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.

FINDINGS OF FACT AND CONCLUSIONS OF LAW

This consolidated case pertains to various CIBA Vision Corporation ("CIBA") patents for extended wear contact lenses. This dispute started with a declaratory judgment action brought by Johnson & Johnson Vision Care, Inc. ("J&J") against CIBA, seeking a declaration that five of CIBA'S United States Patents, U.S. Patent Nos. 5,760,100 ("'100 Patent"), 5,776,999 ("'999 Patent"), 5,789,461 ("'461 Patent"), 5,849,811 ("'811 Patent") and 5,965,631 ("'631 Patent") ("Nicolson patents") are invalid and/or unenforceable, and alternatively that J&J's new silicone hydrogel contact lenses, the Phoenix contact lens, marketed under the name ACUVUE®OASYS™ ("Acuvue Oasys" or "Oasys"), does not infringe upon the CIBA patents. (Case No. 3:05-cv-135-J-32TEM, Doc. 1.) CIBA answered and counterclaimed that J&J's lens infringes upon the '100, '461, '811, and '631 CIBA

Patents. In case No: 3:06-cv-301-J-32TEM, CIBA as plaintiff filed an action alleging that J&J has and continues to infringe upon CIBA's United States Patent No. 6,951,894 ("'894 Patent"), also a Nicolson patent. J&J counterclaimed, seeking a declaration that the '894 Patent is invalid and unenforceable.[1]

On March 14, 2008, this Court issued its Corrected Markman Order construing terms found in one or more of all six patents at issue. (Doc. 121; Johnson & Johnson Vision Care, Inc. v. CIBA Vision Corp., 540 F.Supp.2d 1233 (M.D. Fla. 2008). The case was subsequently trimmed to 31 asserted claims from five of the six patents in suit, with CIBA alleging infringement of the 31 claims (Docs. 189, 190 at 9; 191).[2] Following extensive briefing and submission of evidentiary material and argument, the Court, on December 3, 2008, entered an Order denying J&J's motion for summary judgment as to noninfringement and invalidity, and denying CIBA's motion as to infringement and in part as to invalidity. (Doc. 190.) The Court granted CIBA's motion for summary judgment pertaining to J&J's invalidity defense/claim based on anticipation by prior art (with one exception), and "best mode." (Doc. 190 at 55-56.)

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[1] The complex procedural background of these and related patent cases between these same parties is set forth in an earlier Order. (See Doc. 121 at 2 n.2; Johnson & Johnson Vision Care, Inc. v. CIBA Vision Corp., 540 F.Supp.2d 1233, 1237 n.2 (M.D. Fla. 2008).

[2] CIBA's claims for infringement and J&J's defenses/request for declaratory relief as to invalidity of the remaining nonasserted claims were dismissed without prejudice. (See Docs. 189, 191.)

The Court conducted a ten day bench trial[3] from March 30 through April 10, 2009 (Docs. 269-78), and heard closing arguments on June 10, 2009, the record of which is incorporated here. (Docs. 310, 311.) At trial, CIBA asserted as infringed nine claims in three patents which CIBA owns (Docs. 257; 287 at 6-11): claims 1, 28 and 56 of the '100 Patent; claims 28 and 29 of the '811 Patent; and claims 89, 90, 96 and 99 of the '894 Patent.[4] Having stipulated to the issues to be decided (Doc. 281),[5] the parties submitted post-trial proposed findings of fact and conclusions of law (Docs. 286, 287) and responses. (Docs. 303, 305.) The Court has exhaustively reviewed the extensive record in this case, examined the evidence presented at trial,[6] observed the witnesses, read the parties' post-trial submissions, and considered the arguments. The Court now makes the following findings of fact and conclusions of law as required by Federal Rules of Civil Procedure 52(a).

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[3] Pursuant to Rule 38(d), Federal Rules of Civil Procedure, CIBA and J&J jointly withdrew their respective demands for a jury trial and consented to a bench trial before the undersigned. (Doc. 216.)

[4] The nine asserted claims are set out in full in the attached Appendix A.

[5] The issues tried were the infringement and invalidity of the nine asserted claims, and the unenforceability of all six patents. (Doc. 286 at 9.) The parties dispute the disposition of the remaining 22 claims not asserted at trial, but not dismissed from the case by stipulation. (See Docs. 189; 191; 287 at 6, 15-16; 305; Tr. X at 112-114.) This matter is unresolved.

[6] The Court has considered all of the evidence admitted at trial. The Court does not include any evidence that it has rejected as unreliable or that it finds irrelevant. Implicit in this Order is that the Court denies all *Daubert* motions seeking to exclude the testimony of various experts. The Court finds that all the witnesses were well steeped in their respective fields and qualified to offer testimony in this case. Accordingly, any and all outstanding *Daubert* motions are **DENIED**. The weight ascribed to each expert's testimony, of course, varies and is stated in this Opinion as appropriate.

I. Infringement

A. CIBA's Infringement Contentions

CIBA asserts a total of nine claims from three of the patents in suit. ('100 Patent cls. 1, 28, and 56; '811 Patent cls. 28 and 29; '894 Patent cls. 89, 90, 96 and 99.) The asserted claims relate to silicone hydrogel contact lenses suitable for continuous periods of extended wear of "about" or "at least" 24 hours or "at least" seven days. The claims teach that the patented lens exhibits an oxygen permeability and/or transmissibility of at least or about 70 barrers; and threshold levels of ion permeability. Four claims require a "surface treatment process" while the other five asserted claims do not recite this limitation. The three claims asserted from the '100 Patent recite that the lens must have separate "phases," while the remaining asserted claims do not.

CIBA contends that the evidence establishes that J&J's Acuvue Oasys product meets each and every limitation in the nine asserted claims. (Doc. 287 at 16-17; D.Dem 2-9 (citing Tr. II at 54 (Harris), 110-14 (Pitt), 242 (Gido); Tr. III at 113-14, 126-28 (Hoffman), 201-07 (Mays)).)[7]

J&J asserts that the Acuvue Oasys does not meet four sets of claim limitations, based upon a (1) lack of "oxygen permeability," "high oxygen permeability" and "oxygen transmissibility;" (2) lack of a "surface modified by a surface treatment process;" (3) lack of "polyvinylpyrrolidone at a surface of the lens;" and (4) lack of "phases." (Doc. 281.) J&J

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[7] The transcript of the trial in this case appears in the record at Documents 258-267. All references to the transcript volume and specific page will be cited as "(Tr. ___ at __ (Witness).)". Trial exhibits and Bates stamped pages will be cited as "PTX __ at ___ " (plaintiff J&J's exhibits), and "DTX ___ at __ " (defendant CIBA's exhibits).

does not dispute that Acuvue Oasys meets each of the other limitations of the asserted claims. (Tr. II at 43-46; Tr. X at 123-24; Docs. 253, 281.)

The Court finds that CIBA has proved that Acuvue Oasys meets all of the other limitations of the asserted claims (with the following exceptions as set forth in the footnote)[8] and addresses J&J's four non-infringement contentions below. In doing so, the Court observes that an infringement analysis involves two steps: (1) claim construction and (2) comparison of the properly construed claims to the accused device, here the Acuvue Oasys. Cook Biotech Inc. v. Acell, Inc., 460 F.3d 1365, 1372 (Fed. Cir. 2006). The Court accomplished the first step in its *Markman* Order. (Doc. 121.)

"To establish infringement, every limitation set forth in a patent claim must be found in an accused product or process exactly or by a substantial equivalent." Laitram Corp. v. Rexnord, Inc., 939 F.2d 1533, 1535 (Fed. Cir. 1991); see also Dynacore Holdings Corp. v. U.S. Philips Corp., 363 F.3d 1263, 1273 (Fed. Cir. 2004). "Literal infringement requires that each and every claim limitation be present in the accused device." Abraxis Bioscience, Inc. v. Mayne Pharma (USA) Inc., 467 F.3d 1370, 1378 (Fed. Cir. 2006). Under the doctrine of equivalents, a claim limitation is equivalently present if there are only "insubstantial differences" between the limitation and the corresponding aspects of the device. CAE Screenplates, Inc. v. Heinrich Fiedler GmbH & Co. KG, 224 F.3d 1308, 1318-19 (Fed. Cir.

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[8] CIBA acknowledges that the Acuvue Oasys lens does not infringe to the following extent: "the -1.00, 5.00-6.00, and -12.00 power lenses do not infringe claims 1, 28, and 56 of the '100 patent and claims 28 and 29 of the '811 patent, and the 5.00-6.00 and -12.00 power lenses do not infringe claims 89, 90, 96 or 99 of the '894 patent." (Doc. 287 at 80; see also id. at 25-26; Tr. II at 109-14, 158-60, 183 (CIBA expert Dr. William George Pitt ("Pitt")); D Dem. 11, 17, 50.)

2000). "A finding of infringement under the doctrine of equivalents requires a showing that the difference between the claimed invention and the accused product was insubstantial." Crown Packaging Tech. v. Rexam Beverage Can Co., 559 F.3d 1308, 1312 (Fed. Cir. 2009). CIBA, as patentee, has the burden of proving infringement by a preponderance of the evidence. Warner-Lambert Co. v. Teva Pharm. USA, Inc., 418 F.3d 1326, 1341 (Fed. Cir. 2005).

B. J&J's Non-Infringement Positions

1. Lack of "oxygen permeability," "high oxygen permeability" and "oxygen transmissibility"

CIBA contends that J&J's Acuvue Oasys lens satisfies the oxygen permeability and transmissibility limitations that are a part of all nine asserted CIBA patent claims, which set minimum values of permeability and transmissibility. Both of these properties relate to a lens' ability to allow oxygen from the atmosphere to travel through the lens to the cornea of the eye to promote the health of the eye. (Tr. I at 61 (CIBA inventor Dr. Paul C. Nicolson ("Nicolson")).) The dispute over the "oxygen permeability" and "oxygen transmissibility" terms centers upon whether the CIBA patent limitations teach that oxygen permeability (and oxygen transmissibility) values as measured by the single point coulometric method specified in the patents do not change with the thickness of the lens measured. J&J contends that the CIBA patents teach that the oxygen permeability ("Dk") does not change with thickness and thus, because the evidence established that the Acuvue Oasys lens Dk values are dependent on thickness, the Acuvue Oasys does not infringe this limitation.

"Oxygen transmissibility" ("Dk/t") is defined first in the patent as being:

> The rate at which oxygen will pass through a specific ophthalmic lens. Oxygen transmissibility, Dk/t, is conventionally expressed in units of barrers/mm, where *t* is the average thickness of the material [in units of mm] over the area being measured . . . .

('100 Patent col.4 ll.51-56.) In seeking a *Markman* construction of the term, CIBA had pressed for a definition which specified that oxygen permeability "Dk", as used in the oxygen transmissibility formula Dk/t, referred to "the oxygen permeability of the lens measured by the coulometric method disclosed in the CIBA patents . . . without any corrections." (See Docs. 121 at 84; 86 at 16-17.) J&J offered no alternative construction, contending that the term was "indefinite" as it related to the definition of "barrer." (Docs. 94 at 33; 121 at 84-86.) Concluding that the measurement technique of oxygen permeability ("Dk") and oxygen transmissibility ("Dk/t") need not be resolved at the claim construction phase of the proceedings, (Doc. 121 at 86), the Court adopted CIBA's claim term construction, without reference to the coulometric method, relied upon the patent's definition, and construed "oxygen transmissibility" to mean:

> The rate at which oxygen will pass through a specific ophthalmic lens denoted as Dk/t, where *t* is the average thickness of the material [in units of mm] over the area being measured and Dk is the oxygen permeability of the lens.

(Id. at 87.)

Appearing immediately following the patent's definition of "oxygen transmissibility" is the patent's definition of the term "oxygen permeability":

> The "oxygen permeability", Dk, of a lens material does not depend on lens thickness. Oxygen permeability is the rate at which oxygen will pass through a material. Oxygen permeability is conventionally expressed in units of "barrers". . . .

('100 Patent col.4 ll.58-61.)[9] In seeking construction of the term "oxygen permeability," CIBA first urged that the term be construed as "the rate at which oxygen will pass through a material" (Doc. 86 at 14) and later revised its argument urging that "[o]xygen permeability is measured in accordance with the coulometric method described in the CIBA patents, without any corrections, and can vary with thickness." (Docs. 91-2 at 3; 121 at 71.) CIBA argued that "the actual measurement technique taught in the patents does depend on thickness because a liquid boundary layer is present [on the contact lens] and no regression analysis [which is performed to correct for the effect caused by a layer of slow moving or non-moving water boundary layer that is immediately adjacent to the lenses] is taught." (Doc. 121 at 72.) J&J proposed that "oxygen permeability" be defined as "the rate at which oxygen passes through a material, which does not depend on lens thickness," (Docs. 94 at 31; 121 at 71), saying "that '[o]xygen permeability is a physical property of the material . . . [that] is not a function of the shape or thickness of the material sample." (Doc. 121 at 73 (citing Doc. 84-97 (J&J Ex. 92 at 1)).) The Court adopted the patent's specification which expressly defined "oxygen permeability," declining to graft the patent's specified measurement technique onto the definition of "oxygen permeability," noting that defining "oxygen permeability" as independent of thickness "'is true mathematically,' and is to be distinguished from 'the actual measurement technique taught in the patents [which] does depend on thickness because a boundary layer is present and no regression analysis is taught.'" (Doc. 121 at 74 (quoting CIBA argument Doc. 91 at 21).) The Court construed the term as follows:

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[9] This is the first reference to "Dk," as "oxygen permeability," even though the preceding definition for "oxygen transmissibility" included the term "Dk."

> The "oxygen permeability", Dk, of a lens material does not depend on lens thickness. Oxygen permeability is the rate at which oxygen will pass through a material.

(Id. at 74.)

Both CIBA and J&J agree that the CIBA patents teach that the uncorrected single point coulometric method of measurement is to be used to determine oxygen permeability and transmissibility. (Docs. 286 at 11; 287 at 17.)[10] The patent further describes the coulometric method of measurement as the "'Wet' measurement of oxygen permeability" as distinguished from the "dry measurement" or a "straight Dk value" which are "usually values determined on dry material." The patent specifications note that the so-called wet and dry measurements differ greatly. ('100 Patent col.51 ll.19-50; DTX 1448 ¶ 78 (CIBA inventor Dr. Lynn Cook Winterton ("Winterton") Decl. on Re-examination).) "The coulometric method was chosen because unlike other methods, such as a polarographic method, the coulometric method can accurately measure permeabilities above 70 barrers (Dk units)." (DTX 1448 ¶ 78 (Winterton Decl. on Re-examination).)

CIBA acknowledges that the oxygen permeability values of high Dk materials as measured by the uncorrected single point coulometric method, will vary with thickness (ie. different powers of contact lenses). (Tr. I at 170, 172 (Winterton); Tr. II at 96 (CIBA expert Dr. William George Pitt ("Pitt")).) This is because the boundary layer of water that remains

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[10] "The thickness (t) of the lens in the area being exposed for testing is determined by measuring about 10 locations . . . and averaging the measurements. . . . The oxygen transmissibility (D_k/t) of the material may be calculated by dividing the oxygen permeability (D_k) by the average thickness (t) of the lens." ('100 Patent col.15 l.42-col.16 l. 11.)

on the lens when measuring Dk using the single point coulometric method creates more resistance to the transport of oxygen molecules than the high Dk polymer lens material; the oxygen molecule meets resistance and has relatively low permeation through the water boundary layer, and then passes through the highly permeable contact lens at a higher rate. (Tr. II at 96 (Pitt); see also Tr. I at 169 (Winterton).) The effect of the boundary layer becomes more pronounced when the Dk of the material becomes much greater than that of water, which has a Dk of about 80 to 88 - "[s]o as you go above that value, water becomes a great constraint." (Tr. II at 37-38 (Winterton).) The water layer has a constant thickness; it's the lens polymer thickness that is changing. The resulting measurement is the uncorrected single point coulometric value of Dk. (Tr. II at 94-97 (Pitt) D.Dem 47.)[11]

> That presence of the water layer makes it appear that the Dk is changing as the thickness of that polymer changes. The intrinsic Dk is the same all the time. But our measurement gives us a value that appears to change. It [uncorrected value] actually does change. But that's because we are measuring a single-pont Dk instead of the intrinsic Dk [of the lens].

(Tr. II at 100 (Pitt).) "[T]he intrinsic permeability . . . does not depend on thickness." (Id. at 104.)[12] Further, the single-point uncorrected Dk will always be less than the intrinsic Dk

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[11] Pitt effectively illustrated the boundary layer phenomenon with a football field analogy. (Tr. II at 98.) The longer the grassy field, the truer the total measured speed of the running player (Dk value), because the effect of running through the muddy end zone (boundary layer) becomes less relative to the field. Dk is the measure of the rate, or speed of the football player running (or the oxygen molecule passing through the contact lens). Transmissibility is how long it actually takes for the runner (or oxygen molecule) to get there - the longer the football field, the longer to get to the end.

[12] The "intrinsic" value of oxygen permeability is determined by making a series of measurements on lenses of different thicknesses, or on a series of stacked lenses. Then a regression is performed to correct for the effect caused by the water boundary layer.

values because of the contribution from the boundary layer. (Id. at 105.) While the single-point coulometric values of Dk vary with thickness of the lens, the intrinsic value of Dk - which is the rate at which oxygen travels through the lens material - does not vary with the thickness of the lens. (Id. at 100-01, 181-82; Tr. V. at 96 (J&J expert Dr. William Joseph Benjamin ("Benjamin")).) According to CIBA, the definition of "oxygen permeability" in the patent, and as construed by the Court, represents "a mathematical statement" as opposed to the measured value of Dk. (Tr. II at 42 (Winterton).)

Using the single point coulometric method of measurement, CIBA's test data on the Acuvue Oasys shows that the Dk (and Dk/t) of the Oasys varies with thickness, with Dk of 69.8 to 119.7 barrers and Dk/t from 66.2 to 114.7 barrers depending on thickness for the 8.4 base curve lens, and Dk of 73 to 120 barrers and Dk/t of 80 to 115 barrers depending on thickness for the 8.8 base curve Acuvue Oasys lens. (Tr. II at 57-60, 66 (CIBA employee Larry A. Alvord ("Alvord")), 157-58 (Pitt); Tr. V at 24-26 (Benjamin); DTX 1138, 1042 at 1 (Dk for 8.4 base curve lens ranged between 67.8 and 124.5 barrers); D Dem. 11, 14; Doc. 286 at 12.) As the thickness of the Oasys lens increased from 60 to 180 microns, the oxygen permeability values increased from less than 70 to nearly 125 barrers. (Tr. V at 25-26 (Benjamin); PTX 29A.) While "the values that we measured for oxygen permeability did vary with the thickness of the lens," CIBA's test also showed that the "permeability of the material

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This is contrasted with the single point coulometric method, which involves making a measurement on a single lens, without performing a regression analysis to correct for the boundary layer effect, resulting in an "apparent" or "single-point" or "uncorrected" oxygen permeability measurement. (Tr. I at 215-16 (Winterton).) The intent in using the coulometric method in the patents was so that one could determine Dk value by measuring a single lens. (Id. at 172; Tr. II at 156 (Pitt); DTX 1445 at 75-76.)

was uniform throughout the thickness of the lens." (Tr. II at 78-79 (Alvord).) In CIBA expert Pitt's opinion, the powers of the Acuvue Oasys lenses meet the oxygen permeability and transmissibility terms and high oxygen permeability terms set out in the CIBA patents, with the exception of several designated powers (thicknesses) of Oasys lenses. (Id. at 182-83; D. Dem 17; see Doc. 287 at 25-26, 80.) J&J's expert agrees that J&J's Acuvue Oasys "has high oxygen permeability." (Tr. VIII at 66 (J&J expert Dr. Paul L. Valint ("Valint")); see also Tr. V at 65 (Benjamin)("people in the field would say that it [Acuvue Oasys] has an oxygen permeability that's up there"); Id. at 60-61 (intrinsic Dk of most Acuvue Oasys lenses fall into the "hyper-transmissible" category as do the CIBA contact lenses.)

According to J&J, the CIBA patent, as construed by the Court, teaches that measuring different thicknesses of the same lens material, using the single point coulometric method would result in the same Dk. (Doc. 286 at 11-12.) Because the Dk value of the Acuvue Oasys varies with thickness when measured by the single point coulometric method, the Oasys does not satisfy the CIBA claim terms. (Tr. V at 23, 37 (Benjamin).) "Only lenses having this property, independence of thickness, are within CIBA's claims," argues J&J. (Doc. 286 at 12.) Further, J&J argues that CIBA has not presented any evidence that the Acuvue Oasys lenses have the oxygen transmissibility required by the CIBA patents because of the flaw in its thickness-independent Dk limitation. (Id. at 12.)

J&J contends that a 1987 article published by CIBA inventor Winterton and others entitled "Coulometric Method for Measuring Oxygen Flux and Dk of Contact Lenses and Lens Materials" (PTX 208) supports J&J's argument that the CIBA patents require that Dk

not change with the thickness of the lens.[13] J&J relies on Figure 4 in the 1987 article (id. at V111928), which is a graph illustrating Dk versus thickness of the Monocurve Modified Tefilcon (38% Water) lens (average Dk 7), that shows an ever so slight decrease ("asymptotic curve") in Dk as thickness increases, for the proposition that CIBA inventor Winterton, and by extrapolation the CIBA patents, require that Dk values do not "depend on" or vary with the thickness of the lens. (Tr. V at 54-56, 67, 104 (Benjamin); Doc. 286 at 14-15; Doc 303 at 11.) J&J also cites to a higher Dk material (Dk 63.7) referred to in Table I of the article (PTX 208 at V111926), which J&J says proves that CIBA inventor Winterton advocates that Dk does not change with the thickness of the lens even for higher Dk materials. (Doc. 303 at 11.) J&J cites to the article's conclusion, specifically that "'this technique . . . has been shown to be . . . thickness independent (for Dk).'" (Doc. 286 at 14 (quoting in part PTX 208 at V111931).)

"The oxygen permeability is typically, in science, referred to as . . . a material property that is independent of the thickness. The transmissibility tells you how much flux, or the Dk divided by thickness or the t. . . . [F]lux is analogous to transmissibility" ((a "near cousin" to transmissibility). (Tr. I at 175 (Winterton).) The "intrinsic value" of oxygen permeability does not depend on the shape or character of the material itself." (Tr. I at 197 (Winterton).)

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[13] CIBA cited the article to the United States Patent and Trademark Office ("USPTO") examiner on Re-examination in 2000, for the proposition that to "achieve an accurate (and reproducible) measurement of the high oxygen permeability, it was determined by the inventors . . . the oxygen permeability measurements were to be in accordance with the 'Coulometric Method.'" (PTX 300 ¶ 25 (Nicolson Decl.).) That the article was repeated as a book chapter in 1988 does not affect the Court's analysis of the relevance of the 1987 article. (See PTX 207.)

According to CIBA inventor Winterton, the '100 Patent's definition of "oxygen permeability" "flowed from a descriptor of transmissibility . . . [a]nd they were trying to delineate the difference in context between transmissibility and the Dk that would later be used" to help the reader differentiate between transmissibility which does depend on thickness, and permeability. (Id. at 197-98.) J&J's expert Benjamin defines oxygen permeability consistently: "[i]t's an intrinsic property of the lens material. And it doesn't depend upon the lens thickness or the shape of the lens or the design of the lens. The material has an oxygen permeability. . . . [I]t's . . . the rate at which oxygen will pass through the material under the standard conditions of the test." (Tr. V. at 24 (Benjamin).) Oxygen permeability, mathematically, does not have any dependency on thickness. (Tr. II at 189 (Pitt).)

Here, the parties do not dispute that the oxygen permeability of the Acuvue Oasys lens, when measured at various thicknesses, meets the oxygen permeability (and transmissibility) limitation values of the CIBA patents, with the exception of those few powers listed by CIBA. (Doc. 287 at 25-26, 80.)[14] J&J contends, however, that because the oxygen permeability of the Oasys varies with its thickness, it does not infringe. J&J seeks further construction of the term "oxygen permeability" to include a limitation that the Dk *value* of a highly permeable silicone hydrogel contact lens as measured by the single point coulometric

[14] Whether or not the water boundary, with an oxygen permeability of between 80 and 88 barrers, would work as a "barrier" for oxygen passing through a lens with a Dk of 70, which J&J argues disproves CIBA's position that "Dk always varies with thickness because of the boundary layer effect" (Doc. 303 at 10) is not dispositive of whether the Acuvue Oasys infringes upon the CIBA patent "oxygen permeability," "oxygen transmissibility" and "high oxygen permeability" claim limitations. The evidence established that the Dk and Dk/t of the Oasys falls within the patent limitations, with the exception of the few specific powers acknowledged by CIBA.

method, does not vary with or depend on the thickness of the lens. The flaw in this argument is that nowhere in the patent, the patent specifications, prosecution history,[15] or the state of the art in 1995, does it say that the value of the oxygen permeability of an extended wear silicone hydrogel lens, when measured by the single point coulometric method, may not vary

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[15] CIBA contends that the prosecution history for the '894 Patent, dated October 4, 2005, includes a reference to CIBA's post-trial proposed findings in the Georgia litigation which states that "[a]n apparent Dk will necessarily be a different number than an intrinsic Dk, and, in fact, will always be a significantly lower number. . . . An uncorrected or apparent Dk will also vary with the thickness of the sample." (Tr. I at 181-82; DTX 1445 ¶ 177.) Likewise, J&J cites to the 1987 Winterton article, cited to the USPTO in 2000 on re-examination, as relevant to its construction of oxygen permeability. (Doc. 286 at 14.)

"[T]he prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be." Phillips v. AWH Corp., 415 F.3d 1303, 1317 (Fed. Cir. 2005). While this intrinsic evidence found in the 2004 prosecution history clearly informs the interpretation of oxygen permeability in the '894 Patent, it is unclear how it can be applied to interpret the claim terms in the earlier patents. CIBA cites to case law which appears to permit such a retroactive application to a related patent. See Microsoft Corp. v. Multi-Tech Sys., Inc., 357 F.3d 1340, 1350 (Fed. Cir. 2004); see also Howmedica Osteonics Corp. v. Zimmer, Inc., No. 05-897 (WHW), 2008 WL 80403, at *10-11 (D.N.J. Jan. 2, 2008); Biovail Labs. Int'l SRL v. Abrika, LLLP, No. 04-61704-CIV, 2006 WL 6111777, at *1 n.8 (S.D. Fla. Aug. 24, 2006). The Federal Circuit states: "[w]e have held that statements made by the inventor during continued prosecution of a related patent application can, in some circumstances, be relevant to claim construction. [Citation omitted.] As with statements made by the inventor during the prosecution of an ancestor patent application, statements made during the continued prosecution of a sibling application 'may inform the meaning of the claim language by demonstrating how the inventor understood the invention.'" Ventana Medical Systems, Inc. v. Biogenex Labs., Inc., 473 F.3d 1173, 1184 (Fed. Cir. 2006)(citing Phillips, 415 F.3d at 1317)(noting that the utility of this analysis is diminished when the subsequent claim language is different)). Here, the assertion contained in the prosecution history to the '894 Patent is clearly applicable to assist in construing the '894 Patent claim term "oxygen transmissibility of at least about 70 barrers/mm," found in all four of the asserted '894 Patent claims. The subsequent prosecution history is consistent with the Court's interpretation of the language of the earlier patents, but is not necessary to its conclusion here.

with thickness. Rather, the '100 Patent defines "oxygen permeability" in its ordinary and mathematical meaning, and further specifies that oxygen permeability is to be measured using the single point coulometric method. The patent's mathematical definition of "oxygen permeability" in no way limits or dictates the results of the coulometric measurements or resultant values.

