UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
JACKSONVILLE DIVISION

JOHNSON & JOHNSON VISION CARE, INC.,

Plaintiff, Counterclaim-Defendant,

v.

CIBA VISION CORPORATION,

Defendant, Counterclaim-Plaintiff.

CASE NOS. 3:05-CV-135-J-32TEM
3:06-CV-301-J-32TEM

JOHNSON & JOHNSON VISION CARE, INC.'S BRIEF IN RESPONSE TO CIBA'S POST-TRIAL PROPOSED FINDINGS OF FACTS AND CONCLUSIONS OF LAW

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I. INTRODUCTION

CIBA's Proposed Findings of Fact and Conclusions of Law ("CIBA's Proposed Findings") reargue claim construction to avoid CIBA's failure to prove infringement. The Court should find CIBA has failed to prove that the Oasys lens infringes the asserted claims and should reject CIBA's latest attempt to undo the Court's *Markman* rulings. The Court should also rule that the asserted claims are invalid and the CIBA patents are unenforceable.

II. INFRINGEMENT

A. Lack Of "Oxygen Permeability" And "Oxygen Transmissibility" As Construed By The Court

In 1995, when CIBA filed its original patent application, CIBA set forth a clear and unmistakable definition of oxygen permeability "[i]n order to properly describe the invention and to delineate the metes and bounds of the claims." (PTX 1 at 4:25-28). CIBA defined oxygen permeability ("Dk") as a property "of a lens material [that] does not depend on lens thickness." (*Id.* at 4:58-59). The Court adopted CIBA's own language as the controlling definition for purposes of this litigation. (DI 121 at 74). In addition, CIBA agrees that, for its patents, the single point coulometric method ("SPCM") is the *only* method that can be used to determine Dk and that this method yields "apparent" or "uncorrected" Dk – not "intrinsic" Dk obtained through a regression analysis (*i.e.*, the stacked lens test), which is a method not taught in the patents. (DI 287 at 12-13). At trial, CIBA conceded that the very purpose of using the SPCM was so a single measurement can determine the Dk of a material – one that is valid for any lens, thick or thin, made of that material. (*Id.*).

CIBA acknowledges that its Dk data for Oasys lenses obtained using the SPCM show that the Dk of Oasys lenses varies with the thickness of the lens being measured. (*Id.* at 14-

16, 20-21). Under the Court's claim construction, these undisputed facts compel the conclusion that CIBA has not carried its burden to show that any of the Oasys lenses meet CIBA's oxygen permeability and transmissibility claim limitations.

Nevertheless, CIBA insists this Court should rule in CIBA's favor. CIBA again asks the Court to change its claim construction – which was the result of extensive briefing, hearing and motions – to remove the requirement that Dk (as measured by the SPCM) not depend on thickness. This latest attempt should be rejected. The Court's claim construction is legally correct, and the reasoning underlying CIBA's proposed change is legally erroneous.

1. The Court's Construction Of Oxygen Permeability And Transmissibility Is Correct

Since its *en banc* 2005 decision in *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005), the Federal Circuit has emphasized the controlling effect of intrinsic evidence, that is, the patent and its file history, when construing claims, and cautioned against relying on extrinsic evidence. *See id.* at 1315-17, 1320-21. In construing oxygen permeability and oxygen transmissibility here, the Court followed this approach. The Court relied on the intrinsic evidence, which shows that one of skill in the art in 1995 would have had no doubt that when the patents say "oxygen permeability, Dk, of a lens material does not depend on lens thickness," they are defining a property of the lens material that does not change with lens thickness. (DI 121 at 71-74, 85). That is also the ordinary meaning of "oxygen permeability," consistent with the science at the time. (*Id.* at 73; PTX 208 at V111927, 929, 932; PTX 207 at CSFJ050422, 424-25).

Here, the Court adopted the definition the inventors set forth in the "Definitions" section of the patents' specification. (PTX 1 at 4:58-60). And it is consistent with CIBA's

patent examples, which set forth Dk values but do not specify any thickness of the lens measured. The Dk values for these examples are meaningful *only* if the Dk values of lenses made of the same material do not vary with thickness. (DI 286 at 8). Finally, CIBA distinguished prior art lenses based on a single Dk value obtained using the SPCM. (*See, e.g.*, PTX 300 at ¶ 25; PTX 296 at 13; Tr. II at 154:9-155:17).

In light of this clear intrinsic evidence, CIBA's interpretation of "depend" – which redefines that everyday term as something different from vary – borders on the preposterous.

2. CIBA's Reasoning For Changing The Court's Construction Of Oxygen Permeability And Transmissibility Is Legally Erroneous

CIBA ignores this intrinsic evidence. CIBA does not discuss the contents of the specification, analyze the plain meaning of the words used in the patents to define oxygen permeability, address how a person skilled in the art would have understood the patents when filed in 1995, or analyze the use of SPCM oxygen permeability data during prosecution. Instead, CIBA improperly relies on *extrinsic* evidence about events that occurred *after* its original application was filed – when CIBA discovered that in some lenses, SPCM measurements do change with thickness.

CIBA's position is deeply flawed. *First*, CIBA requests that the Court ignore the intrinsic evidence and change the definition of oxygen permeability based solely on the opinions of CIBA's experts and witnesses that oxygen permeability values measured by the SPCM may in fact vary with thickness. (DI 287 at 16-19). This is contrary to Federal Circuit precedent that is directly on point. *See Dow Chem. Co. v. U.S.*, 226 F.3d 1334, 1341 (Fed. Cir. 2000) (reversing construction and infringement analysis based on "the testimony of

one of the inventors and other witnesses" that a patent formula was "irrelevant" when specification stated it was "critical to the practice of the present invention"); (DI 121 at 74).

