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.

***MARKMAN* ORDER**

This consolidated case pertains to CIBA Vision Corporation's ("CIBA") six patents for extended-wear contact lenses, and related methodology. In Case No. 3:05-cv-125-J-32TEM, Johnson & Johnson Vision Care, Inc. ("J&J") brought an action for declaratory judgment against its competitor CIBA, seeking a declaration that CIBA United States 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") (collectively "the Nicolson patents" or "CIBA patents") are invalid and/or unenforceable, and alternatively that J&J's new silicone hydrogel contact daily wear

lenses, the Phoenix contact lens, to be marketed under the name ACUVUE®OASYS™, does not infringe upon the CIBA patents. (Doc. 1). CIBA answered and counterclaimed that J&J's lens infringes upon the '100, '461, '811, and '631 CIBA Patents.[1] In case No: 3:06-cv-310-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," entitled "Extended Wear Opthalmic Lens." J&J counterclaimed, seeking a declaration that the '894 Patent is invalid and unenforceable.[2] This matter is before the Court for patent claim

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[1] CIBA does not allege infringement of the '999 Patent entitled "Methods Of Using And Screening Extended Wear Ophthalmic Lenses."

[2] J&J originally filed two declaratory judgment actions in this Court on September 17, 2003 and December 16, 2004, concerning its ACUVUE©ADVANCE™ contact lenses. (No. 3:03-cv-800-J-32TEM; 3:04-cv-1297-J-32TEM.) The Acuvue lenses involved in the original actions were sold for daily wear and provide a wearable soft silicone hydrogel lens without a surface treatment. J&J sought a declaration that the ACUVUE©ADVANCE™ lenses do not infringe upon the five CIBA Nicolson patents (Patents '100, '999, '461, '811 and '631), and that the Nicolson patents are invalid and unenforceable. CIBA filed an answer and counterclaim in each of these actions. (See Doc. 34 at 5-6.) In February 2005, J&J filed a third case, seeking a declaratory judgment action seeking identical rulings with respect to its ACUVUE®OASYS™ lenses. (3:05-cv-135-J-32TEM.) Subsequently, on April 3, 2006, CIBA filed two additional cases against J&J, 3:06-cv-300-J-32TEM (relating to J&J's ACUVUE©ADVANCE™ with Hydraclear™ and ACUVUE©ADVANCE™ for Astigmatism with Hydraclear™), and 3:06-cv-301-J-32TEM (pertaining to J&J's ACUVUE®OASYS™ with Hydraclear™ Plus). On May 24, 2006, the Court consolidated the ACUVUE®OASYS™ cases (Case nos. 3:05-cv-135 and 3:06-cv-310) in the instant action. The Court stayed the ACUVUE©ADVANCE™ cases (Case nos 3:06-cv-300, 3:03-cv-800 and 3:04-cv-1297), and proceeded with the instant action. (Doc. 51 at 3-4.)

construction, as described in Markman v. Westview Instruments, Inc., 52 F.3d 967 (Fed. Cir. 1995)(en banc), aff'd, 517 U.S. 370 (1996). The Court has considered the voluminous submissions by the parties, including memoranda, summaries, charts, and exhibits (Docs. 84, 86, 87, 90, 91, 92, 94), as well as argument of counsel at a day-long *Markman* hearing held on July 25, 2007.

I. Background

The six patents at issue in this case ("the CIBA patents") stem from a single application for the '100 Patent entitled "Extended Wear Ophthalmic Lens," which was filed with the United States Patent & Trademark Office ("USPTO") on December 8, 1995. (Doc. 84-23.) The original application presented 158 claims and listed 19 inventors from all over the world. The original application was subsequently divided into four distinct patent applications which eventually resulted in the '100, '811, '999, and '461 Patents. The patents, informally referred to by the name of the lead inventor, Dr. Paul C. Nicolson, include both device and method patents, along with divisionals and continuations thereof.[3]

The CIBA patents relate to silicone hydrogel lenses suitable for extended continuous wear periods of at least 24 hours to up to 30 days. The '100 Patent describes the requirements for the invention.

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[3] The Nicolson family of patents currently includes seven separate U.S. patents as well as a pending application for an eighth patent. (See Doc. 21 at 4.)

> One ophthalmic compatibility requirement for contact lenses is that the lens must allow oxygen to reach the cornea in an amount sufficient for long-term corneal health. The contact lens must allow oxygen from the surrounding air to reach the cornea because the cornea does not receive oxygen from the blood supply like other tissue. If sufficient oxygen does not reach the cornea, corneal swelling occurs. Extended periods of oxygen deprivation causes the undesirable growth of blood vessels in the cornea. "Soft" contact lenses conform closely to the shape of the eye, so oxygen cannot easily circumvent the lens. Thus, soft contact lenses must allow oxygen to diffuse through the lens to reach the cornea.
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> Another ophthalmic compatibility requirement for soft contact lenses is that the lens must not strongly adhere to the eye. Clearly, the consumer must be able to easily remove the lens from the eye for disinfecting, cleaning, or disposal. However, the lens must also be able to move on the eye in order to encourage tear flow between the lens and the eye. Tear flow between the lens and eye allows for debris, such as foreign particulates or dead epithelial cells to be swept from beneath the lens and, ultimately, out of the tear fluid. Thus, a contact lens must not adhere to the eye so strongly that adequate movement of the lens on the eye is inhibited.

('100 Patent col.1 ll.29-53.) The patents sought to address these two ophthalmic compatibility requirements.

CIBA's patented contact lens addresses the first requirement, providing for a flow of oxygen through the lens to the cornea of the eye, by incorporating "phases" into its lens structure. The purpose of the phases is for the oxygen to reach the cornea of the eye by diffusing through the oxyperm material, whereas the ions and water move back and forth and diffuse through the ionoperm material. The '100

Patent specifies:

> 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 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 resistence to ion diffusion.

('100 Patent col.8 ll.40-48.)

The USPTO issued the '100 Patent on June 2, 1998.[4] CIBA released the silicone hydrogel extended wear lenses protected by these patents under the name Focus® NIGHT & DAY™, providing, until recently, the only 30-day extended wear lenses on the domestic market. (See Doc. 49 at 3.)