J&J's argument conflates the mathematical definition of "oxygen permeability" of "a lens material"[16] which does not vary with thickness, with the methodology for measuring oxygen permeability by the uncorrected single point coulometric method, which, for highly permeable lenses, does vary with thickness. J&J concedes that the intrinsic Dk of a contact lens does not vary with the thickness of that lens. That is how the patent defines oxygen permeability. "[T]he words of a claim 'are generally given their ordinary and customary meaning.'" Phillips v. AWH Corp., 415 F.3d 1303, 1312 (Fed. Cir. 2005)(citation omitted). Further, "the ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application." Phillips, 415 F.3d at 1313.

J&J's reliance on the 1987 Winterton article for the proposition that the CIBA patents teach that Dk does not vary with thickness is misplaced. The article demonstrated that the

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[16] The '100 Patent's definition, and the Court's construction of "oxygen transmissibility" states that it is dependent on thickness and is the rate at which oxygen will pass through "a specific ophthalmic lens." (Doc. 121 at 87.) In contrast, the "oxygen permeability" of "a lens material" does not depend on thickness and is the rate at which oxygen will pass through "a material." (Id. at 74, 87.) The placement of the two definitions in the '100 Patent, suggests that the definition of "oxygen permeability," defines the "Dk' used in the "oxygen transmissibility" ("Dk/t") formula as well as in the claims.

coulometric method was reproducible and provided an alternative means of permeability measurement. (Tr. II at 127-29 (Pitt); PTX 208 at V111923.) The article stated that

> boundary layer contributions were found to be insignificant for relevant thicknesses; as predicted by Fick's law. Measurement of commercially available hydrogels reinforces the observation that water content most commonly determines the oxygen transmission of the material.

(PTX 208 at V111923.) The article did not discuss the measurement of oxygen permeability in highly permeable silicone hydrogel lenses. (See id. at V111925 ("[m]aterials were generally commercially purchased hydrogel and RGP [rigid gas permeable] lenses").) Further, the higher permeability (Dk 63) material measured at one thickness in Table 1 was not the subject of the Table 4 graph upon which J&J relies, (Tr. V at 106 (Benjamin)), but rather, Table 1 reports a film material measured over at least six days, as an "example of good oxygen transmitting material[ ]," that illustrates "the high day-to-day reproducibility of the Dk and oxygen flux" with a low standard deviation. (PTX 208 at V111926.) The authors concluded, in full, that

> From the data given, this technique [coulometric method] of measuring oxygen flux, and resultant Dk's, has been shown to be extremely reproducible, thickness independent (for Dk), and fits the boundary layer predictions of Fick's law. That is to say, as the thickness of the sample increases, the contribution of the boundary layer becomes insignificant."

(Id. at V111931.)

Figure 4 of the article (id. at V111928), relied on by J&J, shows a very slightly decreasing Dk on a lens material with a very low Dk of 7 barrers. Like the football player running at a low rate of speed through a muddy end zone and then onto the field, the

boundary effect on a low Dk material is very small, and sometimes does not even show up in the data. (Tr. II at 186 (Pitt).) By contrast, the boundary effect on a high Dk lens (analogous to the speedy football player being slowed by the mud) has a much greater impact on the value of oxygen permeability as measured by the single point coulometric method. CIBA measured the Acuvue Oasys lens using the single point coulometric method and determined that Oasys met the Dk and Dk/t limitations of the asserted claims at nearly all thicknesses.

The Court finds that one of ordinary skill in the art would know that the single point coulometric measure of a highly oxygen permeable lens would vary with thickness because of the boundary effect. The patent, and to a certain extent Winterton's1987 article, inform this result. The patent simply defines oxygen permeability in its mathematical terms ("Dk, of a lens material does not depend on thickness"). However, this definition is not determinate of the oxygen permeability measurement results of a high Dk lens using the single point coulometric method.

J&J's interpretation of the patent would render the patent impossible and inoperable, because the single point oxygen permeability values of silicone hydrogel lenses with high oxygen permeability, as required by the CIBA patents, including CIBA's own commercial embodiment Focus Night & Day, will always vary with the thickness of the lens. (See Tr. V at 33, 68-70 (Benjamin).) In other words, no high oxygen permeability silicone hydrogel lens would ever infringe upon the limitations of the CIBA patents, according to J&J. An interpretation excluding a preferred embodiment "is rarely, if ever, correct and would require highly persuasive evidentiary support." Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576,

1583-84 (Fed. Cir. 1996); see also Helmsderfer v. Brobrick Washroom Equip., Inc., 527 F.3d 1379, 1383 (Fed. Cir. 2008)("case law generally counsels against interpreting a claim term in a way that excludes the preferred embodiment from the scope of the invention.").

The patent's definition of "oxygen permeability" ('100 Patent col.4 ll.58-63) and the Court's construction of "oxygen permeability" which did *not* include a reference to the single point coulometric method, (Doc. 121 at 74), is not determinative of infringement. It is merely a definition of oxygen permeability, understood by those skilled in the art in 1995. The Court's construction of the term "high oxygen permeability," which includes that it be "measured in accordance with the coulometric method described in the CIBA patent" (id. at 78), as well as all of the asserted claims, which refer to "high oxygen permeability," or specific oxygen permeability or transmissibility values, as measured by the coulometric method, all refer to the "apparent" Dk, which, as established by the patents, the prosecution history, and the evidence in this record, varies with thickness. CIBA has proven by the preponderance of the evidence that J&J's Acuvue Oasys lens infringes upon the "oxygen permeability," "high oxygen permeability" and "oxygen transmissibility" limitations of all asserted claims (with the exception of those few powers acknowledged by CIBA).

2. Lack of "surface modified by a surface treatment process"

J&J argues that CIBA has failed to prove by the preponderance of the evidence that the Acuvue Oasys lens meets the limitation "a surface modified by a surface treatment process" found in claims 1 and 28 of the '100 Patent and claims 28 and 29 of the '811 Patent, because the Oasys is a "monolith" with no separate surface treatment process.

The Court construed the claim term "surface treatment process" as follows:

> "Surface treatment process" is a process (or processes) to render a surface more ophthalmically compatible, in which, by means of contact with a vapor or liquid, and/or by means of application of an energy source (1) a coating is applied to the surface of an article, (2) chemical species are adsorbed onto the surface of an article, (3) the chemical nature (e.g. electrostatic charge) of chemical groups on the surface of an article are altered, or (4) the surface properties of an article are otherwise modified.

(Doc. 121 at 23.) This construction is the verbatim definition of "surface treatment process" lifted from the '100 Patent's specifications. (See '100 Patent col.42 ll.44-52.) The parties do not dispute that the Acuvue Oasys does not meet the first three enumerated types of "surface treatment process," and that the fourth category, "(4) the surface properties of an article are otherwise modified" is at issue here.

The *Markman* Order noted that the patent specifications describe "a variety of methods disclosed in the art for rendering a surface of a material hydrophilic," including coating or grafting onto a lens a hydrophilic polymeric material by using a "number of processes." "Another set of methods of altering the surface properties of a lens involves treatment prior to polymerization to form the lens," including treating a lens mold with an energy source "causing the prepolymerization mixture immediately adjacent to the mold surface to differ in composition from the core of the prepolymerization mixture." (Doc. 121 at 21 (quoting '100 Patent col.42 ll.53-67 to col.43 ll.1-3).)

CIBA expert Dr. Allen S. Hoffman ("Hoffman") testified that in his opinion, the Acuvue Oasys meets the claim term "surface modified by a surface treatment process" because of

the addition of PVP [polyvinylpyrrolidone],[17] which is a wetting agent, to the lens formula, which is then subjected to an energy source. (Tr. III at 74, 189-90 (Hoffman).) Hoffman testified that the PVP component in the Oasys lens is referred to as the additive "Hydra-Clear Plus" in the J&J advertisements of its product and on its internet website, which "show that if you put a drop of water on the surface of the lens it will spread over that surface, which is a very wettable surface. . . . very good evidence of the fact that there is a wettable surface on that lens.. . . They essentially say the additive makes the surface more wettable and moist." (Tr. III at 76-77 (Hoffman); see also Tr. VII at 199 (Valint)(HydraClear Plus refers to PVP that's immeshed in the lens).)[18] The addition of PVP to the Acuvue Oasys lens is the first step toward rendering the surface more ophthalmically compatible, according to CIBA.

Critical to understanding whether the Acuvue Oasys meets the "surface modified by a surface treatment process" claim term is an overview of the Oasys manufacturing process. First the ingredients that form the lens are mixed together in a liquid prepolymerization mixture, which involves mixing hydrophillic "HEMA" (6%), "DMA" (24%) and "PVP K90" (or "PVP") (7%)) with hydrophobic silicone compounds "SiGMA" (or "SiMAA2" or ""SiMAA") (28%) and "mPDMS" (31%)) with a solvent to disperse them and make them compatible

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[17] "Polyvinylpyrrolidone" ("PVP") is "a homopolymer that is produced by the polymerization of N-vinylpyrrolidone ["NVP"]." (Doc. 121 at 19.) The parties agreed to the construction of this term.

[18] "Wettability" is a surface phenomenon. It refers to the interaction of tears with the lens that is placed on-eye. (Tr. VII at 92 (Valint).) "Wettable" means "how the tears flow across the lens in the eye to make sure that it's a uniform film. And also . . . that it resists these globs and deposits in the tear film." (Tr. IV at 108 (J&J researcher Dr. David Carl Turner ("Turner")).) "[W]ettability is talking about the surface of the lens." (Tr. VIII at 67 (Valint); see also id. at 67-68.)

with one another.[19] The PVP K90 used in the Acuvue Oasys lens is a very hydrophilic ("water loving") water soluble large molecule, with a high molecular weight of 360,000. It comprises 7% (by weight) of the Acuvue Oasys lens. (Doc. 235-8 at 3 (stipulated list of ingredients).) The PVP is introduced into the prepolymerization mixture, and SiMAA2 serves as a small compatiblizing molecule. (Tr. IV at 27-28, 52, 66-68 (J&J scientist Dr. David Carl Turner ("Turner")); Tr. VII at 182-85, 192 (Valint).)

The mixture is then placed into plastic hydrophobic molds and irradiated with visible light, or "cured" by the application of an energy source. (Tr. VII at 211 (Valint); Tr. VIII at 66 (Valint); Tr. III at 190 (Hoffman).) The light reacts chemically and starts the polymerization process, during which the individual monomer materials knit together into long chains called polymers. (Tr. IV at 29-30,112 (Turner).) The mixture is "cured" by a "light-activated" curing process for 240 seconds, (plus a 30 second pre-cure) creating a network by crosslinking chains to form a mesh that entraps the long PVP molecules in it. (Tr. IV at 31, 78, 79 (Turner); Tr. III at 140 (Hoffman).) The PVP molecule is not "reactive," but rather is a large homopolymer that is entangled in a network formed by the other reactive ingredients during the cure or polymerization process. (Tr. III at 78 (Hoffman); Tr. VIII at 81 (Valint).) Once the lens is cured, it becomes a "gel material." (Tr. IV at 32 (Turner).) "So when the polymerization is complete, that entanglement . . . is permanently retaining that PVP by

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[19] The main chemical compounds in the mixture are 2-hydroxyethyl-2-methyl-2-propenoate ("HEMA"), N,N-dimethylacrylamide ("DMA"), Poly(1-vinylpyrrolidone) ("PVP K90" or "PVP"), hydrophobic silicone compounds 2-hydroxy-3[3-[1,3,3,3-tetramethyl-1-[(trimethylsilyl)oxy]disiloxanyl] propoxy]propyl-2-methyl-2-propenoate ("SiGMA" or "SiMAA2"), and Monomethacryloxypropyl Terminated (n-butyl)polydimethylsiloxane ("mPDMS"). (Doc. 235-8 at 3.)

physical interaction, just the entanglement. There's no chemical reaction." (Tr. VIII at 81 (Valint).)

The "cure" process is followed by the "extraction" step in which the lens is removed from the mold. Unwanted substances, such as unreacted ingredients, are removed. (Tr. IV at 32 (Turner).) The extraction step is vigorous, using a 70 percent isopropanol solution, a rubbing alcohol and water to clean the lens and extract impurities. (Id. at 32, 113; Tr. VII at 213 (Valint).) The extraction process lasts at least 30 minutes. (Tr. IV at 116 (Turner).)

The Acuvue Oasys lens is then "hydrated" by immersing the lens in a water and alcohol mixture, placed in a saline packing solution, packaged, and sterilized by "autoclaving." (Id. at 37-38, 113.) This step involves contact with a liquid. (Tr. VIII at 66 (Valint).) During "hydration," the lenses swell with the water like a sponge. (Tr. IV at 37 (Turner).)

One of the challenges encountered by J&J was keeping the hydrophillic PVP from leaching out of the lens during hydration. J&J chose the heavy-weight PVP molecule to better anchor the molecule in the polymerized network and avoid its leaching away upon hydration of the lens. (Tr. VII at 192 (Valint)(very large PVP molecule gets entangled into the polymer mesh).) The long PVP molecules provide "a very efficient way to get water content into the lens" and "tenaciously holds on to whatever water it brings in. . . And it provides wettability to the whole construct of the lens, the internal part . . . and provides wettability to the surface, too." (Id. at 190; see also Tr. IV at 45 (Turner).) At the end of the process, there is PVP throughout the lens, including in the bulk of the lens and at its surface. (Tr. IV at 106-07 (Turner); Tr. VII at 191 (Valint)(a portion of a PVP is going to be at the

surface).) Adding PVP to the composition, some of which rests at the surface of the lens, produces a very wettable, lubricious lens, contributing to the lens' ability to permit tears to flow across the lens in the eye and resisting globs and deposits in the tear film. "[T]he use of PVP in the formulation produces a lens that is wettable on the eye." (Tr. IV at 108-09 (Turner).) The Acuvue Oasys lens is more wettable and more ophthalmically compatible with the PVP wetting agent than without it. (Tr. VIII at 66, 68 (Valint).)

CIBA's expert testified that the hydration step causes the hydrophillic PVP molecule to migrate to the surface of the Oasys lens. "[A]t the end of the process of curing, when the network has been formed and the PVP is entangled in it, they [J&J] wash the lens with a mixture of water and isopropanol, at least an aqueous solution of some sort. And that helps to draw out the PVP to the surface." (Tr. III at 79 (Hoffman).) Being a non-reactive component of the lens, the PVP is "free to move." (Id. at 83.) "And when you wash that out with an aqueous solution, it's able to reptate its way . . . like a snake, reptate its way through the network and out of the lens. . . . [T]hat gets it to the surface . . . [and] helps to make the surface wettable." (Id. at 84, 140 (Hoffman).) The hydration would naturally attract PVP molecules, or segments, to the surface, where they would remain as the rest of the molecule is entangled in the bulk. (Id. at 83-84.) CIBA relies on a J&J internal document written about the J&J hydrogel lens Acuvue Advance.[20] That one-page document, entitled

[20] Counsel for J&J identified the document as relating to the Acuvue Advance lens. (Tr. III at 80.)

"HYDRACLEAR™"[21] describes PVP in the lens as follows:

> PVP is not covalently linked into the network; rather it is entangled in the crosslinked polymer network, since it was present (in solution with the other components) while the reactive monomer mix was polymerizing. It has limited mobility inside the bulk of the lens, and migrates ever so slowly out of the lens (<1.5%/month). The fact that it associates so well with water results in its great molecular mobility. . . . It is therefore very flexible in the crosslinked matrix where it acts as an internal wetting agent.) *Since it does migrate to the surface, it contributes to the wettability at the surface of the lens as well.*

(DTX 85 (emphasis added); see also DTX 289 (J&J 2005 memorandum discussing HYDRACLEAR™ "breakthrough technology that combined the oxygen transmissibility of silicone with exceptional wettability and low modulus from an internal wetting agent (PVP)").

CIBA acknowledges that migration of PVP in the Acuvue Oasys does not occur during the "cure" step, and that after "curing" the polymer mesh is fully formed. (See (See Tr. III at 139-40 (Hoffman).) CIBA's position is that J&J's use of nonreactive PVP in the formulation, coupled with J&J's manufacturing process involving the application of an energy source during the "cure" step and contact with liquid during the extraction and hydration steps, results in the Acuvue Oasys lens surface being more wettable and ophthalmically compatible. The use of a nonreactive polymeric additive such as PVP to "modify" the surface has been commonly understood to be a "surface treatment process,[22] argues CIBA,

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[21] CIBA expert Hoffman testified that the same scientific principles that apply to HydraClear also apply to HydraClear Plus, which is a component of the Acuvue Oasys lens. And, because HydraClear Plus has "more PVP . . . that even enhances its driving force to get to the surface." (Tr. III at 85 (Hoffman).)

[22] (See generally DTX 1273 at V072880 (Ward, Robert S., "Surface Modification Prior to Surface Formation: Control of Polymer Surface Properties via Bulk

and meets the "surface modified by a surface treatment process" limitation. (Doc. 311 (Tr. 17, 19).)

In response, J&J characterizes the Acuvue Oasys as a "monolith." J&J expert Valint testified that the Oasys "is inherently wettable because of its composition. . . . There is no process there that involves surface treatment" or a modified surface, argues J&J. (Tr. VII at 197 (Valint); Doc. 311 (Tr. 69).) The addition of PVP does not constitute a surface treatment, but rather is a part of a monolithic inherently wettable lens. (Tr. VII at 92, 199 (Valint).) To J&J, a "surface treatment" as defined in the CIBA patent is "an additional process step beyond what is commonly used for soft contact lenses." (Tr. IV at 117 (Turner); PTX 1019.)

In support of its monolith argument, J&J cites to x-ray photoelectron spectroscopy ("XPS") testing done by CIBA to determine and compare the concentration of nitrogen atoms, an element found in PVP, on the surface with the bulk of the Acuvue Oasys. J&J contends that the test establishes that the amount of nitrogen at the surface of the Oasys lens is not greater than the amount to be expected if the Acuvue Oasys were a homogeneous material with PVP evenly distributed throughout, and not enriched at the

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Composition," *Medical Plastics and Biomaterials*, Spring 1995 (scientific article discussing methods for selectively modifying polymer surfaces, including surface-modifying additives causing the surface to "develop" "as the additive diffuses from the bulk to the surface region"); Tr. III at 110-11 (Hoffman)); DTX 1278 (U.S. Patent No. 6,348,507 issued Feb. 19, 2002 ("Surface Treatment of Silicone Hydrogel Contact Lenses") col.1 ll.47-53 ("The patent literature has disclosed various surface treatments for rendering the surface of silicone lenses more hydrophilic and more wettable, including changing the chemistry of the surface layer, coating the surface, and compounding the polymer with additives that subsequently diffuse to the surface").)

surface. (Doc. 286 at 28; Tr. III at 169-83 (Hoffman); Tr. VII at 206-07 (Valint)(CIBA testing shows surface of Acuvue Oasys is "essentially the same or slightly less in terms of the total nitrogen as the calculated total lens . . . formulation"); Tr. VIII at 74-77 (Valint); PTX 501.) J&J also cites to a "contact angle" test which it performed and which it contends illustrates that the wettability of the surface of the Acuvue Oasys lens is the same as the wettability of the core, measured on an exposed portion of the lens' bulk material. (Doc. 286 at 28; Tr. VII at 201-04 (Valint); Tr. III at 148-49 (Hoffman).)

J&J expert Valint disagrees with CIBA's migration theory, asserting that the large size and weight[23] of the PVP molecule precludes migration "because it is being effectively entangled into the network of the polymer that's being built from the rest of the constituents of the Oasys formulation . . . essentially locking that . . . into that total construct." (Tr. VII at 209-10 (Valint).) Further, J&J contends that "[i]f the PVP were to migrate to the lens surface, the PVP would simply be washed away and therefore leave the lens altogether, decreasing its water content." (Doc. 286 at 28.) J&J argues that the stability of the PVP is confirmed by the fact that the Acuvue Oasys has a shelf life of six years, and retains a water content of 38 percent during that period. However, J&J expert Valint conceded that as a result of the polymerization process, there is a distribution of molecular weights of PVP - some very big, and some small - and that "[t]he small ones will leach out of the lens during the processing of the material, yes, during the extraction process." (Tr. VIII at 79-80 (Valint).)

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[23] PVP, at molecular weight of 360,000, is more than 300 times larger than the next largest molecule of the other ingredients that make up the polymer network. (Tr. VII at 192 (Valint); PTX 1130.)

The Court holds that "surface modified by a surface treatment process" requires a showing that a lens is more ophthalmically compatible with the surface treatment process than without it, and that, by means of contact with a vapor or liquid, *and/or* by means of the application of an energy course, the surface properties of the lens are modified. The components of surface treatment process - "contact with liquid or vapor" and/or "application of an energy source" are not required by the patent to be applied to the surface of the lens. (Tr. III at 75 (Hoffman).) A "surface modified by a surface treatment process" is not limited to a post-manufacturing process, nor does it require that the surface of the lens be more hydrophillic than the core. The Court finds that the surface of the Acuvue Oasys is more ophthalmically compatible as a result of the addition of the non-reactive molecule PVP plus the process by which the PVP molecule is entangled in the polymer mixture of the lens allowing portions of the hydrophillic wetting agent to remain at the surface of the lens.[24]

That the Oasys' PVP wetting agent is non-reactive distinguishes the Acuvue Oasys

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[24] A J&J Phoenix R&D Technical Report # 1407 dated January 12, 2004 is a report about the use of "Pharmaceutical Grade PVP K-90 . . . in senofilcon A Reactive Monomer Mix, referring to the J&J HydraClear Plus formulation. (Tr. III at 107 (Hoffman); DTX 1446.) That report states that

> Senofilcon A is a silicone hydrogel material being developed for the manufacture of higher Dk contact lenses. One of the components of this formulation is poly(vinylpyrrolidone) K-90 (PVP K-90). PVP K-90 is a non-functional polymer that forms an interpenetrating network (IPN) within the cured lens material. It is hydrophilic and is one of the chief drivers in the formulation to increase lens water content. It also contributes to a lower dynamic contact angle of the lens to water, which is an indicator of the lens wettability.

(DTX 1446 at W120010.)

lens from non-surface treated lenses cited by J&J, including CIBA patent Example D-2 ('100 Patent col.59 l.58-col.60 l.13 and col.68 Table G) and prior art conventional hydrogels with no surface treatment. (See Doc. 286 at 30.) These comparisons are inapposite because their wetting agents - DMA and methacrylic acid - are reactive "ionoperm polymerizable materials," while the PVP in the Acuvue Oasys is non-reactive, remaining a homopolymer throughout the manufacturing process.

The addition and presence of PVP in the lens in and of itself does not constitute a "surface treatment process." The evidence establishes that the "cure" step - with its application of an energy source in the form of light - entangles the large (long) and heavy PVP molecule in the bulk, preventing it from escaping out of the lens in its entirety when the lens is exposed to liquid during hydration, storage and wear. As a result of the "cure," through the application of an energy source, a portion of that anchored PVP molecule is positioned at the surface.[25] This PVP at the surface makes the surface hydrophilic and wettable, and thus more ophthalmically compatible. (See DTX 154 at V830422 (J&J "Phoenix" diagram illustration of lens entitled "PVP: Wetting Agent"); Tr. IV at 106 (Turner)("all the materials are uniformly mixed, there's PVP in the middle of the lens, there's PVP pieces - bits and pieces, loops, whatever, near the surface of the lens. It's all throughout.").) "[T]he very fact that you put PVP into the formulation means that some of it

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[25] CIBA's relies only upon the opinion of its expert and one page from a J&J document about a related, but different, contact lens as support for its "migration" theory. It has adduced no evidence proving that the PVP molecule "migrates" or "reptates" to the surface during hydration. The Court does not base its decision on this theory. Rather, the application of the energy source during the "cure" alone satisfies the "surface treatment" limitation which is written in the disjunctive.

is . . . at or near the surface, some of it is in the bulk. And that obviously plays a role in the wettability." (Tr. IV at 108-09 (Turner); Doc. 311 (Tr. 72).) The goal of the Oasys "surface treatment process" was to lock the PVP (HydraClear Plus) into the lens, permitting it to remain in and at the surface of the Oasys lens to provide wettability, while preventing the PVP from leaching out of the lens. (See Tr. IV at 106 (Turner)(the higher molecular weight PVP is used so it will be trapped in the mesh or network within the lens and will not leach out).)[26]

The CIBA claim term does not require that there be a post-manufacturing "surface treatment process," or that the surface be more hydrophillic than the bulk. (See Tr. III at 115 (Hoffman)("It doesn't matter what the core is like. What really matters is that the surface is more wettable than it was before you added the PVP"); id. at 134 ("If you have modified the wettability of the surface by adding PVP to the system, whether there's more or less on the surface than the bulk doesn't matter. You have modified the wettability of the surface. That's a surface treatment process.").) Other non-asserted claims in the patent series specifically express this "post manufacturing" limitation which is not to be imported into the

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[26] The Court does not find the statement made in a report by former CIBA scientist Fiona Carney, that "Acuvue Advance and Oasys do not have a surface treatment" (PTX 633 at CSFJ962140) to be determinative. That report, entitled "Lipid fouling of commercially available Silicone Hydrogel Lenses", dated October 14, 2005, stated that "[t]his lack of surface treatment may provide a more irregular surface with silicone blooms on the surface, increasing the amount and variability of lipid affinity." (Id.) Carney testified that she based the statement that Oasys does not have a surface treatment on what she read in the J&J patent, that she had no expertise to conclude whether or not the Acuvue Oasys had a "surface treatment" such that it would or would not meet CIBA claim terms, and that her paper was making a hypothesis concerning lipid deposits on lenses without a surface treatment based on what she had read in the literature. (Tr. VII at 72-78.)

asserted claims. (See '461 Patent cls. 1, 12, and 14). Seachange Int'l, Inc. v. C-COR, Inc., 413 F.3d 1361, 1368 (Fed. Cir. 2005)("The doctrine of claim differentiation stems from 'the common sense notion that different words or phrases used in separate claims are presumed to indicate that the claims have different meaning and scope.'" (citation omitted)). The surface "modification" occurs during the "surface treatment process" as the lens and its surface are being formed, not after. (See DTX1273.)

The Court's holding that the Acuvue Oasys meets the "surface modified by a surface treatment process" limitation in the CIBA patents does not come without reservation. The CIBA specifications do not appear to contemplate a very hydrophillic homopolymer being entangled in the network of polymers during polymerization and lodging, in part, at the surface as a result of the polymerization process. Rather, the CIBA specifications refer to either a post-manufacturing "coating" or "grafting" of a material on the surface, or "altering the surface properties of a lens involv[ing] treatment *prior* to polymerization to form the lens." J&J does neither of these - it adds PVP to the initial mixture, and polymerizes the mixture such that the non-reactive PVP does not polymerize but gets entangled in the materials that do. Without question, J&J's use of high molecular weight PVP, its "cure" process, and the resultant structure of the Acuvue Oasys lens is innovative; no other silicone hydrogel lenses have this. (Tr. X at 50 (CIBA expert Dr. Jimmy Wayne Mays ("Mays")).) But, while J&J has succeeded in constructing an innovative lens that is different from CIBA's commercial embodiment of its invention, or even the embodiments described in the patent specifications, J&J's invention, nevertheless falls within the broad scope of CIBA's claims, which defines the scope of CIBA's right to exclude. The accused product, the Acuvue Oasys, must be

compared to the claim language as interpreted. Cybor Corp. v. FAS Technologies, Inc., 138 F.3d 1448, 1454 (Fed. Cir. 1998). "'It is the claims that measure the invention,'" Amgen Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313, 1325 (Fed. Cir. 2003)(citation omitted), and the claims are not to be limited to the embodiments disclosed in the specification. Id., at 1328. "[T]he scope of the asserted claims may be ascertained from the plain language of the claims." Prima Tek II, L.L.C. v. Polypap, S.A.R.L., 318 F.3d 1143, 1151 (Fed. Cir. 2003).

