infringing in the unlikely event that Plaintiffs can show that the basic characteristics of the claimed invention are not altered by the presence of so great a number of smaller particles.

b. Construction of the '046 Patent **Regarding the Appropriate Method for Particle Size Measurement**

The second claim interpretation issue which this Court must consider is the method which must be used to measure the bioactive glass particles involved in the claims and Defendants' product. Plaintiffs argue vociferously that the '046 patent claims call for particle size to be measured by scanning electron microscopy ("SEM") or an equivalent technique, while Defendants contend that particle size should be measured using sieving.FN14 The Court recognizes, from the various test data which has been placed on the record, the sharp contrast in results which can be achieved using these two particle size measuring techniques. Indeed, utilizing the results of SEM or what the Plaintiffs contend is an equivalent method, it would appear that Defendants' product BioGran(R) clearly infringes upon the ranges of particle sizes cited in Claims 1 and 4 of the '046 patent. *See, e.g.,* Corning CELS Analytical Report, (Doc. 106, Exh. 6 at p.16)(showing particles in each of the three size ranges cited in Claim 4 of the '046 patent using a Microtrac particle analyzer); Aveka, Inc. Analytical Report, (Doc. 106, Exh. 7 at p. 19)(showing the same). However, utilizing the sieving test data proffered by Defendants for their product, such a finding is not nearly as readily apparent; in fact, from the sieving data on the record, the Court could very well draw the opposite conclusion. Plaintiffs have conceded that should sieving be found to be the controlling measurement technique, there is at least a disputed issue of material facts as to whether Defendants' BioGran(R) infringes the '046 patent claims. *See* Plaintiffs' Responsive Memorandum (Doc. 102, p.15).

FN14. SEM technology uses a beam of emitted electrons to scan particles individually in order to determine the shape and morphology of individual particles within a sample, and in order to measure both particle size and size distribution within the sample. Sieving, on the other hand measures particle size by passing a composition through a series of mesh screens, each screen having differing opening sizes. Particles larger than a screen's aperture will be retained on the screen, while those particles smaller than the screen's aperture will pass through to the next sized screen. Sieving is essentially a process of sifting the sample material and collecting individual particles in between the nominal sized screens.

In order to determine the proper construction of the '046 patent claims regarding which particle size measuring technique is to be employed in determining infringement, the Court must again look to the claim language, the patent specification, and the prosecution history of the patent. As mentioned, *supra,* it is not appropriate for the Court to consider extrinsic evidence such as the testimony of experts, prior art, dictionaries, and treatises in determining the scope of a claim if the claim language, specification, and prosecution history unambiguously define the terms at issue. *See* Vitronics, 90 F.3d at 1584. Even where extrinsic evidence should be considered to evaluate an ambiguous term, expert testimony is the least favored form of extrinsic evidence available to the Court since such information would not be available to the general public for their consideration in advance of infringement litigation. *See* id. at 1585. The disfavorability of expert testimony is premised on the idea that the public has a right to know just what the patent is claiming protection over so that it can design around the patented claims. *See* id. at 1583 (citing Markman, 52 F.3d at 978-79, and stating that "competitors are entitled to review the public record, apply the established rules of claim construction, ascertain the scope of the patentee's claimed invention, and, thus, design around the claimed invention").

i. The Claim Language

Plaintiffs contend that the claim language of the '046 patent itself should guide the Court to the conclusion that the terminology found therein is consistent with measuring particle size by SEM and not sieving. Defendants, on the other hand, assert that the claim language is consistent with the interpretation that particle size can be determined using sieve analysis. Alternatively, Defendants assert that the patent should be held

invalid for its failure to specify which particle size measurement method is to be employed.

Plaintiffs assert that the claim language qualifies the claimed particle size values with the word 'about,' and that this terminology is consistent with SEM analysis reporting yet inconsistent with sieve analysis reporting. (Doc. 102, p.9). Defendants contend that the use of the term "about" in reference to particle size is consistent with measurement by sieve analysis, and that it accounts for the "permissible variation in sieve size from the nominal size of standard test sieves." (Doc. 93 p.19 n.17). Plaintiffs state that their experts have made it clear that the "about" language indicates measurement by SEM analysis, but as stated earlier, this Court cannot allow extrinsic evidence, especially in the form of expert testimony, to alter the meaning of a term which is set forth in the claim language, specification, and prosecution history of the patent. Even if the Court were to consider Plaintiffs' experts' testimony as to this issue, those experts have stated that the term "about" could be representative of the margin of error which accompanies measurement by sieve analysis. *See* Horowitz Deposition (Doc. 93, Exh.2, pp. 109-113). Additionally, the prior art Gross patent, which no party has contended calls for particle size measurement by any technique other than sieving and which patent not once refers to SEM, utilizes the "about" terminology to refer to particle size. *See* Gross Patent No. 4,239,113 at col. 6, ll.15-35. The Court is unconvinced that the "about" language clearly establishes that SEM is the contemplated measurement technique called for in the '046 patent.

Aside from the "about" language of the claims, Plaintiffs have not directed the Court to any other direct claim language to support their contention that SEM is the particle size measurement technique called for in the '046 patent. To the contrary, Defendants note that, with the exception of one typographical error,FN15 out of all of the outer limits of the particle size ranges cited in the existing '046 patent claims as well as those claims originally applied for, each numerical limit contained therein corresponds precisely with standard sieve opening sizes which were in existence both at the time the patent application was made and when the '046 patent issued. FN16 Thus, Defendants argue, one skilled in the art of measuring particles would recognize the limits of the '046 patent claims as referring to the standard sized sieve openings generally available to those in the industry. Despite this, a review of the claim language itself is still insufficient for this Court to make a conclusive determination as to which particle size measurement technique is to be read into the '046 patent claims.

FN15. Claim 4 refers to a smaller particle size range of "from about 90 to about 350mum." The Court agrees with Defendants that the numeral '350' is clearly one of several typographical errors contained within the '046 patent. The only occurrence of the numeral '350' is within Claim 4, all other references to the same numerical limit cite it as '355'. As noted by Defendants, '350' was first inserted into the patent by amendment without being underlined, and contrary to PTO rules any intended change by amendment would have been indicated by underscoring the same. *See* (Doc. 106, p.19, n.11)(citing 37 C.F.R. s. 1.121). The Court notes that another typographical error, in the form of transposed numbers, occurs in Figure 1 of the '046 patent where the obvious particle size range of '90 to 710mum' is scripted as being '70 to 910mum' instead. This Court is unwilling to base its construction of these claims on what is obviously a typographical error, and Plaintiffs' attempt to rebut the obvious correlation between the limits of the stated claims and standard sieve sizes, by stating that there "is not a standard sieve size of '350'mum," is completely devoid of merit.

FN16. The standard sized sieves which were available on the filing date of the '046 patent were as follows: *90,* 106, 125, 150, 180, 212, 250, 300, *355,* 425, *500,* 600, and *710* mum. *See* (Doc. 106, p.18). The particle size range limits of the '046 patent claims are underlined.

ii. The Specification

Perhaps the biggest point of contention between the parties regarding the measurement claim interpretation issue, is with regard to what the patent *specification* contemplates as being the appropriate measurement method. Both parties argue vociferously that the specification makes explicit reference to their preferred method of particle size measurement.

Plaintiffs suggest that the specification is replete with references that would lead one skilled in the art to conclude that SEM is called for by the patent. They begin by pointing out that the very first page of the '046 patent contains a large graphic image of a scanning electron micrograph of the patented product, which image appears again on the second page of the patent as "Figure 1." FN17 Additionally, Plaintiffs note that "Figure 3" is a histogram representing the number of particles within each of fourteen size intervals, which data was purportedly obtained from scanning electron microscopy. However, the Court notes that aside from identifying the smallest interval on the histogram as representing a particle sized at approximately 90mum, Figure 3 is lacking either a descriptive title identifying it as representing SEM results or any meaningful description of the limits of the size intervals contained therein, nor for that matter does the histogram indicate which dimension of the particle was measured to determine its "particle size." Next, Plaintiffs direct the Court's attention to the reference to Figure 3 in column 10 of the '046 patent as evidence that SEM is contemplated. The pertinent reference provides:

FN17. As noted at *supra* note 15, the particle size range cited on the cover sheet and in Figure 1 of "70-910mum" is clearly a typographical error and should read "90-710mum."

Even a dry arrangement of this broad size range of glass powders, such as shown in a scanning electron micrograph (FIG.1) illustrates how the particles can fit together in a tightly packed array. FIG. 3 shows the size distribution as measured in the micrograph of FIG. 1.
United States Patent No. 4,851,046, column 10, lines 13-18.
Plaintiffs contend that these references in the patent specification are conclusive proof that the specification calls for particle size to be measured by SEM and not sieving. Considering only these references, the Court agrees that one could conclude that SEM appears to be the contemplated method, however, these references cannot be considered in isolation from the remainder of the specification.

Defendants have directed the Court's attention to those references in the specification which they argue would lead one skilled in the art to the opposite conclusion than that proffered by Plaintiffs, i.e. that sieving should be used to determine particle size, not SEM. Defendants have repeatedly pointed to the language in the patent specification related to the "lone" example of the claimed invention cited therein. The example describes a test of the '046 patentees' hypothesis that compositions containing glass particles within a wider range of particle sizes would perform in a preferred manner. In describing how the various test compositions used in the test were prepared, the specification provides:

Bioactive glasses (Table 2) were prepared by placing the premixed components into a covered platinum crucible.... The resultant glass frit was washed with acetone, ground with a mortar and pestle and *sized with a series of calibrated sieves*. Three different particle size ranges were obtained....

United States Patent No. 4,851,046, column 5, lines 54-60 (emphasis supplied).

Defendants contend that this direct reference to "sizing" of particles with sieves is evidence that "on its face, the patent specification confirms that sieving was the method of particle size determination used to establish the numerical limitations of the particle size ranges to which the patent claims are directed." (Doc. 106, pp.17-18). Defendants also re-direct the Court's attention to the fact that each and every particle size referred to in the specification, and every numerical limitation thereof, corresponds precisely with standard sieve sizes, i.e. 90, 355, 500, and 710mum, respectively. Thus, in isolation it would appear that the reference to sizing by sieves, and the fact that the patent's particle size range limits correspond exactly with standard sieve sizes, would lead one skilled in the art to conclude that the '046 patent contemplates sieving as the appropriate method for determining particle size. Yet, as this Court has noted above, these references must be considered in light of the entire specification.

Based upon the specification of the '046 patent, even when read in conjunction with the claim language, the Court is unable to conclude that either of the two measurement techniques championed by the parties is more explicitly called for than the other.

iii. The Prosecution History

According to Plaintiffs, the prosecution history of the '046 patent is "silent" with regard to the appropriate particle size measurement technique to be employed in evaluating claims of infringement thereof. However, Defendants are quick to point out that the prosecution history does reveal some evidence which supports a finding that sieving should be used. Defendants note that when the original patent application Claim 1 for a range from 90 to 710mum was rejected over the prior art Gross patent which cited a range of particles from about 10 to 200mum, the Plaintiffs did not amend their application to cite a range of from 201 to 710mum, but rather chose the next standard sieve size interval as its lower limit for Claim 1, i.e. 355mum. This, according to Defendants, is evidence that the prosecution history, rather than being silent, supports a finding that the '046 patent claims contemplate the use of sieving as the method for measuring particle size. Yet, in spite of this argument, the Court is still unable to conclude without doubt that the patent claim calls for one of either sieving or SEM any more than it does for the other.

