UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
JACKSONVILLE DIVISION

JOHNSON & JOHNSON
VISION CARE, INC.,

Plaintiff and
Counterclaim Defendant,

vs.

Case No. 3:05-cv-135-J-32TEM
Case No. 3:06-cv-301-J-32TEM

CIBA VISION CORPORATION,

Defendant
Counterclaim Plaintiff.

ORDER[1]

Before the Court are pending issues raised by the parties in anticipation of the trial of this case, which is scheduled to begin March 30, 2009. Specifically, the Court has considered the matters raised by the parties in the following papers: CIBA Vision Corporation's Brief On Issues Left Open By Court's Summary Judgment Order (Doc. 192) and Johnson & Johnson Vision Care, Inc.'s Response (Doc. 195); Johnson & Johnson Vision Care, Inc.'s Supplemental Summary Judgment Memorandum (Doc.

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[1] Under the E-Government Act of 2002, this is a written opinion and therefore is available electronically. However, it is intended to decide the matters addressed herein and is not intended for official publication or to serve as precedent.

193) and CIBA Vision Corporation's Response (Doc. 194); Corrected CIBA Vision Corporation's Motion In Limine (Doc. 225) and Johnson & Johnson Vision Care, Inc.'s Response (Doc. 232); Johnson & Johnson Vision Care, Inc.'s Consolidated *Daubert* Motions And Motions *In Limine* (Doc. 217) and CIBA Vision Corporation's Opposition in response (Docs. 231, 238); CIBA Vision Corporation's Second Motion In Limine (Doc. 234) and Johnson & Johnson Vision Care, Inc.'s Response (Doc. 242); CIBA Vision Corporation's Third Motion In Limine (Doc. 236) and Johnson & Johnson Vision Care, Inc.'s Response (Doc. 243); CIBA Vision Corporation's Motion In Limine To Preclude Reference To RD-677/Balafilcon A (Doc. 245); and Johnson & Johnson Vision Care's Motion To Seal Or Redact A Portion Of The Joint Pre-Trial Statement And Portions Of CIBA Vision Corporation's Summary Judgment Materials (Doc. 250), and CIBA Vision Corporation's Opposition in response. (Doc. 241.) The Court conducted a Final Pretrial Conference, with all parties in attendance, on March 18, 2009, the record of which is incorporated herein. (Docs. 244, 248.)

I. Reconsideration or Clarification of Order on Summary Judgment Motions

On December 3, 2008, the Court entered its Order on the parties' cross motions for summary judgment, granting in part and denying in part CIBA Vision Corporation's ("CIBA") motion for partial summary judgment, and denying Johnson & Johnson Vision Care, Inc.'s ("J&J") motion for summary judgment. (Doc. 190). The Court invited the parties to file supplemental briefing to address any outstanding issues.

Considering the parties' filings (Docs. 192, 193, 194, 195), the Court determines that the following issue merits discussion.

A. Asserted Claims That Do Not Mention "Surface Treatment"

The Court determined that there are disputed issues of fact as to whether the CIBA patents enable claims not requiring any "surface treatment process." (Doc. 190 at 12-15.) At issue is whether the five remaining asserted claims that do not recite "surface treatment process" ('100 Patent cl. 56; '894 Patent cls. 89, 90, 96, 99) must be enabled and practiced both with and without a surface treatment process, as argued by J&J. CIBA argues to the contrary. (See Doc. 190 at 14 n.10.) Both parties ask the Court to rule on this issue as a matter of law. (See Docs. 192 at 2; 193 at 6.)

During the *Markman* proceedings, the Court declined to construe the CIBA patent claims to all be limited by the term "surface modification," which J&J argued was to be equated with "surface treatment." (Doc. 121 at 23-29.) As a result, the five asserted claims listed above do not contain a "surface treatment process" limitation. By contrast, the remaining asserted claims concern "[a]n ophthalmic lens having a surface modified by a surface treatment process . . . ." ('100 Patent cls. 1, 28; '811 Patent cls. 28, 29.)