The "law allows for after-arising technology to be captured within the literal scope of valid claims that are drafted broadly enough." Innogenetics, N.V. v. Abbott Labs., 512 F.3d 1363, 1371-72 (Fed. Cir. 2008); see also, Superguide Corp. v. DirecTV Enterprises, Inc., 358 F.3d 870, 876-79 (Fed. Cir. 2004)(patent terms did not limit the scope of the claimed invention to analog technology, but rather, covered digital signals; patentees were aware of the existence of analog and digital signals and did not explicitly limit the disputed claim language to technologies that were "conventional" at the time of the invention).[27] "'The law 'does not require that an applicant describe in his specification every conceivable and possible future embodiment of his invention.'" Superguide Corp., 358 F.3d at 880 (quoting SRI Int'l. v. Matsushita Elec. Corp. of America, 775 F.2d 1107, 1121 (Fed. Cir. 1985)). The broad language of the term as construed - "the surface properties of an article are otherwise modified" - reaches the J&J's Acuvue Oasys lens; the broad coverage of the "surface modified by a surface treatment process" limitation, as construed, affords CIBA the right to

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[27] J&J does not challenge the broad claim term as being invalid for lack of enablement or written description, or for indefiniteness. See SmithKline Beecham Corp. v. Apotex Corp., 403 F.3d 1331, 1340-41 (Fed. Cir. 2005).

exclude J&J's Acuvue Oasys lens. CIBA has proved by a preponderance of the evidence that the Acuvue Oasys infringes upon the "surface modified by a surface treatment process" term found in '100 Patent cls. 1, 28 and '811 Patent cls. 28., 29.

3. Lack of "polyvinylpyrrolidone at a surface of said lens"

Dependent claim 96 of the '894 Patent recites: "The contact lens of claim 89 further comprising polyvinylpyrrolidone [PVP] at a surface of said lens." J&J contends that to infringe upon this claim, the accused contact lens must have the entire molecule of PVP at the surface of the lens. CIBA argues that the claim term does not require that the entire molecule be at the surface, and that the claim term is met by J&J's Acuvue Oasys because a portion of the PVP molecule rests at its surface. (See Tr. III at 74, 126-27 (Hoffman).) Neither party sought construction of the limitation PVP "at a surface" of the lens during the *Markman* proceedings; they both seek a construction of the term now.

J&J contends that claim 96 requires the "homopolymer" PVP be at the surface of the lens, "not simply a few NVP chemical groups that form a portion of the PVP" at the surface. (Doc. 303 at 15.) "The evidence established that while some NVP units contained within the homopolymer are at the surface of the Oasys lens, the entire PVP homopolymer molecules are not." (Doc. 286 at 31 (citation omitted).) CIBA expert Valint testified that "a portion of a PVP molecule is going to be at the site. It . . . better not be totally there, because it won't remain there." (Tr. VII at 191 (Valint); see also Tr. IV at 106-08 (Turner)(bits and pieces of PVP at the surface of the lens); Tr. III at 78 (Hoffman)(PVP "ends up at the surface of the [Oasys] lens").) "[O]nly a small portion . . . of that [PVP] molecule can reside . . . at or near the surface, because otherwise it would be lost. . . . [A] major share of the molecule has to

be entangled into the lens matrix in order for it to remain and be a stable contact lens." (Tr. VIII at 79 (Valint).

J&J cites the F-Examples of the '100 Patent ('100 Patent col.64 l.60-col.67 l.40), which teach that "the lens surface is coated with polyvinylpyrrolidone," as the only CIBA patent disclosures teaching PVP "at a surface." The examples disclose a lens with a "PVP co-polymer" with crosslinks covalently and chemically attached to the surface of the lens as "a covalently bound coating." (Doc. 286 at 31.) According to J&J, the F Examples demonstrate that claim 96 teaches that the entire PVP molecule must be at the surface of the lens. J&J expert Valint opines that the Acuvue Oasys does not infringe upon claim 96 of the '894 Patent because "[t]he CIBA patent is teaching coating by plasma polymerization [of] an existing contact lens. And that . . . co-polymer of polyvinylpyrrolidone is being chemically attached during this formation in the plasma chamber. J&J is teaching mixing all the ingredients together, putting them in the molds, and you just get a physical entanglement that does not allow the PVP to escape out of the lens." (Tr. VIII at 81-83 (Valint)(discussing the surface treatment in the F Examples).) CIBA responds that the F Examples teach a surface treatment process which results in a homopolymer PVP at the surface of the lens that is produced by the polymerization of NVP. (Tr. 1 at 153-56 (Winterton); Tr. X at 33, 57, 59, 61 (Mays).) CIBA cites by contrast to claim 97 of the '894 Patent which teaches a contact lens dependent upon claim 96 "wherein said polyvinylpyrrolidone coats said surface of said lens."

J&J's discussion of the structure of one of CIBA's preferred embodiments is not determinative of the construction here. See Phillips, 415 F.3d at 1323 ("although the

specification often describes very specific embodiments of the invention, we have repeatedly warned against confining the claims to those embodiments"); Comark Communications, Inc. v. Harris Corp., 156 F.3d 1182, 1187 (Fed. Cir. 1998)("'[a]lthough the specification may aid the court in interpreting the meaning of disputed claim language, particular embodiments and examples appearing in the specification will not generally be read into the claims'")(citation omitted). Further, under the doctrine of claim differentiation, 'the presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim.'" Halliburton Energy Services, Inc. v. M-I LLC, 514 F.3d 1244, 1251 n.3 (Fed. Cir. 2008)(quoting Phillips, 415 F.3d at 1315). Inasmuch as claim 97 is dependent upon claim 96, the limitation in the latter claim creates the presumption that the PVP referred to in claim 96 is not to be characterized to require that the PVP "coats said surface" as J&J suggests. J&J has presented no evidence to overcome that presumption.

J&J's proposed construction of the term "PVP at a surface" as meaning that the entire PVP molecule must be located at the surface of the lens results in an impossibility; if the entire hydrophillic molecule were lying at the surface, it would wash away.[28] Thus, pursuant to J&J's claim construction, no contact lens would ever meet the CIBA claim limitation or infringe upon it. (Tr. VIII at 83-84 (Valint).) "'[A] construction that renders the

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[28] As discussed above, the hydrophillic homopolymer PVP leaches out of the lens when in an aqueous environment, such as the eye, unless that elongated PVP molecule is somehow anchored or "entangled" by the network of polymers. (See Tr. VII at 231 (Valint); see also Tr. IX at 144 (CIBA inventor Dr. Paul C. Nicolson ("Nicolson"))("[i]f you just laid the PVP on the surface, it would dissolve off" if it were not attached to the lens).)

claimed invention inoperable should be viewed with extreme skepticism.'" Cordis Corp. v. Medtronic Ave, Inc., 511 F.3d 1157, 1174 (Fed. Cir. 2008)(citation omitted), cert. denied 129 S.Ct. 201 (2008); cf. Honeywell Int'l, Inc. v. Int'l Trade Comm'n, 341 F.3d 1332, 1341 (Fed. Cir. 2003)("an inoperable claim construction would render the claim invalid for lack of enablement").

The Court agrees with CIBA that the claim language says PVP "*at* a surface of said lens" and not PVP "*on* a surface." The Court declines to import a limitation into claim 96 of the '894 Patent that requires that the entire molecule of PVP be lying "at a surface" of the lens. See N. America Container, Inc. v. Plastipak Packaging, Inc., 415 F.3d 1335,1348 (Fed. Cir. 2005)("unless required by the specification, limitations that do not otherwise appear in the [patent] claims should not be imported into claims"). The Court holds that "polyvinylpyrrolidone at a surface of said lens" requires that some portion of the PVP homopolymer molecule be present at the surface of the lens, and finds that under this construction, CIBA has proven by a preponderance of the evidence that the Acuvue Oasys meets this limitation.

4. Lack of phases

Three asserted claims from the '100 Patent teach that the patented contact lens has "phases." ('100 Patent cls. 1, 28, 56.) Independent claims 1 and 56 both include the following "phase" limitation: . . .

> wherein said oxyperm polymerizable material forms a phase or phases substantially separate from the phase or phases formed by said ionoperm polymerizable material . . .

('100 Patent cls. 1, 56) Claim 28 is dependent on claim 1. The parties agreed to the following construction of the claim term "phase":

> A "phase", as used herein, refers to a region of substantially uniform composition which is a distinct and physically separate portion of a heterogeneous polymeric material. However, the term "phase" does not imply that the material described is a chemically pure substance, but merely that certain bulk properties differ significantly from the properties of another phase within the material. Thus, with respect to the polymeric components of a lens, an ionoperm phase refers to a region composed of essentially only ionoperm polymer (and water, when hydrated), while an oxyperm phase refers to a region composed of essentially only oxyperm polymer.

(Doc. 121 at 17.) It is the verbatim recitation of the definition of "phase" found in the specifications. (See '100 Patent col.5 ll.20-31.)[29] The Court construed the claim term "phases substantially separate" to mean "at least two 'phases' as 'phase' is previously defined." (Doc. 121 at 41-42.)

Relevant to the issue of "phases" are the terms "oxyperm polymerizable material" and "ionoperm polymerizable material," which describe the material comprising the phases. ('100 Patent cls. 1, 28, 56.) The patent specifications specifically define these terms as follows:[30]

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[29] The Court declined to further construe several phrases within the definition of "phase." The Court rejected J&J's requests to further construe: the phrase "region of substantially uniform composition" to require "very near consistency of chemical composition throughout"; the phrase "distinct and physically separate portion of a heterogeneous polymeric material" to require "an identifiable boundary"; and "essentially only ionoperm polymer" and "essentially only oxyperm polymer" as "almost pure" with only "minor impurity." (Doc. 121 at 34-41.)

[30] The Court declined to further construe the terms. (Doc. 121 at 96-99.)

oxyperm polymerizable material:

> A "polymerizable material which is capable of polymerizing to form a polymer having a high oxygen permeability" as used herein, refers to monomers, oligomers, macromers, and the like, and mixtures thereof, which are capable of polymerizing with like or unlike polymerizable materials to form a polymer which displays a relatively high rate of oxygen diffusion therethrough. For convenience of reference, these materials will be referred to herein as "*oxyperm polymerizable materials*" and the resultant polymers will be referred to herein as "oxyperm polymers".

('100 Patent col.4 ll.40-50 (emphasis added)) and

ionoperm polymerizable material:

> A "polymerizable material which is capable of polymerizing to form a polymer having a high ion permeability" as used herein, refers to monomers, oligomers, macromers, and the like, and mixtures thereof, which are capable of polymerizing with like or unlike polymerizable materials to form a polymer which displays a relatively high rate of ion or water permeation therethrough. For convenience of reference, these materials will be referred to herein as "*ionoperm polymerizable materials*" and the resultant polymers will be referred to herein as "ionoperm polymers".

('100 Patent col.5 ll.3-12 (emphasis added)).

Related to the claim term "phase" is the term "pathways," also found in asserted claims 1, 28 and 56.[31] The patent specifications refer to the term "pathways" concurrently with "phase," shedding light upon the function of a "phase":

> The existence of separate oxyperm and ionoperm *phases*, rather than a complete blend of oxyperm and ionoperm *phases*, is believed to be advantageous in promoting the diffusion of oxygen and ions. Oxygen will diffuse predominantly through the

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[31] Independent claims 1 and 56 provide: "wherein said lens allows ion or water permeation via ion or water pathways . . . ." ('100 Patent cls. 1, 56.)

> oxyperm polymer, while the ionoperm polymer provides a higher barrier to oxygen diffusion. Similarly, ions will diffuse well through the ionoperm polymer, but the oxyperm polymer provides a higher resistance to ion diffusion. Thus, one homogeneous oxyperm/ionoperm *phase* will provide undesirable resistance to both oxygen and ion diffusion, while two separate oxyperm and ionoperm *phases* will provide low resistance *pathways* for transmission of both oxygen and ions or water. Thus, the ideal extended-wear lens has a *pathway* or series of *pathways* from the outer surface to the inner surface for transmission of oxygen therethrough, and an analogous *continuous pathway* or series of *pathways* for transmission of water or ions therethrough. In a particularly preferred embodiment, the lens has two co-continuous *phases*, one an oxyperm *phase* and the other an ionoperm *phase*, allowing for permeation of water or ions and oxygen between the front and base curves of the lens.

('100 Patent col.8 ll.40-61 (emphasis added).) The Court, however, declined to construe "pathway" as being interchangeable with the term "phase," observing that "'pathways' refers to and defines the function of 'phases' as opposed to the chemical composition." (Doc. 121 at 43-46.) The Court construed "pathways" and "continuous pathways" to mean

> a polymer region that extends from the outer surface of the lens to the inner surface of the lens providing a course for transmission of oxygen therethrough, or transmission of water or ions therethrough.

(Doc. 121 at 46.)

CIBA argues that the preponderance of the evidence establishes that the Acuvue Oasys meets this CIBA claim specification requiring substantially separate phases of oxyperm polymerizable material and ionoperm polymerizable material. J&J contends that CIBA has not proven the existence of separate phases in the Oasys lens.

CIBA relies on the testimony of its experts Dr. Samuel Patrick Gido ("Gido") and Dr.

Mays which it says supports a finding that the Acuvue Oasys has separate phases. The basis for CIBA's phase theory is that the Oasys lens is comprised of oxyperm materials mPDMS and SiMAA, and ionoperm materials DMA and HEMA . (Tr. II at 197 (Gido); Docs. 235-8 at 3; 286 at 35.) "[I]n general, unlike materials will want to separate from one another." (Tr. II at 197 (Gido).) The polymers comprising the Oasys lens, however, will not separate completely (like oil and water) "because the polymers themselves are very viscous. . . . So those very beginnings of the separation of oil and water, when there's tiny, tiny little droplets, would be frozen in the polymer system due to increasing molecular weight and crosslinking." (Id. at 198.) Gido illustrated his opinion with a graphic of "phase separated morphology" which depicts a "general representation" of a material with "light regions and dark regions." (Id. at 199; D. Dem. 19; see Appendix B.) The illustration shows a "kind of a maze," which Gido stated was not inconsistent with the patent's use of the word "pathway." "[T]his is kind of like a maze rather than a straight shot. A maze also has a pathway. It's just not a straight pathway." (Tr. II at 216 (Gido).)[32] According to CIBA expert Mays, who also opined that the Acuvue Oasys is "phase-separated," the ingredients which include a combination of hydrophobic and hydrophilic materials will not mix upon polymerization, but instead "they'll separate into separate phases." (Tr. III at 202 (Mays).) "The system phase-separates and crosslinks simultaneously. So the phase-separated structure, as it's forming,

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[32] In describing his testing of the Acuvue Oasys, Gido said "when we first started work on this case, the main issue . . . focused on was this continuity of phases. And, in fact, that's a more difficult thing to show than that there just are phases. First of all, you have to show that there are phases, but now we get into the analysis of whether this interwoven maze . . . constitutes an actual pathway that you can follow across the lens." (Tr. III at 52-53 (Gido).)

is being locked in as it's [being] phase-separated." (Tr. VIII at 230 (Gido).) According to Gido, a "phase" is 30 to 50 nanometers ("nm") wide.[33] (Tr. III at 15 (Gido).)

J&J argues that separate phases are not necessary for its extended wear silicone hydrogel contact lens Acuvue Oasys to function. (Doc. 286 at 35.) "[T]he single phase can . . . have permeability to very small molecules like water and oxygen" and a single phase Oasys lens can have oxygen and water diffusing through it. The lens' high water content is evidence that water passes through the single phase. And oxygen permeates through the whole single phase, which contains high oxygen permeable silicone throughout. According to J&J, the materials comprising the Oasys lens make it "inherently permeable," which is further evidenced by the fact that oxygen was able to pass through classic conventional hydrogel lenses that did not have a "silicone phase" or a "continuous pathway." (Tr. VII at 178-81 (Valint).)

J&J's experts contend that the chemistry of the Oasys lens results in it not having phases. Specifically, J&J expert Dr. Frank S. Bates ("Bates") testified that the Oasys' use of the very large PVP molecule, the low-weight mono-functional siloxane (mPDMS polydimethylsiloxane monomer), and a compatiblizer (SiMAA2) allows Oasys lens to remain homogeneous. (Tr. VI at 13 (Bates); PTX 1084; see also Tr. VI at 28 (Bates); Tr. IV at 67-68 (Turner).) According to J&J, the differences between the composition of the cured Oasys lens and the lens taught by the CIBA patents establish that the Oasys does not have "substantially separate" phases of oxyperm polymerizable material and ionoperm

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[33] For comparison purposes, a human hair is 100,000 nanometers across. (Tr. VI at 128 (J&J expert Dr. John Phillip Bradley ("Bradley")).)

polymerizable material. (See PTX 1126.) First, the silicone (oxyperm) PDMS macromer used in the Oasys is smaller and functional at one end only, making it "significantly different," from the di-functional crosslinking macromer PDMS used in the CIBA lens. Second, the Oasys lens is a "wettable construct" while the CIBA patent, in order to be a wettable lens suitable for extended wear, must be surface-treated. (Tr. VII at 183-86 (Valint).) Further, according to J&J, the Oasys lens is able to overcome the tendency of hydrophilic and hydrophobic materials to repel and not mix by using the silicone monomer SiMAA2 as a "compatibilizer" molecule and "compatibilizing diluent" D3O to "allow the hydrophilic and hydrophobic ingredients in the Oasys to mix intimately together to create a homogeneous material." (Doc. 286 at 35; Tr. IV at 67-68 (Turner); Tr. VII at 184 (Valint).) The final ingredient contributing to the homogeneity of the Oasys is the addition of a crosslinker small di-functional molecule that knits the polymers that form during the curing step. (Tr. VII at 184-85 (Valint).) "You want these materials to mix as intimately as possible. You definitely do not want them to separate. . . . [W]hen they separate, light starts to scatter [and] you get haze." (Tr. IV at 68 (Turner).) Valint opined that the Oasys construct does not have a phase structure. "I believe this is a homogeneous, single-phase system, and because of this unique blend of materials, with their attributes, provid[ing] a very high level of compatibilization, resulting in the homogeneous mixture and the homogeneous lens." The PVP in the Oasys provides "a very efficient way to get water content into the lens," providing wettability to the whole construct of the lens." (Tr. VII at 190 (Valint).)[34]

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[34] CIBA expert Mays disagreed, testifying that while SiMAA2 maintains the miscibility of the incompatible monomer combinations, "it's not a potent enough compatibilizer to

CIBA expert Gido relies upon a series of four tests performed on the Acuvue Oasys which he says supports his opinion that the Oasys is phase-separated: Differential Scanning Calorimetry ("DSC"), Field Emission Gun Scanning Transmission Electron Microscopy ("FEGSTEM"), Energy Dispersive X-Ray Spectroscopy ("EDX"), and Atomic Force Microscopy ("AFM"). (See D. Dem. 22.)

The DSC test detects transitions that occur to materials as they are heated. (Tr. II at 201-02 (Gido).)[35] The glass transition temperature ("Tg") of a polymer is the temperature at which the material will change from hard to soft when heated, or from soft to hard when cooled. (Id. at 202; Tr. VI at 59 (Bates).) According to Gido, different phases in a material will have different glass transition temperatures; thus a homogeneous material will have one glass transition temperature and a two-phase material will have two glass transition temperatures. (Tr. II at 203 (Gido).) Gido testified that he conducted two DSC test runs on the dried Acuvue Oasys, heated from -150 decrees C to +100 degrees C. (Id. at 203-04.) According to Gido, the Oasys had two glass transition temperatures, one at -119 degrees C and another at +36 degrees C. (DTX 432B.) Gido conducted a second DSC test starting at -160 degrees C, which he said evidenced glass transition temperatures at -122 degrees C and +34 degrees C. (DTX 432C, 432D; see Tr. VIII at 197 (Gido).) In Gido's opinion, the very low glass transition temperature is characteristic of a material that is very soft under

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retain miscibility once the material is polymerized." (Tr. III at 212 (Mays).)

[35] Gido said he conducted the DSC test on the Acuvue Oasys at the end of his work in this case because J&J expert Bates criticized him for not including the test in his earlier report. (Tr. III at 53 (Gido); Tr. VI at 85 (Bates).)

normal conditions at room temperature, consistent with a highly oxygen permeable siloxane material such as PDMS, a known oxyperm material which has a reported glass transition temperature of about -120 to -125 decrees C. The higher glass transition temperature (36 degrees C) is representative of an ionoperm polymerizable phase. CIBA expert Gido opined that two glass transition temperatures is "suggestive of phase separation." (Tr. VIII at 223 (Gido); see also Doc. 287 at 38 (DSC test "appeared to show two glass transition temperatures").)

J&J challenges the DSC test as producing "widely varying and unreliable results." (Doc. 286 at 39 (citing DTX 635 showing that CIBA SEE3 testing of materials Betacon and Glycon had one glass transition temperature)[36] (Tr. III at 37 (Gido).) J&J expert Bates believes that the lower temperature "dramatic" "glass transition" in Gido's exhibit is due to "something unrelated to the response of the material," though he conceded that Gido's glass transition at -119 degrees C is very close to the range of published results for oxyperm material mPDMS, and similar to the CIBA patent preferred embodiment teaching an oxyperm material with a glass transition temperature of less than or equal to -115 degrees C. (Tr. VI. at 88-89 (Bates); Tr. III at 58 (Gido).) Bates said that "transition" data occurring in the first 25 degrees of heating the sample before the sample "adapts" is "not generally reliable." Further, he questioned Gido's tangent lines as "conventional" and another as an upper curve "extraordinarily broad transition," far wider than a typical glass transition, demonstrating that

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[36] CIBA disputes J&J's inference, pointing out that there is no foundation in the record regarding these tests which may not be comparable to DSC used here. (Doc. 302 at 20; Tr. III at 33-35 (Gido).)

the "phase" is not "essentially pure." (Tr. VI at 60-64, 89 (Bates).) According to Bates, the existence of two glass transitions is not always indicative of the presence of phases. (Id. at 59-60.)

The second test is known as a FEGSTEM, which is an electron microscopy in which a very fine electron beam is focused on a very thin section of the sample material,[37] causing electrons to scatter in different amounts depending on what type of material the beam hits. The heavier elements, such as silicone, will cause the electrons to scatter more, producing a brighter image, and the lighter elements such as carbon or silicone-poor materials will cause the electrons to scatter less, appearing as a darker image. The parties focused upon the silicone content of the Oasys lens "[b]ecause it's being proposed that these phases can be distinguished from one another based on their silicone contents." (Tr. VI at 138, 160 (J&J expert Dr. John Phillip Bradley ("Bradley")).) Moving the beam across the material will produce an image of light and dark points, indicating regions of high or low scattering. The dark regions in the FEGSTEM image are indicative of an ionoperm phase, which should contain less silicone than the oxyperm phase. (Tr. II at 236 (Gido).) The FEGSTEM image measures contrast to indicate variation, but not actual composition. (Tr. VI at 129 (Bradley).) Gido said he conducted a FEGSTEM analysis to address whether the interwoven maze in the Oasys lens constitutes an actual pathway. (Tr. III at 52-53 (Gido).) According to Gido, his FEGSTEM test of the Acuvue Oasys revealed "clearly defined regions that are lighter and regions that are darker" indicative of a phase-separated structure, manifested by a

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[37] The thin slice of the Acuvue Oasys used for this test is approximately the size of the phases themselves. (Tr. II at 217-19 (Gido); D. Dem. 20, 21; PTX 1087.)

"dappled" or "mottled" image of light and dark splotches. (Tr. II at 222, 226 (Gido); DTX 1349B; Doc. 287 at 35-36.)[38] Gido opined that the mottled presentation of his FEGSTEM images of the Acuvue Oasys is due to differences in composition. (Tr. VIII at 199-200 (Gido).)

Closely related is the EDX test,[39] a technique done concurrently with FEGSTEM with the same instrument. In addition to the electron beam scattering electrons upon impact with the tested material, x-rays are generated from the sample with different energies characteristic of the types of material (atoms) that are being irradiated. (PTX 1089.) In this way, EDX illustrates differences in composition. EDX is specifically sensitive to different types of atoms and can detect different materials. (Tr. II at 231-33 (Gido).) "EDX is the only method capable of measuring the composition of this material." (Tr. VI at 121-22 (Bradley); see Tr. VIII at 204 (Gido).)

Gido applied the EDX to his FEGSTEM test of the Acuvue Oasys and superimposed

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[38] Gido testified that the FEGSTEM image of the Acuvue Oasys (DTX 1349B) is comparable to the dappled FEGSTEM image of the CIBA Focus Night & Day lens (DTX 1358A) and Bausch & Lomb's PureVision lens (DTX 1358B), and is unlike the smooth-looking FEGSTEM image of the J&J Acuvue2 lens, which is not a silicone hydrogel and has no phases. (DTX 1358C; 1358D; D. Dem. 59, 62, 63 (adjusted to same scale); Tr. II at 224-30 (Gido).) Unexplained was the effect of the different measurement scales used in the images in the comparison. (See D. Dem. 63 (showing CIBA Focus Night & Day (DTX 1358A) and Bausch & Lomb's PureVision (DTX 1358B) both measured on a scale of 20 nm and compared to J&J's Acuvue Oasys (DTX 1349B) and J&J's Acuvue2 (DTX 1358C) both measured on a scale of 100 nm. Though Defendant's Demonstrative 63 was not admitted into evidence, it was presented by CIBA during closing arguments without objection. (Doc. 311 (Tr. 35).)

[39] Gido performed the EDX test only after he was criticized by J&J expert Bradley for not doing it. (See Tr. VI at 122-23 (Bradley).)

the EDX data for silicone, which is the heaviest element in the lens that produces a strong EDX signal and is characteristic of the oxyperm phase, over the FEGSTEM image. According to Gido, the higher the EDX line profile plot points, the brighter the image, indicating more silicone in the material. Conversely, the EDX line drops in the darker regions, indicating less silicone. (Tr. II at 233-34 (Gido); DTX 1358E; see Appendix B.) The EDX x-ray counts indicate "a relative abundance of silicone." (Tr. VIII at 201 (Gido).) "We certainly saw points where there was more silicone. We saw points where there was significantly less silicone." (Tr. III at 17 (Gido).) The range of the EDX silicone plot had a 25 to 30 percent differential. (Id. at 19.) According to Gido, the EDX signal does not drop to zero in the FEGSTEM dark regions indicative of the "Ionoperm phase" because the sample slice of the lens "is inherently three-dimensional" meaning that the beam does not "have a pure path through the sample in a single phase. . . The phases themselves are separate . . . [but] maybe overlapping one another along that particular trajectory through the sample," though the lightness and darkness in the FEGSTEM image is reflective of predominantly one phase over another, creating a "projection issue."[40] Additionally, "the

[40] J&J dismisses CIBA's overlapping phase "projection issue" explanation, saying that the slices of lens tested in CIBA's FEGSTEM and EDX tests are 30 to 50 nanometers, the same as the size of a phase. This "guarantees that you're sampling just one monolayer, mostly, of ionoperm or oxyperm material in a specimen that thick. So it removes the uncertainty with specimen thickness by reducing the specimen to one monolayer of these alleged phases." This, according to Bradley, would cause the electron beam to pass through one region under CIBA's construct and cause the EDX line plot to spike high and low. (Tr. VI at 135-37, 149-51 (Bradley); PTX 1090.) What is unclear, however, is whether the precision three-dimensional slices of the lens which are submitted to the FEGSTEM and EDX test are exactly cut along a phase or whether they slice through more than one phase such that the sample is a conglomeration of phases.

Ionoperm phase probably, no doubt, contains some silicone. And the oxyperm phase contains some ionoperm material." (Tr. II at 236-37, Tr. III at 16, 20-21 (Gido); Tr. VIII at 202 (Gido)("three dimensional projection issue"); see also Tr. III at 12 (Gido)("I would expect to find silicone in oxyperm polymer").) "[T]here is a statistically significant correlation between the bright and darkness in the [FEGSTEM] image, and the ups and downs in the EDX." (Tr. III at 21-22; see also Tr. VIII at 202 (Gido).)