Unfortunately, consideration of the patent claim language, the specification, and the prosecution history of the '046 patent does not yield a clear and unambiguous answer as to which of the two possible interpretations, i.e. measurement by sieving or measurement by SEM, should be adopted by the Court. Indeed, even after a thoroughly comprehensive and detailed consideration of even the most minute details of the '046 patent, this Court was unable to resolve to its own satisfaction, which measurement technique one skilled in the art would follow, even though each of the alternative techniques were adequately supported by the claim language, specification, and prosecution history of the patent. The Court must, therefore, turn to an evaluation of the extrinsic evidence presented by the parties in an effort to resolve the conflict between the two seemingly equal choices of particle size measuring techniques.

iv. Extrinsic Evidence

Extrinsic evidence may be considered when the claim language, specification and prosecution history do not unambiguously define the scope of a disputed term, however, prior art and other forms of extrinsic evidence are all preferable to the use of expert testimony since the public has no access to litigation inspired expert testimony and reports. *See* Vitronics, 90 F.3d at 1583 (citing Southwall Tech. v. Cardinal IG Co., 54 F.3d 1570, 1578 (Fed.Cir.1995)). In this case, the prior art Gross patent is virtually silent with regard to the method for measuring particle size, except that as mentioned, *supra,* it also contains the "about" language in

reference to particle size. As was noted by Defendants, the treatises available at the time the '046 patent issued, which treatises Plaintiffs' experts Klimpel and Horowitz conceded were authoritative, contradict the experts' opinions by their reference to the fact that sieving was the most widely used and accepted method for measuring particles larger than 50mum,FN18 and that standardization methods for sieving had been published by the American Society for Testing and Materials ("ASTM") regarding the measurement of those materials covered by the patent claims. *See* ASTM Manual on Test Sieving Methods (Doc. 106, Exh.11).

FN18. *See, e.g.,* J.T. Jones and M.F. Berard, *Ceramics* (Doc. 106, Exh. 13, p.140)(in the field of glass ceramics, sieving is the standard method for measuring particles coarser than 50mum).

Plaintiffs have focused a great deal of their argument regarding the proper interpretation of the claims regarding particle size measurement, on the testimony and reports of its two retained-for-litigation experts, Richard Klimpel, and Emanuel Horowitz. Through its experts, Plaintiffs have spent considerable time explaining why SEM is a superior method for determining micron particle size measurements, and how SEM is more accurate, consistent, and reproducible.FN19 However, this Court is hesitant to afford any considerable amount of weight to the experts' theories as to why certain references in the specification or claim language necessarily imply that SEM is what is called for. The Court finds that, as noted above, there are a substantial, if not an equal number of references within the patent specification and claim language that could lead one skilled in the art to the opposite conclusion espoused by Plaintiffs' experts. Despite the experts conclusions regarding what was intended by certain references included by the patentees in the specification and claim language, the Court is unwilling to read into the patent claims the subjective intent of the patentee regarding the scope of the claims, when such intent is not clearly expressed in any of the patent documents. *See* Shanklin Corp. v. American Packaging Machinery, Inc., No. 95C1617, 1998 WL 30691 at (N.D.Ill.1998). Furthermore, as this Court has already acknowledged, the use of expert testimony is extremely disfavored when interpreting the scope of patent claims. *See* Vitronics, 90 F.3d at 1584, Shanklin, 1998 WL 30691 at *4. While expert testimony may be useful in resolving an ambiguous term not clearly addressed in either the claim language or specification, it is not useful or appropriate when, as here, the Court is faced with two conflicting interpretations, both of which find adequate support in the claim language and specification. Thus, this Court is unable to utilize Klimpel's and Horowitz's testimony that SEM is the appropriate measurement technique to contradict the conflicting interpretation that sieving is appropriate, since as has been shown, the latter interpretation has been adequately expressed in the patent documents. *See* Shanklin, 1998 WL 30691 at *4 (stating that extrinsic evidence, and more specifically expert testimony, may not be used to vary claim language or "contradict the import of other parts of the specification"). Thus, even after evaluating the extrinsic evidence in conjunction with all of the intrinsic evidence, the Court is left with the choice between two equally supported interpretations of the claims regarding which particle size measurement technique is called for.

FN19. The Court agrees with Plaintiffs that SEM is apparently a more accurate, precise, and reproducible method for measuring particle size, and it agrees that in a biomedical product, precision should be highly regarded, however, the Court cannot excuse Plaintiffs' failure to clearly articulate the necessity of using such an accurate technique as SEM within the patent, nor their failure to indicate which dimension of the particle the term "particle size" refers, i.e. the maximum or average dimension. As will be discussed, *infra,* Plaintiffs' failure to clearly articulate these matters is contrary to their burden of drafting the patent claims so as to provide notice to the public as to what is being claimed.

v. Resolving the Conflict

In deciding which of the two measurement techniques are called for by the patent, the Court must start with the proposition that the drafter of the patent has the burden of claiming with specificity what it is that his invention covers. *See* 35 U.S.C. s. 112 para. 2 (stating that the "specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention"). This is often referred to as the requirement that the patentee give notice to the public, in order to guide them in determining what area is precluded from any future development or enterprise. *See* Athletic Alternatives, Inc. v. Prince Mfg., 73 F.3d 1573, 1581 (Fed.Cir.1996)(citing among others, McClain v. Ortmayer, 141 U.S. 419, 424, 12 S.Ct. 76, 77, 35 L.Ed. 800 (1891)(stating that one of the objectives of requiring a patentee to distinctly claim the scope of the invention is to "apprise the public of what is still open to them")). As noted, *supra,* the public should be able to "review the public record, apply the established rules of claim construction, ascertain the scope of the patentee's claimed invention, and, thus, design around the claimed invention." Vitronics, 90 F.3d at 1583 (citing Markman, 52 F.3d at 978-79).

The claim language of the '046 patent does not explicitly state how particle size is to be measured. And more importantly, in referring to particle "size," the claim language is silent as to which dimension of the particles should be evaluated in the measurement process. Traditionally, sieving measurements are expressed in terms of the nominal particle size, i.e. the minimum dimension of the particles. In other words, sieving typically reports a particle's smallest dimension. The SEM method suggested by Plaintiffs is generally known by those skilled in the art as a method which measures either the average or mean particle size. Furthermore, the laser light-scattering particle size determination method, suggested by Plaintiffs as an equivalent of SEM, measures yet another different particle dimension, its mean diameter. *See* (Doc. 93, Exh.2, pp.156-57). The claim language is noticeably lacking any mention of either the method for measuring particle size or which particle dimension is intended to be the benchmark for determining infringement. Its silence in these respects is important.

Plaintiffs contend that SEM is implied by the patent claims because the glass particles involved therein are irregularly shaped, and that SEM or its equivalent is the appropriate method for measuring odd-shaped particles. While this Court agrees with Plaintiffs that SEM may be the most accurate and reproducible method for measuring irregularly shaped particles, it notes that the measurement of irregular particles usually involves reference to the particle's maximum or largest dimension.FN20 *See* Application of John E. Ehrreich, 590 F.2d 902, 907-908 nn.3-4 (C.C.P.A.1979)(stating that one skilled in the art, who had knowledge of techniques used to measure irregularly-shaped particles, would measure those particles with reference to the particle's largest dimension). Thus, where it is common in the art to refer to the particle size of irregularly-shaped particles as having a "maximum dimension," and not by reference merely to "particle size, " the '046 patent' s failure to refer to the particle size of the glass particles therein by use of the term "maximum" or even "average size" or "average diameter," concerns the Court.

FN20. The Court also notes that SEM is generally used for the measurement of much smaller particles than those involved in the '046 patent claims. Indeed, SEM is considered to be the preferred method for measuring particles sized smaller than 5mum according to admittedly authoritative texts. *See* Terrence Allen, *Particle Size Measurement* (Doc. 106, Exh. 8, p.56). And, according to authoritative texts, sieving has generally been held to be the appropriate method for determining particle size distribution in ceramic powders coarser than 50mum. *See* J.T. Jones and M.F. Berard, *Ceramics* (Doc. 106, Exh. 13, p.140).

Defendants have argued that Plaintiffs' failure to include a specific reference in the patent claims to either the measurement technique to be employed or the dimension of the particle to be measured in determining infringement, necessarily indicates that they have failed to satisfy their drafting burden, and since the patent is indefinite as to these matters, the claims should be ruled invalid. Contrary to Defendants' assertions, this Court finds that the '046 patent is not invalid for failing to specify a measurement method, rather the two methods for particle size measurement which have been championed by the parties each find support in the patent claims, specification, and prosecution history of the '046 patent. Accordingly, Defendants' alternative motion for summary judgment of invalidity of the '046 for failing to satisfy the definiteness requirement of 35 U.S.C. s. 112 (doc. 93) is DENIED. What is involved in this case is a situation where the Court is faced with two optional interpretations, a broader reading of the claims which requires particle measurement by SEM and a narrower construction which requires the use of sieving. Thus, the issue for the Court is not whether Plaintiffs' failure to include a specific reference to the required measurement technique renders the claims invalid, rather the issue becomes which of the two conflicting measurement techniques the Court should adopt as the proper interpretation of the claims. Additionally, the Federal Circuit has instructed that this Court should seek to construe the claims of a patent in such a manner as to preserve their validity. *See* Applied Materials, Inc. v. Advanced Semiconductor Materials, 98 F.3d 1563, 1569 (Fed.Cir.1996), *cert. denied,* --- U.S. ----, 117 S.Ct. 1882 (1997).

In this situation the Court is guided by the Federal Circuit, which recently held in Athletic Alternatives, Inc. v. Prince Mfg., 73 F.3d 1573 (Fed.Cir.1996), that when a court is faced with two competing interpretations, one broad, and one narrow, and when the narrow has a legitimate basis in the claims, the narrow should be used, since doing otherwise would violate the requirement that the public be put on notice as to what would constitute an infringement of the claims. *See* id. at 1581. Specifically the Federal Circuit stated:

Where there is an equal choice between a broader and a narrower meaning of a claim, and there is an enabling disclosure that indicates that the applicant is at least entitled to a claim having the narrower meaning, we consider the notice function of the claim to be best served by adopting the narrower meaning.

Athletic Alternatives, 73 F.3d at 1581. As is more fully discussed above, in this case, the narrower interpretation, i.e. that the proper measurement method is sieving, is clearly supported by "enabling disclosures" in the '046 patent.

Additionally, where a patent seeks to protect an invention which is merely an improvement over prior art and is not a pioneer in the relative field, the patent claims are not entitled to the broad construction of claims which would ordinarily be granted the "pioneer." *See, e.g.,* PennWalt Corp. v. Durand Wayland, Inc., 833 F.2d 931, 964 (Fed.Cir.1987)(quoting Brothers v. United States, 250 U.S. 88, 89, 39 S.Ct. 426, 63 L.Ed. 859, (1919) ("plaintiff's invention was broadly new, a pioneer in its line, and the patent [was] entitled to a broad construction and the claims to a liberal application of the doctrine of equivalents")); *see also* Georgia Kaolin Co. v. Thiele Kaolin Co., 228 F.2d 267, 273 (5th Cir.1955) (stating that a mere improvement process does not merit pioneer recognition which would justify a broad construction of claims).