Second, it is impermissible to construe claims by ignoring the clear language of the patents based on discoveries made after the patent application was filed. Rather, the relevant consideration for claim construction is the state of scientific knowledge, and how a person of skill in the art would have understood the claims, as of the filing date. *See Phillips*, 415 F.3d at 1312-13 ("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."). This rule serves an important purpose, preventing the construction of patents from changing over time so as to exclude a competing product from their scope one year, yet include the product the next year. *See Unique Concepts, Inc. v. Brown*, 939 F.2d 1558, 1562 (Fed. Cir. 1991).

The uncontradicted evidence here is that, as of December 1995, CIBA's patents presented the SPCM to the contact lens community as a method for obtaining an oxygen permeability value that did not change with lens thickness. In addition, prior to 1995, CIBA's Dr. Winterton published an article and a textbook chapter confirming this important point. (PTX 208 at V111927, 929; PTX 207 at CSFJ050422, 424-25; *see also* DI 121 at 73). A person of skill had no reason to doubt the teaching of CIBA's patents or these publications, and CIBA cited the article to the PTO during the reexaminations as setting forth an "accurate and reproducible" method of measuring Dk. (PTX 300 at ¶ 25).

Not until after the filing of the patent application did CIBA discover internally that it had made a "major mistake," and that for the "Betacon" silicone hydrogel lenses it had

measured, the SPCM did not generate a thickness-independent oxygen permeability value, a result CIBA attributed to the "boundary layer" effect, which Dr. Pitt analogized to a muddy "football field." (DI 286 at 9-10; Tr. V at 217:12-18, 219:22-222:22; PTX 71 at CSFJ064925; Tr. II at 98:4-11). This post-filing discovery does not bear on how CIBA's patent would have been understood by one of skill as of December 1995.

Third, the general canons of construction on which CIBA relies, such as the principle that claims should be construed to preserve their operability, do not apply here. Such canons "should be used as a last resort, not a first principle," *MBO Labs., Inc. v. Becton, Dickinson & Co.*, 474 F.3d 1323, 1332 (Fed. Cir. 2003), and can never be used to "revise or ignore the explicit language of the claims." *Generation II Orthotics Inc. v. Med. Tech. Inc.*, 263 F.3d 1356, 1365-66 (Fed. Cir. 2001). The Federal Circuit has held that courts must construe claims as the language of the patent dictates, even if they are thus inoperable or otherwise nonsensical, or if preferred embodiments are excluded. *See Chef Am. Inc. v. Lamb-Weston, Inc.*, 358 F.3d 1371, 1374 (Fed. Cir. 2004) ("[C]ourts may not redraft claims, whether to make them operable or to sustain their validity.... Even a nonsensical result does not require the court to redraft the claims...."); *Elekta Instrument S.A. v. O.U.R. Scientific Int'l, Inc.*, 214 F.3d 1302, 1308 (Fed. Cir. 2000) (adopting construction even though it would exclude the *only* embodiment, thus rendering claimed device inoperable).

In particular, CIBA's reliance on the presumption that a construction should not exclude CIBA's Focus Night & Day product ignores the premise underlying this presumption. Courts presume that a patent, on its face, should not be construed to exclude a preferred embodiment only because it is "unlikely that an inventor would define the

invention in a way that excluded the preferred embodiment." *Hoechst Celanese Corp. v. BP Chem. Ltd.*, 78 F.3d 1575, 1581 (Fed. Cir. 1996). Here, CIBA unmistakably defined its invention in 1995 in a way that CIBA thought would include all of its embodiments, and "on its face," it does. Later, that turned out to be wrong at least for one embodiment. The presumption that a patentee would likely not intentionally exclude a preferred embodiment does not apply where the patentee explicitly sets forth a clear definition that was only discovered years later to exclude the embodiment.

In any event, CIBA has not proven that the Court's claim construction actually renders the claims inoperable. *See, e.g., Talbert Fuel Sys. Patents Co. v. Unical Corp.*, 275 F.3d 1371, 1376 (Fed. Cir. 2002). CIBA contends that Dk always varies with thickness because of the boundary layer effect, which its expert described as "an end zone that is full of mud" – an effect allegedly due to the slower rate at which oxygen passes through water versus the silicone hydrogel lenses. (Tr. II at 96:4-100:3). This argument has no merit since, according to Dr. Winterton, water has an oxygen permeability of 80 to 88 barrers (Tr. II at 37:21-38:4) – a value *higher* than the Dk of many of CIBA's patent examples. (PTX 1 at Ex. A-2 to A-5, A-8, A-10 to A-12, B-5, B-8, B-12, C-16, C-17, C-22). Thus, contrary to CIBA's argument, the water layer on silicone hydrogel lenses does *not* always act as a barrier (*i.e.*, "mud") to oxygen, and with many of the patent examples, the oxygen actually transports *faster* through the water than through the lens material. Consistently, Dr. Winterton has written that using the coulometric method, boundary layer effects, if any, are negligible for at least one silicone hydrogel lens, PureVision. (PTX 262 at ¶¶ 12, 17).