J&J argues that the EDX test data shows that every region in the Oasys lens tested had a substantial amount of silicone and "was not a region of essentially only ionoperm polymer." (Doc. 286 at 33.) Having measured "thousands of points" in the Oasys lens, the data demonstrated that "the silicone level never dropped to a value even remotely approaching 'little or no silicon.'" (Id. at 33-34 (citing PTX 31C, 31D, 32A (Bradley's data); PTX 33A, 735A, 735C[41] and DTX 1358E (Gido's data).) Not surprisingly, J&J's experts reached the opposite conclusion to CIBA's experts. "My conclusion, based on the imaging and EDX experiments [is] . . . that this Oasys material does not have the . . . alleged phases. . . . [W]hen I measured the composition of this material after many, many analyses of this material using EDX, I found not a single region anywhere in the Oasys lens material that had 'little or no silicone.' In fact, the silicone composition throughout this material is remarkably uniform." (Tr. VI at 122, 134 (Bradley).) Indeed, according to Bradley, EDX

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[41] PTX 735A and 735C are two EDX line profiles of the Acuvue Oasys lens compiled by Gido. (Tr. VI at 145, 148 (Bradley).) The parties have offered no explanation why they are different, and specifically why the silicone level in PTX 735C (lowest single silicone data point at 450) is higher and more mixed as opposed to the more linear and spiked line profile in PTX 735A (lowest silicone single data point at 300).

measurements of the Oasys lens "found the composition to be totally homogeneous across these various regions" and Gido's results "mirror mine. . . [W]e see essentially a uniform distribution of silicone throughout these materials, and not a single data point that even remotely approaches little or no silicone." (Id. at 130.) Because not a single silicone data point drops below 300 count, "[t]his is the signature of chemically homogeneous material." (Id. at 146 (referring to PTX 735A).)[42] Bradley illustrated his opinion by comparing his Brightness Line Profile of the Oasys to Gido's EDX Line Trace superimposed upon an enhanced FEGSTEM image, and a "native" un-enhanced FEGSTEM image. (PTX 31C, 33A; see Appendix B.) "[T]here is not a single data point along the entire profile [PTX 31C] that even remotely begins to spike down to little or no silicone counts. In fact, it's essentially a straight line . . . that is a signature of a chemically homogeneous material." (Tr. VI at 139-40 (Bradley).)[43] Additionally, J&J criticizes Gido's FEGSTEM image (DTX 1357D) used to

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[42] Bradley also said that his EDX conclusion also confirms that any contrast exhibited in Gido's FEGSTEM tests is not due to compositional differences in areas of the Oasys lens, but rather is due to variations in density or thickness of the material. (Tr. VI at 130, 164-65 (Bradley)), which of course is disputed by Gido. (Tr. VIII at 199-200 (Gido).)

[43] Gido questioned Bradley's EDX test results which plot a line for carbon and for silicone, the silicone line being level in contrast to Gido's. (PTX 31C, 31D.) Bradley contends that his test verifies that the Acuvue Oasys is a homogeneous material. Bradley's EDX plot line shows about 10 to 20 times more carbon than silicone in the sample. In actuality, the lens contains 25-30 percent silicone, and about 50 percent carbon, based upon the stipulated ingredients. Gido theorized that Bradley's test shows a much larger differential between silicone and carbon inconsistent with what is actually in the lens because Bradley placed his thin sections of Oasys lens being tested on a carbon support film and focused the EDX electron beam on each point for a dwell time of 20 seconds (compared to Gido's dwell time of one-hundredth of a second), which "is just blowing a smoking hole in this sample" and causing Bradley's results to reflect the carbon composition of the underlying support film. The silicone, meanwhile, "is being vaporized and destroyed", resulting in a low silicone count. (Tr. VIII at 207-10 (Gido); compare PTX

underlay his EDX line profile (DTX 1358E) because it is enhanced to show more contrast. (Tr. VI at 152-53 (Bradley); Tr. II at 233-34 (Gido); Tr. III at 29-30, 57 (Gido); PTX 33A.) J&J's expert Bradley's "Darkfield conventional TEM image" of the Oasys is a "dot-filled" granular "image you would get from a homogeneous polymeric material." (Tr. VI at 131; PTX 31A.) The "darkfield FEGSTEM image" of the Oasys shows "contrast variation" not visible in the TEM image, but because of results in EDX testing, Bradley ruled out phases as the cause of the contrast variation, attributing the light and dark splotches to thickness or density variations. (Tr. VI at 133-34, 165 (Bradley); PTX 31B)[44] In addition, J&J argues that Gido's EDX line profile does not show oscillation of silicone amounts indicative of phases that are 30-50 nanometers wide. (Doc. 311 (Tr. 100); Tr. III at 15 (Gido); Tr. VI at 149-50 (Bradley).) J&J's expert Bradley opines that the EDX test establishes that the Acuvue Oasys does not have phases. (Tr. VI at 155 (Bradley).)

A fourth test conducted by Gido was the AFM test, which is a technique in which a very sharp and small stylus is moved across the surface of the sample, detecting height changes or topography of the sample, and poking the sample to detect hardness and softness. The test is able to plot a two-dimensional image of the lens structure by showing images of darker and lighter colors. (Tr. II at 238-41 (Gido); Tr. VI at 65 (Bates); DTX 1349C

31C with DTX 1358E; PTX 32A, PTX 33A (line profile with raw counts showing less than 5 percent silicone and 90 percent carbon in the sample).) Bradley denies that "beam damage" occurred in his experiments. (Tr. VI at 166 (Bradley).)

[44] CIBA contends that Bradley's EDX bright line profile, which was based upon Gido's "native" image un-enhanced FEGSTEM, is a "very close match" for Gido's EDX data. (Tr. VI at 163-64 (Bradley).)

(CIBA's AFM test of Acuvue Oasys lens surface showing height variation on the left and hardness variation on the right); see Appendix B.) In Gido's opinion, the test demonstrates that "there are separate phases of harder and softer material" at the surface of the lens, which corresponds to the softer silicone oxyperm phase and the more rigid ionoperm phase. (Tr. II at 239-40 (Gido); DTX 1349C).) Gido performed a second AFM test on the interior core of the Oasys lens which he said shows darker softer regions of the core as compared to lighter ionoperm regions. "[T]hose regions occur because the system is phase-separated between a very low Tg, or glass transition temperature oxyperm phase, and a higher glass transition temperature, Ionoperm phase." (Tr. II at 240; Tr. III at 45 (Gido); DTX 1036, 1358F.)

J&J expert Bates criticized Gido's AFM test result because it showed a "dramatic difference" in texture and scale in the topography of the surface and the interior slice of the Oasys lens; "[t]hey really bear little resemblance to each other. . . . You would expect the material to show consistent results between the two different reports." (Tr. VI at 66-67 (Bates); PTX 1063.)[45] Bates also criticized Gido's AFM depiction of the interior of an Oasys lens because the relative proportions of white to brown in the image were not consistent with the known materials in the Acuvue Oasys. (Tr. VI at 69 (Bates); PTX 735B.) Further, J&J contends a comparison of the images generated by Gido's FEGSTEM test and his AFM test shows an inconsistency in the size and distribution of the light and dark images which

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[45] Gido did not de-salt the surface of the lens when conducting the AFM test, but did de-salt the interior slice of the lens before looking at the interior morphology in the later AFM test. (Tr. III at 46 (Gido).)

purport to show phases. (Doc. 286 at 40; PTX 1065; Tr. III at 49-50 (Gido).)

CIBA's expert Gido responded that AFM is not necessarily a technique to quantitatively assess the relative amounts of phases. Additionally, Bates was only considering the pure white areas, and not the light brown areas as being a part of the ionoperm phase, whereas the light brown areas "represent also bits of ionoperm phase that may not be quite as hard as some of the other bits, just because maybe they're not sticking up so much at the surface. . . . But . . . if you total up all of the . . . whiter-looking phase material here, you do get a reasonable estimate of the composition of the phase-separated material." (Tr. VIII at 212-13 (Gido).) Gido also stated that the interior images of the Acuvue Oasys produced by the FEGSTEM and AFM tests "does show similarity in size and arrangement of the phases." The FEGSTEM test did not "look at" the surface. (Tr. III at 48 (Gido).)

In conclusion, CIBA expert Gido opined that the four separate and complimentary testing techniques "indicate to me that the system is phase-separated between an Ionoperm phase and an oxyperm phase," and one of the phases has more silicone in it and the other has less silicone in it. (Tr. II at 241; Tr. VIII at 228 (Gido).)

J&J introduced evidence of tests performed by CIBA's expert Gido which he did not present at trial. The first was a transmission electron microscopy (TEM) test. (Tr. VI at 126-27 (Bradley).) Bradley said the TEM results on the Oasys lens show "fine scale" light and dark contrast image of a homogeneous material. (Id. at 131; PTX 31A.) Gido said that the TEM technique is related to FEGSTEM, which is more advanced and provides a more high resolution image. (Tr. VIII at 186 (Gido).)

The second series of tests conducted by Gido but not reported by him at trial was the small-angle x-ray scattering ("SAXS") test, in which a beam of x-ray probes the sample. The x-ray interacts with whatever structure is present in the lens and produces a scattering of x-rays that are intercepted by a detector. The intensity shown on the detector allows one to deduce the internal structure of the sample. The angles of the scattered x-rays are plotted and peaks and patterns will result in the plotted small angles if phases exist. A beam stop is included in the instrument to protect the detector from the direct x-ray beam; because x-rays do not penetrate the beam stop, the intensity of the x-ray drops and the data plot at the beam stop will drop to zero. (Tr. VI at 29-38 (Bates); PTX 1042-1047.) Gido ran his SAXS test four times to correct procedural concerns, one of which was pointed out by J&J expert Bates (relating to the beam stop being in the way of the measurement)(see PTX 1050; Tr. VI at 46-47 (Bates), to conduct the test on a more powerful instrument, and to show contrast. In the first three tests, Gido did not see a "peak" because the test did not show sufficient contrast. On the fourth test, Gido introduced a staining technique to the lens material and exchanged rubidium chloride salt solution into the lens, which is 15 times more concentrated than sodium chloride saline solution, in order to enhance x-ray scattering. He said it is common to exchange a lighter salt for a heavier salt that scatters x-rays more, to increase contrast to see the proverbial polar bear in a snow storm. (Tr. VIII at 187-89, 218-22 (Gido); Tr. VI at 45-55; (Bates); PTX 844A, 844C.) J&J expert Bates stated that the addition of rubidium chloride "could have many deleterious effects" that would change the structure of the lens, but was unable to specify how. (Tr. VI at 56, 90-92 (Bates).) Gido responded that the chemical crosslinked structure of the Oasys lens prevents the phases from moving

around and rearranging themselves such that the addition of a heavier salt cannot change the crosslinked chemically bonded structure. (Tr. VIII at 229 (Gido).)

J&J expert Bates testified that his SAXS test of the Acuvue Oasys shows no "peak" in the data corresponding to a phase structure of about 30 nanometers, indicating that the Oasys does not have "phases." (Tr. VI at 27, 38-45 (Bates); PTX 844A, 844C (Gido's data), PTX 1052, 1057 (Bates' data).)[46] Bates said that his SAXS test illustrates that the oxyperm materials do not separate from the ionoperm materials to create phases. (Tr. VI at 27, 79-84 (Bates)(homogeneous or uniform related to the length scale associated with phases taught by the CIBA patent, forming a single phase).)

The Court has recited this conflicting and frankly, confusing expert testimony at length to make the point that, in the end, the Court was unpersuaded by any of it. As CIBA has the burden of proof on the "phase" issue, the failure of its experts to persuade is telling. At closing argument, CIBA admitted that the "phase" structure taught in the '100 Patent is simply a theory to explain the high oxygen permeability and high ion permeability which create ophthalmic compatibility. (Doc. 311 (Tr. 38).) However, the Court's construction of the term "phase" requires CIBA to prove by the preponderance of the evidence the presence in the Acuvue Oasys of two separate regions, each "of substantially uniform composition," one composed of "essentially only" ionoperm polymer, and the other composed of "essentially only" oxyperm polymer. CIBA argues that it has met its burden of proof

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[46] Bates said that he believes the SAXS test is preferred and definitive because it tests the contact lens "right out of the package," rather than requiring that much of the water be removed from the lens as required by some of the other testing. (Tr. VI at 39 (Bates).)

"because all these other tests . . . point in the same direction." (Doc. 311 (Tr. 38-39).) However, as the Court has found, these tests are inconclusive.

This issue of whether the Acuvue Oasys infringes upon the "phase" limitation of the asserted '100 Patent claims is to be resolved by proof of their actual existence within the Oasys lens. The '100 Patent's limitation of "phases" is a theory to explain the invention's high oxygen and ion permeability feature. (Doc. 311 (Tr. 38).) CIBA attempts to apply this theory to the Acuvue Oasys, arguing that hydrophilic and hydrophobic polymers naturally separate into phases, and citing Gido's four tests that produced grainy photographic images; illustrations of mottled material; speckled surface images; charts of temperature transitions; and graph line profiles depicting concentrations of silicone in the Acuvue Oasys. CIBA argues that the test results "appear to show that Acuvue Oasys is a phase-separated material." (Doc. 287 at 38.) The closest CIBA comes to proving that the Acuvue Oasys has regions of "essentiality only" oxyperm and ionoperm polymers is with the EDX test which shows the somewhat vacillating presence of silicone in the Acuvue Oasys. Though the EDX test results were inconsistent, they established that the Oasys lens is silicone-rich throughout, so much so that the lens displayed no regions "composed of essentially only ionoperm polymer." (DTX 1358E; PTX 735A; PTX 735C; Doc. 121 at 17.)

CIBA's position amounts to citing to the known ingredients of the Oasys lens and contending that the speckled images and oscillating line graphs represent "phases," with no evidence of whether these regions are "essentially only" "substantially uniform"and "substantially separate" with "bulk properties" that "differ significantly" from the properties of another phase. Further, CIBA presented no evidence, other than the presence of silicone

in the Oasys, that the alleged "phases" or regions displayed a "relatively high rate of" oxygen diffusion and water or ion permeation, merely theorizing that because the Oasys is a mixture of hydrophillic ionoperm materials and hydrophobic oxyperm materials, and because the Oasys has oxygen permeability and a high percentage of water, it must then be comprised of phases. CIBA in essence argues that because the Acuvue Oasys contains the listed substances, and because it demonstrates high oxygen and ion or water permeability, it must be structured internally in "phases." This is not proof by a preponderance of the evidence that its phases "theory" reads on the Acuvue Oasys.

II. Invalidity

A patent enjoys a presumption of validity pursuant to 35 U.S.C. § 282, and that presumption can only be overcome by evidence that is "clear and convincing." Titan Tire Corp. v. Case New Holland, Inc., 566 F.3d 1372, 1376 (Fed. Cir. 2009).[47] "[A]n alleged infringer who raises invalidity as an affirmative defense[48] has the ultimate burden of persuasion to prove invalidity by clear and convincing evidence, as well as the initial burden of going forward with evidence to support its invalidity allegation." Id. "Each claim of a patent (whether in independent, dependent, or multiple dependent form) shall be presumed

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[47] "The 'clear and convincing' standard is a an intermediate standard which lies somewhere in between the 'beyond a reasonable doubt' and the 'preponderance of the evidence standards of proof.'" Pfizer, Inc. v. Apotex, Inc., 480 F.3d 1348, 1359 n.5 (Fed. Cir. 2007)(citations omitted), cert. denied, 128 S.Ct. 110 (2007). "Clear and convincing evidence may be described as "evidence that 'place[s] in the ultimate factfinder an abiding conviction that the truth of its factual contentions are highly probable.'" Id. (quoting Colorado v. New Mexico, 467 U.S. 310, 316 (1984)).

[48] J&J raises the invalidity issues both by way of affirmative defense and in seeking a declaratory judgment of invalidity.

valid independently of the validity of other claims; dependent or multiple dependent claims shall be presumed valid even though dependent upon an invalid claim." 35 U.S.C. § 282; see also Titan Tire Corp., 566 F.3d at 1376.

A. Indefiniteness

Section 112 provides that patent claims must "particularly point[ ] out and distinctly claim[ ] the subject matter which the applicant regards as his invention." 35 U.S.C. § 112 ¶2. "Because the claims perform the fundamental function of delineating the scope of the invention, [citation omitted], the purpose of the definiteness requirement is to ensure that the claims delineate the scope of the invention using language that adequately notifies the public of the patentee's right to exclude." Datamize, LLC. v. Plumtree Software, Inc., 417 F.3d 1342, 1347 (Fed. Cir. 2005). "The definiteness inquiry focuses on whether those skilled in the art would understand the scope of the claim when the claim is read in light of the rest of the specification." Union Pac. Res. Co. v. Chesapeake Energy Corp., 236 F.3d 684, 692 (Fed. Cir. 2001). The Federal Circuit, in Datamize, supra, advises the Court of the requirements of definiteness in patent claims.

> [T]he definiteness of claim terms depends on whether those terms can be given any reasonable meaning. Furthermore, a difficult issue of claim construction does not *ipso facto* result in a holding of indefiniteness. [Citation omitted.] "If the meaning of the claim is discernible, even though the task may be formidable and the conclusion may be one over which reasonable persons will disagree, we have held a claim sufficiently clear to avoid invalidity on indefiniteness grounds." [Citation omitted.] . . .
> *"By finding claims indefinite only if reasonable efforts at claim construction prove futile, we accord respect to the statutory presumption of validity and we protect the inventive contribution of patentees, even when the drafting of their patents has been less than ideal." [Citation omitted.] In this way we also follow the*

requirement that clear and convincing evidence be shown to invalidate a patent.

Datamize, LLC, 417 F.3d at 1347-48 (emphasis added). The definiteness requirement does not require absolute clarity; "[o]nly claims 'not amenable to construction' or 'insolubly ambiguous' are indefinite." Id. at 1347. In the face of an allegation of indefiniteness, general principles of claim construction apply, which involves a review of intrinsic and extrinsic evidence such as expert testimony. Id. at 1348; Exxon Research and Eng'g Co. v. United States, 265 F.3d 1371, 1376 (Fed. Cir. 2001).

1. Ionoton ion permeability term

J&J contends that claims 1 and 28 of the '100 Patent and all asserted claims of the '894 Patent are invalid as indefinite under 35 U.S.C. § 112 ¶ 2, contending that a person of ordinary skill in the art would not know how to calculate claimed Ionoton Ion Permeability values. (Doc. 286 at 41.)[49] J&J says the patent sets forth two "equations" for determining the Ionoton Ion Permeability Coefficient that are "'insolubly ambiguous.'"

Ion permeability is the rate at which ions permeate through a contact lens. The patent states that "[u]nexpectedly, it has been determined that the ion permeability through the lens correlates well with on-eye movement" which is required to ensure good tear exchange and ultimately, good corneal health. ('100 Patent col.9 ll.42-46.) One measurement technique for determining the relative ion permeability of a lens is called the "Ionoton Measurement

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[49] Independent Claim 1 of the '100 Patent claims an "Ionoton Ion Permeability Coefficient of greater than about $0.2\times10^{-6}cm^2/sec$" and Claim 28 is dependent on Claim 1. Independent Claim 89 of the '894 Patent claims "an Ionoton ion permeability coefficient of greater than about $0.25\times10^{-3}cm^2/sec$." Claims 90, 96, and 99 are dependent on Claim 89.

Technique," which produces an "Ionoton Ion Permeability Coefficient." (Id. col.11 l.51-col.12 l.15.) The '100 Patent specifications provide two expressions relating to the Ionoton Permeability Coefficient. First, the '100 Patent specifies:

> The Ionoton Ion Permeability Coefficient, P, is then determined in accordance with the following equation:
> *ln(1-2C(t)/C(0))=-2APt/Vd* [50] *. . .*

(Id. col.12 ll.14-18.) The second expression,[51] following immediately after the first, states:

> The Ionoton Ion Permeability Coefficient, P, having units of cm^2/second, may be determined from the slope of a plot of time (t) v. ln(1-2C(t)/C(0))×(-2At/Vd).[52]

(Id. col.12 ll. 31-34.)[53] The parties agree that the first equation is appropriate for determining

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[50] CIBA in its Proposed Findings of Fact and Conclusions of Law states that this first expression reads: "ln(1-2C(t)/C(0))=2APt/Vd." (Doc. 287 at 46.) CIBA does not explain why its recitation of this expression omits the negative sign ("-") which appears to the right of the equal sign ("=") in the patent specification. ('100 Patent col.12 l.17.)

[51] The parties dispute whether this mathematical expression constitutes an "equation." For convenience sake, the parties and witnesses referred to it as an "equation" throughout the trial. The Court's use of the word "equation" when referring to this second expression or formula is for ease of reference only.

[52] CIBA cites to the second expression as: "(t) v. ln(1-C(t)/C(0))×(-2At/Vd)" (Doc. 287 at 46), omitting the numeral "2" from the patent's expression "ln(1-2C(t)/C(0))." ('100 Patent col.12 l.33-34.)

[53] The second expression contains "a simple Algebraic error" or "typographical error" - "a flipping of the numerator and denominator." (Tr. I at 233, 242 (Winterton).) In addition, the second expression "has the extra t in it" (*t* representing time). (Tr. IV at 212 (J&J expert Dr. Benny Dean Freeman ("Freeman")); Tr. IX at 50-51 (Pitt).) The corrected expression should read:

> ln(1-(2C(t)/C(0))×(-Vd/2A)×t

(PTX 446; Tr. I at 233-34 (Winterton); Tr. IX at 50-51 (Pitt).) However, these errors are not the basis of J&J's indefiniteness claim.

the Ionoton Ion Permeability Coefficient, "P." (Tr. I at 252 (Winterton); Tr. IV at 138 (J&J expert Dr. Benny Dean Freeman ("Freeman")); Tr. IX at 45 (Pitt) Doc. 286 at 42; Doc. 287 at 46.)[54]

J&J expert Freeman opined that the Ionoton ion permeability coefficients that are contained in the CIBA patents are indefinite because one of ordinary skill in the art at the time the patent was filed would not know which of these two equations to use and would face a dilemma in trying to determine whether their invention was inside or outside of the CIBA claim limitations. (Tr. IV at 127, 200 (Freeman).) The patent does not teach which of the two "equations" to use. (Id. at 138 (Freeman).) J&J argues that the two "Ionoton equations" produce very different Ionoton values for the same lens. (Doc. 286 at 42; PTX 1026; Tr. IX at 76 (Pitt).)[55] This is because the second "equation" contains the term for "time." (Tr. IV at 136-37 (Freeman).) Further, though the first equation is correct under "the fundamental laws of physics," the person of ordinary skill in 1995 would have faced a "conundrum" because the Ionoton ion permeability coefficients listed in CIBA examples are much higher than

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[54] While J&J states in its responsive memorandum that it does not "'agree'" that the first equation should be used (Doc. 303 at 19), it did acknowledge in its initial memorandum that it agrees "that the First Equation appears to be derived from the applicable laws of physics and results in values with the claimed units of measurement." (Doc. 286 at 42.)

[55] According to J&J expert Freeman, "if you use that first equation, you get a value of 5.8×10^{-9}. And that's consistent with the values you'll find in the literature for ion permeation in hydrogels. And it's below the claim limitation.

And if you use that second equation, you get a value that's above even the highest claim limitation in the Nicolson patents for Ionoton." (Tr. IV at 156-60 (Freeman); PTX 1029.)

values that may be measured by the first equation, as opposed to the second "equation" which produces higher numbers because it is multiplied by "time." (Id. at 138-42, 150, 160-61, 200; '100 Patent col.64 Table E.)[56] "Using the first equation results in Ionoton values that are several orders of magnitude lower than the values recited in Table E and the claims. . . . [I]t is not possible to achieve the Ionoton values in the patents by using the First Equation. On the other hand, the Second Equation (with an algebraic error corrected), gives values that do comport with the values in the patent but does not result in the correct units." (Doc. 286 at 43 (emphasis omitted).) "[T]he person of ordinary skill in the art would be confused by the fact that, according to the first . . . equation, you get values that are very low with units that are consistent. But with the second equation, you get values that are in range with those given, for example, in Table E, but with the wrong units." (Tr. IV at 218 (Freeman).)

As support for its argument that the two "equations" render the Ionoton ion permeability term indefinite as a matter of law, J&J cites to a series of mistakes made by CIBA inventor Winterton who incorrectly cited the second equation to this Court on several occasions as the correct method for determining the Ionoton ion permeability coefficient of the J&J Phoenix project (Acuvue Oasys) lens.[57] Even after J&J scientist Dr. Douglas G. Vanderlaan ("Vanderlaan") pointed out errors in Winterton's initial calculation, Winterton continued to cite the second equation as his basis for determining the Oasys' Ionoton ion

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[56] CIBA expert Pitt disagrees with Freeman's analysis. (Tr. IX at 54 (Pitt).)

[57] Additionally, J&J argues that each time Winterton calculated the Ionoton ion permeability coefficient using the second "equation," "he reported his results in the 'correct' claimed units of cm^2/sec." (Doc. 286 at 44 (citations omitted).)

permeability coefficient, dismissing Vanderlaan's criticisms as being "in error." Winterton then testified at an evidentiary hearing held on CIBA's motion for temporary restraining order, in which he again referred to the second equation in connection with the Ionoton ion permeability coefficient of the J&J contact lens. Then, after again referring to the second equation in his December 2005 deposition, Winterton overnight reached the determination and acknowledged the next day at his continued deposition that he had been mistaken, and that the first equation was the proper expression to use in determining the Ionoton ion permeability coefficient. (See DTX 1129 ¶ 7; Tr. I at 242-57 (Winterton); PTX 265 ¶¶ 2-4 (Winterton second declaration dated August 5, 2005); PTX 1000; Doc. 47 (Minute Entry for Evidentiary Hearing on CIBA Motion for Temporary Restraining Order held August 9, 2005); Doc. 50 (August 9, 2005 hearing Transcript); DTX 1129; Tr. IV at 151-52 (Freeman).) In his declaration dated September 3, 2008 submitted in opposition to J&J's motion for summary judgment, Winterton acknowledged his mistake, stating:

> 4. In summer 2005, I was asked to measure Ionoton values for Acuvue Oasys in connection with CIBA's motion for temporary restraining order. I had not used the Ionoton method in the intervening 10 years since I used this method to calculate ion permeability values for the 13 examples reported in the CIBA patents. I was on vacation at the time and directed the work to be done by other CIBA personnel, including the development of the software program used to calculate the Ionoton Ion Permeability Coefficient values.
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> 5. . . . For purposes of the TRO hearing, . . . the software program used to calculate the Ionoton Ion Permeability Coefficient values relied on the formula set out in col. 12:33-34 of the '100 patent, which I understand is being referred to as the "Second" Ionoton formula.
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> 6. My reliance on the "Second" Ionoton formula to calculate

> Ionoton Ion Permeability Coefficient values was a mistake. At the time, I did not recognize that this "Second" formula, even adjusted for the inversion error contained in the equation, was not the correct formula to use to calculate Ionoton Ion Permeability Coefficient values for purposes of the CIBA patents.
>
> 7. I did not recognize this mistake until my deposition in December 14-15, 2005 . . . .

(DTX 1129 ¶¶ 4-7; Tr. I at 189-91, 250-52 (Winterton).)