Competitor Bausch & Lomb, Inc. ("B&L") requested a reexamination of four of CIBA's patents ('100, '999, '461, and '811 patents), relying on its own patent, U.S. Patent No. 5,034,461 by Dr. Yu-Chin Lai ("Lai '461 Patent"). (See Doc. 21 at 4.) In March 1999, the USPTO opened reexamination proceedings for the '811 patent and

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[4] The related divisional patents were similarly issued: '999 Patent on July 7, 1998; the '461 Patent on August 4, 1998; and the '811 patent on December 15, 1998. On July 1, 1998, CIBA filed another divisional application to the '100 patent application, which was approved by the USPTO as Patent '631, dated October 12, 1999, followed by another divisional application to the '100 Patent application, filed on August 17, 2000, which matured to the '894 patent on October 4, 2005, followed by a certificate of Correction, dated March 21, 2006.

all of the other then-issued Nicolson patents to examine them in light of the Lai '461 Patent. (Doc. 34 at 7.)[5] Initially, some of the claims in the CIBA patents were rejected as anticipated by prior art and obvious in light of the Lai '461 Patent. (Doc. 84-6 at 19.) However, based on submissions by CIBA, the examiner determined that the amendments to the patents and the arguments made by CIBA overcame all pending rejections. (See Doc. 84-6 at 21 (J&J Ex. 4).) Reexamination certificates were issued by the USPTO on Patents '100, '999, '811, and '461 in November, 2000.

On March 8, 1999, CIBA brought an infringement action against B&L in the United States District Court for the Northern District of Georgia, 2:99-cv-0034-RWS ("B&L case"), alleging that B&L's 30-day extended day silicone hydrogel lenses, marketed under the PureVision™ name, infringed upon the '100, '999, '461, and '811 patents. B&L argued that it, not CIBA, was the first to invent extended wear silicone hydrogel contact lenses, particularly referring to prior art, the Lai '461 Patent and the Nandu Patent (U.S. Patent No. 5,260,000). (See Docs. 21 at 4; 23 at 16; 49 at 4.) The Georgia Court stayed the case pending the reexamination proceedings, and reopened the case on March 28, 2001. The Georgia District Court issued its *Markman* claim construction on March 14, 2003, which is much discussed in this case. Following a 23 day trial, but before the issuance of an opinion, CIBA and B&L reached

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[5] The '631 and '894 Patents had not yet been issued.

a settlement in July 2004,[6] and the district judge signed a consent decree on July 23, 2004.

J&J contends that its new Oasys lenses are soft silicone hydrogel contact lenses that, unlike the older silicone hydrogel lenses sold by CIBA and B&L, do not require a surface treatment for the lens to be wearable. The Oasys lenses have been manufacturered at J&J's facilities in Jacksonville since late 2004. (Doc. 34 at 5.) In November 2004, J&J received U.S. Food and Drug Administration ("FDA") approval to sell the Oasys lens as a daily wear lens only. (Doc. 34 at 7.) In 2005, the product was sold in Europe, and J&J was in the midst of launching the product in the United States. (Doc. 34 at 6.)

II. Claim Construction Standards

A patent describes the scope and limits of an invention to alert the public to what exclusive rights the patentee holds, and by the same token, what remains open to the public. Markman, 52 F.3d at 978. A patent consists of claims which should 'particularly point[ ] out and distinctly claim[ ] the subject matter which the applicant regards as his invention." E.g., Howmedica Osteonics Corp. v. Tranquil Prospects, Ltd., 401 F.3d 1367, 1371 (Fed. Cir. 2005); 35 U.S.C. § 112. A determination of

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[6] As part of the settlement, CIBA granted B&L a non-exclusive license to the Nicolson patent under which B&L could sell its PureVision™ lenses. B&L agreed to temporarily stay off the market, pay CIBA a royalty on the eventual sales of the PureVision™ lenses, and give CIBA a royalty-free cross-license to B&L's silicone hydrogel patents. (Doc. 49 at 4.)

patent infringement requires a two-step analysis: first, the meaning of the claim language is construed, then the facts are applied to determine if the accused device falls within the scope of the claims as interpreted. Markman, 52 F.3d at 976.

Patent claims are construed by the Court as a matter of law. Cybor Corp. v. FAS Techs, Inc., 138 F.3d 1448, 1454-56 (Fed. Cir. 1998)(en banc). "It is a 'bedrock principle' of patent law that 'the claims of a patent define the invention to which the patentee is entitled the right to exclude." Phillips v. AWH Corp., 415 F.3d 1303, 1312 (Fed. Cir. 2005)(en banc)(quoting Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc., 381 F.3d 1111, 1115 (Fed. Cir. 2004)). "[T]he words of a claim 'are generally given their ordinary and customary meaning.'" Phillips, 415 F.3d at 1312 (quoting Vitrionics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996)). Such ordinary meaning "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." Id at 1313. "Courts construe claim terms in order to assign a fixed, unambiguous, legally operative meaning to the claim." Chimie v. PPG Indus., Inc., 402 F.3d 1371, 1377 (Fed. Cir. 2005).

In claim construction, courts first examine the patent's intrinsic evidence to define the patented invention's scope. See Phillips, 415 F.3d at 1312. This intrinsic evidence includes the claims themselves, the specification, and the prosecution history. See Phillips, 415 F.3d at 1314; C.R. Bard, Inc. v. U.S. Surgical Corp., 388

F.3d 858, 861 (Fed. Cir. 2004).

Claim construction begins with the words of the claims themselves. Amgen Inc. v. Hoechst Marion Roussel, Inc., 457 F.3d 1293, 1301 (Fed. Cir. 2006); Phillips, 415 F.3d at 1312. The task of comprehending these words is not always a difficult one. "'In some cases, the ordinary meaning of claim language as understood by a person of skill in the art may be readily apparent even to lay judges, and claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words.'" Acumed LLC v. Stryker Corp., 483 F.3d 800, 805 (Fed. Cir. 2007)(quoting Phillips, 415 F.3d at 1314). However, a patent "specification may reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess. Acumed, 483 F.3d at 805. "In such cases, the inventor's lexicography governs." Phillips, 415 F.3d at 1316. Further, a "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; see also Markman, 52 F.3d at 979 (holding that claims "must be read in view of the specification, of which they are a part").

"When dealing with technical terms, . . . a court should look to 'the words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical

terms, and the state of the art.'" Amgen Inc., 457 F.3d at 1301 (quoting Phillips, 415 F.3d at 1313). Other asserted or unasserted claims can also aid in determining the claim's meaning because claim terms are typically used consistently throughout the patent. Phillips, 415 F.3d at 1314. Differences among the claim terms can also assist in understanding a term's meaning. Id. For example, when a dependent claim adds a limitation to an independent claim, it is presumed that the independent claim does not include the limitation. Id. at 1314-15.

"[T]he specification is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term.'" Id. at 1315 (quoting Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996); Teleflex, Inc. v. Ficosa N. Am. Corp., 299 F.3d 1313, 1325 (Fed. Cir. 2002). This is true because a patentee may define his own terms, give a claim term a different meaning than the term would otherwise possess, or disclaim or disavow the claim scope. Phillips, 415 F.3d at 1316. Also, the specification may resolve ambiguous terms "where the ordinary and accustomed meaning of the words used in the claims lack sufficient clarity to permit the scope of the claim to be ascertained from the words alone." Teleflex, Inc., 299 F.3d at 1325. "'Although 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.'" Comark Commc'ns, Inc. v. Harris Corp., 156 F.3d 1182, 1187 (Fed.