J&J argues that the five claims described above "cover two types of lenses: those with surface treatments and those without. . . . Because CIBA's patents fail to enable one of skill in the art to make lenses without surface treatment, the asserted

claims are invalid as not enabled." (Doc. 195 at 4; see also Doc. 193 at 4-5 ("CIBA's claims encompass two entirely different products, surface treated lenses and non-surface treated lenses"). According to J&J, the claims at issue "encompass wholly distinct embodiments." (Doc. 193 at 7.) In support, J&J cites two cases, Liebel-Flarsheim Co. v. Medrad, Inc., 481 F.3d 1371 (Fed. Cir. 2007) and Automotive Techs. Int'l, Inc. v. BMW of N. America, Inc., 501 F.3d 1274 (Fed. Cir. 2007). In Liebel-Flarsheim, the court affirmed summary judgment in favor of the accused finding that the patent claims directed to a front-loading fluid injector with replaceable syringe for delivering a contrast agent to a patient, were invalid for lack of enablement. 481 F.3d at 1380. There, Liebel removed all reference in its patent claims to a pressure jacket system, aware that a competitor had developed a jacketless injector system. Id. at 1374. The court construed the claims as not requiring a pressure jacket, although all of the described embodiments included a pressure jacket. The court observed "that the asserted claims purposefully did not include a pressure jacket limitation in order to cover devices that lack a pressure jacket," 481 F.3d at 1374-75, and determined that "the front-loading patents . . . are not limited to an injector with a pressure jacket, and therefore the full scope of the claimed inventions includes injectors with and without a pressure jacket." Id. at 1378-79, 1380. However, because the patent specifications did not describe a jacketless injector, id. at 1375, and the evidence established that a pressure jacket was necessary, the patent was found to be invalid

for lack of enablement. Accord Automotive Techs. Int'l, 501 F.3d at 1274 (affirming summary judgment of invalidity because the specification enabled only the mechanical side impact sensors when the claims included both mechanical and electronic side impact sensors); see also ICU Medical, Inc. v. Alaris Medical Systems, Inc., __ F.3d ____, 2009 WL 635630 (Fed. Cir. March 13, 2009).

CIBA's position is that the cases cited by J&J are not applicable; "[t]hese cases pertain to the enablement of the full range of *products* claimed in a patent, not to the enablement of different *methods* or *processes* for making the full scope of claimed products. A surface treatment process is a *method* or *process* of making the claimed contact lenses." (Doc. 162 at 17 (emphasis in original); see also id. at 19 ("a surface treatment process is a *process* limitation, that is, a method of making a contact lens" (emphasis in original).) In distinguishing Leibel, supra, CIBA says that the asserted "device claim covered two different products: an injector with a pressure jacket and an injector without a pressure jacket . . . [that were] physical embodiments that fell within the scope of the device claim," and that the claim was held to be invalid because the patent did not enable one of those products (also referred to by CIBA as structures or devices). (Id. at 18-19.)

Instead, CIBA cites to Invitrogen Corp. v. Clontech Labs., Inc., 429 F.3d 1052 (Fed. Cir. 2005). There, the claims-in-suit described a genetically engineered enzyme without regard for the method used to mutate the genes, in which the written

description in the patent described how to implement the invention by "deletion mutation." The accused argued that the patent was not enabled because it did not describe how to achieve the enzyme by another method, "point mutation." The court held that "[a]lthough Clontech's validity argument might have force had Invitrogen limited its claims to modified RT [enzyme] by reference to point mutation, Clontech overlooks the fact that the claims are not limited by the method of achieving the mutation," and that "'[t]he enablement requirement is met if the description enables any mode of making and using the invention.'" 429 F.3d at 1071 (citation omitted). Thus, "Invitrogen's teaching regarding deletion mutation is sufficient to satisfy its part of the patent bargain, as it fully teaches a mode of making the claimed invention." Id.; see also Amgen, Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313, 1335 (Fed. Cir. 2003)("'the law makes clear that the specification need teach only one mode of making an using a claimed composition'")(citation omitted).