"CIBA acknowledges that Dr. Winterton made a mistake in using the incorrect version of the second formula for the TRO hearing, but [argues] that the hypothetical person of ordinary skill in the art should not be presumed to make such a mistake or to be unable to derive the correct version of the second formula." (Doc. 287 at 48.) CIBA further responds that the corrected second equation is not an "equation" at all, but rather is a "formula" that "is intended to be an algebraic rearrangement of the first equation and is a way to obtain an Ionoton Ion Permeability Coefficient from a plot of the data obtained from the Ionoton experiment." (Id. at 46; Tr. I at 235-36 (Winterton)(the second expression is a rearrangement of the right side of the first equation.) Indeed, the first formula is expressed as an "equation" with two sides separated by an "equal" sign; the second expression has no "equal" sign. Winterton explained that the first equation is purely a mathematical equation describing the permeability coefficient. But it cannot be solved because there are too many unknowns. So the second expression seeks to solve it graphically, which removes one of the terms that cannot be solved. "In this case, we determined that if we plot it against time, the slope would be the permeability coefficient. And so since there's too many unknowns, we can't solve it. But we can do it graphically. And so we attempted [in the second

equation] to help the reader then simplify the equation to how they would then do it graphically . . . ." (Tr. I at 236-37, 240-41 (Winterton).) The inclusion of "t" time in the second expression produces a different number than the first equation. (Id. at 241.) "[O]ne would use the first equation and then derive it appropriately or manipulate it algebraically in the proper amount and plot it and you would get the right answer." (Id. at 253; see also Tr. IX at 46 (Pitt (second "equation" is "attempting to describe a way to create a plot of the data so that you can obtain the value of P [Ionoton Ion Permeability Coefficient]" from the slope of a plot of time)); Id. 47-50 (Pitt (demonstrating how to interpolate the first equation into the second expression of a plot)).)

In response to Freeman's testimony that the Ionoton values reported in the patent and described in the claims are higher than possible under the first equation, CIBA established through cross examination of Freeman that the upper limit for Ionoton values is $2.1\times10^{-5}cm^2/sec$, and that the Ionoton ion permeability coefficient value recited in Claim 1 of the '100 patent is below that value derived using the first equation. Additionally, one of the values taught in Table E of the '100 Patent is also below Freeman's possible upper limit of Ionoton values. ('100 Patent cl.1 ("Ionoton Ion Permeability Coefficient of greater than about $0.2\times10^{-6}cm^2/sec$"); '100 Patent col.64 Table E; Tr. IV at 209, 221-224 (Freeman).)[58] Finally, Freeman's measure of the re-created Nandu lens using the first equation yielded an Ionoton coefficient of $.27\times10^{-6}cm^2/sec$ which is "slightly above or right on the claim limitation for Claim

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[58] This fact was obscured by J&J's initial presentation, in which J&J compared the first equation to the Ionoton value recited in '894 Patent cl.89 alone, and not to '100 Patent cl. 1. Additionally, the J&J exhibit did not compare the *units* for the ion Ionoton permeability coefficient produced by the first equation versus the second equation.

1 of the '100 patent." (Tr. IV at 228-33 (Freeman); PTX1024).) The evidence does not establish that the Ionoton Ion Permeability values produced by the first equation are "several orders of magnitude lower than the values recited in Table E and the claims" (see Doc. 286 at 43) and impossible.

According to CIBA expert Pitt, the errors in the second mathematical expression could have been easily discovered by one of ordinary skill in the industry at the time of the patent application. (Tr. IX at 75, 78 (Pitt).) The second expression is recognizably incorrect because the Ionoton values obtained by it do not yield units for Ionoton values that are set out in the CIBA patent claims, while one skilled in the art would derive the correct units (cm^2/sec) using the first equation. (Id. at 51-53, 78, 88-89; Tr. IV at 218 (Freeman (using the first equation produces a value for P in units cm^2/sec, while using the second equation results in the value of P in units of cm^2, which is not what is claimed in the patent).) As to the typographical error in the second expression, CIBA argues that one of ordinary skill in the art would recognize that there had been an inversion; "[i]t was pointed out to me by [J&J's] expert." (Tr. I at 242 (Winterton).)

The evidence establishes that even J&J's expert knew to use the first equation in calculating the Ionoton ion Permeability Coefficient. "[A]s an expert in this area, the first ionoton equation is the one that you can derive from fundamental physics. This is the one that I would use in my laboratory . . . ." (Tr. IV at 202-05 (Freeman).) Also, J&J inventor and scientist Vanderlaan in 2005 first pointed out Winterton's error in using the second expression as well as the algebraic errors, thus confirming that one skilled in the art was not thwarted by the existence of the two different equations. Moreover, the second (corrected)

algebraic expression may be derived through mathematical manipulation from the first equation, using simple algebra which the hypothetical skilled person in the art could accomplish. (Tr. IV at 213-17 (Freeman)(demonstrating the algebraic manipulation from the first equation to the second corrected algebraic expression).)

"[T]he person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification." Phillips, 415 F.3d at 1313. "[T]he court looks to those sources available to the public that show what a person of skill in the art would have understood disputed claim language to mean. Those sources include the words of the claims themselves, the remainder of the specification, the prosecution history, the extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art." Id. at 1314 (internal quotation marks and citations omitted); Tr. IV at 206 (Freeman ("I believe that a person of ordinary skill in the art would review the patent and the prosecution file histories").)

The prosecution history of the CIBA patents confirms that CIBA indeed used the first Ionoton equation in its development of its patent during the SEE3 program and for the examples listed in the patent.. (Tr. I at 162 (Winterton); see also Tr. IV at 151, 209, 221-22 (Freeman).) Further a person skilled in the art would be able to do the algebra to transform the first equation into a correct plot of time producing a slope for the Ionoton ion permeability coefficient, and also to determine which formula produced values in the correct units.[59]

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[59] J&J expert Freeman opined that a person skilled in the art in contact lenses in 1995 would have a college degree in material science, polymer science or chemistry and

Though ion permeability was not used in the contact lens industry prior to CIBA filing its patent application in 1995, it was a standard technique which was measured in most materials science (Tr. I at 231 (Winterton)), and available to one skilled in the art.

To be sure, CIBA inventor Winterton made a mistake when he testified at the TRO hearing, which he has now acknowledged. But the evidence presented to this Court confirms that mistakes are not uncommon in this complicated and highly specialized field. For example, J&J mistakenly reported the Ionoton ion permeability coefficient of the re-created prior art Nandu lens in German litigation making a "units conversion error" when it converted millimeters into centimeters. Additionally, J&J expert Freeman made mistakes in his opening expert report measuring Ionoton values. (Tr. IV at 227-28 (Freeman); DTX 1419 at 13; see also Tr. V at 77-80 (mathematical error by J&J expert Benjamin in calculating oxygen transmissibility value of Chang prior art; Tr. X at 71-99 (J&J expert Benjamin presenting testimony to "clarify the corrected values," clarifying earlier errors, correcting values that had been "mistranscribed," and acknowledging an order of magnitude error in oxygen permeability data); Tr. VIII at 163, 169 (J&J clinician Dr. Noel Brennan ("Brennan"))(errors in reporting data from clinical study).) "I think in any sort of scientific calculation, it's possible to make mistakes." (Tr. IV at 228 (Freeman).) Thus, Winterton's mistake, while embarrassing, does not prove indefiniteness. Moreover, J&J's experts had

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three to five years of experience. A person skilled in the art "would be able to both do algebra and check units." (Tr. IV at 243, 249-50 (Freeman).) J&J expert Valint testified that one skilled in this art would be "an optometrist or ophthalmologist with three years of experience. And, also, the material scientist or polymer scientist would have . . . three to five years of experience in this contact lens industry." (Tr. VII at 89 (Valint).)

no trouble in discerning that the first equation was the correct one to use.

The Court is not correcting an error in the patent as J&J contends. Rather, J&J has failed to prove by clear and convincing evidence that the hypothetical person of skill in the art would not be able recognize that the first equation rather than the second formula produces Ionoton values with the correct cm^2/sec unit, and would not be able to calculate the correct slope plot line formula for the Ionoton permeability coefficient based on the first equation. Though the drafting of the '100 Patent Ionoton Measurement Technique specifications is "less than ideal," the evidence establishes that the meaning of the specifications, and thus the claims, is "discernable." Datamize, LLC, at 417 F.3d at 1347-48. The Court finds that J&J has not established by clear and convincing evidence that the hypothetical person of skill in the art in 1995 was not be able to calculate the Ionoton ion permeability coefficient for purposes of the CIBA patent, nor that claims 1 and 28 of the '100 Patent and claims 89, 90, 96 and 99 of the '894 Patent are invalid as indefinite.[60]

B. Non-enablement/written description

The invalidity defense of non-enablement is based upon 35 U.S.C. § 112 which

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[60] Even assuming *arguendo* that the two mathematical expressions render the Ionoton ion permeability coefficient limitations in the asserted claims invalid for indefiniteness, the parties did not address whether the claims would be saved by the fact that they each offer an alternative method of determining ion permeability, the Ionoflux Diffusion Coefficient. J&J has attacked the claimed Ionoflux values as not being enabled, but that is a separate argument from whether the asserted *claims* are indefinite as to their "ion permeability" claimed limitations. Inventor Winterton testified that while the first equation was used to calculate the Ionoton values in the patent, including those found in Table E, CIBA never used the Ionoton Measurement Technique after 1995, choosing to commercialize the alternative Ionoflux method of measurement. (Tr. I at 163-64 (Winterton).)

provides, in part, that

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same . . . .

35 U.S.C. § 112 ¶ 1. "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). "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., Enablement is determined as of the filing date of the patent application, here December 1995. Enzo Biochem, Inc. v. Calgene, Inc., 188 F.3d 1362, 1371 (Fed. Cir. 1999).

A patent claim is presumed enabled. See Pharm. Resources, Inc. v. Roxane Labs., Inc., 253 F. App'x 26, 28 (Fed. Cir. 2007). "The party alleging invalidity for lack of enablement bears the burden of proving by clear and convincing evidence that the specification of a challenged patent fails to teach one of ordinary skill in the art how to make the invention." Ormco Corp. v. Align Tech., Inc., 498 F.3d 1307, 1318 (Fed. Cir. 2007), cert. denied, 128 S.Ct. 2430 (2008). Enablement is "the quid pro quo of the patent bargain," in which the patentee receives the right to exclude the public from practicing the invention, and the public knowledge is enriched by the patent's disclosures. Sitrick, 516 F.3d at 999.

The Federal Circuit has set forth eight factors relevant to the enablement analysis:

> (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state

> of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

Pharm. Resources, Inc., 253 F. App'x at 28 (citing In re Wands, 858 F.2d 731, 737 (Fed. Cir. 1988)), cert. denied, 128 S.Ct. 1485 (2008). An enablement analysis begins with the disclosure and teachings of the specifications, and is determined from the vantage point of one skilled in the art. Sitrick, 516 F.3d at 1000-01. Enablement is a legal conclusion based on underlying factual considerations. Sitrick, 516 F.3d at 999; MEMC Elec. Materials, Inc. v. Mitsubishi Materials Silicon Corp., 248 F. App'x 199, 204 (Fed. Cir. 2007)(citing In re Wands, 858 F.2d at 736-37).

The written description requirement is separate and distinct from the enablement requirement. In re Curtis, 354 F.3d 1347, 1357 (Fed. Cir. 2004). The written description requirement of Section 112 ¶ 1 "'serves both to satisfy the inventor's obligation to disclose the technologic knowledge upon which the patent is based, and to demonstrate that the patentee was in possession of the invention that is claimed.'" Ariad Pharms., Inc. v. Eli Lilly and Co., 560 F.3d 1366, 1371 (Fed. Cir. 2009)(citation omitted) To satisfy the written description requirement, the specification must describe the invention in sufficient detail so "that one skilled in the art can clearly conclude that the inventor invented the claimed invention as of the filing date sought." Lockwood v. Am. Airlines, Inc., 107 F.3d 1565, 1572 (Fed. Cir. 1997). "[G]eneralized language may not suffice if it does not convey the detailed identity of an invention." Univ. of Rochester v. G.D. Searle & Co., Inc., 358 F.3d 916, 923 (Fed. Cir. 2004).

1. Whether claims not expressly including a surface treatment limitation are not enabled

a. J&J's Argument

Five of the asserted claims do not include the limitation "surface modified by a surface treatment process." ('100 Patent cl. 56; '894 Patent cls. 89, 90, 96, and 99.) J&J argues that as a matter of law, these five claims must enable one skilled in the art to make both surface treated contact lenses and non-surface treated contact lenses which also meet all of the other limitations of these five claims. (Doc. 286 at 46.) "[B]ecause CIBA's claims cover both a monolith lens and a surface-treated lens, CIBA must enable one of skill to make both kinds of lenses, not one or the other." (Doc. 286 at 48.) In support, J&J cites Liebel-Flarsheim Co. v. Medrad, Inc., 481 F.3d 1371, 1381 (Fed. Cir. 2007), Auto. Techs. Int'l, Inc. v. BMW of N. America, Inc., 501 F.3d 1274, 1284 (Fed. Cir. 2007), and AK Steel Corp. v. Sollac & Ugine, 344 F.3d 1234, 1243-45 (Fed. Cir. 2003).

J&J cites to this case precedent for the proposition that when "the asserted claims are broad enough to cover [two embodiments], the patents must enable both embodiments." Sitrick, 516 F.3d at 1000; see also Auto. Techs., 501 F.3d at 1282. And while it is true that "every embodiment of a claim does not need to be disclosed in the specification," it is also true that "the disclosure must teach the full range of embodiments in order for the claims to be enabled." Liebel-Flarsheim, 481 F.3d at 1378. Here, according to J&J, the five asserted claims cover "two distinct products" and the patent must teach how to make both "versions." (Doc. 254 at 3.)

J&J contends that the omitted limitation - "surface modified by a surface treatment

process" - defines a "physical characteristic of a product - a modified surface" (Doc. 303 at 22) rendering the "product-by-process" distinction and claim construction rules cited by CIBA inapplicable. According to J&J, the two different methods of making a contact lens - with and without a surface treatment process - "result in two different products." J&J distinguishes case law cited by CIBA as applying "only where two different methods lead to the *same* claimed product." J&J argues that "the two methods CIBA points to are not merely different ways of achieving the same product, but are two different ways of achieving two different products." (Doc. 286 at 49.) "[T]he limitation omitted in CIBA's broad claims, 'a *surface* modified by a surface treatment process' is structural and not a process or product-by-process term." (Id. at 50 (emphasis in original); see also Doc. 254 at 5.)

b. CIBA's Argument

CIBA frames the issue to be whether the lack of any reference to "surface treatment process" in the five asserted claims, "when read in context, describes and limits 'the product more by its structure than by the process used to obtain it.'" (Doc. 287 at 51 (quoting Hazani v. United States ITC, 126 F.3d 1473, 1479 (Fed. Cir. 1997). CIBA argues that the five asserted claims are pure product claims that are not required to be enabled by an un-recited process step, and that the patent enables at least one mode of making and using the invention. (Id. at 52.)

CIBA has a different take on the characterization of the "surface treatment" term in its patents. It counters that Liebel-Flarsheim, Auto. Techs., and AK Steel, supra, are inapplicable because those 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," and that "[a] surface treatment process is a *method* or *process* of making the claimed contact lenses" as opposed to a structural limitation as discussed in the cited cases. (Doc. 162 at 17.)

Rather, according to CIBA, the axiom more applicable to the claims that do not include a "surface treatment process" limitation is "that a patent is only required to teach one method of making the claimed invention, not multiple or alternative methods." (Id. at 19-20.) In other words, "'a patent need not teach how to make the claimed invention using every alternative method disclosed in the patent.'" (Id. at 21 (citing AK Steel Corp. v. Sollac & Ugine, 234 F. Supp. 2d 711, 717 (S.D. Ohio 2002), aff'd, 344 F.3d 1234 (2003)). Under CIBA's analysis, whether the claimed contact lens can be achieved with or without a surface treatment is not fatal to the patents' validity.

CIBA asserts the following legal precepts. Pure product claims are not limited by the "method" of achieving the invention; "'[t]he enablement requirement is met if the description enables any mode of making and using the invention.'" Invitrogen Corp. v. Clontech Labs., Inc. 429 F.3d 1052, 1071 (Fed. Cir. 2005)(citation omitted). The "'specification need teach only one mode of making and using a claimed composition.'" Amgen Inc., 314 F.3d at 1335 (citation omitted). "Enablement does not require the inventor to foresee every means of implementing an invention." Invitrogen Corp., 429 F.3d at 1071. And "[e]nablement does not require an inventor to meet lofty standards for success in the commercial marketplace. Title 35 does not require that a patent disclosure enable one of ordinary skill in the art to make and use a perfected, commercially viable embodiment absent a claim limitation to that effect." CMFT, Inc. v. Yieldup Int'l Corp., 349 F.3d 1333, 1338 (Fed. Cir. 2003). To establish

invalidity for lack of enablement, the accused must show "that all of the disclosed alternative modes are insufficient to enable the claims, because '[t]he 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); see also Invitrogen Corp., 429 F.3d at 1052; Amgen, Inc., 314 F.3d at 1335.

c. Discussion

The Court concedes that it has found this to be a challenging area of patent law.[61] However, the Court has determined that the problem presented by the parties necessitates a two-step analysis. The first step is akin to claim construction - do the five claims which do not have the limitation found in other claims - "surface modified by a surface treatment process" - reach extended wear contact lenses made both with and without a surface treatment process? This involves determining "the full scope of the claim," see Sitrick, 516 F.3d at 999, and is a question of law. The Court must determine whether the omitted limitation is a "product" limitation or a "process" limitation. A product claim limitation is "directed to a structural entity that is not defined or limited by how it is made." Amgen, Inc., 314 F.3d at 1329. A process claim limitation "'is a mode of treatment of certain materials to produce a given result. It is an *act*, or a *series of acts*, performed upon the subject-matter to be transformed and reduced to a different state or thing.'" In re Nuijten, 500 F.3d 1346, 1355 (Fed. Cir. 2007)(emphasis in original)(quoting Gottschalk v. Benson, 409 U.S. 63, 70 (1972)). J&J contends that the four asserted claims containing the "surface modified by a

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[61] The Court has grappled with this issue before. (See Docs. 190 at 12-15; 252 at 3-9.)

surface treatment process" limitation ('100 Patent cls. 1, 28; '811 Patent cls. 28, 29) *and* the five asserted claims without the surface treatment limitation ('100 Patent cl. 56; '894 patent cls. 89, 90, 96 and 99) are all product claims, with the latter claiming two products - one with and the other without "a surface modified by a surface treatment process." (Doc. 254 at 4.)

Second, the Court must address the enablement question, that is whether the CIBA patent must enable lenses with or without a surface treatment or both. "When a patentee chooses to claim 'A or B,' . . . the specification must fully enable "B" as well as "A" when the differences between 'A' and 'B' substantially affect the practice of the invention." Soitec, S.A. v. Silicon Genesis Corp., 81 F. App'x 734, 738 (Fed. Cir. 2003).

The first four asserted claims ('100 Patent cls. 1, 28; '811 Patent cls. 28, 29) cited by J&J contain the limitation "[a]n ophthalmic lens [or contact lens] having a surface modified by a surface treatment process . . . ." In its *Markman* Order, the Court construed the claim term "surface treatment process" as being "a process (or processes) to render a surface more ophthalmically compatible," the Court's construction further setting forth the methods of achieving that process, in accordance with the patent's specifications. (Doc. 121 at 23.) "Surface modified by a surface treatment process" as used therein is a process limitation; it describes "an act" performed on the contact lens "to be transformed." In re Nuijten, 500 F.3d at 1355. This is in contrast to other claim terms found to describe a "structure." See Vanguard Products Corp. v. Parker Hannifin Corp., 234 F.3d 1370, 1371-72 (Fed. Cir. 2000) (patent claiming an electromagnetic interference shielding gasket claim describing gasket as having two elastomeric layers describes the structural relationship between the layers, not the means of joining them, and did not limit the claim to the manufacturing process set

forth in the specification); Hazani, 126 F.3d at 1479 ("chemically engraved" is a structural limitation and not a process term); see also ICU Med., Inc. v. Alaris Med. Sys., Inc., 558 F.3d 1368 (Fed. Cir. 2009)(in patent for medical valves used in transmission of fluids to or from a medical patient, claims which did not include a spike limitation as other claims did, did not satisfy section 112's written description requirement because there was no disclosure in the patent specification that described a spikeless valve); see generally Abbott Labs. v. Sandoz, Inc., 566 F.3d 1282 (Fed. Cir. 2009).[62]

Next, 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 at issue here do not contain a "surface treatment process" limitation. "[A]bsent clear and unambiguous evidence to the contrary, a product claim is not limited to, or does not exclude, products made by a particular process." Outlast Techs., Inc. v. Frisby Techs., Inc., 128 F. App'x 122, 127 n.4 (Fed. Cir. 2005)(citing Vanguard Products Corp., 234 F.3d at 1372.)[63]

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[62] "A product by-process claim is 'one in which the product is defined at least in part in terms of the method or process by which it is made.'" SmithKline Beecham Corp. v. Apotex Corp., 439 F.3d 1312, 1315 (Fed. Cir. 2006)(quoting Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 158 (1989). The Federal Circuit, in its *en banc* decision Abbott Labs. v. Sandoz, Inc., 566 F.3d 1282, 1293 (Fed. Cir. 2009), recently clarified that process terms in product-by-process claims serve as limitations in determining patent infringement, and that a product-by-process claim is not infringed by products made by processes other than the one claimed.

[63] "When the specification describes a single embodiment to enable the invention, this court will not limit broader claim language to that single application 'unless the patentee has demonstrated a clear intention to limit the claim scope using "words or

Instructive to the Court's construction of scope of claim is the case Vanguard Products Corp., 234 F.3d at 1372, where the court declined to read a limitation to the method of manufacture of a product into a broad claim, even though the patent specifications described the method of manufacture, and the patentee inventors extolled the economy and superiority of the specified method of manufacture. The court found that "the prosecution history does not support [the accused's] argument that the Vanguard inventors 'expressly disclaimed' claim scope beyond products made by co-extrusion. [A second claim, claim 10] specifically describes the gasket layers as 'co-extruded.' The district court correctly declined to read this limitation into claim 1." 234 F.3d at 1372. "[C]laims containing different limitations are presumed to be of different scope." Id. (citation omitted). "The method of manufacture, even when cited as advantageous, does not of itself convert product claims into claims limited to a particular process." Id.

CIBA chose to write claim 56 of the '100 Patent and claims 89, 90, 96 and 99 of the '894 Patent as product claims. See Hazani, 126 F.3d at 1479 (a claim is properly characterized as a product claim where the "limitation, read in context, describes the product more by its structure than by the process used to obtain it"); Amgen Inc., 314 F.3d at 1329 (replacing product-by-process claim with pure product claim is strong evidence that patentee viewed the claims as "lacking a process component"). Unless there is something in the claim language that quite clearly demonstrates that method steps are claimed, the Court declines to read method steps into the claims; there is nothing to indicate that these five claims at

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expressions of manifest exclusion or restriction."'" Abbott Labs., 566 F.3d at 1288 (citations omitted).

issue are product-by-process claims. The absence of the "surface modification by a surface treatment process" term in a claim does not transform the claim into one with a process limitation. The Court construes the five asserted claims which do not include "surface treatment process" to be pure product claims for a single product - a "contact" or "ophthalmic" lens - with no limitations regarding whether a surface treatment process is required or not.

With this construction, the enablement question follows. Here, the case Johns Hopkins Univ. v. Cellpro, Inc., 152 F.3d 1342 (Fed. Cir. 1998), provides some guidance. In Johns Hopkins, the Court affirmed summary judgment of enablement of a product claim over a challenge that two alternative embodiments disclosed in the patent were not enabled; the court denied the enablement challenge because 'the enablement requirement is met if the description enables any mode of making the invention.'" Id. at 1361 (citation omitted). In the context of a product claim, the accused can carry its burden in an enablement validity challenge "only by showing by clear and convincing evidence that all of the disclosed alternative modes are insufficient to enable the claims, because "'[t]he enablement requirement is met if the description enables any mode of making and using the invention.'" Id. (quoting Engel Indus., Inc. v. Lockformer Co., 946 F.2d 1528, 1533 (Fed. Cir. 1991)). See also Invitrogen Corp., 429 F.3d at 1071 (patent specification which taught at least one mode of making and using patent invention that disclosed genetically modified enzyme where claims were not limited by the method of achieving the mutation); Anheuser-Busch Cos., Inc. v. Crown Cork & Seal Techs. Corp., 121 F. App'x 388 (Fed. Cir. 2004); Durel Corp. v. Osram Sylvania Inc., 256 F.3d 1298, 1307 (Fed. Cir. 2001);

The cases cited by J&J differ from the case at hand in that the claims were construed to require alternative or a range of limitations which then were not enabled. Here, the five asserted claims at issue are product claims with no "surface treatment process" claim term to construe. Thus, unlike the "means-plus-function" claims in Auto. Techs., supra, which were construed as requiring two means (mechanical and electronic) of achieving the function of "initiating an occupant protection apparatus," CIBA's five asserted claims teach a product: an "ophthalmic lens" or "[a] contact lens comprising a polymeric material" which must meet the extensive limitations set forth in the claims. (See '100 Patent cl. 56; '894 Patent cl. 89.) Likewise, the CIBA asserted claims are not "method patents" claiming the method to achieve a function using devices as in Liebel-Flarsheim, 481 F.3d 1371. Finally, in AK Steel, supra, the court construed a specific term "up to about 10%," "aluminum or aluminum alloy," and "an aluminum coating metal" to reach two types of aluminum, 344 F.3d at 1241-42, whereas here, the disputed claims offer no term regarding "surface treatment process"' to construe. Nor has J&J presented evidence that during the prosecution history that CIBA specifically amended its claims to delete the "surface treatment process" limitation in order to encompass J&J's product, which was particularly influential in the Liebel-Flarsheim claim construction, or to overcome a Patent Office concern. See Liebel-Flarsheim Co. v. Medrad, Inc., 358 F.3d 898, 911 (Fed. Cir. 2004)("Liebel-Flarsheim I"); AK Steel Corp., 344 F.3d at 1241-42.

The full scope of the product claimed by these five asserted claims is a contact lens, without regard to the process by which it is made. As a result, the process by which the claimed contact lens product is made - with or without a surface treatment process - is

immaterial and "legally irrelevant," Johns Hopkins Univ., 152 F.3d at 1361, and cannot be relied upon as a basis to render these five claims invalid for lack of enablement. Because the claims do not contain any limitations regarding "surface treatment process" (or lack thereof), the specification need not specifically describe all techniques.[64] It is undisputed that a surface-treated contact lens is enabled by the CIBA patents. (See Doc. 303 at 22.) That is all that it is required to satisfy the enablement requirement.

d. Enablement of a monolith lens

Assuming *arguendo* that the five asserted claims with no surface treatment limitation require enablement of monolith lenses that do not have a surface treatment, J&J nevertheless has failed to adduce clear and convincing evidence that the CIBA patent specifications fail to enable such a lens that is ophthalmically compatible and suitable for extended periods of wear of at least 24 hours or at least seven days. (See '100 Patent cl. 56; '894 Patent cls. 89, 90, 96 and 99; Doc. 286 at 50).[65] Among the prototype lenses created and evaluated by the CIBA inventors were monolith lenses without a surface

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[64] Nor is this a case where the language of the claims and the specifications suggest that the number of inoperable embodiments is "significant," and the number of working examples "do not provide an enabling disclosure commensurate with the entire scope of the claims." Pharm. Resources, Inc., 253 F.App'x at 30.