Cir. 1998)(citation omitted); see also Phillips, 415 F.3d at 1323. Occasionally "the specification may reveal a special definition given to a claim term . . . that differs from the meaning it would otherwise possess. Phillips, 415 F.3d at 1316. The specification may also "reveal an intentional disclaimer, or disavowal, of claim scope by the inventor . . . , [which] is regarded as dispositive." Id.

The prosecution history is another tool to supply the proper context for claim construction because a patent applicant may also define a term in prosecuting the patent. Home Diagnostic, Inc. v. LifeScan, Inc., 381 F.3d 1352, 1356 (Fed. Cir. 2004). However, because the prosecution history represents negotiation between the USPTO and the applicant, "it often lacks the clarity of the specification and thus is less useful for claim construction purposes." Phillips, 415 F.3d at 1317. Nevertheless, the prosecution history can be helpful "by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of the prosecution." Id. "Disclaimers based on disavowing actions or statements during prosecution, however, must be both clear and unmistakable." Sorenson v. Int'l Trade Comm'n, 427 F.3d 1375, 1378-79 (Fed. Cir. 2005). Further, it is the applicant and not the examiner who must "'give up or disclaim subject matter'" that would otherwise be included within the scope of the claim. Sorenson, 427 F.3d at 1380 (citation omitted). The statement of an examiner alone will not necessarily limit a claim. Bell Atlantic Network Servs., Inc. v. Covad Commc'ns Group, Inc., 262 F.3d 1258, 1273 (Fed. Cir.

2001).

Though not preferred over intrinsic evidence, the Court may also rely on extrinsic evidence, which is "all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises." Markman, 52 F.3d at 980. "Extrinsic evidence in the form of expert testimony can be useful to a court for a variety of purposes, such as to provide background on the technology . . . , to explain how an invention works, to ensure that the court's understanding of the technical aspects of the patent is consistent with that of a person of ordinary skill in the art, or to establish that a particular term in the patent or prior art has a particular meaning in the pertinent field." Conoco, Inc. v. Energy Envtl. Int'l, L.C., 460 F.3d 1349, 1362 (Fed. Cir. 2006)(citing Phillips, 415 F.3d at 1318)). Although extrinsic evidence can be useful, it is "less significant than the intrinsic record in determining the 'legally operative meaning of claim language.'" Phillips, 415 F.3d at 1317 (citation omitted). Technical dictionaries and treatises may help a court understand the underlying technology and the manner in which one skilled in the art might use claim terms. However, technical dictionaries and treatises may provide definitions that are too broad or may not be indicative of how the term is used in the patent. Id. at 1321-22. Similarly, expert testimony may aid the court in understanding the underlying technology and determining the particular meaning of a term in the pertinent field, but an expert's conclusory unsupported assertions as to a term's

definition are entirely unhelpful to the court. Id. at 1318. Generally, extrinsic evidence is "less reliable than the patent and its prosecution history in determining how to read claim terms." Id.

Finally, claim construction must proceed "without regard to the accused device." Optical Disc Corp. v. Del Mar Avionics, 208 F.3d 1324, 1333 (Fed. Cir. 2000); Young Dental Mfg. Co., Inc. v. Q3 Special Prods., Inc., 112 F.3d 1137, 1141 (Fed. Cir. 1997).

III. Northern District of Georgia *Markman* Order

On March 14, 2003, the Northern District of Georgia, the Honorable Richard W. Story, United States District Judge, entered a *Markman* order in the B&L case, construing many of the same terms proffered for claim construction by the parties here. CIBA Vison Corp. v. Bausch & Lomb, Inc., No. 2:99-CV-0034-RWS (N.D. Ga. March 14, 2003). (E.g., Doc. 87 Ex. G.)

While uniformity of treatment of a given patent is important, Markman, 517 U.S. at 390, and Judge Story's previous decision is entitled to "reasoned deference" under the broad principles of *stare decisis* and the goals articulated in *Markman*, the Court is not bound to automatically accept the claim construction by Judge Story, as CIBA contends. Rather, the Court has an independent obligation to determine the meaning of the claims, and to render its own independent claim construction. See Visto Corp. v. Sproqit Technologies, Inc., 445 F. Supp. 2d 1104, 1108 (N.D. Cal. 2006); Precor Inc. v. Fitness Quest, Inc., No. C05-0993L, 2006 WL 2469123, at *1 (W.D. Wash.

Aug. 23, 2006); Maurice Mitchell Innovations, L.P. v. Intel Corp., No. 2:04-CV-450, 2006 WL 1751779, at * 4 (E.D. Tex. June 21, 2006)(unpublished opinions); Texas Instruments, Inc. v. Linear Technologies Corp., 182 F. Supp. 2d 580, 586, 589-90 (D. Tex. 2002); see generally McGinley v. Houston, 361 F.3d 1328, 1331 (11th Cir. 2004)(the general rule is that a district judge's decision does not bind another district judge); Ramos v. Boehringer Mannheim Corp., 66 F.3d 346, 1995 WL 540297, at * 1 (Fed. Cir. 1995)("comity is not required between district courts, absent any basis for collateral estoppel")

IV. The Court Does Not Make Indefiniteness Determinations At This Time

In response to CIBA's proposed claim constructions, J&J asserts that thirteen terms are "too indefinite to construe" or "indefinite as a matter of law."[7] (See Docs. 94 at 30, 33, 36; 90-3; 90-4.) J&J argues here that because these terms are too indefinite to be construed, the Court should simply later hold the claims containing

[7] The terms called "indefinite" by J&J are: "without causing substantial wearer discomfort"; "high oxygen permeability"; "extended wear"; "adequate tear exchange"; "without causing substantial wearer discomfort"; "at least about 70 barrers/mm"; "oxygen permeation in an amount sufficient to maintain good corneal health"; "substantially harmed"; "wherein said lens is autoclaved without lowering either said oxygen permeability or said ion permeability below levels sufficient to maintain good corneal health and on-eye movement"; "oxygen transmissibility"; "ionoflux diffusion coefficient" and "ionoflux ion permeability coefficient"; and "ion permeability characterized . . . by . . . an ionotone ion permeability coefficient".

these terms to be invalid. (Tr. 111-12.)[8]

The Federal Circuit advises that the Court must first construe the term, if possible, before engaging in a validity analysis of the claims. "[W]e have certainly not endorsed a regime in which validity analysis is a regular component of claim construction." Phillips, 415 F.3d at 1327 (citing Nazomi Commc'ns, Inc. v. Arm Holdings, PLC, 403 F.3d 1364, 1368-69 (Fed. Cir. 2005)(cautioning the construing court to not "put the validity cart before the claim construction horse"); see generally Landers v. Sideways, LLC., 142 Fed. Appx. 462, 468 (Fed. Cir. 2005)(unpublished opinion)(inappropriate to focus on validity in the process of claim construction). The Court must first attempt to determine what the claim means before it can determine whether it is invalid for indefiniteness. Pharmastem Therapeutics, Inc. v. Viacell, Inc., 2003 WL 124149, at * 1 n.1 (D. Del. Jan. 13, 2003). The issue of indefiniteness is not properly before the Court when construing claims.