The question is whether the claim term "surface treatment process" which is expressly recited in asserted independent Claim 1 of the '100 Patent and Claim 28 of the '811 Patent, and the lack of any reference to "surface treatment process" in the five asserted claims at issue here, when read in context, describes and limits "the product more by its structure than by the process used to obtain it." Hazani v. United States Int'l Trade Comm'n, 126 F.3d 1473, 1479 (Fed. Cir. 1997)(concluding that

"chemically engraved" was a structural limitation and not a process term).[2]

"The 'enablement requirement is satisfied when one skilled in the art, after reading the specification, could practice the claimed invention without undue experimentation.'" Sitrick v. Dreamworks, LLC, 516 F.3d 993, 999 (Fed. Cir. 2008)(citation omitted); see 35 U.S.C. § 112 ¶ 1. "The full scope of the claimed invention must be enabled . . . . A patentee who chooses broad claim language must make sure the broad claims are fully enabled." Id. "[E]nablement is a question of law . . . which may involve subsidiary questions of fact." In re Epstein, 32 F.3d 1559, 1568 (Fed. Cir. 1994). Restated, the enablement inquiry asks whether one skilled in the art could practice the full scope of the claimed invention as taught by the specification. While the cases cited by J&J are, at first blush, seemingly persuasive, further analysis reveals that the limitations recited in the product claims in JJ's cited cases come down on the side of "structure" as opposed to "process," all involving the "structure" of the patented product. The five claims at issue here omit the specification "surface treatment *process*".[3] The omitted claim term in the five claims

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[2] In Hazani, the patent claims for a semiconductor memory cell which recited a plate with a chemically engraved surface were not product-by-process claims, but were pure product claims, since the "chemically engraved" limitation, read in context, described a product more by its structure than by the process used to obtain it. 126 F.3d at 1479.

[3] J&J neglects to acknowledge that the claim term includes the word "process."

on its face refers to a "process" and not to a "structure." Nothing in the claim language suggests that "[a]n ophthalmic lens having ophthalmically compatible inner and outer surfaces" ('100 Patent, cl. 56) or a contact lens "comprising a polymeric material" that "is suitable for continuous and intimate contact with ocular tissue" ('894 Patent cl. 89) requires a particular process (or no process) for achieving the recited lens surface. In this context, then, the Court asks must J&J show "that all of the disclosed alternative modes are insufficient to enable the claims, because 'the enablement requirement is met if the description enables any mode of making and using the invention.'" Johns Hopkins Univ. v. CellPro, Inc., 152 F.3d 1342, 1361 (Fed. Cir. 1998)(citation omitted)? While the Court will eventually rule, the Court still is in need of more guidance from the parties on these basic questions: Is the "product" versus "process" distinction clear in patent law, and if so, what is the reason for this distinction? Why is there a difference in the legal analysis applied depending upon whether the claim term is characterized as a "product" versus a "process"? Further, does the same distinction and analysis apply in determining whether the five asserted claims at issue here read on the prior art and are thus relevant to J&J's obviousness defense? And does the distinction matter in the infringement analysis in this case? Accordingly, the Court will reserve its final decision on the question of whether the five asserted claims that do not recite a surface treatment process limitation are required to be enabled without a surface treatment process. The Court assumes the issue will

be further developed at trial.

B. Remaining Issues Raised

Inasmuch as J&J has announced it will no longer pursue its defense of invalidity by anticipation, (see Doc. 240 at 10-11), the Court need not address CIBA's post-summary judgment issue whether the '579 Lai/Valint Patent anticipates the asserted claims. (Doc. 192 at 3.) In light of the parties own assertions, the Court need not further clarify that oxygen permeability is determined for purposes of the CIBA patents by the single point coulometric method. (Doc. 192 at 6; see e.g. Docs. 217 at 6-9; 231 at 4-7.) Further, J&J is no longer pursuing consideration of RD-677/Balafilcon A as prior art in its "obviousness" defense, (Doc. 240 at 10-11), rendering CIBA's request to address that issue (Doc. 192 at 7) moot. Further requests by CIBA amount to seeking reconsideration or "clarification" of matters ruled upon on summary judgment (some of which are the same as have been raised in the motions *in limine*) and are hereby **DENIED**.