Based upon the foregoing, this Court concludes that to resolve the conflict, it must adopt the narrower construction of particle size measurement which permits measurement of potential infringement by sieving.FN21 Accordingly, for the purpose of determining infringement, this Court interprets the '046 patent claims as requiring measurement of particle size by sieving.

FN21. The Court notes that had the patent explicitly referred to the particles' average or maximum

dimension instead of merely to "particle size," SEM could impliedly be the preferred particle size measurement technique.

2. Second Prong-Literal Infringement or Infringement by Equivalency

Having interpreted the claims, and having determined their meaning and scope as set forth above, the Court now turns to the determination of whether each and every limitation of the properly construed claims occurs in the Defendants' accused device, BioGran(R). *See* Markman v. Westview Instruments, Inc., 52 F.3d 967, 976 (Fed.Cir.1995), *aff'd* 517 U.S. 370, ----, 116 S.Ct. 1384, 1393, 134 L.Ed.2d 577, ---- (1996). When a limitation of a patent is literally found in the allegedly infringing device, literal infringement occurs. *See* General Electric Co. v. Nintendo Co., 983 F.Supp. 512, 519 (D.N.J.1997)(citing SmithKline Diagnostics, Inc. v. Helena Labs. Corp., 859 F.2d 878, 889 (Fed.Cir.1988)). And, in order to establish literal infringement, each claim limitation "must be found in the accused product, *exactly*." Sanders Brine Shrimp Co. v. Bonneville Artemia Int'l, Inc., 970 F.Supp. 892, 910 (D.Utah 1997)(emphasis supplied)(citing Becton Dickson and Co. v. C.R. Bard, Inc., 922 F.2d 792, 796 (Fed.Cir.1990)). The patentee bears the burden of establishing literal infringement by a preponderance of the evidence. *See id*. Furthermore, the determination of whether an allegedly infringing composition falls within the scope of the patent claims that have been interpreted as a matter of law by the Court, is a factual application and may only be decided in a motion for summary judgment where there is no dispute as to any material fact to be applied to the claims as construed.

In this case, Plaintiffs have relied exclusively on their position that Claim 1 not only allows for, but anticipates the presence of particles smaller than 355mum, and upon their position that SEM is the appropriate measurement technique. Specifically, Plaintiffs have argued that Claim 1 is infringed when any more than a *de minimis* amount of a composition's particles are within the 355 to 710mum range and smaller particles are present as well. *See* (Doc. 102, p.17). Should the Court disagree with their claim interpretation argument regarding the method of particle size measurement, Plaintiffs contend that there is at least a disputed issue of fact as to infringement which would prevent the entry of summary judgment of non-literal infringement. *See* (Doc. 102, pp.15, 19).

Plaintiffs first contend that Defendants' own contradictory sieving data creates a disputed issue of fact. They argue that in numerous lots of the BioGran(R) product, there is greater than a *de minimis* amount of particles larger than 355mum if the Court takes into account the number of "lost" particles which were not counted in the data. Yet, even if the Court were to count the "lost" particles against Defendants, the result would be that in only 16 of 251 compositions tested were there more than five percent of the composition's particles above 355mum; and of those 16, never were there more than 8.72 percent of the particles by weight above 355mum.FN22 *See* (Doc. 93, Exh. 28). Plaintiffs further note that when Lot # 382 of BioGran(R) was tested as part of Defendants' quality control process, 2.52 percent of the particles were measured larger than 355mum, and when a portion of the same lot was analyzed using sieving as reported in Defendants' Exhibit 12, the results were that only 1.4 percent of the particles were larger than 355mum. *Cf.* (Doc. 93, Exh. 28, p.4), *with* (Doc. 93, Exh. 12, p.3). While the Court agrees that this apparent ambiguity creates a disputed issue of fact, this disputed fact is not material.

FN22. These results were extrapolated from Defendants' quality control data (Doc. 93, Exh. 28) for the following 16 lots of the 251 reported therein:

lot	*# percentage > 355mum*	*percentage lost*	*percentage assumed > 355mum*
228	4.51	4.21	8.72
259	3.87	3.18	7.05
328	0.49	5.44	5.93
330	1.25	4.46	5.71
376	5.67	0.88	6.55
377	2.37	3.85	6.22
381	4.61	1.04	5.65
398	4.33	3.24	7.57
407	5.26	0.88	6.14
411	2.60	3.60	6.20
412	4.88	0.72	5.60
419	5.22	0.78	6.00
425	3.84	1.42	5.26
449	5.50	0.78	6.78
451	4.46	1.76	6.22
456	3.12	2.70	5.82

Additionally, Plaintiffs' arguments mistakenly assume that Claim 1 has been interpreted to mandate a finding of infringement based on a threshold of merely a *de minimis* amount of particles above 355mum. To the contrary, this Court has construed Claim 1 to exclude from infringement those compositions which contain substantially greater than the one-third fraction cited in Claim 5 of its particles below 355mum, since the presence of so great a number of smaller particles would necessarily affect the performance of the composition in such a manner as to also alter its basic characteristics. As this Court has previously stated, in order to infringe Claim 1, Defendants' product must consist "essentially of" particles between 355 and 710mum. And simply put, compositions which contain no more than 8.72 percent of their particles larger than 355mum, cannot be said, even under a strained interpretation, to consist "essentially of" particulate glass with a particle size range of "from about 355 to about 710 mum" as required by Claim 1 of the '046 patent.

Plaintiffs next contend that the "about" language used in the patent claims actually lowers the limits contained therein by five percent, so that infringement of Claim 1 may be found where it is shown that a composition consists essentially of particles from "337 to 710mum" instead of the 355 to 710mum which is facially apparent. This Court agrees with Defendants and concludes that the "about" language contained in the '046 patent claim language merely acknowledges the inherent discrepancies associated with measuring particle size by sieving, which this Court has already determined is the measurement technique that must be used to determine infringement. Furthermore, since the size identity of particles on either side of a claim limit cannot be measured using standard sieves, the upper and lower infringement limits stated in a claim's particle size range cannot be extended to accommodate the particles which may fall on either side of the expressed limits. Indeed, because only SEM is capable of precisely measuring those particles on either side of a limit, the variance resulting from the "about" language is relevant only where SEM is the method to be used to measure particle size; however in this case, for the reasons set forth in greater detail above, the '046 patent's claim language, specification, prosecution history, and the extrinsic evidence available to the Court, all dictated that the claims therein be construed to require sieving as the appropriate measurement technique. Additionally, the Court notes that it seems likely that the variation of five to ten percent which Plaintiffs

contend is anticipated by the "about" language, has manifested itself in the sieve testing results proffered by Defendants, wherein no more than 8.72 percent of the particles measured by sieve analysis were actually larger than the upper limit sought by use of the 355mum standard sieve.

And while Plaintiffs vigorously contend that Defendants' proffered sieve testing data is disputed and unreliable, in contravention of their burden in establishing infringement by a preponderance of the evidence, they have failed to produce *any* independent evidence that, using sieving, the Defendants' BioGran(R) consists "essentially of" bioactive glass particles in the size range of 355 to 710mum such that it infringes Claim 1. *See* Sanders Brine Shrimp Co., 970 F.Supp. at 910 (citing SRI Int'l v. Matsushita Elec., 775 F.2d 1107, 1123 (Fed.Cir.1985)). Furthermore, even were the Court to assume that Claim 1 was infringed by Defendants' product, which it is not, there is absolutely no evidence in the record which could establish infringement of Claims 2, 3, or 4, using sieving. The only evidence of sieve testing contained in the record of this case is that proffered by the Defendants, and that evidence only indicates what percentages of particles are larger than 355mum. In no manner does this evidence indicate where along the continuum of particle sizes above 355mum, the particles in those percentages lie. Therefore, the Court is without any evidence to conclude that the BioGran(R) product contains particles which would satisfy any of the size ranges of Claims 2, 3, or 4, i.e. from about 355 to about 500mum, from about 500 to 710mum, or within each of the three ranges of from about 90 to 355mum, from about 355 to about 500mum, and from about 500 to about 710mum, respectively. However, consideration of infringement of the dependant Claims 2, 3, and 4 is unnecessary when, as here, the patentee has failed to establish as a matter of law that the independent claim upon which the dependant claims rely is infringed. *See* Wahpeton Canvas Co. v. Frontier, Inc., 870 F.2d 1546, 1552 n. 9 (Fed.Cir.1989). Specifically, the *Wahpeton Canvas* court stated:

One may infringe an independent claim and not infringe a claim dependant on that claim. The reverse is not true. One who does not infringe and independent claim cannot infringe a claim dependant on (and thus containing all the limitations of) that claim.

Id. (citing Teledyne McCormick Selph v. United States, 214 Ct.Cl. 672, 558 F.2d 1000, 1004 (Ct.Cl.1977)).

Based upon the foregoing, this Court concludes that there is no dispute as to any material fact related to the determination of literal infringement of the '046 patent claims. Accordingly, as is set out more fully above, the evidence before the Court regarding the particle size distribution of Defendants' BioGran(R) compels the conclusion that, with no more than 8.72 percent of its particles sized larger than 355mum, BioGran(R) does not consist "essentially of" glass particles within the size range of "from about 355 to about 710mum," and therefore is not literally infringing of Claim 1 of the '046 patent. Furthermore, the Court concludes that the substantially large number of particles sized below 355mum in the BioGran(R) product (at least 91.28 percent), would affect the performance of Plaintiff's claimed invention such that its basic characteristics would be significantly altered, which conclusion also supports this Court's finding of non-literal infringement of Claim 1. Having concluded that Defendants are not literally infringing the only independent claim of the '046 patent, it is axiomatic that there is also no literal infringement of the dependant claims predicated thereon which have been asserted by Plaintiffs. *See* Wahpeton Canvas Co., 870 F.2d at 1552 n. 9. Plaintiffs having failed to satisfy their burden of establishing literal infringement as a matter of law, and the Court is of the opinion that Defendants' motion for summary judgment with respect to Count I of the complaint (doc. 93), i.e. of non-literal infringement, should be and the same is hereby granted. Accordingly, Plaintiffs motion for summary judgment for literal patent infringement (doc. 88) should be and the same is hereby denied.

Doctrine of Equivalents

Where no literal infringement can be established, the Court may still find an accused product infringing of a patent under the doctrine of equivalents. *See* Warner-Jenkinson Co. v. Hilton Davis Chem. Co., --- U.S. ----, ----, 117 S.Ct. 1040, 1045, 137 L.Ed.2d 146, ---- (1997). In their motion for summary judgment (doc. 88), Plaintiffs "reserved for trial" any issue related to the finding of infringement under the doctrine of equivalents. *See* (Doc. 88, p.3). Defendants assert that Plaintiffs have put forth no evidence which this Court may properly consider in determining equivalency, and summary judgment in their favor is therefore appropriate.