The Court declines to make indefiniteness determinations here. The Court will consider the term, the constructions proposed by CIBA and by J&J, and construe the term where necessary. Validity questions may be raised at a later time in the proceedings.

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[8] "Tr. ___" refers to the Transcript of the *Markman* hearing, held on July 25, 2007.

V. The Claims

The six patents at issue present a total of some 251 claims, including both dependent and independent claims. Claim 1 of the reexamined '100 Patent is a representative independent apparatus claim, reciting many of the claim terms that the parties present for construction. It reads as follows (with emphasis on the disputed claim terms and phrases):

> 1. An ophthalmic lens having a surface modified by a surface treatment process, said lens having ophthalmically compatible inner and outer surfaces, said lens being suited to extended periods of wear in continuous, intimate contact with ocular tissue and ocular fluids while having adequate movement on the eye with blinking to promote adequate tear exchange and without producing significant corneal swelling, without having substantial amounts of lipid adsorption, and without causing substantial wearer discomfort during a period of wear of at least 24 hours, said lens comprising a polymeric material which has a high oxygen permeability and a high ion permeability, said polymeric material being formed from polymerizable materials comprising:
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> (a) at least one oxyperm polymerizable material and
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> (b) at least one ionoperm polymerizable material,
>
> wherein said lens allows oxygen permeation in an amount sufficient to maintain corneal health and wearer comfort during the period of extended, continuous contact with ocular tissue and ocular fluids,
>
> wherein said oxyperm polymerizable material forms a phase or phases substantially separate from the phase or phases formed by said ionoperm polymerizable material,
>
> wherein said lens allows ion or water permeation via ion or water pathways in an amount sufficient to enable the lens to move on the eye such that corneal health is not substantially harmed and wearer comfort is acceptable during the period of extended, continuous contact with ocular tissue and ocular fluids,

wherein said ionoperm polymerizable material, if polymerized alone would form a hydrophilic polymer having a water content of at least 10 weight percent upon full hydration, and

wherein said ophthalmic lens has an oxygen transmissibility of at least about 70 barrers/mm and an ion permeability characterized either by (1) an Ionoton Ion Permeability Coefficient of greater than about $0.2\times10^{-6}cm^2/sec$ or (2) an Ionoflux Diffusion Coefficient of greater than about $1.5\times10^{-6}mm^2/min$. wherein said ion permeability is measured with respect to sodium ions.

VI. Claim Construction

A. Agreed Constructions

1. "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**. (Docs. 94 at 19-20; 86 at 20; Tr. 176 (emphasis added).)

The parties agreed to the construction adopted by the Northen District of Georgia in the B&L case. (See Doc. 87 Ex. G at ¶ 15.) It is the verbatim definition of

"phase" found in the patent specifications. (See e.g. '100 Patent col.5 ll.20-31.) However, the meaning of the phrases in boldface are disputed by the parties.

2. "Co-continuous Phases"

> "Co-continuous Phases" refers to at least two regions, each of **substantially uniform composition** which differs from the other, and each of which forms a **continuous pathway** from one surface of an article to another surface of an article. However, each "phase" need not be a chemically pure substance, but merely connotes that certain bulk properties differ significantly from the properties of another phase within the material. Thus, with respect to co-continuous oxyperm and ionoperm phases, the 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**. (Docs. 94 at 22; 86 at 22 (emphasis added).)[9]

The agreed-to construction of the term is that adopted by the Northern District of Georgia, (see Doc. 87 Ex. G at p. 8), which combines the verbatim definition for the term found in the patent specification, ('100 Patent col.5 ll.35-39), with the patent's explicit definition for the term "phase." ('100 Patent col.5 ll.20-31.) The patent's definition of "co-continuous phases" goes on to say that "an ophthalmic lens having co-continuous phases of oxyperm polymer and ionoperm polymer will have two continuous pathways or sets of continuous pathways extending from the inner surface

[9] The parties disagree as to the definition of terms in bold-face.

of the lens to the outer surface of the lens." ('100 Patent col.5 ll.39-43.)

3. "Polyvinylpyrrolidone"[10]

a homopolymer that is produced by the polymerization of N-vinylpyrrolidone. (Tr. at 145.)

4. "Biocompatible"

"Biocompatible" has the same meaning as "ophthalmically compatible." (Docs. 86 at 38; 93-3 at 3.)

The parties agree that the terms "biocompatible" and "ophthalmically compatible" are synonymous for purposes of construing the patents in this case. As discussed in the patent itself, "[i]n the field of ophthalmic lenses, and in particular in the field of contact lenses, a biocompatible lens may be generally defined as one which will not substantially damage the surrounding ocular tissue and ocular fluid during the time period of contact. The phrase 'ophthalmically compatible' more appropriately describes the biocompatibility requirements of ophthalmic lenses." ('100 Patent col.1, ll. 22-28.)

5. "High Water Permeability"

the rate of water permeation through the lens, from one surface to another, of greater than about 0.2 x 10^{-6} cm^2/sec (See Tr. at 222-24.)

[10] See '894 Patent cl. 96.

B. Disputed Constructions

1. "Surface Treatment Process"

J&J's Proposed Construction	CIBA's Proposed Construction
"Surface treatment process" means a post-manufacturing process for rendering a surface of an existing lens more ophthalmically compatible by contacting the existing surface of the lens with a vapor or a liquid or by applying an energy source to the existing surface of the lens, but "surface treatment process" does not encompass the process of curing the lens materials or the process of hydrating the finished lens. (Doc. 94 at 15.)	This claim element requires that the exterior faces of the lens be altered, at least in part, by a process (or processes) that renders the surface more ophthalmically compatible 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, or (4) the surface properties of an article are otherwise modified. However, the aforementioned processes exclude a conventional Yasuda process that was designed to drastically reduce water permeability; a conventional, non-wettable TMS plasma coating; and a process that results in a surface that is completely transient, i.e., changed from a hydrophilic (wettable) surface to a hydrophobic (non-wettable) surface when worn. (Doc. 86 at 23.)