Likewise, the remaining issues raised by J&J in its supplemental memorandum (Doc. 193) are requests for reconsideration of matters decided on summary judgment. Further, J&J raised issues that it has announced it no longer intends to pursue. (See Doc. 193 at 10-15 (re: RD-677 lens; anticipation).) Accordingly, the remaining requests raised by J&J's supplemental memorandum are **DENIED**.

II. Motions in *Limine* and *Daubert* Motions

The parties have raised a total of twenty-seven different issues in their motions *in limine* and *Daubert* motions. (Docs. 217, 225, 234, 236, 245.) As announced at the Final Pretrial Conference, the Court denies the bulk of the motions at this point, deferring final ruling until the trial of this case.

Rule 702, Federal Rules of Evidence, governs the admissibility of expert testimony. In Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579 (1993), the Supreme Court instructed that district courts are to perform a "gatekeeping" role concerning the admission of expert scientific testimony. Id. at 592-93; see also Kumho Tire Co. Ltd. v. Carmichael, 526 U.S. 137, 147 (1999). However, because this is a non-jury trial, the gatekeeping purpose of Daubert is not implicated.[4] N.W.B. Imports and Exports Inc. v. Eiras, No. 3:03-cv-1071-J-32-MMH, 2005 WL 5960920, at *1 (M.D. Fla. March 22, 2005). Indeed, in the context of a non-jury trial, the district court may allow challenged expert testimony to be presented and then later determine issues of admissibility and reliability. Id. at *1 & n.2. The Court notes that some of the objections raised as to the qualifications of experts and the scientific underpinnings of their testimony raise viable questions. However, the Court will allow the experts to all testify, subject, of course to "[v]igorous cross-examination [and the] presentation

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[4] See Gibbs v. Gibbs, 210 F.3d 491, 500 (5th Cir. 2000)("[m]ost of the safeguards provided for in *Daubert* are not as essential in a case such as this where a district judge sits as the trier of fact in place of a jury").

of contrary evidence," Daubert, 509 U.S. at 596, which will aid the Court in its ultimate determination of whether to admit the expert's testimony and, if so, what weight to give it.

Likewise, that this is a bench trial weighs heavily in favor of denying the motions *in limine* and addressing the issues raised if and when they come up at trial. See Lifetime Homes, Inc. v. Residential Development Corp., 510 F. Supp.2d 794, 811 (M.D. Fla. 2007). As to specific issues raised, the Court rules as follows:

A. CIBA's motion to exclude opinion testimony by Dr. Douglas G. Vanderlaan (Doc. 225 at 7-17) is **GRANTED IN PART AND DENIED IN PART** inasmuch as Dr. Vanderlaan is designated by J&J as a fact witness as opposed to an expert witness. Dr. Vanderlaan is permitted to testify about the facts of his re-creations, his observations of his re-creations, and his readings of various prior art patents and the CIBA patents and examples as it relates to preparing his re-creations. He is not permitted to express his opinions on ultimate issues regarding the CIBA patents or to express his opinion in response to CIBA expert Dr. Mays' criticisms, but may respond with factual evidence.

B. CIBA's motion to preclude J&J from mentioning the so-called *Rembrandt* case (Docs. 225 at 20-21; 236 at 1-4) is **GRANTED IN PART AND DENIED IN PART**, to the extent that evidence of the *Rembrandt* verdict is not admissible, subject to reconsideration only if J&J can adduce sufficient legal authority to counsel

otherwise. This ruling, of course, does not limit the parties from offering specific testimony or evidence from the *Rembrandt* case should it become relevant to the issues here and the proponent can establish its admissibility under the Federal Rules of Evidence.

C. CIBA's motion to exclude J&J experts from presenting evidence concerning whether prior art meets or renders obvious the clinical limitations in the CIBA patents (Doc. 225 at 40-49) is **GRANTED** only to the extent that experts at trial will generally be limited to opinions expressed in their expert reports, and is otherwise **DENIED**.