Indeed, the intrinsic evidence before the PTO proves the SPCM can yield thickness-independent Dk values consistent with the patents, even when applied to silicone hydrogel lenses with "high" Dks. (DI 286 at 13-14). Although CIBA asserts that the 1987 Winterton article is not pertinent because it relates only to materials with a very low Dk (DI 287 at 18-19), that is inaccurate. The article reports materials with a stated Dk as high as 63, with no statement disqualifying those materials from the article's thickness-independent principle. (PTX 208 at V111926, 931). CIBA relied on this article in reexamination, citing it to support the SPCM as an "accurate and reproducible" method of determining Dk. (PTX 300 at ¶ 25).

But even if CIBA were right that the SPCM can *never* yield a thickness-independent Dk for a silicone hydrogel lens, that would be CIBA's mistake, which this Court is not empowered to correct. Courts must "construe the claim as written, not as the patentees wish they had written it." *Chef Am.*, 358 F.3d at 1374; *Quantum Corp. v. Rodime, PLC,* 65 F.3d 1577, 1584 (Fed. Cir. 1995) ("[N]o matter how great the temptations of fairness or policy making, courts do not redraft claims.").

CIBA's implicit request that the Court correct CIBA's error is misplaced. CIBA had every opportunity to alter the clear definition of oxygen permeability, but it did not do so during the initial prosecutions of its patents or their reexaminations. And CIBA's assertion that it made a "clear and unmistakable statement" to the PTO in the '894 patent prosecution that the SPCM Dk values will vary with thickness is simply wrong. CIBA's "statement" was an isolated mention of the issue, buried deep within a document that was hundreds of pages long, which CIBA deposited with boxes of other documents *nine years after filing* the patent application and years after the initial patents had issued, without even pointing out the issue

to the examiner. (DTX 1445; PTX 300 at ¶ 25; DI 287 at 19); *see Acacia Media Tech. v. New Destiny Internet*, 405 F. Supp. 2d 1127, 1133-34 (N.D. Cal. 2005) (explaining that for patentee to vary term's ordinary meaning, "special definition" must be clear in file history or specification); *cf. Phillips*, 415 F.3d at 1327. And, CIBA never changed the clear and controlling definition of oxygen permeability in its patent specification.

Not only did CIBA fail to disclose what it had learned about the problem, but – acting *after* it realized its "mistake" – CIBA affirmatively used the SPCM during prosecution to distinguish prior art as having an oxygen permeability just below the claimed threshold of 70 barrers, without including any discussion of the thickness of the lenses tested. (DI 286 at 10). If CIBA had told the PTO what it knew, the examiner would have realized this prior art could easily be modified to have a Dk above the threshold in CIBA's claims, rendering those claims obvious and preventing the patents from issuing.

CIBA also attempts to suggest to the Court that J&J's accused lenses come "close enough" to infringing, because they have high oxygen permeability as measured by a different method, or because it can be inferred from the SPCM data that the oxygen permeability must be above the claimed values. (DI 287 at 19-20). By this reasoning, the prior art that CIBA distinguished during prosecution would also have a high oxygen permeability, since the SPCM values for this prior art are just under 70 barrers, and (according to CIBA) "intrinsic" oxygen permeability is always above the SPCM value. (*Id.*). This is alone a sufficient reason to reject CIBA's argument. But the argument should also be rejected because it would ignore the legally determined *Markman* definitions and unfairly expand the scope of CIBA's patents in a haphazard way. *See Tate Access Floors, Inc. v.*

Interface Architectural Resources, Inc., 279 F.3d 1357, 1367 (Fed. Cir. 2002) ("Fairness and the public notice function of the patent law require courts to afford patentees the full breadth of clear claim language, and bind them to it as well."). For purposes of patent interpretation, oxygen permeability is not an abstract concept – it is a particular property of a material that must be measured by a particular method. It is meaningless to assert generally that the oxygen permeability of Oasys lenses is high, untethered from the limitations placed on that term by the patents themselves. Under the patents' definition of oxygen permeability and this Court's construction, that is the end of the matter.

For all of these reasons, CIBA has not proven that the Oasys lenses meet the oxygen permeability or transmissibility limitations present in every claim at issue, and judgment therefore should be entered in favor of J&J on the question of infringement.

B. Lack Of A "Surface Modified By A Surface Treatment Process"

CIBA has not proven that the Oasys lenses satisfy the "surface modified by a surface treatment process" limitation because Oasys is a "monolith" lens with the same composition throughout – the very opposite of the claimed lens. (DI 286 at 16-23).

To make Oasys, (i) the prepolymerization mixture of all ingredients is cured, forming large polymer chains in a "mesh" structure; (ii) the cured lens is "extracted" (to remove unwanted substances) and hydrated; and (iii) the lens is placed in saline, packaged, and sterilized. (DI 286 at 17-18). There is no step of altering surfaces by contact with a vapor or liquid or by applying energy, as required by the Court's construction. (PTX 1019; DI 121 at 23). PVP, the internal wetting agent, is simply placed in the prepolymerization mixture with other ingredients. (Tr. IV at 52:2-5).

CIBA's theory that the Oasys lens is more ophthalmically compatible than it would be if it did not contain PVP provides no support to CIBA's infringement position. (DI 287 at 21-23). If CIBA's theory were correct, *every* silicone hydrogel lens would meet this limitation, since *every* silicone hydrogel lens includes a hydrophilic ingredient that results in a more ophthalmically compatible surface than a lens without the ingredient. (Tr. VII at 97:14-22). CIBA's theory is flatly contrary to CIBA's own position during prosecution that lenses that contain wetting agents and that are cured and hydrated – including its own patent examples and prior art lenses – are not surface treated lenses. (DI 286 at 22-23).