CIBA's proposed construction reflects verbatim the construction made by the Northern District of Georgia in the CIBA v. B&L case. (See Doc. 87 (CIBA Ex. G at 9).)

The CIBA patent specification defines "surface treatment processes" as follows:

> "Surface treatment processes" as used herein, refers to 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.

('100 Patent col.42 ll.44-54.) The patent specification describes "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 the mold surface to differ in composition from the core of the prepolymerization mixture." ('100 Patent col.42 ll.53-67 to col.43 ll.1-3.)

Focusing upon the prosecution history, J&J contends that CIBA overcame an obviousness objection on reexamination of the CIBA patents by distinguishing its invention from the Lai '461 Patent prior art which taught adding the surface wetting agents during manufacture. Thus, argues J&J, the "surface treatment process" contemplated by the CIBA patents "necessarily means the surfaces already exist before being treated." (E.g. Docs. 84-34 at 46 (J&J Ex. 29); 94 at 17; Tr. 100-01).) Specifically, inventor Nicolson represented to the USPTO on re-examination that "one does not find any prior art on the surface modification of silicone hydrogels prior to our patents." (Doc. 84-5 at 8 (J&J Ex. 3).) In doing so, according to J&J, CIBA specifically disclaimed the pre-polymer addition of a wetting agent and equated "surface

treatment process" to a "post-manufacturing" process, treating the surface of the lens after the lens is made. (Tr. 93-94, 103.) J&J also contends that the language of the defining specification ('100 Patent col.42 ll.44-45) is consistent and should be read as providing that the treatment process is applied to an existing surface to make it more ophthalmically compatible. (Tr. 95).

CIBA contends that rather than making a clear and unmistakable disclaimer during the reexamination procedure, it sought to demonstrate how the Lai '461 Patent prior art failed to solve the wettablity and lipid absorption problem and thus, under Federal Circuit law, establish the non-obviousness of the claimed CIBA invention. (Doc. 84-34 at 45 (J&J Ex. 29)("failure of others to satisfy a long-felt need or develop a commercially successful product is evidence of non-obviousness")(citing Dow Chem. Co. v. American Cyanimid Co., 816 F.2d 617, 623 (Fed. Cir. 1987).) CIBA contends that its prosecution argument on reexamination was that "there's no successful prior art on surface modification of silicone hydrogels out there . . . . you don't find any successful prior art on the surface modification." (Tr. at 87.)

The Court finds that CIBA was its own lexicographer when it defined "surface treatment process" in the patent specification. The statement by inventor Nicolson to the USPTO examiner was not sufficient to clearly and unmistakably disclaim and limit the definition set forth in the specifications to being post-manufacturing. Purdue Pharma L.P. v. Endo Pharm., Inc., 438 F.3d 1123, 1136 (Fed. Cir. 2006). While the

Court of course considers the claim construction of its sister court in the Northern District of Georgia, the parties have provided no basis for embracing the language added by that court to the claim construction. Accordingly, the term "surface treatment process" shall be construed as defined by the patent specification:

"Surface Treatment Process"

"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.

2. Whether All Claims Require Surface "Surface Modification" and "Co-Continuous Phases"

J&J's Proposed Construction	CIBA's Proposed Construction
All of the claims at issue are limited to require "surface modification" and "co-continuous phases." (Docs. 94 at 10; 90-3 at 2.)	"Co-continuous pathways" or "phases" are not a claim requirement for claims that do not expressly recite them. (Doc. 86 at 23.) Surface treatment process is not a claim requirement for claims that do not expressly recite this limitation. (Doc. 86 at 37 (App. A); Doc. 91-2 at 7 (Response App. 1))

Multiple claims in the CIBA patents recite the phrase: "surface modified by a surface treatment process." (E.g. '100 Patent cl. 1, 44, 49-54, 59.) CIBA embraces the construction by the Northern District of Georgia, which held that "'co-continuous

pathways' or 'phases' are not a claim requirement for claims that do not expressly recite them." (Doc. 87 (CIBA Ex. G at 9).) As to both terms, CIBA argues that the Court should not read unstated claim limitations into claim language, see Northern Telecom Ltd. v. Samsung Electronics Co., Ltd., 215 F.3d 1281, 1290 (Fed. Cir. 2000), and that under the doctrine of claim differentiation, different claims are presumed to be of different scope. See Inpro II Licensing, S.A.R.L. v. T-Mobile USA, Inc., 450 F.3d 1350, 1353-54 (Fed. Cir. 2006).

In proposing that "'[a]ll claims at issue are limited to require surface modification and co-continuous phases," (Doc. 94 at 10), J&J first asks the Court find that the term "surface modification" has "the same meaning as surface treatment." (Docs. 94 at 18; 90-3 at 2.) CIBA responds that "surface modification" is not a term found in any claim in the CIBA patent. J&J relies primarily upon the prosecution history. During the 2000 '100 Patent reexamination proceedings before the USPTO, CIBA inventor Nicolson stated:

> 24. It is my opinion that we, the inventors, succeeded because:
>
> (a) We discovered the material requirement for a soft silicone hydrogel contact lens to move on the eye, namely, the presence of co-continuous phases of oxyperm and ionoperm material which would provide the high oxygen permeability and ion permeability; and
>
> (b) We discovered the need for surface modification of silicone hydrogels to achieve ophthalmic compatiblity of the inner and outer surfaces and that the

surface modification had to:

> i) accommodate the maintenance of the high oxygen permeability and ion permeability;
>
> ii) provide deposit resistance comfort; and
>
> iii) not perturb the other inherent properties of the lens bulk polymer such as water content, modulus geometry and the like; and
>
> iv) accommodate the shrinkage and/or expansion that can occur during normal processing including hydration, extraction and autoclaving; and use and wear including exposure to care systems . . . .

(Doc. 84-5 at 7 (J&J Ex. 3 ¶ 24).) In response, the USPTO examiner, in the August 4, 2000 Examiner's Statement of Reasons for Patentability accompanying the Notice of Intent to Issue Reexamination Certificate, stated among the reasons for determining that all pending objections over the prior art Lai patents were overcome:

> It is further observed that, given the patent owner's position that the instant invention was successful because of the presence of co-continuous phases of oxyperm and ionoperm materials providing high oxygen and ion permeability and because of the surface modification of the lens material . . . , the claims, as presently amended, appropriately reflect this position, explicitly or implicitly."

(Doc. 84-6 at 21 (J&J Ex. 4 at 20).) In addition, J&J cites to specifications which describe the separate oxyperm and ionoperm phases and their characteristics ('100

Patent col.8 ll.40-60), defining "co-continuous phases" as used in the patent ('100 Patent col.5 ll.35-39), and stating that "[i]n a particularly preferred embodiment, the lens has two co-continuous phases, one an oxyperm phase, and the other an ionoperm phase . . . ." ('100 Patent col.8 ll.57-61.)