The doctrine of equivalents requires that the accused device must "perform substantially the same function in substantially the same way to achieve substantially the same overall result as the claimed invention." General Electric Co. v. Nintendo Co., 983 F.Supp. 512, 520 (D.N.J.1997)(citing Graver Tanker & Mfg. v. Linde Air Prods., 339 U.S. 605, 608, 70 S.Ct. 854, 856, 94 L.Ed.2d 1097, ---- (1950)). The essential inquiry, whether equivalency is to be established by use of the "triple identity" test which evaluates function, way, and result, or by use of the "insubstantial differences" analysis, is whether the accused device contains elements which are "identical or equivalent to each claimed element of the claimed invention[.]" ' *Id.* (quoting Warner-Jenkinson, 117 S.Ct. at 1054). In making its comparison, the Federal Circuit has cautioned that courts may not compare the accused product with the commercial embodiment of the patentee's claimed invention, rather the comparison must be made to the individual claims of the patent. *See* Zenith Labs. v. Bristol-Myers Squibb Co., 19 F.3d 1418, 1423 (Fed.Cir.), *cert. denied,* 513 U.S. 995, 115 S.Ct. 500, 130 L.Ed.2d 409 (1994). The doctrine of equivalents is considered the exception rather than the rule, and should not be employed by the court merely to rescue a patentee's claim from a finding of non-infringement. *See id.*

Defendants asserted in their motion for summary judgment of non-infringement that Plaintiffs had produced no evidence in the form of expert reports or testimony regarding equivalency which could support a finding of infringement under the doctrine of equivalents, and they sought summary judgment of non-infringement under the doctrine. *See* (Doc. 93, p.24). Plaintiffs responded by contending that while they had not produced expert testimony or reports on the issue, other evidence of equivalency was available, which evidence would preclude summary judgment in favor of Defendants. Plaintiffs assert that two studies carried out by Drs. Rieger and Wheeler, independent researchers at the University of Texas and the University of Oregon, respectively ("the Rieger and Wheeler studies"), show equivalence. *See* (Doc. 102, p.20). According to Plaintiffs, both of these researchers compared the Defendants' accused BioGran(R) product with the commercial embodiment of the '046 patentee's invention, PerioGlas(TM), and each concluded that

the products do substantially the same thing (treat periodontal osseous defects) in substantially the same way (by promoting the formation of new bone) to achieve substantially the same result (filling of the periodontal defect or pocket). Exh. 17; Exh. 18. Both studies concluded that the accused BioGran product and the patented product PerioGlas were indistinguishable.

(Doc. 102, p.20). Plaintiffs also responded that they had further evidence of equivalence in Defendants' own submission to the Food and Drug Administration ("FDA") and Defendant Ducheyne's publications, both of which asserted that the two products, PerioGlas(TM) and BioGran(R) are "equivalent." *See id.* at 20-21 (citing to Exhs. 19, 20). Plaintiffs argue that these combined showings are sufficient to establish a *prima facie* case for infringement under the doctrine of equivalents. *See id.* at 21.

Defendants responded to these arguments by turning the Court's attention to Rule 56(c) of the Federal Rules of Civil Procedure, arguing that none of the available evidence which Plaintiffs referred to fall within the categories of evidence, i.e. pleadings, depositions, answers to interrogatories, and admissions on file, together with affidavits, which the Court can consider in a motion for summary judgment. As such, Defendants contend that at least the Rieger and Wheeler studies, especially since neither researcher has been deposed or supplied an affidavit, are inadmissable hearsay which cannot prevent the entry of summary judgment on the doctrine of equivalents. *See* (Doc. 126, p.5).

Regardless of the inadmissability or propriety of the Court's consideration of such evidence, the Court concludes that the Rieger and Wheeler studies, and Defendants' FDA submission FN23 are fatally deficient in that, they compare the accused BioGran$^{(R)}$ product, not to the patent claims, but to the commercial embodiment of the patentee's invention in contravention of Zenith Labs. v. Bristol-Myers Squibb Co., 19 F.3d 1418, 1423 (Fed.Cir.1994), in which the Federal Circuit stated that it would be "error for a court to compare in its infringement analysis the accused product ... with the patentee's commercial embodiment." *Id*. Rather, an accused device should be compared with the patent claims. *See id.; see also,* Martin v. Balber, 755 F.2d 1564, 1567 (Fed.Cir.1985)(stating that "[i]nfringement, either literal or by equivalence, is determined by comparing the accused device with the claims in suit, not with the preferred or commercial embodiment of the patentee's claimed invention")(and citing ACS Hosp. Sys. v. Montefiore Hosp., 732 F.2d 1572, 1578 (Fed.Cir.1984); *Perkin-Elmer Corp. v. Computervision Corp.,* 732 F.2d 880, 902 (Fed.Cir.1984)(stating that infringement is determined by comparison with the claimed invention, not the patentee's marketed product)). Finally, Plaintiffs' remaining "evidence" of equivalence are publications authored by Defendant Ducheyne, one of which was published in 1985, four years prior to issuance of the '046 patent. Thus, the appropriate comparison between the '046 patent claims and the accused device, which incidently was not even made or sold until 1995, could not even have been made in this paper since the claims upon which a comparison must necessarily have been made were not yet in existence. The Court agrees that Plaintiffs have failed to put forth any evidence under the doctrine of equivalents which the Court could properly consider in determining whether the Defendants' accused BioGran$^{(R)}$ product is substantially equivalent to the '046 patent claims and not the commercial embodiment thereof.

FN23. As Defendants note, the Court cannot use the FDA 510(k) notification in considering infringement by equivalence, since in addition to comparing the commercial embodiment of the '046 patentee's invention, instead of the patent claims, in contravention of the authority cited, infra, the FDA filing is controlled by a separate regulatory scheme. *See* Mahurkar v. C.R. Bard, Inc., No. 92 C 4803, 1993 WL 259446 at n. 16 (N.D.Ill. Jul.6, 1993). The Court notes that references in this FDA submission to the patentee's commercial embodiment, PerioGlas(TM) refer to it as a predicate device, and the technical comparison chart therein notes the marked difference between the two with regard to one of the essential '046 patent claims, particle size. Thus, comparing the accused BioGran$^{(R)}$ with the patent claims, the 510(k) technical comparison charts shows that the two are not substantially equivalent with regard to the relevant claimed particle ranges.

Defendants also note, that while Plaintiffs have failed to put forth any evidence which this Court may properly consider in deciding infringement under the doctrine of equivalents, the fact that the Defendants' product obtained subsequent patent approval of its own, is evidence which the Court could consider in determining non-equivalence, i.e. such evidence establishes the substantiality of the differences between the claims and accused device. *See* Zygo Corp. v. Wyko Corp., 79 F.3d 1563, 1570 (Fed.Cir.1996). Thus,

despite their protestations otherwise, the Court concludes that Plaintiffs have failed, as a matter of law, to make a *prima facie* showing of infringement of the '046 patent by the Defendants' accused BioGran(R) product, under the doctrine of equivalents.

Based upon the foregoing considerations, the Court is of the opinion that Defendants' motion for summary judgment of non-infringement under the doctrine of equivalents (doc. 93) should be and the same is hereby granted.

3. The Defense of Patent Invalidity

Defendants have contended in their alternative motion for summary judgment of patent invalidity, that the '046 patent claims, if construed as urged by Plaintiffs, should be held invalid for violating the definiteness requirement of 35 U.S.C. s. 112, because they fail to indicate what percentage of particles must be within the range cited in Claim 1 to avoid infringement, and because they fail to explicitly state which measurement technique is to be used in determining infringement. With respect to the failure to explicitly enumerate which percentage of particles must be within the range cited in Claim 1, Defendants have failed to satisfy their burden of setting forth clear and convincing evidence that the claims are indefinite, especially in light of the Court's obligation to construe the claims in such a manner as to preserve their validity. *See* Applied Materials, Inc. v. Advanced Semiconductor Materials, 98 F.3d 1563, 1569 (Fed.Cir.1996). With respect to the second claim interpretation issue, this Court has previously stated, the patent claims, specification, and prosecution history do not fail to indicate a measurement technique, rather they indicate both sieving and SEM, and both of these alternative methods find adequate support in the patent claim language, specification, and prosecution history. Thus, an action for invalidity on the grounds of inadequate disclosure cannot survive, and the resulting issue for the Court, i.e. which of the two alternative measurement techniques should be employed, has been resolved above. Furthermore, having already found non-infringement of the valid '046 patent claims, neither literal nor under the doctrine of equivalents, the Court is of the opinion that Defendants' alternative motion for summary judgment should be and the same is hereby denied.

B. Defendant Ducheyne's Motion for Summary Judgment to Dismiss Claims Against Him

Individual Defendant, Paul Ducheyne, has separately moved for summary judgment seeking dismissal of all claims against him individually (doc. 92). Based upon this Court's findings on non-infringement above, Ducheyne's motion as it relates to the claims of patent infringement asserted against him is moot. With respect to the remaining claims (counts II through VI), which deal with false advertising, unfair competition, and trade disparagement, Ducheyne asserts that he did not himself participate in the acts complained of, and that he is merely the chairman of Orthovita's Board of Directors who has co-authored several academic journal articles. It is his contention that he can not be personally liable as a corporate officer for these actions if he merely controls corporate affairs. *See* (Doc. 92, memorandum at p.3)(citing *McCarthy on Trademarks and Unfair Competition* at s. 25:24).

Plaintiffs have responded to Ducheyne's motion by asserting that this Court's denial of a similar motion to dismiss filed by Ducheyne previously, bars him from re-presenting the same issues under the law of the case doctrine, yet this argument overlooks the differing standards applied to motions to dismiss under 12(b)(6) and for summary judgment. Plaintiffs also note that Ducheyne has failed to file a statement of undisputed material facts contemporaneously with his motion for summary judgment as required by Local Rule 56.1(A). This Court's Local Rule explicitly warns that the "[f]ailure to submit such a statement

constitutes grounds for denial of the motion ." However, in this case, the undisputed facts presented by Plaintiffs in their response are sufficient for the Court's use in determining whether summary judgment is appropriate.

Aside from the technical justifications for denying Ducheyne's motion, Plaintiffs only evidence that Paul Ducheyne individually participated in the acts of unfair competition and false advertising is that he reviewed the scientific content of Orthovita's literature which is accused of falsely describing technical aspects of the BioGran(R) product. The remainder of Plaintiffs' arguments for maintaining the claims asserted against Ducheyne revolve around the claims of infringement, which this Court has already determined are moot. In order to maintain an action against a corporate officer individually, it must be shown that the officer personally took part in the accused activities or that he directed employees to do so. With respect to the claims of unfair competition and false advertising alleged in Counts II through VI, the Court finds that the undisputed material facts, as presented by Plaintiffs in their response to Ducheyne's motion for summary judgment, reveal that Paul Ducheyne was not personally involved in the activities complained of therein, but rather served only as chairman of the Board of Directors, controlling corporate affairs. Accordingly, the Court is of the opinion that Ducheyne's motion for summary judgment to dismiss the claims against him (doc. 92) with respect to the claims in Counts II through VI should be and the same is hereby granted. As noted above, the motion with respect to the claim of infringement is moot based upon this Court's finding of non-infringement.