[65] Four of the claims at issue, '100 Patent cl. 56 and '894 Patent cls. 89, 90 and 96, require wear of "at least 24 hours." The fifth claim, '894 cl. 99 requires that the lens be wearable for "at least 7 days." The parties focused primarily on whether the CIBA patents enable a 24-hour monolith lens. (See e.g., Doc. 303 ("[t]o be enabled, the monolith lens must meet *each* limitation of CIBA's claims, which require the lens to be worn for 24 hours . . ." (emphasis in original).) While obviously creation of a monolith contact lens capable of being worn for seven days is more challenging than perfecting a 24-hour lens, J&J's enablement challenge nevertheless fails for failure of proof as to both time requirements.

treatment. One such monolith lens was called the Podium Db. (Tr. I at 82 (Nicolson).) Toxicology results of testing the uncoated Podium Db were favorable. (Id. at 83; DTX 1147 at CSFJ191194 ("[t]he uncoated Podium Db lenses are also considered non-cytotoxic and met the criteria of the Cell Growth Inhibition asay"). CIBA conducted a six-hour clinical study of the uncoated Podium Db lens on five subjects and found no clinically significant difference between the coated and uncoated Podium Db. (Tr. I at 84 (Nicolson); DTX 684 at CSFJ033597, CSFJ033599.) At the time, "[i]t looked like a good lens." (Tr. I at 85 (Nicolson).) However, the inventors learned that the Podium Db lens had "a shelf life problem" with the modulus (stiffness) of the lens increasing "over time." (Tr. IX at 129-31 (Nicolson); PTX 70 at CSFJ032351.) The CIBA SEE3 Program participants made the decision to stop work on the Podium lens and put all resources into development of the Betacon lens (which became its commercial embodiment, Focus Night & Day), with the Glycon lens as the "back-up material." (DTX 1118 at CSFJ075022; see also Tr. I at 86-87 (Nicolson).)

The Podium Db lens was included as an example in the '100 Patent. (Tr. I at 85-86 (Nicolson); '100 Patent col.59 Ex.D-2; col.62 Ex.E-10.) Example D-2 of the patent specifies that the monolith lens has a high Dk (oxygen permeability), about 115 barrers, and the E-10 Example specifies that it has a high Ionoton ion permeability coefficient of $1.4\times10^{-3}cm^2/sec$, and that it "moves on the human eye." (See Tr. I at at 138-39 (Nicolson).) In Nicolson's opinion, the Podium Db "shows a lot of promise" and is ophthalmically compatible - "[i]t follows the teachings of the patent." (Id.) CIBA argues that this evidence establishes a "prima facie case that the lens is likely to be suitable for extended wear." (Doc.

287 at 54.) Further, CIBA contends that there are at least five examples in the patents of lenses made without surface treatments that are reported to "move on the eye." (Doc. 287 at 54; Tr. IX at 132-33 (Nicolson); '100 Patent col.64 Table E (Exs. B-6, E-10); col.68 Table G (Exs. G-1, G-2, G-5).)

J&J expert Valint opined that the CIBA patent specifications do not present a monolith lens that is successful in providing 24-hour extended wear and meets the ophthalmic compatibility limitations of the asserted claims. (Tr. VII at 215, 218 (Valint).) This is because "the Podium lens was determined to be unstable. Its modulus [stiffness] was changing and increasing. . . . I would consider that an unstable lens" because of the methacrylic acid content of the material. The increased stiffness of the lens is "going to affect the biocompatibility . . . in terms of comfort." (Id. at 218-20 (Valint); PTX 70 at CSFJ032351 (Podium D "modulus jumped to an unacceptable high level").) A second Podium monolith, Podium GB failed in a six hour clinical study, with one of six subjects developing corneal opacity after six hours. (Tr. VII at 222 (Valint); PTX 71 at CSFJ064815.) Development of another CIBA monolith, Betacon 30, was abandoned because of problems with comfort and stability. (Tr. VII at 223-29 (Valint); PTX 73 at CSFJ032198.)

Further, J&J argues that CIBA has admitted that it could not make an ophthalmically compatible monolith non-surface treated extended wear lens. As support, J&J cites to CIBA inventor Nicolson's 2000 Declaration made to the USPTO on re-examination of the '100 Patent which it says confirms that the only way CIBA knew to achieve an ophthalmically compatible extended wear silicone hydrogel was to surface-treat the lens; "'[w]e discovered the need for surface modification of silicone hydrogels to achieve ophthalmic compatibility.'"

(Doc. 286 at 51 (citing PTX 300 at ¶¶ 24, 27).) At trial, Nicolson testified that he was referring to a "true extended wear" soft contact lens that can be worn for up to 30 days, though J&J argues that the declaration was submitted in support of claims for "24-hour" lenses. (Tr. V at 154 (Nicolson); Doc. 286 at 51.) Further, J&J cites to Nicolson's 2005 declaration submitted in this case, in which he said:

> 27. In my declaration to the USPTO, I was explaining our belief as to why we succeeded in making a true extended wear silicone hydrogel contact lens, where others had failed. For us, this included the need for surface modification of the lens to achieve ophthalmic compatibility. At that time, we were not aware of any other method for achieving a true extended wear lens.

(PTX 260 ¶ 27; Doc. 286 at 52.) At trial, Nicolson testified that the "true extended wear lens" he was referring to was "a highly oxygen permeable, ophthalmically compatible, soft contact lens that can be worn for up to 30 days." (Tr. V at 154-55 (Nicolson).)

A patent claim is presumed enabled unless proven otherwise by clear and convincing evidence. Ormco Corp., 498 F.3d at 1318. That CIBA did not continue with its development of the non-surface treated Podium Db lens into a commercial product, including conducting further clinical testing up to 24 hours or seven days, opting instead to focus on the Betacon lens which CIBA developed into its commercial embodiment Focus Night & Day, does not establish that the Podium Db monolith was not enabled. "Enablement does not require an inventor to meet the lofty standards for success in the commercial marketplace. Title 35 does not require that a patent disclosure enable one of ordinary skill in the art to make and use a perfected, commercially viable embodiment absent a claim limitation to that effect." CFMT, Inc. v. Yieldup Int'l Corp., 349 F.3d 1333, 1338 (Fed. Cir. 2003); cf. Atlas Powder Co.

v. E.I. du Pont De Nemours & Co., 750 F.2d 1569, 1577 (Fed. Cir. 1984)(patentee's experiments designated as "failures" because they were "not optimal under all conditions" did not establish nonenablement; "such optimality is not required for a valid patent"); CMFT, Inc., 349 F.3d at 1339 (lengthy experiments do not show nonenablement because the "inventors undertook that work to satisfy . . . particular commercial requirements, not to show enablement of the scope of the claimed inventions"). This is not a case where the inventor "taught away" from or disparaged the monolith lens. Rather, the monolith Podium Db was included in the patent as an embodiment. Compare Liebel-Flarsheim, 481 F.3d at 1379, 1380 (patent specification expressly "teaches away" from a disposable syringe without a pressure jacket as being "'impractical'"); AK Steel Corp., 344 F.3d at 1244 (specification "teaches against" embodiment; "[w]orse than being silent as to that aspect of the invention, the specification clearly and strongly warns that such an embodiment would not wet well").

Nor has J&J established that CIBA was unable to develop a monolith that could be worn for 24 hours. Cf. Ormco Corp., 498 F.3d at 1318-19 (clear and convincing evidence established that a person of ordinary skill in the art could not have accomplished the patent claims for automatic computer determination of teeth finish positions based upon specification where inventor testified that attempt had never been made to do so and inventor was unsure if problems could be overcome; "[i]If an inventor attempts but fails to enable his invention in a commercial product that purports to be an embodiment of the patented invention, that is strong evidence that the patent specification lacks enablement").[66]

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[66] See also Novo Nordisk Pharmaceuticals, Inc .v. Bio-Technology Gen. Corp., 424 F.3d 1347, 1362 (Fed. Cir. 2005)("an inventor's failed attempts to practice an invention

J&J's mere citation to CIBA's six-hour clinical study does not establish, by clear and convincing evidence, that the patent does not enable an 24-hour extended wear lens without a surface treatment. (See Tr. IX at 155 (Nicolson); Johns Hopkins Univ., 152 F.3d at 1360 ("[a] party who wishes to prove that the claims of a patent are not enabled by means of a failed attempt to make the disclosed invention must show that the patent's disclosure was followed"). Nor may J&J hang its enablement argument on CIBA inventor Nicolson's statement that the Podium Db lens showed "promise." See Nat'l Recovery Techs., Inc. v. Magnetic Separation Sys., Inc., 166 F.3d 1190, 1198 (Fed. Cir. 1999)(patentee's "promising the ideal result" without delivering is not enablement). Finally, Nicolson's declarations embracing the surface-treated preferred embodiment does not make "highly probable", see Pfizer, Inc., 480 F.3d at 1359 n.5, that the monolith was impossible to accomplish. Though it otherwise spared no expense in this litigation, J&J did not attempt to re-create the Podium Db in an effort to prove non-enablement. (Tr. VIII at 85-86 (Valint).) Rather, it relied on CIBA's incomplete development and testing of its specified monolith, Podium Db. While this gets J&J part of the way home, it is insufficient on this record to overcome the presumption of enablement and to prove by clear and convincing evidence that the CIBA patent does not enable a non-surface treated monolith extended wear hydrogel contact lens.[67]

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are relevant evidence of non-enablement"); Enzo Biochem, Inc. v. Calgene, Inc., 188 F.3d 1362, 1375 (Fed. Cir. 1999)("numerous failures in attempting to practice" the broad claims in an invention provides evidence of non-enablement)

[67] This is not to say that to prove non-enablement J&J was required to attempt to re-create the Podium lens, only that its failure to do so becomes a part of its inability to prove its non-enablement position by clear and convincing evidence.

2. Whether PVP at the surface of said lens is not enabled

As noted above, claim 96 of the '894 Patent provides that the contact lens taught is "further comprising polyvinylpyrrolidone at a surface of said lens." ('894 Patent cl. 96.) J&J argues that this claim is invalid for lack of enablement "because the specification does not enable a lens with a homopolymer of PVP 'at a surface of said lens.'" (Doc. 286 at 53; Tr. VII at 234 (Valint).) Important to this determination is the Court's *Markman* construction of the claim term "polyvinylpyrrolidone" ("PVP") to mean "a homopolymer that is produced by the polymerization of N-vinylpyrrolidone ["NVP"]," a definition agreed upon by the parties. (Doc. 121 at 19.)

J&J argues that "a PVP homopolymer is water-soluble, and that if it were at the surface of a lens, it would dissolve into the surrounding saline solution and leave the lens." (Doc. 286 at 54; Tr. VII at 231, 233 (Valint).) Thus, according to J&J, the only way that the PVP can remain at the surface is if it is covalently bonded to the surface of the lens. Restated, J&J argues that the fact that the PVP at the surface of the CIBA lens examples "is not water-soluble" demonstrates that it is "permanently attached to the surface of the lens." (Doc. 286 at 54.) It follows then, according to J&J, that "[a] homopolymer that bonds to another polymer is, by definition, no longer a 'homo' polymer. It is a copolymer - a polymer in a distinctly different chemical class than a homopolymer." (Id. at 54.)

J&J expert Valint testified that CIBA's patent only discloses a "copolymer" of PVP at the surface of a lens. (Tr. VII at 234-36 (Valint); Doc. 286 at 54.) Valint cites to Example F-1

of the '100 Patent ('100 Patent, col.65 l.36-col.65 l.37 and ll.36-53)[68] which he said achieves PVP at the surface "using a pulse plasma polymerization process" of NVP. "[T]he PVP that results from doing this plasma polymerization process is really not a homopolymer of polyvinylpyrrolidone. It's covalently attached to the surface" becoming part of the polymer that is coating the surface, and thus a co-polymer as opposed to a homopolymer. (Tr. VII at 234-37 (Valint); PTX 1127.) According to Valint, none of the examples in the CIBA patent depict a lens with a homopolymer of PVP at a surface. (Tr. VII at 237 (Valint).)

CIBA expert Mays, predictably, disagreed with Valint. He said that the F examples in the '100 Patent ('100 Patent col.64 l.57-col.67.l.40) describe a "cold plasma treatment" process, in which NVP monomer vapor is introduced, and reactive sites (single electrons) on the surface of the contact lens initiate polymerization of NVP and the lens, "[s]o it grows PVP on the surface, actually from the surface of that lens."[69] Mays said that the process disclosed by the F examples is different from the hot plasma treatment process described by Valint "which leads to scrambling of structure." Rather, here, the lens "surface is a material that's already been polymerized. So you cannot form a co-polymer with it." In short, "this process grows a homopolymer of PVP from the surface, by surface-initiating polymerization;" the PVP chain which is bonded to the initiator site at the surface of the F

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[68] The F examples in the patent describe a plasma surface treatment process whereby "the lens surface is coated with polyvinylpyrrolidone." ('100 Patent, col.65 ll.64-65.)

[69] CIBA inventor Winterton described the surface treatment process disclosed by the F examples as "a plasma-induced polymerization of N-vinylpyrrolidone that would react with the surface of the lens and result in a polyvinylpyrrolidone coating of the lens." (Tr. I at 153 (Winterton).)

Example lenses is a homopolymer, according to Mays. (Tr. X at 33-34, 49-50, 54-55, 57, 59, 61-62, 68 (Mays); see also Tr. I at 154 (Winterton)(surface treatment process described in F examples results in a homopolymer at a surface of the lens that is produced by the polymerization of N-vinylpyrrolidone, confirmed during the SEE3 program using surface infrared spectroscopy); Tr. IX at 142 (Nicolson)(CIBA SEE3 testing showed that PVP at the surface of the lens was identical to commercial PVP); Tr. I at 155-56 (Winterton)(lenses are placed in a reactor with the precursor to the polyvinylpyrrolidone, "and the plasma would initiate a reaction of the N-vinylpyrrolidone and monomer that's used to make PVP, and it would begin grafting from the surface of the lens . . . once we ignite one [building block] . . . it grows like a chain. And that chain would be attached to the surface of the lens").)

Though J&J does not acknowledge it, and CIBA does not address this point, J&J's argument is premised upon its position that "polyvinylpyrrolidone at a surface of said lens" requires that the entire PVP molecule reside at the surface. J&J paints a picture that the PVP must be attached by covalent bond to the surface of the lens to meet the claim. (PTX 1127.) However, as discussed earlier in this Order, the claim limitation PVP "at a surface" does not require that the entire PVP molecule be "at a surface." Rather, the claim limitation is satisfied if a portion of the large PVP molecule is at the surface, with the remaining portion of the molecule being entangled and embedded in the lens' polymer network. Further, the Court has determined that J&J's Acuvue Oasys lens infringes upon claim 96 of the '894 Patent based upon the portion of PVP at the surface of its lens, the very claim that J&J here seeks to invalidate as not enabled. (See supra pp. 33-36.)

In any event, J&J has further failed to adduce clear and convincing evidence that the

patents do not enable a homopolymer of PVP at the surface of the lens. As to whether the PVP at the surface of the F examples in the '100 Patent is a homopolymer or a co-polymer, the Court is confronted by a difference of opinion between J&J expert Valint and CIBA expert Mays and CIBA inventors Winterton and Nicolson.[70] Valint has not made a clear and convincing case; rather his opinion was more conclusory, resting on the premise that a homopolymer covalently bonded to a polymer must necessarily become a co-polymer, without delving into the actual process by which "the lens is coated with polyvinylpyrrolidone" in the F examples. Mays description was more detailed; Valint's more theoretical. Valint did not dispute the Mays' description of the PVP molecule growing from an initiator, nor did he explain how a bond with an initiator on the lens surface which triggers the growth of the PVP molecule and is incorporated into that molecule, transforms the PVP from a homopolymer into a co-polymer with the already polymerized lens surface. J&J's argument suffers from a failure of proof. J&J has not established by clear and convincing evidence that claim 96 of the '894 Patent is not enabled.

3. Whether claimed Ionoflux values are too low

J&J contends that all nine asserted claims ('100 Patent cls. 1, 28, 56; '811 Patent cls.

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[70] J&J's citation to CIBA inventor Nicolson's testimony in support of its position is not to be given weight. Nicolson said "we don't know how it [PVP] is attached" to the lens, and in response to J&J's hypothetical question, Nicolson said: "Well, I've never heard of a co-polymer of a contact lens copolymerized with a PVP, but if . . . by that you mean that there's a chemical bond between the PVP and the lens, I guess there's - one way to call that is a co-polymer, yeah." (Tr. IX at 145 (Nicolson).) This is not the type of testimony, standing alone or in tandem with the other evidence presented by J&J, that establishes by clear and convincing evidence that a homopolymer of PVP at a surface of the lens is not enabled.

28, 29; '894 Patent cls. 89, 90, 96, 99) are invalid for lack of enablement because "the claimed Ionoflux values exist in a broad range that extends far below what CIBA was able to achieve for an actual workable lens." (Doc. 286 at 55.) This is because, according to J&J, "[a] lens at the lower end of this broad range does not move on patients' eyes, as required by CIBA's claims." (Id.) J&J cites to AK Steel Corp., 344 F.3d at 1244, in which the court stated that "when a range is claimed, there must be reasonable enablement of the scope of the range." "By setting the threshold Ionoflux values in its claims to a level that it was never able to attain, CIBA did not fulfill its 'part of the *quid pro quo* of the patent bargain' to fully disclose how to make and use the 'full scope' of its claimed invention." (Doc. 286 at 58 (citing AK Steel, 344 F.3d at 1244).)

The CIBA patents teach that "ion permeability through the lens correlates well with on-eye movement" and that "above a certain threshold of ion permeability through a lens . . . the lens will move on the eye, and below the threshold the lens will adhere to the eye." ('100 Patent col.9 l.42-col.10 l.3.) The Ionoflux measurement technique is the preferred method for determining the ion permeability (or the rate of transmission of ions through a material) of a lens to determine the likelihood of adequate movement on the eye. ('100 Patent col.10 ll.57-60; Tr. IV at 164 (Freeman).) The asserted claims teach varying ranges of Ionoflux Diffusion Coefficient values.[71]

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[71] The asserted claims teach the following Ionoflux Diffusion Coefficient values: "an Ionoflux Diffusion Coefficient of greater than about $1.5\times10^{-6}mm^2/min$." ('100 Patent cl. 1); "an Ionoflux Diffusion Coefficient of greater than about $2.6\times10^{-6}mm^2/min$" ('100 Patent cl. 56); "an Ionoflux Diffusion Coefficient of greater than about $1.5\times10^{-6}mm^2/min$" ('811 Patent cl. 28); "an Ionoflux Diffusion Coefficient of greater than about $2.6\times10^{-6}mm^2/min$." ('811 cl. 29); "an Ionoflux diffusion coefficient of greater than about $1.3\times10^{-5}mm^2/min$"

Table F in the ‘100 patent recites Ionoflux Diffusion Coefficient values in “square millimeters per minute” units, for the F examples, and a notation about whether the sample lens moves on the eye. (‘100 Patent col.67 Table F; Tr. IV at 163-64 (Freeman).) The patent teaches that “[c]onsidering only Examples F-1 through F-13 of Table F, the lowest value of Ionoflux Ion Permeability Coefficient for which a lens moves on the eye is 2.6×10^{-6} mm^2/min.” (‘100 Patent col.67 ll.60-62 & Table F (Ex. F-4); Tr. IV at 164 (Freeman).)

According to J&J’s expert Freeman, the Ionoflux value of $1.5\times10^{-6}mm^2$/min recited in claim 1 of the ‘100 Patent, while “not impossibly low, . . . they’re very low values of ion permeability, at least based on my measurements of . . . polymer films.” (Tr. IV at 166-67 (Freeman).) Freeman calculated the Ionoflux Diffusion Coefficient for re-creations of examples F-4, F-5, F-6, F-10 and F-12 in Table F of the ‘100 Patent, all examples reported by CIBA to exhibit “on-eye movement,” and found that the values reported in Table F were “significantly below” the measurement he obtained for the same example, “[i]n some cases, . . . by more than a factor of 10, and often approaching a factor of 100.” (Tr. IV at 169-70 (Freeman); PTX 1035.) According to J&J, the Ionoflux values of the re-created CIBA examples “were anywhere from more than 3 to more than 70 times higher than *any* of the threshold values recited in the patents.” (Doc. 286 at 57.)

Freeman also calculated Ionoflux values for re-creations of prior art, and compared the Ionoflux values he obtained on prior art with the Ionoflux value recited in the CIBA ‘100

(‘894 Patent cl. 89.)

Patent claim 1 limitation. (Tr. IV at 168 (Freeman); PTX 1033).) He concluded that the only value that came close to the Ionoflux claim limitation was the Fluoroperm lens "which is a very low ion permeability material, [that] has practically no water in it" and is not a silicone hydrogel lens. The rest of the numbers were "significantly greater" than the CIBA claim limitation floor. (Tr. IV at 168-69, 245 (Freeman); PTX 1033.)

J&J and its expert Freeman support their view with the statements of CIBA co-inventor John Court who took the view that the CIBA Ionoflux values stated in the patent were too low by an order of magnitude, (Tr. IV at 172-76, 180, 182 (Freeman); Tr. I at 186 (Winterton); PTX 71 at CSFJ064919 and CSFJ064921; PTX 352; PTX 458; PTX 1036; DTX 618 at CSFJ762531), and a series of 1997 CIBA documents. (PTX 353; PTX 631 at CSFJ919071, 073.)

Additionally, to support his opinion, Freeman examined a graphic plot prepared by CIBA of relative Ionoflux coefficients of reference material Alsacon (B and C examples in the CIBA patent) representing the numbers CIBA actually measured in the laboratory. Using mathematical interpolation, Freeman found that the absolute Ionoflux values reported by CIBA in Table F were "systematically lower" than the Ionoflux values calculated from the graph conversion, and that the numbers he calculated "in many of these cases" were "a factor of ten higher" than those in Table F, which is consistent with CIBA co-inventor John Court's concerns. (Tr. IV at 183-88 (Freeman); PTX 458 at CSFJ207295; PTX 1034.) From this exercise, Freeman concluded that the Ionoflux coefficient value set as the lowest limit in claim 1 of the '100 Patent was less than the value found by CIBA to "[bind] to the cornea" and that the Ionoflux value must be higher to "move on the cornea." (Tr. IV at 189-90

(Freeman); PTX 453 at CSFJ029146.)[72]

Freeman concluded, based upon his review of the documentary evidence, independent mathematical interpolations and the 1997 article by CIBA co-inventors, that the Ionoflux Diffusion Coefficient values reported in Table F were too low, and that "[t]here was some sort of mistake in those values getting into the patent, and then the claim limitations were set based on . . . the erroneous values that are in Table F." (Tr. IV at 195-96 (Freeman.) Freeman opined that the bottom threshold Ionoflux values reported in the CIBA claims are lower than the Ionoflux values that CIBA actually measured, and that CIBA never measured values that are as low as those that are shown in the patents. (Tr. IV at 128, 190-91 (Freeman).)

CIBA responds that when enablement is at issue, "[a] specification need not contain *any* working examples if the invention is otherwise disclosed in such a manner that one skilled in the art will be able to practice it without an undue amount of experimentation." (Doc. 287 at 58 (emphasis in original) (citing In re Borkowski, 422 F.2d 904, 908 (C.C.P.A. 1970).) CIBA frames the issue as "whether a skilled artisan, following the teachings of the patents, would have been able to make a lens at the lower end of the various claimed

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[72] J&J also cites to an article co-authored by CIBA co-inventors Domschke, Winterton and Dieter Lohman, published in the Spring 1997, discussing the relation of ion permeability and on-eye movement in contact lenses which said that "[a lens with a] relative Ionoflux value below 0.1 on this scale . . . would adhere to the eye," while above that level the lens becomes mobile on the eye, referring to the Alsacon lens (Example C in the CIBA patent). J&J expert Freeman said that the article is consistent with the graph and plot that Freeman used in his mathematical conversion and comparison. (Tr. IV at 191-94 (Freeman); PTX 149, 458.)

Ionoflux ranges that also met the other limitations of the respective claims." CIBA argues that "J&J has not shown that a skilled artisan would not have been able to make a lens at the low end of the claimed Ionoflux ranges that meet the rest of the respective claims." (Doc. 287 at 58.) Though with its commercial product, CIBA desired to keep the ion permeability high, the patent presents a range of Ionoflux values: "my understanding is that we were trying to show what the limit - the lower limit that one could have and still have on-eye movement." (Tr. I at 189 (Winterton).) The lower values represent the floor.

CIBA inventor Winterton said that the ion permeability values, including the Ionoflux Diffusion Coefficient values, recited in the patent claims "represented a threshold that we could achieve through various chemistry manipulations of our materials." (Id. at 188.) Winterton testified that the SEE3 team, worldwide, discussed concerns raised by John Court. "We actually met together and began looking at [Court's] assertions that we had made an error. And to our best knowledge, that we concluded at that time, that we had not made an error and that [Court] was the one that had made an error." (Tr. I at 186 (Winterton); see also id. at 186-87; Tr. II at 28 (Winterton).) However, there are no documents in evidence reflecting the CIBA discussions or meeting, though CIBA cites to handwritten notes on a CIBA JUMP application document dated March 18, 1997 saying "no known problems with example data." (PTX 504; Tr. II at 28 (Winterton).)

CIBA contends that J&J presented no evidence that it ever attempted and was unable to re-create a contact lens taught in the CIBA patents at the low end of the Ionoflux range. (Doc. 287 at 58 (citing Tr. IV at 234-35 (Freeman)).) However, J&J did test prior art lens Fluoroperm, a commercial contact lens, which has an Ionoflux Diffusion Coefficient which

is just less than the 1.5×10^{-6} value claimed by CIBA's '100 Patent cl.1. (Tr. IV at 235 (Freeman); PTX 1033.) Furthermore, CIBA points to Freeman testimony acknowledging that the patent does teach "different techniques" for affecting the ion permeability of the lens which were "outside the scope of my investigation here." (Tr. IV at 233 (Freeman).) Finally, CIBA argues that the Ionoflux limitations in the asserted claims do not lack written descriptive support, citing "literal written descriptive support" in the specifications. (Doc. 287 at 60.)

On cross-examination, Freeman acknowledged that if CIBA inventor John Court were correct about an order of magnitude error, the values taught in Table F of the '100 Patent would be wrong by a factor of 10. (Tr. IV at 237-38 (Freeman).) However, the Ionoflux values Freeman obtained when testing re-created examples, while consistently higher than the values reported in Table F, did not reflect a systematic order of magnitude error. (Tr. IV at 238 (Freeman); Tr. IX at 55-58 (Pitt); PTX 1035.) Additionally, CIBA expert Mays testified that J&J scientist Vanderlaan, who re-created the CIBA samples tested for Ionoflux by Freeman, (see Tr. VI at 173; Tr. VII at 19-21 (Vanderlaan); PTX 527 at W121129-30, W121141, W121148; PTX 524 at W120217; PTX 528 at W121309), and Freeman himself, did not follow the procedures set forth in the CIBA '100 Patent for re-creating the CIBA materials tested for their Ionoflux values. (Tr. X. at 22-31 (Mays).) Mays opined that these variations in the re-creations would affect the Ionoflux Diffusion Coefficient values obtained by Freeman. (Id. at 29, 31-32.)

Finally, CIBA expert Pitt, in analyzing measurements made on CIBA's re-creations of J&J's Acuvue Oasys lens, found that the Ionoflux Diffusion Coefficient of the Acuvue Oasys lens meets the limitations of all of the asserted claims. (Tr. II at 108-09 (Pitt); DTX

1414, 1429.) Though J&J expert Freeman contends that CIBA expert Pitt's analysis is not correct, (Tr. IV at 196 (Freeman)), J&J presented no substantive evidence disputing Pitt's conclusion that the Acuvue Oasys meets the CIBA Ionoflux claim limitation.

Important to the Court's analysis is that J&J has framed its argument as one of non-enablement as opposed to challenging the CIBA patents' written description of the Ionoflux claim limitation under 35 U.S.C. § 112. (Doc. 286 at 55.) J&J, of course, carries the high burden of proving by clear and convincing evidence that the CIBA patent is not enabled.

J&J contends that the fact that its expert Freeman's determined in his testing that the examples listed in Table F of the '100 Patent all have higher Ionoflux Diffusion Coefficients than listed by CIBA, supports its position that the Ionoflux claim limitations in the nine asserted claims are too low. J&J argues that "the absence of such a working example [in the patent] is strong evidence that the claims are not enabled." (Doc. 303 at 25.)