First, J&J seeks to equate "surface treatment" with "surface modification." (Doc. 94 at 18.) "Surface treatment process" appears in the claims as part of the phrase "surface modified by a surface treatment process." As set forth above, the term "surface treatment process" is defined by the patentee in the specification to the patent. J&J equates "modification" with "treatment," based upon inventor Nicolson's statement to the USPTO during the reexamination proceedings. J&J's proposed construction would re-write the claims to read: "surface modified by a surface modification process," creating a tautology. None of the claims or the specifications use the phrase "surface modification"; rather, the claims provide that the lens surface is modified *by* a surface treatment process, indicating that the terms "modification"and "treatment" as used in the CIBA patent claims have different meanings. The Court declines to equate and substitute "surface modification" with "surface treatment." See Purdue Pharma L.P., 438 F.3d at 1136-37 ("[w]ithout any specific claim language to interpret, . . . the trial court impermissibly imported a limitation into the claims"). "[E]xtraneous limitations cannot be read into the claims from the . . . prosecution history." Bayer AG. v. Biovail, Corp., 279 F.3d 1340, 1348 (Fed. Cir. 2002)(citations

omitted).

The next question is whether the Court should construe all 251 claims set forth by CIBA's six patents as being limited by the terms "surface modification" and "con-continuous phases," as proposed by J&J based upon the prosecution history.[11]

J&J argues that the above-cited prosecution history represents a disclaimer by CIBA, relying upon the case Alloc, Inc. v. Int'l Trade Comm'n, 342 F.3d 1361 (Fed. Cir. 2003), in which the Federal Circuit construed the claims to include a feature that was common to all the disclosed embodiments but was not explicitly recited as a limitation in any of the claims. The Court held that "the specification makes clear at various points that the claimed invention is narrower than the claim language might imply" based upon a reading of the specification as a whole. Id., at 1370.

"When the specification 'makes clear that the invention does not include a

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[11] No claims contain the phrase "co-continuous phases," and not all embodiments of CIBA's invention demonstrate "co-continuous phases"; only the "particularly preferred embodiment" of the lens has two co-continuous phases. ('100 Patent, col.8 ll.57-61.)

A number of claims do not mention "surface treatment." For instance, '100 Patent, cls. 56, 60 teach "[a]n ophthalmic lens having ophthalmically compatible inner and outer surfaces . . . ." without reference to the term "surface treatment process." The '461 Patent, cls. 1, 9-14, describe "a method of forming a biocompatible lens" and "altering the surface of said core material to produce a surface which is more hydrophilic . . . ." See also '811 Patent, cl. 25 ("inner surface is adapted . . ." and "lens is autoclaved"); '631 Patent, cl. 1 ("ophthalmically compatible inner and outer surfaces").

particular feature, that feature is deemed to be outside the reach of the claims of the patent, even though the language of the claims, read without reference to the specification, might be considered broad enough to encompass the feature in question.'" Microsoft Corp. v. Multi-Tech Sys., Inc., 357 F.3d 1340, 1347 (Fed. Cir. 2004)(citation omitted). "A patentee may also limit the scope of the claims by disclaiming a particular interpretation during prosecution." Id.

While the Court recognizes that explicit arguments made during prosecution to overcome prior art can lead to narrow claim interpretations, Seachange Int'l, Inc. v. C-COR, Inc., 413 F.3d 1361, 1372-73 (Fed. Cir. 2005)(citation omitted)("[w]here an applicant argues that a claim possesses a feature that the prior art does not possess in order to overcome a prior art rejection, the argument may serve to narrow the scope of otherwise broad claim language"), any disclaimer must be clear and unambiguous. Id. at 1373; see also Purdue Pharma L.P., 438 F.3d at 1136 ("[u]nder the doctrine of prosecution disclaimer, a patentee may limit the meaning of a claim term by making a clear and unmistakable disavowal of scope during prosecution"). Despite the representations and the examiner's observation, the examiner did not require CIBA to amend all claims to reflect in each and every one the term "surface modification" and "co-continuous phases," and CIBA did not do so. The Court determines that Dr. Nicolson's representation to the USPTO examiner did not clearly and unambiguously disclaim and disavow the scope of the CIBA patents' claims.

Further, unlike the patent described in Alloc, the language of the claims and specifications here do not criticize prior art as lacking the proposed limitations, nor do all embodiments contain the limitations, and thus, the claims and specifications are not "sufficiently clear" that all claims are limited by the terms "surface modification" and "co-continuous phases."

The claims and specifications do not support the narrowing construction proposed by J&J.

3. "Altering the surface of said core material to produce a surface which is more hydrophilic than said core material"

"Altering the surface of said core material to produce a surface which is more hydrophilic than said core material by a surface treatment process"

J&J's Proposed Construction	CIBA's Proposed Construction
"Altering the surface of said core material to produce a surface which is more hydrophilic than said core material" and "Altering the surface of said core material to produce a surface which is more hydrophilic than said core material by a surface treatment process" means that a core contact lens material that has a surface be created, and then the surface of that core material is altered by a post-manufacturing surface treatment process. (Doc. 90-3 at 2 (J&J Ex. 101).)	[N.D. Ga.] "This term refers to modifying the material such that the exterior or surface of the modified material is more clinically wettable than the material without modification." (Docs. 86 at 26; 96 at 37 (App. A).) This term refers to modifying the material such that the exterior or surface of the modified material is more clinically wettable than the material without modification by a surface treatment process (as defined above). (Doc. 86 at 40 (App. A); Doc. 91-2 at 11 (Response App. 1).) Altering the surface is not a claim requirement for claims that do not expressly recite this limitation. (Doc. 86 at 37 (App.A); 91-2 at 8 (Response App.1).) Altering the surface is not limited to post-manufacture modifications for claims that do not expressly recite them. (Doc. 86 at 37 (App.A); 91-2 at 8 (Response App.1).)

The "altering the surface" language is found in Claims 1, 12 and 14 of the '461 Patent, a method patent. As an example, Claim 1 states:

> 1. A method of forming a biocompatible lens having high oxygen permeability and high water permeability, said method comprising the steps of:
>
> (a) forming a polymeric core material including:
>
> (1) at least one continuous pathway from front curve to base curve surfaces for oxygen transmission therethrough, and

> (2) at least one continuous pathway from front curve to base curve surfaces for water transmission therethrough; and
>
> (b) *altering the surface of said core material to produce a surface which is more hydrophilic than said core material,*
>
> whereby said lens allows oxygen permeation in an amount sufficient to maintain corneal health and wearer comfort during a period of extended, continuous contact with ocular tissue and ocular fluids . . . .

('461 Patent, cl. 1 (emphasis added).)