C. Plaintiffs' Motion for Summary Judgment on False Advertising, Unfair Competition, and Trade Disparagement Claims, and for Summary Judgment on Defendants' Counterclaims

Plaintiffs have also moved for summary judgment on their false advertising, unfair competition, and trade disparagement claims brought under Section 43(a) of the Lanham Act and Florida state law, as well as for summary judgment on Defendants' counterclaims for false patent marking. In considering this motion, the Court will be guided by the principle that summary judgment is not appropriate where there is a genuine dispute as to material facts, such that a reasonable juror could return a verdict for the non-moving party based thereupon. *See* Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248, 106 S.Ct. 2505, 2510, 91 L.Ed.2d 202, ---- (1986). All reasonable factual inferences shall be drawn in a light most favorable to the non-moving party. *See* Atlantic Richfield Co. v. USA Petroleum Co., 495 U.S. 328, 332, 110 S.Ct. 1884, 1888, 109 L.Ed.2d 333 (1990)(*citing* Matsushita Electric Industrial Co. v. Zenith Radio Corp., 475 U.S. 574, 587, 106 S. *Ct. 1348, 1356 (1986)).*

False advertising and unfair competition under Section 43(a) of the Lanham Act

Plaintiffs first assert that they are entitled to judgment as a matter of law on their claims of false advertising and unfair competition under Section 43(a) of the Lanham Act. This section of the Lanham Act creates a civil remedy for those injured by a competitor's misleading or false advertisements. Specifically, the relevant statutory provision states:

(a)(1) Any person who, ... in connection with any goods or services ... uses in commerce any word, term, name, symbol, or device, or any combination thereof, or any false designation of origin, false or misleading description of fact, or false or misleading representation of fact, which-

(B) in commercial advertising or promotion, misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person's goods, services, or commercial activities, shall be liable

in civil action by any person who believes that he or she is or is likely to be damaged by such act.

15 U.S.C. s. 1125(a)(1)(B).

Generally, a party must establish the following five elements in order to succeed on a claim for false advertising under the Lanham Act:

1) That the defendant made a false or a misleading statement concerning the plaintiff's product in advertising materials;

2) That the advertisements actually, or had the tendency to deceive a significant number of the consumers to which they were directed;

3) That the defendant's deception was material, i.e. that it likely influenced consumers' purchasing decisions;

4) That the advertised product of the defendant traveled in interstate commerce; and,

5) That the plaintiff is likely to be, or already has been, injured by the misleading or false advertising as evidenced by either declining sales or a loss of goodwill among consumers.

See Tire Kingdom, Inc. v. Morgan Tire & Auto, Inc., 915 F.Supp. 360, 364 (S.D.Fla.1996)(citing among others Ditri v. Coldwell Banker, 954 F.2d 869, 872 (3d Cir.1992)(internal citations omitted)). False advertising may be established under the Lanham Act in one of two ways: 1) by establishing that the advertisement is facially false; or 2) by establishing that an advertisement, though literally true, is likely to confuse or mislead the consumers to which it is directed. *See* Johnson & Johnson v. GAC Int'l, Inc., 862 F.2d 975, 977 (2d Cir.1988). In the former situation, the plaintiff need not demonstrate that there would be any adverse affect on purchasing consumers, and must only show that the advertising is false, that the defendant's goods are sold in interstate commerce, and that injury to the plaintiff is likely. *See* Castrol Inc. v. Pennzoil Co., 987 F.2d 939, 943 (3d Cir.1993); Energy Four, Inc. v. Dornier Med. Sys., Inc., 765 F.Supp. 724, 732 (N.D.Ga.1991). Accordingly, when the advertising material cannot be shown to be facially false, the plaintiff must establish the remaining elements set forth above, i.e. that the alleged deceptive advertisements were material, and that the accused advertising had already, or is likely to, have an impact on consumer purchasing decisions.

Plaintiffs contend that Defendants' advertisements are literally false in five respects, and that no showing of consumer confusion or impact is therefore required in order for the Court to enter summary judgment against Defendants for false advertising under the Lanham Act. However, Defendants argue that Plaintiffs have presented "no proof-let alone any undisputed facts-establishing that Orthovita's advertisements are either literally false, or are likely to mislead and confuse consumers." (Doc. 105, p.4.) The Court will now consider each of the five categories of alleged falsehoods, and the amenability of each to disposition at the summary judgment stage will be addressed below.

1. Claims of superiority.

Plaintiffs' first argue that Defendants' advertisements falsely claim that BioGran$^{(R)}$ is superior to PerioGlas(TM). This allegation is based upon the fact that Defendants' brochures state "BIOGRAN-The

superior alternative for your patients and you" and also state that "BioGran provides clinicians with the best alternatives for their patients." *See* (Doc. 89, Exhs.7,8). And since BioGran(R) and PerioGlas(TM) are the only two commercially available bioactive glass products on themarket, Plaintiffs insist that these remarks can only be understood to assert superiority over Plaintiffs' PerioGlas(TM). According to Plaintiffs, there is ample evidence, some of which was commissioned by Defendants themselves, which establishes the equivalency of the two products, and that the tests relied upon by Defendants to support this claim are unreliable.

Defendants contend first that the "superior choice" statements are not actionable as a matter of law because they constitute mere puffery. The Court agrees that, unless a claim that a product is "better" than a competitor's is "backed-up" with false allegations that "tests prove" superiority when no such tests or only unreliable tests exist to support such a claim, the superiority claim constitutes no more than unactionable puffery. *See* Nikkal Indus. v. Salton, Inc., 735 F.Supp. 1227, 1234 n. 3 (S.D.N.Y.1990). For non-puffing superiority claims, an affirmative showing that the claim is false is required, i.e. a showing that defendant's product is equal or inferior. *See* Castrol, Inc. v. Quaker State Corp., 977 F.2d 57, 63 (2d Cir.1992). In this case, Defendants have not even implied in their advertisements that "tests prove" superiority of the BioGran(R) product, thus the existence or reliability of tests supporting the statement of superiority is irrelevant, and as mere puffery, the statement is not actionable as a matter of law under Section 43(a) of the Lanham Act.

Furthermore, Defendants also note that Plaintiffs interpretation of these "superior choice" statements as referring to the only choices as either BioGran(R) or PerioGlas(TM) is improper when viewed in full context of the market for periodontal restoratives. That market is dominated, not by these two bioactive glass compositions, but is rather a crowded market of various similar products, with freeze-dried bone compositions taking the lion's share of the market. Thus, in context, these "superior choice" statements more accurately reflect Defendants' efforts at convincing clinicians that a bioactive glass composition, like BioGran(R) *or* PerioGlas(TM) is the superior alternative to freeze-dried bonecompositions. Indeed,a closer examination of Orthovita's advertising materials reveals an emphasis on how a bioactive glass composition has the advantage ofeasing consumerweariness about having bone matter,which has been extracted from a cadaver and thrice sanitized, implanted into theirmouths. *See, e.g.,* (Doc. 89, Exh. 7). Thus, even were theCourt to have concluded that the superiority puffery statements were actionable as false advertising under the Lanham Act, which they are not, the dispute created by the context in which the advertised claims are made, constitutes a genuine dispute as to a material fact sufficient to preclude entry of summary judgment in Plaintiffs' favor.

As further evidence creating a genuine dispute as to the material facts of this claim, Defendants note the existence of a separate patent for the BioGran(R) product based on its "improved performance" over prior the relevant prior art, thus creating a dispute as to whether or not Defendants' product truly is superior in some aspect to PerioGlas(TM).

2. Claims that all of the particles in BioGran(R) are between 300 and 355mum.

Plaintiffs next argue that Defendants' claims within promotional materials that the BioGran(R) glass particles are all within the optimal particle size range of from 300 to 350mum are literally false. In one instance, a document which appears to be an outline for a visual presentation, and not any document which is itself distributed as advertising, contains the statement that "100% of the BioGran(TM) granules is the optimal

range for healthy bone growth. Only 9% of PerioGlas(TM) is in the optimal size range; the balance is either too small or too large to be fully effective." *See* (Doc. 89, Exh. 6, at para. 7). Plaintiffs also refer to tests which conclusively show that Defendants' BioGran(R) contains glass particles both larger and smaller than the 300 to 355mum range. Furthermore, Plaintiffs note that even Defendants own internal quality control data indicates that only 80% of the particles in BioGran(R) must fall in the cited range in order to be marketable, and that in most cases 15 to 20% of the particles in BioGran(R) fall outside of the cited range. These undisputed facts, according to Plaintiffs, establish that Defendants' statements that all of the BioGran(R) particles are within the optimal 300 to 355 mum size range are literally false.

Defendants, on the other hand, assert that the very facts relied upon by Plaintiffs are the subject of dispute, and that in proper context, their claims are true. Defendants note that the tests relied upon by Plaintiffs were conducted using measurement methods other than sieving, which this Court has already determined is the appropriate measurement method for patent infringement analysis. Defendants note also that the consumers to which these advertising statements are directed understand sieving to be the proper measurement technique, and that like Plaintiffs' own experts, these individuals understand that the nominal sizes of a sieve-based particle size range will naturally encompass a margin of error of plus or minus of upwards of 10%. These assertions again create a genuine dispute as to material facts which necessarily preclude this Court from entering summary judgment of literal false advertising in favor of Plaintiffs with regard to these of Defendants' claims.

3. Claims that PerioGlas(TM) does not regenerate boneand that particles larger than 355mum have inferior characteristics.

Next, Plaintiffs argue that Defendants have false represented that PerioGlas(TM) does not regenerate bone and that bioactive glass particles sized larger than 355mum have incomplete glass reaction, no reactant glass core, and no protective pouch. These allegations arise from the following statements in one of Defendants' brochures:

[w]hen bioactive glass granules of a smaller size range than BioGran were implanted, many of the particles became completely or almost entirely resorbed as indicated by the many particle fragments. Although some of the largest particles in this small size range excavated, there is little evidence of new bone formation.

... [w]hen bioactive glass granules larger than BioGran were implanted, cracks formed as the material chemically reacted, but no real excavation was seen as the chemical reactions were limited to the surface. Again, minimal or no bone formation was seen.

(Doc. 89, Exh. 4, at BL 00304, BL 000306).

According to Plaintiffs, these statements "clearly indicate[ ] that PerioGlas, the only other bioactive glass product known to have particle sizes below 300mum or above 355mum is bad, and that such particles are not present in BioGran." FN24 (Doc. 89, p.17). Plaintiffs argue that Defendants have made these statements despite the fact that more than one half of the particles in their own BioGran(R) product are either smaller or larger than the cited range, and despite the fact that their own studies (e.g. the Rieger and Wheeler studies, Doc. 89, Exhs. 17, 19) show that excavation and hollowing out of the particles' central core occurs in particles of bioactive glass of smaller and larger size ranges.

FN24. Such an indication is not as "clear" to the Court as Plaintiffs assert. Facially, these statements appear to compare the results of compositions which contain only particles which are either smaller or larger than the 300 to 355 mum range, not to compositions which contain some additional particles smaller or larger than the range.

Defendants respond to Plaintiffs' argument that BioGran(R) itself contains greater than 50% of its particles either smaller or larger than the cited range, by repeating the fact that this assertion relies on measurement of particle size by methods other than sieving. They also note that the Rieger study relied upon by Plaintiffs involved a non-periodontal application of the bioactive glass in the ilium of New Zealand White rabbits.