CIBA has adduced evidence that raises questions as to the validity of J&J's Freeman Ionoflux results. First, Freeman's Ionoflux values, while all higher than the values recited for the examples in Table F, do not present an order of magnitude variation, nullifying the argument that John Court was correct. Second, CIBA expert Mays testified that J&J's Vanderlaan did not re-create the examples in Table F in accordance with the specifications of the CIBA patent, and Freeman also did not follow procedures set forth in the patent, which Mays opined could have an effect on the Ionoflux values. While Vanderlaan states that he accurately followed the procedures set forth in examples B-5 and B-7 and attempted to follow the steps in the CIBA patent for re-creating examples C-16, C-18, and C-19 (Tr. VII

at 20-22 (Vanderlaan),[73] CIBA's expert Mays pointed to specific variances in procedure, comparing the Vanderlaan laboratory notes with the specifications in the patent. (Tr. X at 22-31 (Mays).) The Court gives more weight to Mays' opinion concerning the accuracy of the re-creations.

Further, even if J&J expert Freeman's testing of the CIBA Table F examples is accepted as correct, it alone is not fatal to the validity of CIBA's patents, which are presumed valid and enabled. Working examples can provide a means to show enablement, but working examples are not required by § 112. "Nothing more than objective enablement is required, and therefore it is irrelevant whether this teaching is provided through broad terminology or illustrative examples." In re Wright, 999 F.2d 1557, 1561 (Fed. Cir. 1993). "The first paragraph of § 112 requires nothing more than *objective* enablement. How such a teaching is set forth, either by the use of illustrative examples or by broad terminology, is irrelevant." In re Vaeck, 947 F.2d 488, 496 n.23 (Fed. Cir. 1991). "[R]epresentative examples are not required by the statute and are not an end in themselves. Rather, they are a means by which certain requirements of the statute may be satisfied. Thus, inclusion of a number of representative examples in a specification . . . is one way of teaching how to make and/or how to use the claimed invention, thus satisfying that aspect of § 112." Application of Robins, 429 F.2d 452, 457 (C.C.P.A. 1970); but see Soitec, 81 F. App'x at 738 ("[c]onsidering the unpredictability of the art, the lack of direction and guidance in the

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[73] CIBA objected to J&J's question to Vanderlaan, a J&J scientist and fact witness, whether he "accurately" re-created the CIBA patent examples, noting that while Vanderlaan may testify about what he did, whether he re-created the examples accurately is a question for an expert. (Tr. VII at 22 (Vanderlaan).) The Court agrees.

specification and the absence of working examples, the jury's finding" of invalidity for nonenablement "is well supported"); Emergency Fuel, LLC v. Penzoil-Quaker State Co., 71 F.App'x 826, 832 (Fed. Cir. 2003)(while specification need not contain a working example to satisfy enablement requirement, the lack of working examples in specifications may be considered as further evidence that the asserted claims are not enabled).

J&J did not attempt to re-create a contact lens with the Ionoflux Diffusion Coefficient values actually recited in the asserted claims and made no showing that the patents failed to enable them to do so. (Significantly, though, it did re-create a prior art lens - the Fluoroperm - which did possess the low Ionoflux value taught in the CIBA claims.) Rather, J&J constructed an argument based on the lens examples listed in Table F of the '100 Patent in an attempt to establish that CIBA did not possess the ability to create lenses with "on-eye movement" at Ionoflux Diffusion Coefficient values as low as those taught by the asserted claims. CIBA did little in defense; but, given the requirements of enablement law, and the burden of proof on J&J, it did not have to. J&J has failed to show by clear and convincing evidence that the nine asserted claims are not enabled based upon their Ionoflux Diffusion Coefficient limitations.

4. Whether certain Ionoton values lack adequate written description and/or are not enabled[74]

"J&J contends that claims 1 and 28 of the '100 Patent are invalid as not enabled under 35 U.S.C. § 112 ¶ 1 because the ion permeability values recited in those claims cover

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[74] While the parties agreed that the heading of this issue would include a reference to the "written description" defense, (Doc. 281 at 2), J&J presents only a non-enablement argument in its post-trial briefing.

lenses that do not move on the eye," as required by the asserted claims. (Doc. 286 at 58.)[75] J&J focuses on Table E in the '100 Patent ('100 Patent col.64 Table E) which it says "sets forth all of the Ionoton Coefficients for CIBA's example lenses, and significantly, discloses that a lens will *not* move on the eye if it has an Ionoton Coefficient of $8\times10^{-6}cm^2/sec$ (equivalent of $0.008\times10^{-3}cm^2/sec$) in Table E." (Doc. 286 at 58 (citing '100 Patent col.64 ll.50-52).)[76] J&J argues that the Ionoton limitation in claims 1 and 28 of "greater than" $0.2\times10^{-6}cm^2/sec$ sets the bar "40 times lower than the 8×10^{-6} value for a lens that does not move." (Id.) Thus, argues J&J, "the specification fails to enable the full scope of the claimed invention of claims 1 and 28 of the '100 patent" despite the fact that the claims also recite adequate on-eye movement. (Id. at 58-59 (citing AK Steel, 344 F.3d at 1244).)

Additionally, J&J posits that claims 89, 90, 96 and 99 of the '894 Patent are invalid because "these claims recite physically impossible Ionoton values." (Id. at 59 (citing Process Control Corp. v. HydReclaim Corp., 190 F.3d 1350, 1359 (Fed. Cir. 1999)("'a claim

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[75] Claims 1 and 28 teach a contact lens with an "Ionoton Ion Permeability Coefficient of greater than about $0.2\times10^{-6}cm^2/sec$ . . . ." ('100 Patent cl. 1.)

[76] The specification cited by J&J reads as follows:

> Considering Examples E-1 through E-13 of Table E, the lowest value of Ionoton Ion Permeability Coefficient for which a lens moves on the eye is $0.25\times10^{-3}cm^2/sec$. The highest value of Ionoton Ion Permeability Coefficient for a lens which bound on the eye is $0.008\times10^{-3}cm^2/sec$. Thus, a contact lens preferably has an Ionoton Ion Permeability Coefficient greater than about $0.008\times10^{-3}cm^2/sec$., more preferably greater than about $0.25\times10^{-3}cm^2/sec$.

('100 Patent col.64 ll.48-55.)

containing a limitation impossible to meet may be held invalid under § 112'" (citation omitted)).)[77] J&J cites to its expert Freeman's testimony that the highest possible physical limit for Ionoton permeability values in polymers and water is $2.1\times10^{-5}cm^2/sec$. (Id. at 59; Tr. IV at 224 (Freeman)("ion permeability of sodium chloride through . . . hydrated polymers should be capped at the level of the ion permeability through water, since it's really the water that's enabling the ion diffusion and transmission to occur").) J&J states that the Ionoton permeability values in the '894 Patent asserted claims is $0.25\times10^{-3}cm^2/sec$, or "approximately ten times above this physical limit." (Doc. 286 at 59.) "CIBA is claiming that in the patented lenses ions move ten times faster than physically possible." (Id.)

CIBA responds that J&J did not present evidence regarding this issue at trial. Specifically, CIBA argues that the entirety of Freeman's expert opinion was limited to the issues of whether the Ionoton limitations are indefinite, and whether the Ionoflux limitations are enabled. (Doc. 287 at 60 (citing Tr. IV at 127-28 (Freeman) and 120-121 (Buchanan (J&J attorney)).) According to CIBA, "Dr. Freeman did not give an opinion that the Ionoton limitations are not enabled or that they lack written description." (Id.) CIBA contends that expert opinion testimony is necessary to establishing that a claim is not enabled.

CIBA's expert Pitt testified that he disagreed with Freeman's opinion that a workable Ionoton value could be no greater than the value obtained for the diffusion of ions through

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[77] Claim 89 of the '894 Patent teaches a lens with "ion permeability characterized either by (1) an Ionoton ion permeability coefficient of greater than about $0.25\times10^{-3}cm^2/sec$, or (2) an Ionoflux diffusion coefficient of greater than about $1.3\times10^{-5}mm^2/min$, wherein said ion permeability is measured with respect to sodium ions." ('894 Patent cl. 89.) Claims 90, 96 and 99 are dependent on claim 89.

water. (Tr. IX at 54 (Pitt).) Pitt said that Ionoton permeability values are to be distinguished from diffusion through water, and that "[t]here's no law of physics or chemistry that says it's impossible to have an Ionoton value that's . . . higher than. . . what Dr. Freeman says the diffusivity limit is. It's possible to have higher values." (Id.) J&J dismisses Pitt's testimony as being "confused," saying that Freeman did focus upon ion permeability as opposed to diffusion when rendering his opinion about its physical limits. (Doc. 286 at 59.)

As to J&J's challenge of claims 1 and 28 of the '100 Patent, the Court may not draw inferences from J&J's readings of the specifications without more guidance. The specification cited by J&J is directed to "[c]onsidering Examples E-1 through E-13 of Table E." ('100 Patent col.64 l.48.) It is unclear that the conclusions recited in the specification apply universally, or are merely conclusions confined to the 13 examples discussed in Table E. While not stating a per se rule, the Federal Circuit has noted that "relevant expert testimony regarding matters beyond the comprehension of laypersons is sometimes essential." Centricut, LLC v. Easb Group, Inc., 390 F.3d 1361, 1369-70 (Fed. Cir. 2004). "'[T]ypically expert testimony will be necessary in cases involving complex technology. Id. at 1370.

It goes without saying that the matter of ion permeability and the question of whether a contact lens with "an Ionoton Ion Permeability Coefficient of greater than about $0.2\times10^{-6}cm^2/sec$" is enabled involves complex technology. Here, a person skilled in the art of contact lenses in 1995 would at least have a college degree in material science, polymer science or chemistry and three to five years of experience. (See Tr. IV at 243, 249 (Freeman).) This is not the type of patent question that the fact finder can determine without

the assistance of expert testimony. Accord Proveris Scientific Corp. v. Innovasystems, Inc., 536 F.3d 1256, 1267 (Fed. Cir. 2008)(inasmuch as patent for a device used in calibrating aerosol spray drug delivery devices "is sufficiently complex to fall beyond the grasp of an ordinary layperson," no abuse of discretion in requiring accused to present expert testimony in order to establish invalidity).

As to the '894 Patent asserted claims, Freeman's testimony that the Ionoton values taught by the '894 Patent claims are impossibly higher than the "upper physical limit for Ionoton value" (Tr. IV at 224 (Freeman)) is scant to the point of being conclusory. Freeman offers no support or explanation for this opinion except to say that the ion permeability of a "hydrated polymer" is the same as water.[78] J&J rests its lack of Ionoton enablement argument as to the '894 asserted claims totally on Freeman's opinion, an unsupported assertion which the Court is not required to credit. See Rohm and Haas Co. v. Brotech Corp., 127 F.3d 1089, 1092 (Fed. Cir. 1997); see also Aspex Eyewear, Inc. v. Concepts In Optics, Inc., 111 F. App'x 582, 588 (Fed. Cir. 2004); Dayco Products, Inc. v. Total Containment, Inc., 329 F.3d 1358, 1369-1370 (Fed. Cir. 2003).

Again, J&J, which has made this challenge one of non-enablement, has failed to adduce clear and convincing evidence that a skilled artisan would be unable to make without undue experimentation a lens at the low end of the Ionoton range that also moves on the eye, as taught by claims 1 and 28 of the '100 Patent. Likewise, J&J has produced no

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[78] CIBA expert Pitt disagrees. CIBA states in its brief that "there are specific examples in the patent with Ionoton values that meet the higher Ionoton threshold of $0.25\times10^{-3}cm^2/sec$ of claim 89 of the '894 patent," but failed to provide any citation to any such examples. (Doc. 302 at 24.)

evidence, other than Freeman's conclusory and disputed opinion, that one skilled in the art could not make a lens meeting the threshold taught in the asserted claims of the '894 Patent.

C. Obviousness

J&J argues that the asserted claims of the '811 Patent and the '894 Patent are invalid as obvious based primarily on the disclosures in the prior art U.S. Patent No. 5,712,327 (filed June 16, 1992)("Chang '327 Patent"). (See Doc. 303 at 25 (asserted claims "are invalid as obvious over Chang"); PTX 125.)[79] 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). J&J bears the burden of proving obviousness by clear and convincing evidence.

"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, 416 (2007). "[A] court must ask whether the improvement is more than the predictable use of prior art elements according to their established functions." Id. at 417 "One of the ways in which a patent's subject matter can be proved obvious is by noting that there existed at the time of invention a known problem for which there was an obvious solution encompassed by the patent's claims." Id. at 419-20. "[A]ny need or problem known

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[79] J&J made its obviousness argument in the alternative to its non-infringement argument regarding the requirement in CIBA's patents that "oxygen permeability" does not depend on thickness. (Doc. 286 at 60.) The Court has determined that J&J's Acuvue Oasys lens infringes upon the oxygen permeability term in the CIBA asserted claims. (See supra at 6-20.) J&J's obviousness argument is ripe for determination.

in the field of endeavor at the time of the invention and addressed by the patent can provide a reason for combining the elements in the manner claimed." Id. at 420. "[O]bviousness does not require absolute predictability of success . . . all that is required is a reasonable expectation of success.'" In re Kubin, 561 F.3d 1351,1360 (Fed. Cir. 2009) (quoting In re O'Farrell, 853 F.2d 894, 903-04 (Fed. Cir. 1988)). However, the Court must be cautious to avoid the "'temptation to read into the prior art the teachings of the invention in issue.'" KSR Int'l Co.. 550 U.S. at 421 (citation omitted).

While the ultimate question of patent validity is one of law, the proper resolution of that ultimate question typically turns on underlying factual inquiries. Commonwealth Scientific and Indus. Research Organisation v. Buffalo Tech. (USA), Inc., 542 F.3d 1363, 1375 (Fed. Cir. 2008). "The factual determinations underpinning the legal conclusion of obviousness include 1) the scope and content of the prior art, 2) the level of ordinary skill in the art, 3) the differences between the claimed invention and the prior art, and 4) evidence of secondary factors, also known as objective indicia of non-obviousness." Eisai Co. Ltd. v. Dr. Reddy's Labs., Ltd., 533 F.3d 1353, 1356 (Fed. Cir. 2008). Secondary considerations of non-obviousness include the commercial success of the invention at issue, its satisfaction of long-felt need and failure of others. KSR Int'l Co., 550 U.S. at 406 (citing Graham v. John Deere Co. of Kansas City, 383 U.S. 1, 17-18 (1966)). "[E]vidence relating to secondary considerations 'constitutes independent evidence of nonobviousness.'" Sud-Chemie, Inc. v. Multisorb Techs., Inc., 554 F.3d 1001, 1008 (Fed. Cir. 2009)(citation omitted). The obviousness inquiry must rely on evidence available at the time of the invention. Eisai Co. Ltd., 533 F.3d at 1359. Expert evidence may "'constitute independent evidence of

nonobviousness.'" Commonwealth Scientific and Indus. Research Organisation, 542 F.3d at 1377 (citation omitted).

1. Whether '327 Chang in combination with the knowledge of a person of ordinary skill in the art makes CIBA's invention invalid as obvious.

J&J frames the issue as being whether "there are any differences between CIBA's claimed invention and the disclosures of the Chang patent and, if so, whether the claimed invention would have been obvious to a person of ordinary skill in the art as of December 8, 1995, despite those differences." (Doc. 286 at 61.) J&J contends that "the disclosures in Chang, which the law presumes are correct, refute CIBA's claim that it was the first to achieve" an extended wear silicone hydrogel lens. (Doc. 303 at 25.) J&J's expert Valint opined that the subject matter of the CIBA '811 and '894 Patents would have been obvious to one skilled in the art. (Tr. VII at 88 (Valint).)

a. Scope and content of prior art

Silicone hydrogel contact lenses had been the subject of industry research since the late 1970's. (Tr. I at 143-44 (Nicolson).) The CIBA SEE3 Program's mission (begun in November 1992) was to develop and market by December 1997 a soft and comfortable extended wear lens with high oxygen permeability greater than Dk 70 and transmissibility, good wettability, deposit resistance and manufacturable at a reasonable cost. (Id. at 89, 142; DTX 664 at CSFJ066591.) Nicolson testified that though approved for seven-day wear, the conventional hydrogels did not provide adequate oxygen permeability necessary for good corneal health. The conventional hydrogels on the market in the early 1990's contained

water and acrylic polymers, and lacked silicone, which increases the amount of flux of oxygen through the lens. Because silicone was known to impart high oxygen permeability to the polymer in which it is incorporated, CIBA chose to pursue a silicone hydrogel to produce an extended wear lens meeting its criteria. According to Nicolson, prior art extended wear lenses on the market in 1995, including the Chang lens, did not have oxygen permeability exceeding a Dk of 70. (Tr. I at 142 (Nicolson).) "There was no such product on the market. And we [CIBA] felt that this offered a tremendous market opportunity to introduce a product that would deliver safe and extended wear contact lenses." (Tr. 1 at 45 (Nicolson); see also id. at 44-46, 89-90.)

According to J&J, it was known that the combination of silicone material and hydrogels (hydrophilic materials) creating silicone hydrogels "provided workable lenses," but not for 30-day extended wear periods. (Tr. VII at 91, 93-94 (Valint) None of the existing silicone hydrogel prior art lenses cited could be worn for extended periods, nor were they commercially successful. (Id. at 97.) Consistent with Nicolson, J&J expert Valint testified that as of 1995, there was literature in the field stating that the cornea required more oxygen than conventional hydrogels were supplying. "So one skilled in the art knew that silicone materials have very, very high permeability to oxygen." (Id. at 91 (Valint).) It was also known that the conventional hydrogels were "quite biocompatible in all other respects." (Id.) According to Valint, "the combination of something that has silicone in it with the conventional hydrogel may be effective at supplying the total package of properties needed for an effective extended wear contact lens." (Id.)

The addition of silicone to a conventional hydrogel contact lens presented a new set

of problems. First, it is necessary to effectively mix the hydrophobic silicone with the hydrophillic materials in the lens to achieve a uniform, homogeneous lens that is clear and not hazy. Second, because silicone is hydrophobic, likened to bathroom caulk, it affects the lens surface wettability and lens comfort. (Tr. IV at 16-18 (Turner); Tr. X at 8 (Mays).) "[T]he CIBA patent teaches the surface treatment of these to obtain a biocompatible lens." (Tr. VII at 97 (Valint).)

In 1991, the Chang patent was first described in a European patent application. The patent taught that a silicone hydrogel formulation could be "chemically surface treat[ed]" for use as an extended wear lens. It is equivalent to the United States patent, which was filed June 16, 1992. (Tr. VII at 99-100 (Valint); PTX 125, 292.) The Chang '327 Patent is entitled "Soft Gas Permeable Contact Lens Having Improved Clinical Performance." The Abstract of the '327 Chang Patent describes:

> A hydrophillic soft gas permeable contact lens having substantially improved clinical performance by the provision of a sufficient higher proportion of hydroxy acrylic units to silicon units in the lens surface layer, as compared to that existing in the lens core, by the surface treatment of the lens, such as by reacting of the lens surface with polyols and base or acid or by radiation treatment of the base lens to graft, deposit or coat thereon hydroxy acrylic units.

(PTX 125 ('327 Patent (Chang) Abstract).) Inventor Chang, in the '327 Patent, addressed the "need for plastic contact lenses of the [soft gas permeable] type which not only possess a high degree of oxygen permeability, but also exhibit excellent clinical performance, such as functional wettability, deposition resistance, and comfort, thus making the lenses suitable for extended wear." (PTX 125 ('327 Chang Patent col.2 ll.1-7).) According to J&J expert

Valint, the '327 Chang Patent differed from other prior art because it provided extended wear performance to a silicone hydrogel lens by surface treating the lens. (Tr. VII at 101 (Valint).) The '327 Chang Patent describes surface treatment to reduce the silicone content at the surface and replace it, either using a chemical reaction on the lens surface or by radiation treatment to graft or deposit onto the surface, a "hydroxy acrylic monomer" that is "very hydrophilic" to provide wettability. (Id. at 102; PTX 125 ('327 Chang Patent col.2 ll.22-31).) The '327 Chang Patent specifies "substantial" high oxygen permeability (Dk), and Example 1 of the patent teaches that it is a lens with "high Dk, about 4 to 5 times higher than that of the conventional poly HEMA soft lens." (Tr. VII at 103 (Valint); PTX 125 ('327 Chang Patent col.1 ll.14-21; col.2 ll.16-21; col.6 ll.21-22).) Based on these specifications, J&J expert Valint testified that "the Chang patent teaches a surface treatment of a silicone hydrogel lens that was shown to be successful for extended wear." (Tr. VIII at 128 (Valint).) Nicolson countered that the "modest" oxygen permeability achieved by the silicone in Chang's lens was lowered by the Chang surface treatment. (Tr. I at 142-43 (Nicolson).) This is because during the glycerine surface treatment to remove silicone from the surface, the silicone at the surface and within the lens body corrodes away, which in turn, reduces the oxygen permeability and transmissibility of the lens. (Tr. X at 9 (Mays).) CIBA expert Mays described the phenomenon as a trade off; the more silicone eliminated from the surface (and the bulk) of the lens, the more wettable and comfortable the lens, but the less permeable to oxygen. (Tr. X at 20 (Mays).) The chemical surface treatment taught by the Chang patent has not been adopted in the contact lens industry; no other contact lens manufacturer is using the process. (Tr. VIII at 26-27 (Valint).)

b. Comparing CIBA Invention With Prior Art

J&J focuses on Example 3 of the '327 Chang Patent which describes a silicone hydrogel contact lens where the silicone component TRIS is polymerized with hydrophilic monomers dimethlacrylamide and HEMA. The lens has a water content of 38, "high Dk," soft properties, and a highly hydrophilic lens surface. The example describes a surface treatment using glycerine, a chemical method for removing some of the silicone on the surface to make the lens more wettable and more comfortable in the eye. This treatment "converted the lens to one which on the same patient could be used for weekly extended wear for a three week testing period with stable vision and no observable deposition, and demonstrated a liquid layer over the lens surface." (Tr. VI at 190 (Vanderlaan); Tr. VII at 103-104 (Valint); PTX 125 ('327 Chang Patent col.7 ll.7-22.)

J&J scientist Vanderlaan made 24 batches of the Chang Example 3 lens between December 2005 and March 2008 in connection with this litigation. (Doc. 286 at 63; Tr. VI at 191-201 (Vanderlaan); Tr. VII at 105-106 (Valint); PTX 527; DTX 1461.) Inasmuch as the Chang Example 3 specification does not identify the thickness of the lens, Vanderlaan produced Chang Example 3 lenses of different thicknesses. (Tr. VII at 8-9 (Vanderlaan).)

J&J expert Benjamin determined and reported in his 2006 report that the oxygen permeability (Dk) of the 2005 and 2006 Example 3 re-creations was 125.9 barrers (mean value), and the transmissibility (Dk/t) was 90.7 barrers using the single point coulometric method of measurement,[80] both values meeting the threshold values stated in the CIBA

[80] On cross-examination, Benjamin acknowledged that he had made a mathematical error in calculating the oxygen transmissibility value, which, if corrected in accordance

patent claims. (Tr. V at 42-44, 76 (Benjamin); Tr. VII at 107-109 (Valint); PTX 27A; PTX 773 at W120061.) J&J expert Freeman found the Ionoflux permeability coefficient of the Example 3 of the Chang patent to be $4.2\times10^{-3}mm^2/min$. Another preparation of the Example 3 lenses yielded a "quite similar" Ionoflux value of $2.6\times10^{-3}mm^2/min$. (Tr. IV at 168-69 (Freeman); Tr. VII at 110-11 (Valint); PTX 1033, 1046.) According to Valint, the tested Example 3 re-creations also met the CIBA patent threshold level for ion permeability. (Tr. VII at 110 (Valint); PTX 1146.) The 2005 and 2006 Example 3 re-creations (batches 1, 2, and 5) measured by Benjamin for oxygen permeability and transmissibility were never submitted to a clinical study. (Tr. V at 73 (Benjamin).)

In May, 2008, J&J clinician Brennan conducted a clinical study of Chang Example 3 re-creations made in March, 2008, on six patients for a 21-22 hour period.[81] (Tr. V at 47 (Benjamin); Tr. VIII at 139-40 (Brennan); PTX 239; PTX 529 at W122925.) Brennan reported his findings on the elements of ophthalmic compatibility as construed in this case. (PTX 239.) He found the median corneal swelling to be 6.9%, with the "top five" subjects ranging from 5.5% to 8.3%. Brennan characterized the sixth patient with unacceptable 17.3% corneal swelling as a "rogue" and an "outlier," and excluded those results from his calculations. (Tr. VIII at 148-53 (Brennan).) Brennan concluded, "We measured five different parameters with the contact lenses and we found that the [six] subjects were able

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with the testimony, would yield a mean Dk/t value of 97.5. (Tr. V at 77-81 (Benjamin).)

[81] Brennan concluded his study after 22 hours as opposed to 24 hours for "logistical" reasons to avoid having to retain the study subjects for two days instead of one. (Tr. VIII at 140, 168 (Brennan).)

to wear the contact lenses . . . except in the case of the one person with deposits, and the one person with corneal swelling of 17 percent, without any major problems." (Tr VIII at 165 (Brennan).)[82]

Benjamin tested the oxygen permeability and transmissibility of the 2008 batch of Chang lenses which were submitted for clinical testing, and found those values to be Dk (oxygen permeability) of 36.16 and Dk/t (oxygen transmissibility) of 58.32, which did not meet the CIBA claim limitations. (Tr. V at 75-76, 81, 86 (Benjamin); DTX 456.)

Ticking off the limitations in the asserted CIBA patents, J&J argues that the Chang '327 Patent specifications and embodiments, the results of J&J testing on its re-creations of the Chang Example 3 lens, and the opinions of the experts establish that the asserted claims of the '811 and '894 Patents were obvious to one of ordinary skill in the art as of December 8, 1995 based on the Chang '327 Patent. (Tr. VII at 151-62, 172 (Valint).)[83] J&J contends

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[82] J&J scientist Vanderlaan wore one of the December 2005 Chang re-created lenses for four hours. Vanderlaan reported that "it was pretty comfortable" though he experienced "a very slight burning feeling," that his vision was "good," and that the lens could easily be moved in the eye. (Tr. VI at 203-08 (Vanderlaan); Tr. VII at 6 (Vanderlaan); PTX 527 at W121123.)

[83] Valint's opines that the Chang '327 Patent renders claim 96 of the '894 Patent (relating to PVP at the surface of the lens) obvious when in combination with another patent, U.S. Patent No. 4,143,949 (filed Oct. 28, 1976)('949 Chen Patent). (PTX 93; Doc. 286 at 65; Tr. VII at 161-62 (Valint).) J&J did not test a Chang plus Chen combination lens for ion or oxygen permeability, or for its ophthalmic compatibility, and J&J expert Valint conceded that he did not have an opinion as to whether Chang plus Chen met all the terms of claim 89 upon which claim 96 is dependent. (Tr. VIII at 31-33 (Valint).) Additionally, the surface treatment involving PVP taught in Chen is not consistent with the purpose of the Chang patent. (Id. at 35.) J&J has not established by clear and convincing evidence that asserted claim 96 of the '894 Patent was made obvious by a combination of the Chang plus Chen patents.

that the Chang patent recites the same material components as the CIBA patents. J&J cites to the results of its permeability testing of the 2005 and 2006 batches of Chang Example 3 re-creations as a basis for arguing that Chang makes obvious the CIBA patents numerical oxygen and ion permeability limitations. (Doc. 286 at 63-64.) Further, J&J cites to the Chang patent itself which it says teaches that its examples are lenses with "'high DK.'" (Doc. 286 at 67 (citations omitted); Tr. VIII at 10 (Valint).) With regard to the "period of wear" requirements of "at least 24 hours" and "at least 7 days," recited in the '811 and '894 CIBA Patent asserted claims, J&J argues that the specification in Chang Example 3 which teaches that the Chang lens was worn by one patient "for weekly extended wear for a three week testing period" establishes that the lens can be worn for a period of at least seven days. (PTX 125 ('327 Chang Patent col.7 ll.19-20); Tr. VIII at 22 (Valint)), and that the Chang patent specification and the Brennan clinical study establish that the Chang Example 3 meet the "at least 24 hours" limitations (See Tr. V at 47 (Benjamin).)