J&J contends that the language of the claimed method for forming a biocompatible contact lens requires that the steps listed in the patent - "forming a polymeric core material" and "altering the surface of said core material" must be performed in "sequential" order because the claim language "implies" that the core material exists before the surface of "said core material" is altered. For this reason, J&J urges that the language be construed to provide that the "core material is altered by a post manufacturing surface treatment process."

CIBA responds that the "post-manufacturing" limitation pressed by J&J should not be imported into the patent because the plain language of the claims imposes no sequence or order of methods, and that such order is belied by the specfications.

"Unless the steps of a method actually recite an order, the steps are not ordinarily construed to require one. . . . [Citation omitted.] However, such a result can ensue when the method steps implicitly require that they be performed in the order

written." Interactive Gift Express, Inc. v. Compuserve Inc., 256 F.3d 1323, 1342-43 (Fed. Cir. 2001).

The Federal Circuit has offered a two-part test for determining whether the steps of a method claim that do not otherwise recite an order, must nonetheless be performed in the order in which they are written. Altiris, Inc. v. Symantec Corp., 318 F.3d 1369-70 (Fed. Cir. 2003). First, the court is directed to look at the claim language to determine if, as a matter of logic or grammar, they must be performed in the order written. Id. at 1369. If not, the court next looks to the rest of the specification to determine whether it "'directly or implicitly requires such a narrow construction.'" Id. at 1370. If that construction is not applicable, the sequence in which such steps are written is not a requirement. Id. at 1370.

In this case, nothing in the claim or the specification requires such a narrow limiting construction. Looking at the claim language, there is no reason why the formation of the polymer core material and the alteration of the surface of the core material must be consecutive steps; the language of the claim does not exclude the possibility that the two steps occur simultaneously or concurrently. In other words, under the language of the claim, the formation of the core material could conceivably include a process which results in an alteration of the surface of that core material. See Interactive Gift Express, Inc., 256 F.3d at 1343.

The patent specifications do not nullify this possibility. The '461 Patent contains

the same specification cited above, defining "surface treatment processes" which includes "[a]nother set of methods of altering the surface properties of a lens involv[ing] treatment prior to polymerization to form the lens" by, for example, treating the lens mold to cause the prepolymerization mixture immediately adjacent to the mold surface to differ in composition from the core. ('461 Patent col.42 ll.53-68 and col.43 ll.1-13.) J&J does not cite any provision in the patent that requires the "altering the surface" step to be performed *after* the "forming a polymeric core material" step. See Altiris, Inc., 318 F.3d at 1371; see also Bell Communications Research, Inc. v. Fore Systems, Inc., 62 Fed. Appx. 951, 954-56 (Fed. Cir. 2003)(nothing in claim's grammar, precedent, logic, specification or prosecution history dictated that "filling" of "empty payload fields" in patent for telecommunications device could not begin prior to payload fields being completed).

CIBA proposes that the Court adopt the construction set forth by the Northen District of Georgia in the B&L case:

'461 Patent cl.12	**N.D. Ga. (proposed by CIBA)**
Altering the surface of said core material to produce a surface which is more hydrophilic than said core material by a surface treatment process	"This term refers to modifying the material such that the exterior or surface of the modified material is more clinically wettable than the material without modification." (Docs. 86 at 26 87 (CIBA Ex. G at 10).)

While observing reasoned deference to the previous claim construction, the Court concludes that the language at issue here needs no further construction. The

chief dispute between the parties here is whether the claim contemplates a sequencing of steps in the production of an extended wear opthalmalic lens having a hydrophilic surface. That being resolved, the parties do not dispute the remaining terms. The B&L case construction, which consists of re-phrasing the terms of the claim, introduces more questions and ambiguities than the original claim term. Accordingly, the Court declines to construe the language further.[12]

4. "Region of Substantially Uniform Composition"[13]

J&J's Proposed Construction	CIBA's Proposed Construction
region having very near consistency of chemical composition throughout (Doc. 94 at 20)	*None proposed.*

J&J seeks further construction of three phrases found in the patent specification definition and agreed-to construction for the claim term "phase." As to the first term, J&J's proposes that the term "region of substantially uniform composition" should be construed to mean "very near consistency of chemical composition." J&J cites to the Federal Circuit's treatment of the phrase "substantially uniform" in the case Ecolab, Inc. v. Envirochem, Inc., 264 F.3d 1358 (Fed. Cir. 2001), as support for its proposed construction. CIBA contends that it is entitled to be its own lexicographer and entitled

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[12] The Court declines to include the "altering the surface" language in claims that do not expressly recite this limitation.

[13] This phrase is part of the agreed-to construction of "Phase."

to specify its own definition of claim terms. Thus, according to CIBA, it is not proper for the Court to construe the terms of the explicit patent definition of "phase." (Tr. 176.)

The parties have not cited any case which addresses whether, as a matter of law, the Court may construe terms which appear in specifications and definitions found in a patent, in addition to the terms found in the claims.[14] Moreover, the Court is not persuaded that CIBA's definitional use of "substantially uniform composition" for each phase requires further construction. First, a prior construction of the term "substantially" in another case does not dictate a construction here. "A particular term used in one patent need not have the same meaning when used in an entirely separate patent, particularly one involving different technology. . . . A patentee may define a particular term in a particular way, and in that event the term will be defined in that fashion for purposes of that particular patent, no matter what its meaning is in other contexts." Medrad, Inc. v. MRI Devices Corp., 401 F.3d 1313, 1318 (Fed. Cir. 2005). Indeed, "the term 'substantially' is a descriptive term commonly used in patent claims to 'avoid a strict numerical boundary to the specified parameter.'" Ecolab, Inc.,

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[14] The case Abbott Laboratories v. Novopharm Ltd., 323 F.3d 1324, 1330 (Fed. Cir. 2003), cited by J&J as support for construing the terms of a definition, (Tr. 183) does not offer such clear support. In Abbott Laboratories, the Federal Circuit affirmed the District Court's construction of a *claim term*, and in doing so, made reference to the inclusion of a specific term in an explicit definition. 323 F.3d at 1330.

264 F.3d at 1367 (citation omitted).

Second, when a patent specification reveals a special definition of a claim term that differs from meaning it would otherwise possess, the inventor's lexicography governs. Phillips, 415 F.3d at 1316. "However, '[t]he patentee's lexicography must, of course, appear "with reasonable clarity, deliberateness, and precision" before it can affect the claim.'" Abbott Labs. v. Syntron Bioresearch, Inc., 334 F.3d 1343, 1354 (Fed. Cir. 2003); Renishaw PLC v. Marposs Societa' per Azioni, 158 F.3d 1243, 1249 (Fed. Cir. 1998). Here, the parties *agreed* to the patent lexicographer's definition of the term "phase." The accused may not now go back and contend that the agreed-to definition lacks in "reasonable clarity, deliberateness, and precision" and thus should be further construed. Compare Abbott Labs., 334 F.3d at 1355 (where specification provided two alternative definitions for the claim term, specification did not define the term with reasonable clarity, deliberateness and precision).