At a very minimum, there is a dispute as to whether the various studies indicate that the additional presence of glass particles larger and smaller than the cited 300 to 355mum range, has a negative effect on the process of bone regeneration in periodontal applications. This is sufficient to preclude a grant of summary judgment of literal false advertising in favor of Plaintiffs on these claims.

4. Claims that inflammation occurs with particles smaller than 250mum.

Plaintiffs have also argued that Defendants have falsely informed the public through their advertising that particles smaller than 250mum "react too quickly leading to full particle resorption, [and] inflammatory response follows." (Doc. 89, Exh. 4, at BL 000298). According to Plaintiffs, the only evidence which Defendants have to support this claim is the research of Schepers and Ducheyne and an article written by Wilson and Low, which indicate that particles up to 40mum may cause inflammation. According to Plaintiffs, there is no evidence that particles in the 90 to 250mum range cause inflammation, and this makes the claim that particles smaller than 250mum cause inflammation unsupported and thus literally false.

Referring to Dr. Ducheyne's declaration, made in response to Plaintiffs' challenge of the patentability of the Schepers patent, and to other of his writings and deposition testimony, Defendants simply assert that their claims that particles smaller than 250 mum tend to dissolve more rapidly, thus leading to an inflammatory response, is well grounded and is not "unsupported" as Plaintiffs would have the Court believe. Again, Defendants' assertions create the necessary dispute as to a material fact, i.e. the alleged falsity of the statement, which precludes entry of summary judgment on this claim in Plaintiffs' favor.

5. Claims regarding products' FDA approval.

Plaintiffs lastly argue that Defendants' advertising that "BioGran is the only bioactive glass product which has FDA market clearance for periodontal defects, extraction sites, and ridge augmentations" was false. *See* (Doc. 89, Exh. 7, at OVIT 01768). Defendants had previously represented to this Court that it had stopped distributing this statement, but it was later discovered that some materials containing this statement were disseminated, though allegedly by inadvertence. Defendants consented to the entry of an injunction by this Court prohibiting any further distribution of materials making this claim.

Defendants note that until September of 1996, they were the only ones who had secured FDA approval for marketing *all three* of the indications of periodontal defects, extraction sites, *and* ridge augmentations. Until that time, Plaintiffs only had FDA approval for periodontal defects. It is Defendants position, that aside from the few, inadvertently distributed leftover brochures noting this disparity between the two parties' products, it discontinued the use of this claim as soon as PerioGlas(TM) was approved for all three indications as

well. To the extent that this claim is still relevant, there is a dispute as to the extent to which Defendants either did or did not advertise this claim after September of 1996, thus rendering summary judgment of false advertising based thereupon, inappropriate.

Plaintiffs have failed to establish that any of the five alleged false statements categorized above, are literally false, and since none of the alleged falsities are undisputed, summary judgment of literal false advertising is therefore, inappropriate. Having failed to establish the literal falsity of the accused advertising, Plaintiffs may alternatively establish false advertising by showing that the accused advertisement, though literally true, is likely to confuse or mislead the consumers to which it is directed. *See* Johnson & Johnson v. GAC Int'l, Inc., 862 F.2d 975, 977 (2d Cir.1988). In this situation, Plaintiffs must establish the remaining elements set forth above, i.e. that the alleged deceptive advertisements were material, and that the accused advertising had already, or is likely to, have an impact on consumer purchasing decisions. In this case, however, aside from mere allegations, Plaintiffs have failed to put forth any evidence that the challenged advertisements actually deceived any of the parties' customers or that they had a tendency to deceive a substantial percentage of the targeted audience, nor have the Plaintiffs put forth any evidence that the alleged deception was material in that it influenced any consumer purchasing decisions. *See* Tire Kingdom, Inc. v. Morgan Tire & Auto, Inc., 915 F.Supp. 360, 365 (S.D.Fla.1996)("[t]o survive a motion for summary judgment, the Plaintiff must support each element of its Lanham Act claim with more than mere allegations") (citing McLaughlin v. City of La Grange, 662 F.2d 1385 (11th Cir.1981), *cert. denied,* 456 U.S. 979, 102 S.Ct. 2249, 72 L.Ed.2d 856 (1982)). Plaintiffs failure in this respect "fatally flaws" the claims for false advertising under the Lanham Act at the summary judgment stage. *See id*. Based upon the foregoing, consideration of the remaining elements of false advertising would be an exercise in futility, and the Court is of the opinion that Plaintiffs' motion for summary judgment on their false advertising claims under the Lanham Act should be and the same is hereby denied.

Trade disparagement under Section 43(a) of the Lanham Act and Florida law

In addition to summary judgment on their false advertising claims, as part of the same motion, Plaintiffs also seek summary judgment on their claims of trade disparagement under the Lanham Act and under Florida law. As a preliminary matter, the Court must note that Plaintiffs are not entitled to summary judgment for trade disparagement under Section 43(a) of the Lanham Act by simple virtue of the fact that no such claim for relief was ever made in the supplemental complaint. Rather, in Count VI of the supplemental complaint, Plaintiffs have only pleaded "a count for trade disparagement under the common law of Florida for Defendants [sic] false statements to the public concerning Plaintiffs' PerioGlas product." (Doc. 51, p.12).

According to Plaintiffs, Defendants have made statements that "[i]n essence, PerioGlas is what we throw in the garbage." *See, e.g.,* (Doc. 89, Exh. 34). The evidence cited to demonstrate that these statements have been made includes internal memoranda and marketing tips to sales members, which were not distributed to purchasing consumers. Additionally, while Plaintiffs would have the Court believe that all of the cited examples of disparagement say that "Orthovita throws out PerioGlas," some of the cited examples state "PerioGlas uses the particle sizes that we throw away." *See, e.g.,* (Doc. 89, Exhs.36, 37). Furthermore, the deposition testimony cited for the same proposition involves statements that "words to the effect of" PerioGlas(TM) being what Orthovita throws away were used, not those precise words. *See, e.g.,* (Doc. 89, Exh. 13 at pp.33-34, Exh. 35 at p. 25). Only Ms. Knudsen's deposition avers that the precise reference that PerioGlas was the garbage from BioGran's production was ever made, yet her testimony is based solely on multiple hearsay which is inappropriate as a basis for granting summary judgment.

Under Florida law, an action for trade disparagement must establish that the defendant intentionally made a false statement about the plaintiff's product, and that as a result thereof, plaintiff has suffered a special injury or damage. *See* State Farm Fire & Casualty Co. v. Compupay, Inc., 654 So.2d 944, 948 (Fla. 3d DCA 1995). Mere negligence or the lack of reasonable grounds for a defendant's belief in the veracity of a statement is not grounds for a trade disparagement claim. *See* Collier County Pub. Co. v. Chapman, 318 So.2d 492, 494 (Fla. 2d DCA 1975), *cert. denied,* 333 So.2d 462 (Fla.1976)(addressing the standard for injurious falsehoods). The Defendants' intent in making the statements is clearly in dispute in this case, with Plaintiffs asserting that Defendants intended to imply that PerioGlas(TM) is garbage material, and with Defendants asserting that the intent was to note that the smaller and larger particle sizes found in PerioGlas(TM) are systematically eliminated from the composition of BioGran$^{(R)}$. This dispute renders summary judgment on Plaintiffs' trade disparagement claim, inappropriate.

False advertising under Chapter 817 of the Florida Statutes and Unfair competition under Florida law and the Florida Deceptive and Unfair Trade Practices Act

The parties agree that the standard to be applied under Florida's statutory and common law for Plaintiffs' unfair competition and false advertising claims based thereupon, mirrors that to be applied under the Lanham Act. Having already determined that summary judgment on the claims brought under the Lanham Act is inappropriate, analysis of these claims under state law would be futile, and the Court is of the opinion that the motion for summary judgment on these claims brought under state law should also be and the same is hereby denied.

Defendants' counterclaims of false patent marking

Lastly, Plaintiffs have moved for summary judgment on Defendants' counterclaims of false patent marking pursuant to 35 U.S.C. s. 292, and for false designation of origin and false descriptions under Section 43(a) of the Lanham Act. Defendants assert in these counterclaims that Plaintiffs' PerioGlas (TM) product, which is sold in containers marked with the '046 patent, is not covered by that patent.

Plaintiffs first allege that the counterclaims are improperly before the Court, since, as compulsory counterclaims, they should have been asserted in the first responsive pleading, i.e. the original answer. Thus, according to Plaintiffs, the counterclaims should be deemed to have been waived. Defendants contend that they were unaware of these claims at the time they served their original answer and that allowing the claims now would not be prejudicial to the Plaintiffs. Despite Defendants' failure to timely assert their counterclaims, and to properly seek leave to file compulsory counterclaims after the first responsive pleading was served, the Court agrees that Plaintiffs will suffer no prejudice by the Court permitting the Defendants to assert these counterclaims now.

Plaintiffs next assert, that based upon the merits, the undisputed facts demonstrate that PerioGlas(TM) does in fact contain particles within each of the three size ranges cited in the '046 patent, in compliance with Claims 1 and 4 thereof. Defendants incorrectly construe Plaintiffs' loosely worded allegation that PerioGlas(TM) contains "bioactive glass particles within the size range 90-710 microns, which the various Low et al. patent claims recite" as trying to improperly allege compliance with the original application Claim 1 which was rejected by the PTO and the Board of Appeals. This statement more accurately reflects an assertion that the particle size range of PerioGlas(TM) is consistent with Claims 1 and 4 of the '046 patent which anticipate the presence of particles over the entire range of 90 to 710mum, but only where there are particles present in each of the three individual ranges cited in Claim 4. As evidence of '046 patent

claim compliance, Plaintiffs direct the Court's attention to several undisputed studies of the composition of PerioGlas (TM) which they argue indicate compliance with the claims of the '046 patent.

The results and conclusions of these studies are not disputed, however, Defendants attempt to create a dispute by arguing first that some of these tests rely on the improper particle size measurement method, and do not use sieving, the appropriate method. This Court refuses to accept this argument since as discussed more fully, *supra,* sieving was determined to be the appropriate method for measuring others' infringement of the Plaintiffs' patent. Indeed, this Court specifically noted that since both particle size measurement techniques found support in the '046 patent, the least restrictive method should be employed in order to determine infringement. To imply that sieving should be used against Plaintiffs to determine infringement of their own patent defies logic and the Court rejects such a suggestion, especially where SEM has been determined to be far more precise at determining actual particle dimensions. Defendants next try to create a dispute as to Plaintiffs' evidence by noting that two of the references deal with a study that tested bioactive glass in the ilium of rabbits, not in periodontal applications. However, the method of testing is irrelevant to whether or not the particles in PerioGlas(TM) fall within the ranges cited in the '046 patent, which these references establish it does. Finally, Defendants contend that the one exhibit showing sieve test results on PerioGlas(TM) indicates that its composition falls well outside of the '046 patent claims. The Court finds the opposite to be true, in that this exhibit shows that PerioGlas(TM) contains particles within each of the three ranges cited in Claim 4, and the Court can presume only that Defendants arguments to the contrary are based upon its claim interpretation argument, which this Court rejected, *supra,* that in order to comply with Claim 1, all particles must be in the 355 to 710mum range. *See* (Doc. 89, Exh. 24, pp.4-5).