J&J relies entirely on the specifications of the Chang '327 Patent, including the teaching in Example 3 that one patient wore the Chang lens for one-week intervals, as predicting the future ophthalmic compatibility limitations of the seven-day wear asserted CIBA claims. J&J argues that the measured oxygen permeability of the Example 3 Chang lens means that the Chang patent "also meets the [CIBA] limitation 'without producing significant amounts of corneal swelling,'" based upon CIBA's own teaching that lenses with oxygen permeability above 72 barrers prevents substantial corneal swelling. (Doc. 286 at 64-65 (citing PTX 4 ('811 Patent col.4 ll.11-14).) J&J also relies upon the specification for Chang Example 3 which states that the example was worn with "no observable deposition"

as meeting CIBA's "without having substantial amounts of lipid adsorption" limitation. (Id. at 65.) J&J contends the CIBA claim limitation "adequate movement on the eye with blinking to promote adequate tear exchange" is met by Chang because the Chang lens "produces a liquid layer over the lens surface" confirmed by the fact its ion permeability is "'well above'" that recited in the CIBA claim. (Id. at 64.)

As to the asserted claims specifying 24-hour wear, J&J argues that along with the patent specifications set forth above, "[t]he Brennan study showed that [Chang Example 3] lens passed the four ophthalmic compatibility requirements in CIBA's claims: (1) corneal swelling, (2) on-eye movement, (3) deposits, and (4) comfort." (Id. at 65 (citations omitted).)

CIBA attacks J&J's evidence on several fronts. Addressing the 24 batches of Chang Example 3 re-creations, CIBA expert Mays testified that Vanderlaan used "[a] whole series of different processes" causing variations between the batches, in part because the Chang patent is not very detailed in how to make the lens. (Tr. X at 9-11, 15 (Mays); Tr. VII at 27-29 (Vanderlaan)("I made . . . technical judgments"); DTX 421, 1461.) Vanderlaan used a higher grade glycerine to surface-treat the lens than specified in the Chang '327 Patent. (Tr. VII at 35 (Vanderlaan).)[84] Also, Vanderlaan made some Example 3 batches by casting them in molds, and others by creating rods and lathing the rods into lenses and then surface

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[84] CIBA expert Mays said that the Chang patent taught the "lower" purity glycerine, because the water "impurity" was necessary for eroding away the siloxane material, such that Vanderlaan's use of a different glycerine also affected the properties of the Chang re-creations. (Tr. X at 18-20 (Mays).) Valint opined that the Vanderlaan recreations were correctly made, disputing CIBA expert Mays' criticisms. (Tr. VII at 107 (Valint).) Vanderlaan subsequently made Chang Example 3 lenses with a different glycerine percentage and "couldn't see any difference. They looked just the same." (Tr. VI at 199-200 (Vanderlaan).)

treating them. (See id. at 40-47; PTX 125 ('327 Chang Patent col.6 l.1).)[85] CIBA expert Mays said that the variations affected the properties of the re-created lenses. (Tr. X at 14 (Mays).)

The final batch of Example 3 Chang lens re-creations was made in March 2008 for the purposes of the Brennan clinical study. (Tr. VII at 55-56 (Vanderlaan).) Vanderlaan made several adjustments in this batch of lenses: he used a different grade of TRIS from the 2005 batches; filtered the monomer blend for the first time; de-gassed the lenses (removed oxygen) up to 60 minutes, as opposed to 30 minutes in earlier batches; and used a more vigorous shaking device for the glycerine surface treatment in contrast to the stirring method used earlier, removing more silicone from the later batch to make it more wettable (but also reducing the oxygen permeability). (Tr. VII at 30-35, 54-60 (Vanderlaan); Tr. X at 13-16, 19-20 (Mays); DTX 421.) Additionally, Vanderlaan made the later lens re-creations with a much thinner center thickness in response to J&J expert Mays' criticisms. (Tr. VII at 68-69 (Vanderlaan).) The 2008 lenses that were clinically tested had an average center thickness of 50 to 80 microns, reflecting the Chang preferred thicknesses, and were measured to have an oxygen permeability value (Dk) of 36. Valint agreed that it is likely, given those facts, that Example 3 of the Chang patent has a Dk in the range of 36. (Tr. VIII at 27-29 (Valint).)

CIBA clinical expert Dr. Michael Gene Harris ("Harris") disputes that the Brennan clinical study establishes that the Chang Example 3 lens that was tested is ophthalmically

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[85] Example 3 of the Chang '327 Patent does not specify whether the lens is to be made by mold or by lathing rods. However, the patent specifications provide for both methods. (PTX 125 ('327 Chang Patent col.3 l.63-64).)

compatible, as defined by the CIBA patents. (Tr. IX at 93 (Harris).) Harris opined that a six patient study is not a large enough patient sample to determine ophthalmic compatibility; he criticized the Brennan study for not measuring on-eye movement and lipid deposits on the eye at the end of the sleep period; he noted that three of the six patients had an increase in lipid deposits from 30 minutes to 12 hour testing, a fourth patient was at "moderate" from the beginning, and all patients had lipid deposits after 12 hours of wear; and he criticized Brennan for excluding the "outlier" patient from his corneal swelling conclusion (without excluding that patient from other evaluations). (Tr. IX at 93-99 (Harris).) Further, Harris opined that the disclosures of the Chang patent do not establish ophthalmic compatibility as defined by the CIBA patent. Even accepting the Chang Example 3 statement that one patient wore the lens for one-week intervals over a three-week period, the only one of the four CIBA ophthalmic compatibility factors "that was even described is the lipid deposit. There's no mention whatsoever of patient comfort, adequate lens movement, or the effect of corneal swelling as a result of this particular patient wearing this lens." (Id. at 102.)

c. Level of ordinary skill in the art

J&J argues that competitor Bausch & Lomb's ("B&L") "near-simultaneous success in achieving an extended wear silicone hydrogel lens at about the same time CIBA filed its '100 Patent application - in fact one year before - is strong evidence confirming that the 'breakthrough' that CIBA claims to have achieved was in reality an innovation (if any) that was an 'expected' improvement in the art that 'would occur in the ordinary course without real innovation.'" (Doc. 286 at 70-71 (citing KSR, 550 U.S. at 419).) This is because "'[t]he fact of near-simultaneous invention, though not determinative of statutory obviousness, is

strong evidence of what constitutes the level of ordinary skill in the art.'" Ecolochem, Inc. v. S. Cal. Edison Co., 227 F.3d 1361, 1379 (Fed. Cir. 2000). J&J cites to a September 1994 symposium presentation by B&L inventor George L. Grobe discussing surface treatment of "a proprietary silicone hydrogel" lens and concluding that "wettability of this silicone hydrogel can be positively affected by the application of oxidizing radiation," a surface treatment. (PTX 157 at CSFJ783343-44.)[86]

That same month, B&L submitted a 510(k) pre-market application to the FDA for approval to market the lens with surface treatment for daily wear described in the Grobe paper. The FDA application was approved in December 1994 and an abbreviated summary of the 510(k) application was made public. The pre-market application related to B&L's lens material named RD-677-Balafilcon A, which eventually was used after further development and study in B&L's commercial hydrogel contact lens product, called PureVision, under the

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[86] The surface treatment process discussed by Grobe in his 1994 presentation eventually led to a B&L patent. (Tr. VIII at 36-37 (Valint); DTX 354 (U.S. Patent No. 6,193,369 B1 (provisional application filed May 5, 1998)("B&L '369 Patent").) B&L co-inventor Valint acknowledged that in 1998, when applying for the patent, B&L would not have considered it obvious to apply plasma surface treatments to a silicone hydrogel, but said that the B&L patent offered a novel surface composition, and that at the time, the transientness of plasma surface treatments was known and discussed in the literature. (Tr. VIII at 38-39 (Valint).) Indeed, Valint and Grobe's patent states, as of 1998,

> Although such surface treatments have been disclosed for modifying the surface properties of silicone contact lenses, the results have been problematic and of questionable commercial viability, which has no doubt contributed to the fact that silicone hydrogel contact lens have yet to be commercialized.

(DTX 354 (B&L '369 Patent col.2 ll.1-6); Tr. VIII at 54-55 (Valint).)

B&L '369 Patent. (Tr. VII at 115-17, 124-26, 138 (Valint); Tr. V at 108, 111 (Nicolson); Tr. VIII at 36-37 (Valint); PTX 157 at CSFJ 783342, CSFJ 783344; PTX 409 at CSFJ117903; PTX 411; PTX 502; Doc. 190 at 20; Doc. 152 (CIBA Ex. 4 ¶ 10).) CIBA inventor Nicolson testified that CIBA was in competition with B&L and that CIBA inventors monitored B&L's patents during the period leading up to 1995. (Tr. I at 102, 104, 107-08 (Nicolson); PTX 595 at CSFJ060446; PTX 603, 604; see also Tr. V at 179, 207-08, 211 (CIBA co-inventor and former CIBA employee Richard C. Baron ("Baron")).) J&J also cites to other prior art patents to support its argument that the CIBA patents were obvious and not innovative. (Doc. 286 at 70 (citing PTX 103, 110, 123).)

CIBA responded that there is no evidence in this record that the RD-677/Balafilcon A lens is the *same* material as is in B&L's commercial PureVision lens, that as of 1995 the RD-677/Balafilcon A lens was suitable for extended wear, or that it met the limitations set forth in the CIBA patents. (Doc. 302 at 25-26 (citing DTX 1445 at ¶¶ 99-112).) Nicolson said that Grobe's presentation talked "about extended wear material." (Tr. V at 112 (Nicolson).) J&J expert Valint, an employee and consultant for B&L, acknowledged that Grobe's presentation "was approved [by B&L] with the appropriate masks of . . . certain proprietary information" and that the surface treatment discussed was "pretty well-known" in the literature at the time. (Tr. VIII at 6, 94-95 (Valint); see also PTX 157 at CSFJ783343 (Grobe symposium presentation referring to "[a] proprietary silicone hydrogel").) As of 1994, plasma surface treatment "was not routine in the industry, but it was . . . published and presented in September of 1994. And that information was then available." (Tr. VIII at 40 (Valint).) However, in 1995, it was known in the art that there were problems surface-treating silicone

hydrogels. (Id. at 43 (Valint).) Also, ex-CIBA employee Baron acknowledged that in 1995, he was not aware whether B&L's testing of an extended wear lens was successful, and agreed that there was no information in B&L's FDA 510(k) publically available summary detailing how to make the lens. (Tr. V at 214-17 (Baron); PTX 411.)[87] CIBA cited to publications and treatises contemporary to 1995, to establish that surface treatments were not part of the art. (See e.g. DTX 1379 at CSFJ918619.) Nonetheless, J&J expert Valint opined that "if you look at the Chang patent that's teaching a surface treatment to provide . . . an extended wear lens, if you have the information from the [1994 Grobe symposium presentation], you would have knowledge . . . of a surface treatment of a silicone hydrogel lens, and that it would be reasonable to expect that one skilled in the art could do that . . . . [T]he disclosures that were in the public domain were teaching that surface treatment on a silicone hydrogel lens would work." (Tr. VIII at 40, 42 (Valint).)

d. Discussion

J&J rests its "obviousness" argument on the Chang '327 Patent. Yet its evidence and testing failed to establish that the Chang lens could predictably lead to the CIBA invention - particularly the successful implementation of the difficult dual goals of high oxygen permeability and transmissibility, and surface wettability and comfort. The Example 3 lens that was clinically tested to determine ophthalmic compatibility of the Chang lens for 24 hours, and thus the obviousness of '894 Patent claims 89, 90 and 96, does not disclose a

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87 The B&L 510(k) summary states that its contact lens material is "indicated for daily wear." It describes its surface treatment as follows: "[t]he dry lenses are then plasma treated on both sides with a water/hydrogen peroxide saturated air plasma." (PTX 411 at CSFJ783350-51.)

lens with oxygen permeability equal to or greater than about 72 barrers and oxygen transmissibility of at least 70 barrers as measured by the coulometric method. The evidence suggests that the more vigorous surface treatment of Batch 24 of the Chang Example 3 lens used in the Brennan clinical test improved the wettability and comfort of the lens, but reduced the oxygen permeability and transmissibility. Furthermore, the Brennan 22-hour clinical test does not establish by clear and convincing evidence that the lens sample tested has all four components of "ophthalmically compatible" for a 24 hour period. While "ophthalmic compatibility" as defined by the CIBA patents does not require a successful clinical study of a "significant number of patients," (Doc. 121 at 47-49), a study in which four out of six subjects successfully wore a version of the Chang lens (which was never commercially successful) for 22 hours, and who were somewhat imprecisely evaluated does not provide the clear and convincing evidence of obviousness required. J&J attempted to mix and match data, measuring thicker Chang lenses from earlier batches of Example 3 to yield higher Dk and Dk/t values. These lenses, however, were never clinically tested.

Further, the Chang patent Example 3 statement that the lens "could be used for weekly extended wear" on one patient for a three week testing period "with stable vision and no observable deposition, and a demonstrated liquid layer over the lens surface" does not in an of itself make obvious the ophthalmic compatibility limitations of CIBA's seven-day asserted claims, '811 Patent claims 28 and 28, and '894 Patent claim 99. On this record, the Court determines that the Chang disclosure does not establish that the Chang lens is ophthalmically compatible as later defined by the CIBA patents, for the seven day period or

even the 24 hour limitation set forth in the asserted claims,[88] either through the Chang specifications or by clinical testing.[89] While the '327 Chang patent taught a silicone hydrogel lens with a surface treatment to promote wettability and comfort for extended wear, based on evidence in this record, it was unable to attain at the same time the desired high oxygen permeability and transmissibility.[90] Given these differences between the disclosures in the Chang '327 Patent and CIBA's claimed invention, and the knowledge of one of ordinary skill

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[88] While J&J's expert Valint opined that the Chang specification establishes that Chang meets the seven-day ophthalmic compatibility requirements of the CIBA claims, he is not a clinical expert. (Tr. VIII at 9 (Valint).) J&J's clinical expert Benjamin did not offer an opinion on whether the Chang specifications predicted the CIBA ophthalmic compatibility claim limitations. CIBA's clinical expert Harris opined that it does not. (Tr. IX at 100-02 (Harris).)

[89] J&J's argument that the combination of Chang's teaching that Example 1 "has high DK, about 4 to 5 times higher than that of a conventional poly HEMA soft lens," with Example 3's specification that "on the same patient could be used for weekly extended wear for a three week testing period with stable vision and no observable deposition" (PTX 125 col.6 ll.21-22, col.7 ll.18-21) makes CIBA's invention obvious (Doc. 303 at 26 (citing Boston Scientific Scimed, Inc. v. Cordis Corp., 554 F.3d 982, 991 (Fed. Cir. 2009)(petition for cert. filed 7/22/09)(combining adjacent embodiments to find obviousness) is more of an attempt to overcome the gap in J&J's evidence proving that the '327 Chang Patent predicts both the oxygen permeability/transmissibility *and* ophthalmic compatibility limitations of the CIBA patents. The references in the Chang patent examples do not make obvious - even in combination - all of the limitations set forth in the CIBA patents.

[90] J&J argues that because the Chang prior art is a United States patent, "its disclosures are presumed to be enabled - that is, to work as described." (Doc. 286 at 61 (citing Amgen, 314 F.3d at 1355 ("a presumption arises that both the claimed and unclaimed disclosures in a prior art patent are enabled" for purposes of anticipation)).) Based on J&J's experience re-creating the '327 Chang Example 3 lens, and the expert testimony that Chang does not provide specific guidance or direction, the Court determines that excessive experimentation would have been necessary to practice the invention. CIBA has presented persuasive evidence that the '327 Chang Patent is not enabled to achieve high permeability and high surface wettability simultaneously. See Impax Labs., Inc. v. Aventis Pharms., Inc., 545 F.3d 1312, 1315-16 (Fed. Cir. 2008).

in the art as of December 1995, based upon the evidence in this record, The Chang '327 Patent does not render the CIBA invention obvious.

With regard to objective evidence of nonobviousness or secondary considerations, the evidence establishes that CIBA's effort to develop an extended wear silicone hydrogel contact lens was successful, not only scientifically, but also commercially.[91] Success was possible because CIBA was the first to perfect a highly permeable silicone hydrogel simultaneously with a comfortable lens surface through a surface treatment process, resolving a long-felt need. Its commercial success underscores that CIBA's invention was innovative. J&J expert Valint represented to the USPTO in 1998 that though surface treatments of silicone hydrogel lenses had been disclosed, "the results have been problematic and of questionable commercial viability." (DTX 354 (B&L '369 Patent col.2 ll.1-5).) Even J&J expert Benjamin acknowledged in 2000 and still believes that B&L's and CIBA's "hyper-transmissible" new silicone hydrogel material "is the most significant single advance in hydrogel contact lens materials since they were invented . . . . ." (DTX 1387 at V216808-09; Tr. V at 59-60 (Benjamin).)

KSR, Int'l directs that obviousness arises "where a skilled artisan merely pursues 'known options' from a 'finite number of identified, predictable solutions.'" In re Kubin, 561

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[91] CIBA's Focus Night & Day commercial lens, introduced in December 1998 in Mexico and 2001 in the United States, was the world's first commercial silicone hydrogel lens. (Tr. I at 50 (Nicolson); Tr. IX at 14 (CIBA senior vice president and global general counsel Scott Chyatte ("Chyatte")).) Chyatte said that CIBA's Focus Night & Day lens earns approximately $100 million a year for the company, representing a 10 percent market share. The lens has earned "hundreds of millions of dollars" since it has been on the market plus "hundreds of millions of dollars" from its licenses. (Tr. IX at 8-10, 13-17, 30 (Chyatte).)

F.3d at 1359 (quoting KSR, 550 U.S. at 421); see also Proctor & Gamble Co., 566 F.3d 989, 996 (Fed. Cir. 2009). But an invention is not obvious "where researchers can only 'vary all parameters or try each of numerous possible choices until one possibly arrive[s] at a successful result where the prior art [gives] either no indication of which parameters [are] critical or no direction as to which of many possible choices is likely to be successful." Proctor & Gamble Co., 566 F.3d at 996-97 (quoting In re O'Farrell, 853 F.2d at 903). "Similarly, patents are not barred just because it was obvious 'to explore a new technology or general approach that seemed to be a promising field of experimentation, where the prior art gave only general guidance as to the particular form of the claimed invention or how to achieve it.'" Id.; see also In re Kubin, 561 F.3d at 1359. "In such circumstances, where a defendant merely throws metaphorical darts at a board filled with combinatorial prior art possibilities, courts should not succumb to hindsight claims of obviousness." In re Kubin, 561 F.3d at 1359.

The CIBA patent does not represent a "predictable variation" of the prior art, as J&J contends. (Doc. 303 at 26.) While a silicone hydrogel extended wear contact lens with a surface treatment may have been "obvious to try" in 1995, none of the prior art cited by J&J gave direction as to how to successfully achieve that end. Compare In re Kubin, 561 F.3d at 1360 ("an obviousness finding was appropriate where the prior art 'contained detailed enabling methodology' for practicing the claimed invention, a suggestion to modify the prior art to practice the claimed invention, and evidence suggesting that it would be successful'"); see also PharmaStem Therapeutics, Inc. v. ViaCell, Inc., 491 F.3d 1342, 1364 (Fed. Cir. 2007), cert. denied, 128 S.Ct. 1655 (2008); Medichem, S.A. v. Rolabo, S.L., 437 F.3d 1157,

1165 (Fed. Cir. 2006)("prior art fails to provide the requisite 'reasonable expectation' of success where it teaches merely to pursue a 'general approach that seemed to be a promising field of experimentation, where the prior art gave only general guidance as to the particular form of the claimed invention or how to achieve it'" (citation omitted)).

Without question, in 1995 the close-knit and competitive contact lens industry was busy investigating how to make a high permeability silicone hydrogel lens that was wettable, comfortable, and compatible for extended wear, and that fact was no secret to the players. But the technical and detailed laboratory developments were kept highly confidential, with only general public statements being available for consumption. The testimony was that the parties kept up with the patents in the industry. The Chang '327 Patent, the Grobe symposium presentation and B&L's 510(k) FDA application did not provide the critical direction of possible choices or more than general guidance to CIBA for it to create a highly permeable and ophthalmically compatible extended wear silicone hydrogel lens.[92] The experts agreed that the Chang '327 Patent provided few details about how to make its contact lens. And Chang's Example 3 chemical surface treatment is not used in the industry. Moreover, there were no other commercially successful extended wear silicone hydrogels that pre-dated the CIBA patents. J&J has failed to establish by clear and convincing

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[92] Indeed, in determining that the B&L RD-677/Balafilcon A prior art discussed by Grobe and summarized in the 510(k) application did not anticipate the CIBA patents, the Court has earlier noted that "while the record establishes that CIBA inventors knew by 1994 that its competitor, B&L, had developed a soft hydrophilic extended wear contact lens, presentations at symposiums and knowledge that a competitor has submitted a pre-marketing 510(k) application to the FDA (and review of an 'abbreviated summary' of that application), cannot, by clear and convincing evidence" establish anticipation. (Doc. 190 at 25; see also id. at 20-25, 55.)

evidence that the asserted claims of the CIBA '811 and '894 Patents are obvious.

III. Unenforceability: Inequitable Conduct

J&J contends that CIBA intended to deceive the USPTO by failing to disclose that Alsacon lenses listed as examples in the CIBA patents were "toxic" (Doc. 286 at 72-76), and by "misrepresenting" prior art, stating on re-examination the "prior art did not teach surface modification of silicone hydrogels and that CIBA discovered the need for such surface treatment." (Id. at 76).

To prove inequitable conduct, J&J must present evidence that CIBA "'(1) made an affirmative misrepresentation of material fact, failed to disclose information, or submitted false material information, and (2) intended to deceive the [PTO].'" Star Scientific, Inc. v. R.J. Reynolds Tobacco Co., 537 F.3d 1357, 1365 (Fed. Cir. 2008)(quoting Cargill, Inc. v. Canbra Foods, Ltd., 476 F.3d 1359, 1363 (Fed. Cir. 2007)), cert. denied 129 S.Ct. 1595 (2009)). J&J has the burden of proving each element by clear and convincing evidence. Id. As to the intent element, "the accused infringer must prove by clear and convincing evidence that the material information was withheld with the *specific intent to deceive* the PTO." Id. (emphasis added). Even though specific intent may be inferred from indirect and circumstantial evidence, "such evidence must still be clear and convincing, and inferences drawn from lesser evidence cannot satisfy the deceptive intent requirement." Id. "And even if this elevated evidentiary burden is met as to both elements, the district court must still balance the equities to determine whether the applicant's conduct before the PTO was egregious enough to warrant holding the entire patent unenforceable." Id.

J&J's first contention is that CIBA did not disclose to the USPTO that the Alsacon

family of lenses, the "A" Examples in the CIBA patents (see '100 Patent col.46 l.9-col.49 l.5) were found to be "toxic" in CIBA's clinical testing. CIBA's preliminary evaluation indicated that freshly prepared Alsacon New Coke lenses performed well in clinical studies and CIBA determined to pursue the Alsacon material as a commercial candidate. (Tr. I at 60-74 (Nicolson); Tr. VIII at 87-88 (Valint); DTX 1037 at UNSW000597, 1437, 1438.) Further testing revealed, however, that "the material demonstrated a shelf-life problem. It was degrading over time. . . . We found the problem occurring with lenses that were more than six months old." (Tr. I at 74-78, 114-15 (Nicolson); DTX 561 at CSFJ033805; PTX 67 at CSFJ033805.) The "toxicity" was "referring to the performance of the older lenses to the cytotox test." (Tr. I at 79, 141 (Nicolson); PTX 350.) As a result, CIBA abandoned Alsacon as its lead commercial candidate and pursued further development of other materials. (Tr. I at 79-80 (Nicolson); PTX 67 at CSFJ033805.) CIBA did not report the Alsacon cytotox test results to the USPTO with its 1995 patent application; "[w]e considered that to be a commercial viability problem, not a patent problem." (Tr. I at 79 (Nicolson).) Nicolson testified that he never intended to deceive or mislead the USPTO. (Tr. IX at 153 (Nicolson).).

J&J's second allegation is based upon a Nicolson declaration submitted to the USPTO on July 14, 2000 on re-examination, in which he stated that in his opinion, CIBA "succeeded because . . . [w]e discovered the need for surface modification of silicone hydrogels to achieve ophthalmic compatibility . . . ." (PTX 300 ¶ 24.) J&J also cites to other alleged Nicolson misrepresentations. (PTX 300 ¶ 27.) Nicolson satisfactorily addressed these issues in his testimony. (see Tr. V at 125-26, 128-29, 156-58, 167-68, 170 (Nicolson); see also Tr. VIII at 100-02 (Valint)(international Chang patent disclosed CIBA's 1995 patent

application); PTX 300 at ¶¶ 28, 36-38.)

J&J's arguments as to "materiality" are circumstantial at best, and speculative at worst, falling far short of its "clear and convincing" burden. Further, J&J has failed to adduce *any* evidence tending to show that CIBA had the specific intent to deceive the USPTO. J&J has failed to meet its high burden of proof to establish inequitable conduct; the Court declines to hold the CIBA patents unenforceable.

Conclusion

The Court now pauses and seeks the parties' guidance as to where we go from here. What are the necessary implications of the Court's rulings? Work still needs to be done in this case, but what exactly and the sequence of events remains to be determined. Moreover, these consolidated suits are but two of many between the parties pending in this Court involving patents for contact lenses. And, the suits keep piling up, with CIBA having filed yet another one shortly before trial in this case and J&J having filed a new suit just in the last few days. How to bring an end to all of this litigation? Obviously, settlement talks, tried before, should be tried again (and again). Should the Court certify this case as it now stands for interlocutory review by the Federal Circuit so that the parties could get some appellate rulings on the difficult issues they have asked me to decide? If I did certify the case, would the Federal Circuit likely take it or not? Or, do I just need to complete this case and hope it (as finally determined on appeal) will stand as precedent for the remaining, as yet unlitigated, cases? Are the parties willing to continue spending unlimited resources in pursuit of victory when the finish line keeps getting moved farther away every time one or the other of them files a new lawsuit? These are some things I ask the parties to think about

while they review the Court's findings and conclusions.

On **October 20, 2009**, at **2:00 p.m.** (eastern time), I will have an in person **Status Conference** with the parties to discuss these and other pertinent topics.[93] No later than **October 13, 2009,** the parties will submit a joint statement of matters and proceedings they have agreed upon. If necessary, also by **October 13, 2009**, each party may submit a pleading of up to 15 pages (no footnotes) of matters they want to urge upon the Court concerning the future sequence of events in this case, and the larger issue of how to resolve all disputes between the parties.

DONE AND ORDERED at Jacksonville, Florida, this 14th day of August, 2009.

TIMOTHY J. CORRIGAN
United States District Judge

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Copies to:
Counsel of Record

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[93] The Status Conference is will be held in the United States Courthouse, Courtroom 10D, 300 North Hogan Street, Jacksonville, Florida. All persons entering the Courthouse must present photo identification to Court Security Officers. Although cell phones, laptop computers, and similar electronic devices are not usually allowed in the building, counsel will be permitted to bring those items with them for purposes of this hearing upon presentation of a copy of this Order to Court Security Officers.