CIBA's theory that the PVP migrates to the surface of the Oasys lens also lacks proof. CIBA does not dispute J&J's evidence that if the PVP molecules migrated to the surface during extraction or hydration, as CIBA's expert speculated, the PVP molecules would simply be *extracted* from the lens and washed away. Rather than challenge this evidence, CIBA revised its theory, positing that there is "no persuasive evidence to dispute the proposition that at least some portions of this large, non-reactive PVP molecule, entangled in the polymeric network, migrate to the surface…." (DI 287 at 26). CIBA's new "proposition" finds no support in the record. CIBA's expert did not testify that "portions" of each PVP molecule migrate to the surface, but opined that entire molecules migrate *out* of the lens, with the PVP left in the bulk acting as "a reservoir" to replenish the PVP that leaves. (Tr. III at 133:4-11, 84:1-18). With no support in the record, CIBA cannot meet its burden of proof on this revised migration theory.

CIBA next attempts to explain away the results of XPS testing that also refute its migration theory. CIBA argues that the presence of water in the tested lenses would make

the nitrogen concentration appear smaller than it actually is, but CIBA ignores that even spots that did *not* have water (spots "3" and "4"), averaged *exactly* 5% nitrogen – nitrogen is an element in PVP – which is the same nitrogen percentage one would expect if PVP were evenly distributed and did not migrate to the surface. (PTX 501 at 3; Tr. III at 172:13-173:20; Tr. VIII at 113:5-115:10). CIBA's contentions regarding J&J's contact angle tests are also unsound. (*See* DI 286 at 20-21).

CIBA argues that J&J's non-infringement position "rests on two incorrect interpretations of the definition of 'surface treatment process,'" but in doing so CIBA mischaracterizes J&J's arguments. (DI 287 at 25). First, J&J does not argue that the Court's construction requires an additional post-manufacturing process step, but rather that CIBA must prove that the surface of the Oasys lens is somehow "modified" by a surface treatment process, and that CIBA has failed to do so. Second, CIBA incorrectly contends that J&J's position "requires a showing that the surface is more hydrophilic than the core." (*Id.*). J&J's theory is not that this showing is *required*, but that the proof that the surface and core of the Oasys lens are equally wettable confirms CIBA has not met its burden of proving that the Oasys lens has a "surface modified by a surface treatment process."

C. Lack Of "Polyvinylpyrrolidone At A Surface Of Said Lens"

CIBA contends that claim 96 of the '894 patent requires only a portion of the PVP be at the lens surface, and that J&J's construction "read[s] a limitation into the claim" and contradicts the limitation's "ordinary meaning." (DI 287 at 28-29). But CIBA's interpretation evades the Court's construction, which requires the "homopolymer" PVP, not simply a few NVP chemical groups that form a portion of the PVP, be present at the surface.

The *only* disclosure of a material the CIBA patents identify as "PVP" is a "coating" applied to the lens by plasma polymerization in which the entire molecule of what CIBA's patents call "PVP" is located at the lens surface. (*See, e.g.*, PTX 1 at 66:54-55: "the lens surface is coated with [PVP]"). When CIBA added claim 96 in prosecution, CIBA relied on as support for that claim "Examples F1 to F12 and Table F" – which disclose only that the lens surface is "coated with [PVP]." (PTX 18 at 587). Thus, the patents and file histories indicate that *all* of the PVP molecule, not just part, must be at the surface.

CIBA argues that its new construction should be adopted simply because "Dr. Valint admitted that under his construction, no contact lens could ever infringe this limitation." (DI 287 at 29). But whether a lens could infringe does not determine the correctness of a particular construction. *See Elekta Instrument*, 214 F.3d at 1309. CIBA could have requested a construction such that "PVP," as used in its patents, did not refer to a homopolymer, or that only "NVP" need be at the lens surface. But CIBA did not do so because that would defeat CIBA's infringement argument for this claim.

CIBA also argues that "[t]he conclusion that J&J's construction is incorrect is further supported by the doctrine of claim differentiation." (DI 287 at 29). But, the Federal Circuit has held that "[w]hether or not claims differ from each other, one can not interpret a claim to be broader than what is contained in the specification and claims as filed." *Tandon Corp. v. ITC*, 831 F.2d 1017, 1023-24 (Fed. Cir. 1987).

This Court should reject CIBA's attempt to improperly broaden its claim, and hold that CIBA has not proven that the Oasys lens satisfies the "PVP at a surface" limitation.

D. Lack Of "Phases"

CIBA did not meet its burden to prove that the Oasys lens has separate phases because CIBA did not show that the Oasys polymer material has regions composed of "essentially only" ionoperm or oxyperm polymer. (DI 286 at 25-27). CIBA now asks the Court to ignore this lack of proof and again requests that the Court change its claim construction, this time to delete the "essentially only" language in the definition of "phase." CIBA contends that "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…." (DI 287 at 34-37). Using this truncated definition, CIBA asserts: "Given the high levels of oxygen and ion permeability of Acuvue Oasys, ... the separate phases have this bulk property." (*Id*. at 37).

In support of this new claim construction, CIBA mistakenly argues that J&J seeks to import the limitation "little or no silicone" into the definition of ionoperm phase. (*Id*. at 35). CIBA's expert, Dr. Gido, testified at deposition and trial that the Court's construction of "essentially only" ionoperm polymer required "little or no silicone" in the ionoperm phase. (Tr. III at 12:16-13:6; Tr. VIII at 226:17-227:15; PTX 903 at 3). J&J's evidence merely responded to CIBA's infringement proofs, which relied on Dr. Gido's interpretation.