Defendants have failed to direct this Court's attention to any disputed issue of material fact which would preclude it from entering summary judgment on Defendants' counterclaims in favor of Plaintiffs. Thus, the Court is of the opinion that Plaintiffs motion for summary judgment, to the extent that it relates to Defendants' counterclaims, should be and the same is hereby granted.

D. Cross-Motions for Summary Judgment of Defenses of Inequitable Conduct and Unclean Hands

In yet another attempt to have this Court conclude that the '046 patent is "unenforceable," Defendants have asserted the defense of inequitable conduct and unclean hands by Plaintiffs' predecessor's counsel in obtaining approval of the '046 patent, and both Plaintiffs and Defendants have moved for summary judgment thereupon. The Federal Circuit has stated that inequitable conduct may "consist[ ] of '... failure to disclose material information ... coupled with an intent to deceive." ' Micro Chemical, Inc. v. Great Plains Chem. Co., 103 F.3d 1538, 1549 (Fed.Cir.1997)(quoting Molins PLC v. Textron, Inc., 48 F.3d 1172, 1178 (Fed.Cir.1995)). The party asserting inequitable conduct as a defense bears the burden of establishing "the threshold elements of materiality and intent by clear and convincing evidence." *Id*. The district court must consider these threshold elements in light of all the circumstances in order to determine whether a finding of inequitable conduct is appropriate, and the determination in this regard is committed to the court's discretion. *See id.; see also* Consolidated Aluminum Corp. v. Foseco Int'l, Ltd., 910 F.2d 804, 809 (Fed.Cir.1990)(stating that the court must determine whether the conduct, in its totality, "manifests a sufficient culpable state of mind to warrant a determination that it was inequitable").

Since a finding of inequitable conduct eliminates all of the patentee's rights and the professional or commercial reputation of the patentee could be seriously damaged, such consequences demand that the moving party bear "a heavy burden of persuasion." KangaROOS U.S.A. v. Caldor Inc., 778 F.2d 1571, 1576 (Fed.Cir.1985); *see also* Kolmes v. World Fibers Corp., 107 F.3d 1534, 1541 (Fed.Cir.1997); *Yol-* O-Matic,

Inc. v. Proma Produkt-Und Marketing Gesellschaft m.b.H., 945 F.2d 1546, 1554 (Fed.Cir.1991)(stating that forfeiture of patent enforceability is not favored as a remedy where actions are not shown to be "culpable"). The clear and convincing evidence must show that the applicant had the specific intent to mislead the PTO. In *Molins,* the Federal Circuit stated

Thus, the alleged conduct must not amount merely to the improper performance of, or omission of, an act one ought to have performed. Rather, clear and convincing evidence must prove that an applicant had the specific intent to accomplish an act that the applicant ought not to have performed, *viz.,* misleading or deceiving the PTO. In a case involving nondisclosure of information, clear and convincing evidence must show that the applicant made a deliberate decision to withhold a *known* material reference.

Molins, 48 F.3d at 1181 (emphasis supplied). It is imperative that the applicant be shown to have known of the materiality of the undisclosed reference. The evidence of intent need not be direct in form, rather an inference of intent to deceive may be found from the circumstantial evidence, however, if the circumstantial evidence leads only to the conclusion that an applicant was grossly negligent in failing to disclose information to the PTO, no inference of intent to deceive can result therefrom. *See id.* (citing Kingsdown Medical Consultants, Ltd. v. Hollister, Inc., 863 F.2d 867, 876 (Fed.Cir.1988), *cert. denied,* 490 U.S. 1067, 109 S.Ct. 2068, 104 L.Ed.2d 633 (1989)).FN25

FN25. In *Molins,* the court noted
This court's *in banc* decision in *Kingsdown* resolved conflicting precedent regarding whether a finding of gross negligence compels a finding of intent to deceive. *Compare* J.P. Stevens & Co. v. Lex Tex, Ltd., 747 F.2d 1553, 1564, 223 USPQ 1089, 1092 (Fed.Cir.1984), *cert. denied,* 474 U.S. 822, 106 S.Ct. 73, 88 L.Ed.2d 60 (1985)(gross negligence was sufficient to prove intent, whereas simple negligence, oversight, or an erroneous judgment made in good faith was insufficient) *with* FMC Corp. v. Manitowoc Co., 835 F.2d 1411, 1415 n. 9, 5 USPQ2d 1112, 1116 n. 9 (Fed.Cir.1987)(gross negligence alone did not mandate a finding of intent to mislead).
Molins, 48 F.3d at 1181 n. 11.

When, as here, the material facts are not in dispute, and both parties have moved for summary judgment based thereupon, the Court may decide the issue of inequitable conduct as a matter of law. In this case, the original patent application was filed on June 19, 1985, at which time the inventors and Plaintiff UFRF's assignor, the University of Florida, were represented by Dennis Clarke ("Clarke"), an outside attorney. The PTO examiner initially rejected the application claims in the PTO's first Office Action on March 19, 1986, over the prior art Gross patent, which prior patent cited a particle size range of about 10 to 200mum. On June 19, 1986, Clarke filed a written response to the first Office Action, amending the application claims with respect to glass composition, and he presented arguments relating to the differences between the chemical compositions of the two glasses. He did not mention particle size as a basis for patentability. Also in June of 1986, Clarke filed a patent application in Europe which corresponded to the claims sought from the PTO.

On August 28, 1986, the PTO issued its Final Office Action in which the examiner maintained his previous rejection of the application claims. Mr. Clarke again responded in writing to the rejection, but to no avail. On May 26, 1987, Clarke filed a notice of appeal and brief in support thereof. In his brief, Clarke argued the differences between the two glass compositions, without ever specifically citing particle sizes. The PTO

examiner filed his responsive brief directing the Board of Appeal's attention to the fact that the application claims cited particle size ranges found in the Gross patent. Clarke filed a reply brief on November 12, 1987, arguing patentability based upon the differences in chemical compositions and uses of the two glass compositions.

One month after filing his reply brief on the appeal of the United States PTO's Final Office Action, in December of 1987, Clarke received a prior art search report which had been issued in conjunction with the pending European patent application. The search report noted six references, three of which were noted collectively within a category "Y." According to the report, each of the references in category "Y" were "particularly relevant if combined with another document in the same category." (Doc. 90, Exh. 7 at FL001171). The three items noted in category "Y" were: first) a Dutch patent ("De Groot patent") deemed relevant to claims 1, 2, 7, and 8; second) an article entitled *Biomedical applications and glass corrosion,* authored by L.L. Hench and deemed relevant to claims 1, 2, 3, 7, and 8, and; third) the Bluethgen patent deemed relevant to claims 1, 2, and 3. Clarke notified his clients about the receipt of the European search report and indicated that he felt the European examiners would reject the claims based upon a combination of the references contained therein.

On September 16, 1988, the United States PTO's Board of Appeals rendered its opinion affirming in part and reversing in part the PTO examiner's rejection of the U.S. patent application claims. The Board distinguished the particle size ranges of the application claims and the prior art and stated that the group of claims reciting larger particle size ranges was patentable. Clarke accepted the Board's allowance of narrower ranged claims on December 30, 1988, and the PTO examiner revised the application claims to reflect the Board's decision. Clarke paid the patent issuance fee on March 30, 1989, and the '046 patent was formally issued on July 25, 1989.

Approximately one month prior to issuance of the '046 patent, on June 20, 1989, Clarke received from the European Patent Office ("EPO") its Official Letter regarding the pending European application. In it, the EPO allowed one claim and rejected the remainder based upon a combination of the three references previously disclosed in the search report. The European examiner specifically noted that the Dutch De Groot patent cited a particle size range of 200 to 250mum, that the Hench paper failed to cite a particle range, and that the Bluethgen patent cited a particle size range of 90 to 250mum. On August 31, 1989, Clarke wrote to his European correspondent attorney, Mr. Hedley, providing instructions on how to respond to the EPO's Official Letter. Clarke advised Mr. Hedley to amend the European application to reflect the particle size ranges allowed in the '046 patent. In his correspondence, Clarke indicated to Mr. Hedley that the most pertinent reference cited by the EPO was the Dutch patent which cited a particle range similar to that of the Gross patent, which was relied upon by the PTO in the United States. After receiving the EPO's rejection, Clarke conceded that he made a conscious decision not to disclose the EPO's reference to the Bluethgen patent to the United States PTO. His decision in this regard is the subject of the inequitable conduct defense presently before this Court.

Defendants have based their inequitable conduct defense on Clarke's failure to disclose the Bluethgen patent to the PTO, which patent makes a singular reference to a particle size of 500mum in its specification. Defendants have not contested Plaintiffs' assertion that aside from the singular reference to the 500mum value, the Bluethgen patent is cumulative to the prior art Gross patent cited by the PTO examiner as the basis for his rejection of the application claims.FN26 This is important since Plaintiffs have no obligation to report to the PTO any prior art which is cumulative or less relevant than information already before the PTO. *See* 37 C.F.R. s. 1.56(b).

FN26. The 500mum value cited in the Bluethgen patent is found in the specification which refers to a material with a particle size range of about between about 50mum and 500mum and "preferably between about 90 mum and about 250 mum." Indeed, the Bluethgen patent claims themselves, cite only a range of 90mum to 250mum.

As noted above, in order to establish inequitable conduct based upon Clarke's failure to disclose Bluethgen to the PTO, Defendants must establish by clear and convincing evidence both the materiality of the Bluethgen patent and Clarke's intent to mislead the PTO by not disclosing it. *See* Molins, 48 F.3d at 1178.

1. First ProngMateriality

Information is material for purposes of an inequitable conduct analysis if there is a substantial likelihood that a "reasonable examiner" would have considered the undisclosed information to be important in the decision as to the patentability of application claims. *See* Molins, 48 F.3d at 1179. And as noted above, where undisclosed information is either cumulative to or is not as relevant as information already before the United States PTO, the failure to disclose such information can not serve as the basis for inequitable conduct. *See id*.

Plaintiffs concede that as of today, the Bluethgen patent may be assumed to be material, but that at the time of the alleged inequitable conduct, i.e. when he received notification of the EPO's rejection of the foreign application, Clarke was unaware that Bluethgen was material. It is their position that at the time, Clarke felt that the Bluethgen patent was at best cumulative to the Gross patent and that he therefore had no duty to disclose it. According to Plaintiffs, Clarke's contemporaneous correspondence with his foreign associate indicates that he was unaware of the 500mum reference in the Bluethgen specification. They note that even the EPO itself, which rejected patent claims based partially upon Bluethgen in its Official Letter, never mentioned the 500mum figure, but rather explicitly stated that Bluethgen involved a particle size range of 90 to 250mum. It is the Plaintiffs position that Clarke never saw the 500mum reference in Bluethgen when he first reviewed it, and that its materiality was therefore unknown at the time of the alleged inequitable conduct.