E. J&J's motion to preclude CIBA from presenting evidence of "oxygen permeability" not calculated by the single point coulometric method (Doc. 217 at 6-9) is **DENIED** without prejudice. However, the Court cautions that the relevance of oxygen permeability measurement by the intrinsic or polarographic methods is marginal at best, and the parties will not be permitted to digress into collateral litigation concerning these other methods.

F. In its Motion In Limine To Preclude Reference To RD-677/Balafilcon A (Doc. 245), CIBA asks that the Court preclude J&J's witnesses from mentioning the RD-677/Balafilcon A prior art as part of its obviousness defense because J&J has designated that it is basing this defense upon the '327 Chang prior art. CIBA requests this pre-trial ruling in order to determine whether it will call a witness who must travel

to the trial from Australia. A patent claim is invalid for obviousness "if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art . . . ." 35 U.S.C. § 103(a). "[The] combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." KSR Int'l Co. v. Teleflex, Inc., 550 U.S. 398, 127 S.Ct. 1727, 1739 (2007). The obviousness inquiry relies on evidence available at the time of the invention. Eisai Co. Ltd. v. Dr. Reddy's Labs., Inc., 533 F.3d 1353, 1359 (Fed. Cir. 2008). While J&J's obviousness defense is based upon the '327 Chang, evidence referring in some way to the RD-677/Balafilcon A prior art may be relevant to the Court's consideration of the '327 Chang and obviousness, such that the Court declines at this pre-trial stage to preclude J&J from mentioning the RD-677/Balafilcon A lens at all. The extent of permitted discussion regarding the RD-677/Balafilcon A lens awaits development of evidence at trial. Accordingly, this motion is **DENIED**.

G. While CIBA Second Motion In Limine (Doc. 234) is due to be **DENIED** without prejudice, the Court will require J&J expert Dr. Benjamin to cite those portions of his expert reports produced during expert discovery where he addressed the ophthalmic compatibility of prior art before he is permitted to testify at trial on this topic.

H. The Court has considered all of the remaining matters raised *in limine*, and hereby **DENIES** the motions without prejudice to re-assert the objections at trial for further consideration.

Accordingly, it is hereby

ORDERED:

1. CIBA Vision Corporation's Brief On Issues Left Open By Court's Summary Judgment Order (Doc. 192) and Johnson & Johnson Vision Care, Inc.'s Supplemental Summary Judgment Memorandum (Doc. 193) are addressed as set forth above, and are otherwise **DENIED**.

2. Corrected CIBA Vision Corporation's Motion In Limine (Doc. 225) is **GRANTED IN PART AND DENIED IN PART**, without prejudice, as set forth above.

3. Johnson & Johnson Vision Care, Inc.'s Consolidated *Daubert* Motions And Motions *In Limine* (Doc. 217) are **DENIED** without prejudice.

4. CIBA Vision Corporation's Second Motion In Limine (Doc. 234) is **DENIED** without prejudice.

5. CIBA Vision Corporation's Third Motion In Limine (Doc. 236) is **GRANTED**. Reference to the *Rembrant* litigation will be limited, as previously stated in this Order. References at trial to the J&J clinical study produced in this case on March 6, 2009 are precluded.

6. CIBA Vision Corporation's Motion In Limine To Preclude Reference To

RD-677/Balafilcon A (Doc. 245) is **DENIED**.

7. Johnson & Johnson Vision Care's Motion To Seal Or Redact A Portion Of The Joint Pre-Trial Statement And Portions Of CIBA Vision Corporation's Summary Judgment Materials (Doc. 250) is **DENIED**.

8. The Court may alter any of these rulings depending upon the evidence adduced at trial, the applicable law and objections made by the parties at trial.

9. Each party will control six and one-half trial days (assuming reasonable cross-examination), leaving the Court to allocate the remaining two trial days as appropriate and necessary. However, the Court will not be drawn into overly technical arguments regarding the time allocation.

DONE AND ORDERED at Jacksonville, Florida, this 26th day of March, 2009.

TIMOTHY J. CORRIGAN
United States District Judge

jl.
Copies to:
Counsel of Record