CIBA's about-face on claim construction arose only after trial when CIBA realized it could not establish the required regions of "essentially only" ionoperm polymer in the Oasys lens. This latest reversal continues a pattern CIBA and Dr. Gido followed throughout this litigation when evidence debunked CIBA's latest theory as to why Oasys had phases. (Tr. VIII at 219:10-18, 227:20-228:16 (Dr. Gido admitted J&J's SAXS data showed his testing

was flawed, forcing him to perform numerous revised tests; J&J's EDX data caused Dr. Gido to "revise that – that opinion" as to what "essentially only" meant)).

Notably, while CIBA's Proposed Findings expressly rely on a "pattern of light and dark splotches," Dr. Gido admitted that he *enhanced* these light and dark regions in his images. (DI 287 at 30-31; Tr. III at 29:7-30:10, 57:8-21). J&J's expert, Dr. Bradley, "made this discovery after a very long and plodding search through [Dr. Gido's] native [computer] files." (Tr. VI at 153:22-154:1). Thus, Dr. Gido's testimony concerning the existence of phases is simply not credible, and CIBA clearly has not met its burden of proving Oasys has separate phases.

Even if the Court's definition of phases only required different bulk properties, as CIBA contends, CIBA has not presented any evidence of these properties in the Oasys lens – that is, that ions permeate through a separate ionoperm phase or oxygen permeates through an oxyperm phase. (DI 287 at 37). Indeed, none of CIBA's tests establish the bulk property of ion or oxygen permeation. (*Id.* at 30-31). This lack of proof further establishes that CIBA has not met its burden on phases.

Finally, contrary to CIBA's assertions that SAXS testing is akin to searching for "a white polar bear in a white snow bank," the SAXS data shows that Oasys does not have the 30-50 nm phases of oxyperm and ionoperm polymer. (DI 287 at 38-39; Tr. VI at 30:1-3, 56:16-20). As Dr. Bates explained, the SAXS tests confirm that Oasys does not have the alleged 30-50 nm phases. However, as he also explained, due to structures in the material on a much smaller scale, approximately 6-7 nm, it is simply impossible to definitively identify the morphology of Oasys across all such length scales. (Tr. VI at 109:4-110:21). CIBA's

belated attempt to impugn SAXS testing is easily dispatched by the simple question: if it is so unhelpful, why did CIBA's expert begin with SAXS testing in his initial infringement report and continue to revise and alter it throughout the litigation? (Tr. VIII at 218:14-221:4).

III. INVALIDITY

A. Indefiniteness – Ionoton Ion Permeability

The evidence establishes that (i) CIBA's patents describe two distinct equations for determining the claimed Ionoton coefficients, and (ii) one of skill in the art would not be able to determine which equation to apply. (DI 286 at 34-37). J&J proved that the patents provide no direction as to which equation to use. As such, a person of skill would not know whether to choose the First Equation, which results in the claimed units but not the claimed values, or the Second Equation, which generates the claimed values but not the units. (*Id*. at 35). Therefore, the claims containing Ionoton limitations are "insolubly ambiguous" and indefinite. *Honeywell v. ITC*, 341 F.3d 1340-42 (Fed. Cir. 2003).

CIBA's response mischaracterizes the evidence. J&J does not "agree" that the First Equation "is correct and can be used to calculate an Ionoton Ion Permeability Coefficient." (DI 287 at 41). Dr. Freeman testified that one of skill in the art would face a "conundrum" as to which of the two equations should be used to calculate an Ionoton coefficient. (Tr. IV at 160:15-161:15). Further, Dr. Freeman never testified that the Second Equation "[was] intended to be an algebraic rearrangement of the first equation…." (DI 287 at 41). He instead stated he did not know Dr. Winterton's state of mind on the use of that equation. (Tr. IV at 137:16-138:11). Dr. Freeman also explained that using the Second Equation was the only way to achieve Ionoton values as high as those claimed, and that if one of skill in the art

tried "to apply that first equation or … this algebraically rearranged one … they cannot get the values in Table E [of the patents]." (Tr. IV at 217:6-17, 139:24-140:16).

CIBA's response to this evidence is to argue that Dr. Freeman wrongly asserts the claimed Ionoton values are "higher than the physical upper limit for such values…." (DI 287 at 43). However, Dr. Freeman testified it would be impossible to achieve the minimum claimed Ionoton values *by using the First Equation* and that his own testing resulted in values much lower than the minimum claimed values. (Tr. IV at 139:24-140:16, 217:6-17, 218:15-219:1; PTX 1030). CIBA offered no evidence to the contrary.

Although CIBA contends one of skill would use the First Equation because it alone generates the claimed units, Dr. Winterton used the Second Equation containing the extra variable "t" (for time) yet always generated the claimed units. (DI 286 at 36). At trial, he could not explain if use of the extra variable "t" in the Second Ionoton equation was appropriate. (*Id.*; Tr. I at 247:24-248:17). Thus, CIBA's reliance on his testimony that he used the First Equation to determine the patents' Ionoton values deserves little weight.

Because, as CIBA concedes, "Dr. Winterton made a mistake in using the incorrect version of the second formula for the TRO hearing," a person of skill in the art could easily make the same mistake Dr. Winterton himself made several times. (DI 287 at 43). When filed, the patent application was the only source of information on Dr. Winterton's unique Ionoton equations, and an accused infringer would have only the specification to determine which equation to use. (Tr. IV at 130:24-131:25).