Defendants contend that Bluethgen was material since the Board's allowance of certain claims in the '046 patent was premised upon assuring that the particle sizes cited therein were larger than those cited in the prior art Gross patent. Thus, according to Defendants, the higher range cited in the specification of Bluethgen was relevant, in that certain of the claims allowed in the '046 patent would not have been permitted if the PTO was aware of prior art citing such a range. Defendants argument is premised on the assumption that the range of the Bluethgen patent is for particles sized between 50 and 500mum instead of the 90 to 250mum range explicitly stated in the claims thereof. Defendants have stated that "it is inescapable that claims 1 and 2 of the 046 patent would not have issued had the examiner been advised of the Bluethgen patent." (Doc. 104, p. 7). Yet, this assertion overlooks the EPO's rejection which was explicitly based upon the range of 90 to 250mum cited in Bluethgen; like Clarke, the EPO failed to recognize the relevant range of the Bluethgen patent as being 50 to 500mum. Defendants also note that Clarke is chargeable with knowing the materiality of any prior art which he reviewed, thus what he claims to have been unaware of today is irrelevant. *See* FMC Corp. v. Manitowoc Co., 835 F.2d 1411, 1415 (Fed.Cir.1987). In this case, Clarke admitted that he reviewed the Bluethgen patent, but contends that he missed the 500mum reference since the range cited by the EPO led him to believe that Bluethgen was material only to the extent that it

cited a range of 90 to 250mum.

While this Court disagrees with Defendants' suggestion that the singular 500mum reference in Bluethgen, had it been disclosed to the PTO, would have necessarily resulted in rejection of certain '046 patent claims, and while the Court agrees with Plaintiffs that Clarke was unaware of the materiality of the 500mum reference at the time of the alleged inequitable conduct, it does find that Bluethgen was nonetheless material to the '046 patent application, though not so highly material as to lower Defendants' burden in establishing the intent to mislead the PTO, as Defendants have argued is the case.FN27

FN27. Defendants have argued that the 500mum reference in Bluethgen was so highly material that a lesser showing of intent is required in order to find inequitable conduct. *See* (Doc. 104, p. 8) (citing Critikon v. Becton Dickinson Vascular Access, Inc., 120 F.3d 1253, 1257 (Fed.Cir.1987)). The cases relied upon by Defendants for this position involve situations where the undisclosed reference would have clearly led to rejection by the PTO. In this instance, the Court is not convinced that the PTO would have rejected the '046 patent claims based upon Bluethgen. As evidence of this, the Court notes the EPO's failure to recognize the relevant particle size range of Bluethgen as being 50 to 500mum instead of the range of 90 to 250mum which is explicitly recited in the Bluethgen claim language. Furthermore, the *Critikon* case involved a situation where the attorney for the patentee knew of the material disclosure in a withheld reference, had studied that reference in prior litigation, had cited the same reference in other patent proceedings, and was unable to provide an explanation for failing to disclose the reference. These facts are wholly incongruent with those of the case pending in this Court.

2. Second ProngIntent

The determination that the undisclosed Bluethgen reference was material does not, in and of itself, establish inequitable conduct. To prevail on this defense, Defendants must also establish by clear and convincing evidence that Clarke had the specific intent to mislead the PTO. *See* Molins, 48 F.3d at 1181.

It is undisputed in this case that Clarke made a conscious decision not to disclose the Bluethgen patent to the PTO when he learned of it from the European Patent Office's search report. Plaintiffs contend that this conscious decision was made based upon Clarke's belief that Bluethgen was less pertinent than the DeGroot patent cited by the EPO and was cumulative to the Gross patent already under consideration by the United States PTO. Thus, contrary to Defendants' assertion, Plaintiffs argue that Clarke was under no obligation to file a petition with the PTO to withdraw the application from consideration so that the PTO could re-consider the claims in light of Bluethgen.FN28 It was Clarke's belief that Bluethgen was cumulative to Gross, and he had no reason to file a petition to withdraw the application, since pursuant to 37 C.F.R. s. 1.56(b), such otherwise material information need not be disclosed, even where as Defendants have noted here, an "especially strong" inference of materiality arose from the EPO's use of Bluethgen to reject the foreign application claims. *See* PTO Manual of Patent Examining Procedure s. 2001.06(a). Based upon the undisputed evidence, it is clear that Clarke intentionally chose not to disclose Bluethgen to the PTO, however, the same can not be said with regard to whether or not he intended to mislead the PTO by withholding disclosure thereof.

FN28. It is important to note that, under 37 C.F.R. s. 1.313(b) (1988), at a time after the issuance fee has been tendered and the patent has been given an issue date and patent number, the application is not to be withdrawn except for the following reasons "(1) mistake on the part of the Office, (2) a violation of s. 1.56

[which includes the duty of disclosure] or illegality of the application, (3) unpatentability of one or more claims, or (4) for interference."

This Court agrees with Defendants that the intent to mislead need not be shown by direct evidence, but rather may be inferred from actions which have natural consequences that are intended by the actor. *See* Molins, 48 F.3d at 1180. However, in this case the undisputed evidence is unlike that in the cases relied upon by Defendants where the totality of the circumstances surrounding the non-disclosing attorney's actions established enough culpability "to require a finding of intent to deceive." Halliburton Co. v. Schlumberger Tech. Corp., 925 F.2d 1435, 1443 (Fed.Cir.1991). This Court is convinced that at the time of the alleged inequitable conduct, Mr. Clarke was unaware of the materiality of Bluethgen, and this fact alone is sufficient to lead this Court to the conclusion that Clarke did not have the requisite intent to mislead the PTO which would warrant a finding of inequitable conduct. *See* Molins, 48 F.3d at 1181. And furthermore, despite the fact that Clarke could be charged with knowledge of the materiality of any reference in prior art reviewed by him, the Court concludes that in the circumstances involved herein, such a charge against Clarke would be inequitable in itself, since it is clear that the EPO, which rejected the foreign application claims based upon Bluethgen, implied in its Official Letter that the only material particle size range contained therein was that which was explicitly stated in the claim language. Indeed the EPO explicitly noted that Bluethgen cited a particle size range of "90 to 250mum" without once referring to the 500mum reference in the Bluethgen specification which Defendants now assert is so crucial.

In this case, the Court concludes that the Defendants have failed to present clear and convincing evidence that the undisclosed Bluethgen reference was known to be material or that Mr. Clarke had the requisite intent to mislead or deceive the PTO. Furthermore, even if knowledge of the materiality thereof were to be imputed to Clarke, based upon the totality of the circumstances involved, his failure to disclose could at best, be described as grossly negligent, which the Federal Circuit has explicitly instructed will not support a claim for inequitable conduct based upon intentional nondisclosure. *See* Halliburton, 925 F.2d at 1442-43 (stating that gross negligence does not rise to the level of clear and convincing evidence which would justify an inference of intent to deceive the PTO); *see also* Molins, 48 F.3d at 1181 (stating that no inference of intent to deceive may be drawn from circumstantial evidence which leads only to the conclusion that the applicant was grossly negligent in failing to disclose)(citing Kingsdown Medical Consultants, Ltd. v. Hollister, Inc., 863 F.2d 867, 876 (Fed.Cir.1988)).

Thus, having considered the undisputed material facts in light of all of the circumstances, this Court concludes that Mr. Clarke's actions do not rise to level of culpability which would compel a finding of inequitable conduct. And based upon the foregoing, the Court is of the opinion that Plaintiffs' motion for summary judgment on Defendants' fifth and seventh affirmative defenses of inequitable conduct and unclean hands FN29 (doc. 90) should be and the same is hereby granted. Accordingly, the Court is also of the opinion that Defendants' cross-motion for summary judgment on the same (doc. 107) should be and the same is hereby denied.

FN29. The unclean hands defense, though sparsely mentioned by either party in their cross-motions, is subsumed in the analysis of inequitable conduct which has been defined as the unclean hands defense as applied to specific conduct before the PTO. *See* Consolidated Aluminum Corp. v. Foseco Int'l Ltd., 910 F.2d 804, 812 (Fed.Cir.1990) (citations omitted). Thus, where a claim of inequitable conduct fails, so must the claim under the equitable doctrine unclean hands.

E. Plaintiffs' Motion for Summary Judgment on Defendants' Equitable Estoppel Defense

Plaintiffs filed a separate motion for summary judgment on Defendants' sixth defense of equitable estoppel (doc. 91). The equitable estoppel defense revolves around the Defendants' contention that, based upon Plaintiffs' own actions or inaction, it would be inequitable to allow Plaintiffs to proceed with their claims of patent infringement. It is the Defendants' position that Plaintiffs engaged in misleading conduct that created a reasonable inference that Plaintiffs had abandoned any claim for patent infringement, and that as a result of reliance on that inference, Orthovita has suffered prejudice. This defense relates solely to the claims of patent infringement asserted by Plaintiffs. Having already determined that the Defendants' BioGran(R) product does not infringe the '046 patent, the Court is of the opinion that the Plaintiffs' motion for summary judgment on the defense of equitable estoppel (doc. 91) should be and the same is hereby denied as moot.

Having properly construed the '046 patent claims as set forth above, having applied the undisputed material facts thereto, and having applied all other undisputed facts to the various pending motions for summary judgment, it is hereby,

ORDERED AND ADJUDGED:

(1) Plaintiffs' motion for summary judgment of patent infringement (doc. 88) is DENIED in all respects;

(2) Defendants' motion for summary judgment with respect to Count I of the complaint, non-infringement, (doc. 93) is GRANTED to the extent that the Court finds no infringement, either literal or under the doctrine of equivalents, and this Court having concluded that the properly construed claims are valid under 35 U.S.C. s. 112, Defendants' alternative motion for summary judgment of patent invalidity is DENIED.

(3) Defendant Ducheyne's motion to dismiss all claims against him (doc. 92) is MOOT with respect to claims of infringement brought against him, since this Court has already held that the BioGran(R) product does not infringe the '046 patent, and for the reasons set forth above, the motion is GRANTED with respect to all remaining claims asserted against him. Accordingly, the Clerk is hereby directed to dismiss Paul Ducheyne as a Defendant in this action on the remaining Counts II, III, IV, V, and VI.

(4) Plaintiffs' motion for summary judgment on Plaintiffs' false advertising, unfair competition, and trade disparagement claims (Counts II, III, IV, V, and VI), and on Defendants' counterclaims (doc. 89) is GRANTED only to the extent that it relates to Defendants' counterclaims, and is DENIED in all other respects.

(5) Plaintiffs' motion for summary judgment on Defendants' inequitable conduct and unclean hands defenses (doc. 90) is GRANTED and Defendants' cross-motion for summary judgment on the same defenses (doc. 107) is DENIED.

(6) Plaintiffs' motion for summary judgment on Defendants' equitable estoppel defense (doc. 91) is MOOT.

(7) The attorneys for the parties are hereby directed to meet with one another no later than May 11, 1998 for the purposes of preparing the pre-trial stipulation, and the pre-trial stipulation on all remaining claims (Counts II, III, IV, V, and VI) shall be filed with the Court no later than May 25, 1998.

(8) A pre-trial conference shall be held in this matter on May, 28, 1998 at 1:00 p.m.

(9) The parties are hereby advised that, prior to the trial on the remaining issues, the Court will require each side to prepare and submit to the Court, in both hard-copy and on diskette (WordPerfect version 6.0 or higher), their proposed findings of fact and conclusions of law.