Finally, failing to offer any Ionoton data of its own, CIBA wrongly criticizes Dr. Freeman for not measuring Ionoton values on recreated examples. (DI 287 at 43-44). But

Dr. Freeman did measure Ionoton values for recreated examples and on that basis testified that "[t]he values that are shown in Table E … are … higher than any value I've ever measured in my laboratory for an ion permeability coefficient." (Tr. IV at 140:4-12). His conclusion was corroborated by his data on CIBA's FND and prior art Nandu lenses. (Tr. IV at 159:9-160:13; PTX 1024, 1026, and 1030).

Thus, the claims containing an Ionoton coefficient limitation are invalid as indefinite.

B. Non-Enablement

1. CIBA Failed To Enable An Extended Wear Monolith Lens

As construed by the Court, five of CIBA's asserted claims admittedly embrace both lenses with surfaces that have been modified with a surface treatment process and lenses with surfaces that have not been so modified, *i.e.*, "monolith" lenses. J&J argues that the law requires that, to be valid, the patents must enable both. CIBA tries to deflect the issue by suggesting that the determinative issue is whether a limitation that is not contained in any of these five claims is a "product-by-process" limitation. CIBA's argument appears to be that because this omitted limitation has aspects of a process rather than structure, cases like *Liebel-Flarsheim* and *Automotive Technologies* – where the omitted limitation was structural – do not apply. CIBA's argument has no merit.

The controlling question is not whether some claims other than the five at issue include a product-by-process term, but whether CIBA has enabled the "full scope" of products covered by the five claims that are at issue. Simply stated, the law requires that both kinds of lenses embraced by these five claims must be enabled. *See, e.g., AK Steel Corp. v. Sollac & Ugine*, 344 F.3d 1234, 1241 (Fed. Cir. 2003). None of the five cases CIBA

cites dealing with whether a term is a product-by-process term – *Hazani*, *Garnero*, *Vanguard*, *Smithkline* and *Bonito Boats* – even relates to enablement. (DI 287 at 46-47).

Moreover, even if the characterization of the term not present in the five claims at issue, *i.e.*, "surface treatment process," were relevant, CIBA's conclusion that this term is a product-by-process limitation is wrong. The relevant term is "*surface* modified by a surface treatment process," which clearly defines a physical characteristic of a product – a modified *surface*. Thus, the five broad claims at issue do not merely omit a process limitation. They omit the *structure* of a modified surface – the structure that differentiates a surface-treated lens from a monolith lens. *See Hazani v. ITC*, 126 F.3d 1473, 1479 (Fed. Cir. 1997).

Claim 96 of the '894 patent involving PVP at a surface illustrates this clear structural difference. As shown in J&J's figure PTX 1129, the surface modified lens on the left has a clearly different structure from the monolith lens on the right. While CIBA may have enabled a lens as shown on the left, which is disclosed in the "F" Examples in CIBA's patents, CIBA did not enable the monolith lens structure on the right, which CIBA contends is covered by its claim 96.

On the facts, CIBA argues that the admissions in Dr. Nicolson's Declaration that CIBA did not know how to make an extended wear monolith lens applied *only* to 30-day lenses, not to the claimed 24-hour or 7-day lenses. (DI 287 at 48-49). But CIBA relied on Dr. Nicolson's statements to argue that claims specifically directed to 24-hour lenses were patentable over the prior art. (PTX 298 at 54; PTX 300 at ¶27). Thus, CIBA told the PTO that Dr. Nicolson's statements – including his statement that CIBA recognized "the need" for surface treatment to achieve ophthalmic compatibility – applied to 30-day and 24-hour

lenses, and CIBA cannot argue to the contrary here. (PTX 300 at ¶ 24); *see Hockerson-Halberstadt, Inc. v. Avia Group Int'l, Inc.*, 222 F.3d 951, 957 (Fed. Cir. 2000).

CIBA's attempt to counter Dr. Nicolson's admission with the contention that CIBA did achieve an extended wear monolith lens during the SEE3 program also has no support. Specifically, CIBA argues that clinical testing of its monolith lens showed "good initial results," including acceptable cytotoxicity, on-eye movement, and high oxygen and ion permeability. (DI 287 at 49). But this is insufficient. To be enabled, the monolith lens must meet *each* limitation of CIBA's claims, which require the lens to be worn for 24 hours without "causing substantial wearer discomfort" or "having substantial amounts of lipid adsorption." CIBA does not even allege that its monolith lens met these requirements, which are not simply "exacting commercial requirements." (DI 287 at 48). In addition, CIBA's argument that its monolith lens showed "a lot of promise" and that CIBA "experienced at least some degree of success" (*Id.* at 49-50) is not enough for enablement. *Nat'l Recovery Techs., Inc. v. Magnetic Separation Sys., Inc.*, 166 F.3d 1190, 1198 (Fed. Cir. 1999) (claims not enabled since "[t]he most that NRT can be credited with is promising the ideal result in claim 1, even though the specification does not completely deliver on this promise").

In short, CIBA never achieved a monolith lens that could be worn even for 6 hours without exhibiting "stinging," "burning," and "discomfort." (*See, e.g.*, Tr. VII at 221:24-222:7, 228:2-13). CIBA's failed attempts are "strong evidence" of nonenablement. *See, e.g., Ormco Corp. v. Align Tech., Inc.*, 498 F.3d 1307, 1319 (Fed. Cir. 2007) (failure to enable invention in commercial product that purports to be embodiment of invention "is strong

evidence that the patent specification lacks enablement."). Thus, CIBA's claims without the "surface modified by a surface treatment process" limitation are invalid as not enabled.

2. PVP At The Surface Of Said Lens Is Not Enabled

J&J contends that claim 96 of the '894 patent is invalid for lack of enablement for the additional reason that the specification does not enable a lens with a homopolymer of PVP "at a surface of said lens." The evidence at trial established that CIBA's patents disclose only a *copolymer* of PVP at the lens surface. (Tr. VII at 234:19-22, 235:19-236:8).

CIBA argues that its expert, Dr. Mays, testified that reactive sites on the lens surface initiate polymerization of PVP and the PVP chains that grow from the reactive sites are covalently bonded to the lens surface. (DI 287 at 51-52). His testimony on this issue is consistent with Dr. Valint's – and Dr. Nicolson's – testimony that the "PVP" molecules CIBA's patents teach are covalently bonded to the surface, which means they are not a homopolymer of PVP, but rather are a copolymer. (Tr. VII at 234:19-22, 235:19-236:8). Dr. Nicolson testified that if "there's a chemical bond between the PVP and the lens … one way to call that is a co-polymer" and that a co-polymer is different from a homopolymer. (Tr. IX at 145:9-18). And Drs. Mays and Winterton agreed that according to the CIBA patents, PVP was covalently bound to the surface. (Tr. X at 49:20-50:4, 52:1-54:22, 56:19-21, 58:17-20).

CIBA also argues that "the Federal Circuit has held that a construction which excludes preferred embodiments is rarely correct." (DI 287 at 51-52). CIBA's argument ignores the fact that the construction of PVP was *agreed to by both parties* because it is the commonly understood meaning of the term.

Accordingly, the evidence shows that claim 96 of the '894 patent is not enabled.

3. Claimed Ionoflux Values Are Too Low

J&J's Proposed Findings set forth the clear and convincing evidence that CIBA's patents do not enable the full scope of the claimed Ionoflux range. (*See* DI 286 at 47-50). CIBA's argument that a working example within the claimed range is unnecessary ignores a key legal principle: the *absence* of such a working example is strong evidence that the claims are not enabled. *See Emergency Fuel, LLC v. Pennzoil-Quaker State Co.*, 187 F. Supp. 2d 575, 582 (D. Md. 2002), *aff'd in relevant part*, 71 Fed. Appx. 826, 832 (Fed. Cir. 2003); *In re Colianni*, 561 F.2d 220, 222 (C.C.P.A. 1977).

4. Certain Ionoton Values Lack An Adequate Written Description And/Or Are Not Enabled

Contrary to CIBA's position, J&J presented evidence on this issue at DI 286 at 50-51.

C. Obviousness

CIBA ignores the clear evidence that the asserted claims in the '894 and '811 patents are invalid as obvious over Chang. CIBA asserts that researchers had tried for 20 years "without success" to achieve an extended wear silicone hydrogel lens. (DI 287 at 58, 60). But the disclosures in Chang, which the law presumes are correct, refute CIBA's claim that it was the first to achieve such a lens. Ignoring this presumption, CIBA criticizes J&J's recreations and tests on Example 3 Chang lenses (DI 287 at 59-60), none of which J&J had a burden to perform. *See, e.g.*, *Pfizer v. Apotex*, 480 F.3d 1348, 1367-68 (Fed. Cir. 2007).

CIBA's assertion that J&J required more than two years to achieve an Example 3 lens has no merit. J&J made successful Example 3 lenses on its first attempt, creating more lenses for testing or to address CIBA's litigation-motivated criticisms. (Tr. VII at 65:12-66:6; DTX 1461). CIBA's argument that J&J recreated lenses using "hind-sight driven"

modifications (DI 287 at 60) ignores that the alleged modifications, "rigorous exclusion of oxygen" and use of 98% pure glycerine, were either well known in the art and/or specifically taught in *Chang itself*, and were at most "predictable variations" of what was disclosed in Chang. *KSR v. Teleflex*, 550 U.S. 398, 417 (2007) ("If a person of ordinary skill can implement a predictable variation" of what is disclosed in the art, "§ 103 likely bars its patentability."); (Tr. X at 44:11-47:14; PTX 125 at 6:10-11; PTX 68 at CSFJ033763; PTX 109 at 22:53-62; Tr. VI at 194:22-195:19, 197:19-198:16). CIBA also criticizes the oxygen permeability data of J&J's expert, Dr. Benjamin, as "unreliable." (DI 287 at 64). Tellingly, however, CIBA offers no criticism of the methodology he used or the values he obtained. Nor can CIBA do so. While tables in his expert report had typographical errors, that is no basis to challenge the underlying data, which conclusively show that "thicker" Example 3 lenses had permeability and transmissibility values well above the claimed values.

CIBA next argues that the fact that "thinner" recreations were clinically tested while "thicker" lenses were tested for permeability and transmissibility defeats J&J's obviousness defense. (DI 287 at 64). The Federal Circuit has rejected this argument. *See, e.g., Boston Scientific Scimed, Inc. v. Cordis Corp.*, 554 F.3d 982, 991 (Fed. Cir. 2009) (claims found obvious based on combination of "two embodiments disclosed adjacent to each other in a prior art patent [which] does not require a leap of inventiveness"). Moreover, the parties do not dispute that the Dk for Example 3 lenses depends on thickness, and thus that J&J could obtain higher Dk values simply by using thicker lenses. *KSR*, 550 U.S. at 417-18.

IV. UNENFORCEABILITY

A. Failure To Disclose To The PTO That Some Patent Examples Were Toxic

CIBA's Proposed Findings assert that the Alsacon toxicity problems were not material because they related only to shelf-life issues in lenses more than six months old, and no claims have such shelf-life requirements. (DI 287 at 70). But CIBA's documents reveal that Alsacon lenses exhibited *immediate* toxicity problems due to the PEG ingredient's degradation during manufacture and sterilization. (PTX 540 at CSFJ052326, 330-31). Indeed, Dr. Nicolson discontinued Alsacon clinical studies due to corneal infiltrates, attributing this problem to the instability of the PEG component, *not* a shelf-life issue. (PTX 350 at CSFJ083191). Tellingly, CIBA never addresses J&J's argument. (DI 287 at 69-70).

CIBA cites clinical studies for the proposition that *freshly prepared* Alsacon lenses were not toxic. (DI 287 at 69-70). But those studies reveal serious problems with the lenses, with one study reporting that all three subjects developed surface anomalies during lens wear, and a separate three-patient study showing that one patient discontinued *after a single night* "due to reduced comfort." (DTX 1437 at CSFJ033192; DTX 611 at CSFJ034164).

CIBA asserts that it notified the PTO of the Alsacon toxicity problems when it disclosed its proposed findings in the B&L litigation during the '894 patent prosecution. (DI 287 at 70). But CIBA failed to disclose the toxicity problems when it should have, namely years before during the prosecution of the '100 and '811 patents. *See Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1182 (Fed. Cir. 1995) (affirming judgment of inequitable conduct where "the references were not cited when they should have been"). The fact that the PTO ultimately allowed the '894 claims does not diminish the materiality of the information CIBA

failed to disclose. *See, e.g.*, *Digital Control Inc. v. Charles Mach. Works*, 437 F.3d 1309, 1318 (Fed. Cir. 2006) ("Under the 'reasonable examiner' standard, a misstatement or omission may be material even if disclosure of that misstatement or omission would not have rendered the invention unpatentable.").

Similarly, the Court should discount CIBA's evidence that it did not intend to deceive the PTO. (DI 287 at 70-71). Dr. Nicolson's testimony that Alsacon toxicity was merely a commercial (*i.e.*, shelf-life) problem is directly contradicted by the evidence that CIBA knew that degradation products formed during manufacturing and sterilization, and also knew that its clinical studies revealed serious problems even with "freshly prepared" Alsacon lenses. Dr. Nicolson's conclusory denial of intent to deceive the PTO is insufficient to overcome evidence of deceptive intent. *Paragon Podiatry Lab., Inc. v. KLM Labs., Inc.*, 984 F.2d 1182, 1191 (Fed. Cir. 1993).

B. Misrepresentations To The PTO On The Existence Of Prior Art Silicone Hydrogels With Surface Modification

Significantly, CIBA *never* addresses CIBA's failure to disclose the meeting minutes from the Grobe presentation, or the Federal Circuit's *Monsanto* decision, which held a patent unenforceable under highly similar circumstances. *Monsanto Co. v. Bayer Bioscience N.V.*, 514 F.3d 1229, 1233-42 (Fed. Cir. 2008).

With respect to the Grobe abstract, CIBA argues that it disclosed *other* prior art on surface treatment of silicone hydrogels during the original prosecution and reexamination of the '100 and '811 patents, thus making the Grobe abstract "cumulative." (DI 287 at 73-75). But the 510(k) summary and '733 Lai patent were never before the Examiner during the original prosecution of CIBA's patents. *See* 37 C.F.R. 1.56 ("[I]nformation is material to

patentability when it is not cumulative to information *already of record or being made of record in the application....*"). And Dr. Nicolson's reexamination declaration specifically stated that the Lai patent was a "failure," so the Grobe abstract could hardly be cumulative based on that disclosure. (PTX 22 at 758-59, ¶¶ 36-37; PTX 300 at ¶¶ 36-37). The Grobe abstract is also not cumulative of the Chang and Harvey patents because, according to CIBA, those patents fail to disclose a working surface-treated silicone hydrogel lens with high Dk. (Tr. I at 143:11-12; Tr. VIII at 53:25-54:4; *see* DTX 1328 at 1:59-66).

Finally, CIBA argues that Dr. Valint admitted that CIBA did not conceal prior art on the surface treatment of silicone hydrogels in its initial application. (DI 287 at 73). But Dr. Valint testified only that (i) CIBA cited Chang and Harvey to the PTO and (ii) *those cited references* were thus not concealed from the PTO. (Tr. VIII at 99:5-103:2).

V. CONCLUSION

CIBA has not proven by a preponderance of the evidence that the Oasys lens infringes the asserted claims. Moreover, J&J has proven by clear and convincing evidence that the asserted claims are invalid and that CIBA's patents are unenforceable.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on May 20, 2009, I electronically filed the foregoing **JOHNSON & JOHNSON VISION CARE, INC.'S BRIEF IN RESPONSE TO CIBA'S POST-TRIAL PROPOSED FINDINGS OF FACTS AND CONCLUSIONS OF LAW** with the Clerk of the Court by using the CM/ECF system, which will send a notice of electronic filing to the following: Rutledge R. Liles, Esq., Liles, Gavin, Costantino & George, One Enterprise Center, 225 Water Street, Suite 1500, Jacksonville, Florida 32202 and Raphael V. Lupo, Esq. and Thomas P. Steindler, Esq., McDermott, Will & Emery, 600 Thirteenth Street, N.W., Washington, D.C. 20005-3096. Additionally, a true and correct copy of the foregoing was served via overnight delivery to Rutledge R. Liles, Esq. and Thomas P. Steindler, Esq.

/s/ Timothy J. Barron
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