The Court also notes that J&J attempts to import a further limitation into CIBA's definition of "phase," not apparent on the face of the claim or in any cited specification or prosecution history, to the effect that J&J defines "substantially uniform composition" as referring to the phase's "*chemical* composition throughout." Cf. MBO Labs., Inc. v. Becton, Dickinson & Co., 474 F.3d 1323, 1334 (Fed. Cir. 2007)("[l]imiting claims from the specification is generally not permitted absent a clear disclosure that the patentee intended the claims to be limited as shown").

The Court declines to further construe the phrase: "region of substantially uniform composition."

5. "Distinct and Physically Separate Portion of a Heterogeneous Polymeric Material"

J&J's Proposed Construction	CIBA's Proposed Construction
portion characterized by an identifiable boundary (Doc. 94 at 21)	*None proposed.*

The contested phrase: "distinct and physically separate portion of a hetergeneous polymeric material" is found in the agreed-upon construction of "phase." Arguing that the word "distinct" is different from the term 'physically separate," J&J contends that the phases must be "characterized by an identifiable boundary." J&J cites to the Merriam-Webster's Collegiate Dictionary definition of "distinct" to mean "distinguishable to the eye or mind as discrete." (Doc. 84-87 at 4 (J&J Ex. 82).)

CIBA opposes any additional construction of the term, citing to the '100 Patent specification which describes "distinct phases" in one preferred embodiment as follows:

> While there may be two distinct phases, it is believed that there may be a transition phase, or interphase, in which the material composition and the material properties are a blend of those of the oxyperm and ionoperm materials. Thus, there may exist a distinct oxyperm phase or plurality of distinct oxyperm phases, a distinct ionoperm phase or a plurality of distinct ionoperm phases, and an amphipathic

phase mixture or blend of oxyperm and ionoperm phases.[15]

('100 Patent col.8 ll.29-37.) The specification rejects a lens structure "which includes large phase separated regions" as reducing visible light transmission and causing undesirable image distortion. ('100 Patent col.8 ll.17-21.)

"While dictionaries may be used to ascertain the plain and ordinary meaning of claim terms, the intrinsic record is used to resolve ambiguity in claim language or, where it is clear, trump inconsistent dictionary definitions." W.E. Hall Co. v. Atlanta Corrugating, LLC, 370 F.3d 1343, 1350 (Fed. Cir. 2004). J&J's cited dictionary definition speaks of phases with "boundaries" that are "distinguishable to the eye or mind as discrete." The patent's specification discusses an "interphase" between the two phases which may more gradually move from one phase to another; the very image described by the patent specification does not necessarily require "identifiable boundaries."

Accordingly, the Court declines to further construe the phrase: "distinct and physically separate portion of a hetergeneous polymeric material" as suggested by J&J.

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[15] To this specification, J&J responds that "even if you say boundary is the transition phase, the oxyperm phase and the ionoperm phase still have to be distinct. And they have to be distinct from the transition phase itself." (Tr. at 187.)

6. "Essentially Only Ionoperm Polymer" and "Essentially Only Oxyperm Polymer"

J&J's Proposed Construction	CIBA's Proposed Construction
almost pure ionoperm material with oxyperm material present only as a minor impurity that does not affect the ion, water and oxygen permeability values of pure ionoperm. (Doc. 94 at 20) almost pure oxyperm material with ionoperm material present oxyperm [sic] only as a minor impurity that does not affect the ion, water and oxygen permeability values of pure oxyperm. (Doc. 94 at 20)	*None proposed.*

J&J argues that the "essentially only" language in the definition of "phase" provides no guidance to the factfinder as to what level of ionoperm or oxyperm material impurity can be included in a phase such that the phase retains its permeability level. J&J contends that its proposed construction using the terms "almost pure" and "minor impurity" does provide the necessary guidance. According to J&J, "it doesn't have to be mathematically precise, but there has to be some guidance to the finder of fact on how to decide is this essentially only ionoperm [or oxyperm] or not." (Tr. 172.) J&J acknowledges that the permeability of a phase need not be equal to that of a pure ionoperm or oxyperm polymer, but rather "there would have to be some allowance given" on the permeability level differential from pure. (Tr. 167-72.) J&J contends that the additional language is "taught" by the specifications explaining the purpose of the phases. (Tr. at 170.)

CIBA responds that 1) J&J is not entitled to re-write the definitions which CIBA, as its own lexicographer, included in its patent, and 2) J&J's proposed construction of the definition is contrary to its meaning. CIBA argues that the patent's definition does not imply that a "phase" is "chemically pure," but rather defines the differences in the phases "in terms of bulk properties, not in terms of chemical purity. . . .[16] So long as there's a significant difference in bulk properties [of the phases], the impurities absolutely can affect the ion water or oxygen permeabilities." (Tr. at 180.)

Again, J&J is asking the Court to construe a specification definition term. J&J's proposed definition does nothing to advance the understanding of "essentially only,"[17] which CIBA, acting as its own lexicographer, has set forth with "reasonable clarity, deliberateness, and precision," when coupled with the rest of the definition of "phase," to accomplish the purpose of the patent. See Abbott Labs., 334 F.3d at 1354. The

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[16] The definition of "phase" also provides 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 within the material." ('100 Patent col.5 ll.20-31.)

[17] The Court does not find the cases Glaxo Group Ltd. v. Ranbaxy Pharmaceuticals, Inc., 262 F.3d 1333, 1336-37 (Fed. Cir. 2001) and In re Marosi, 710 F.2d 799, 802-03 (Fed. Cir. 1983), both cited by J&J, as providing guidance. In Glaxo, the Federal Circuit determined that in the context of the patent claims being construed, the term "essentially" found in a dependent claim was narrower in scope than the term "substantially" found in the independent claim. In Marosi, the court determined that process claims for synthesizing zeolite compounds "essentially free" of alkali materials was not indefinite for failing to specify a particular amount of alkali materials.

Court declines to further construe the phrases.

7. "Phases Substantially Separate"

J&J's Proposed Construction	CIBA's Proposed Construction
at least two phases, both physically separate from each other, and each being substantially uniform in composition. (Doc. 90 at 13.)	[N.D. Ga.] "Phases substantially separate" means at least two regions (e.g. an ionoperm region and an oxyperm region), each of substantially uniform composition which differs [from composition which differs][18] from the other. However, each "phase" need not be a chemically pure substance, but merely connotes that certain bulk properties differ significantly from the properties of another phase within the material. Thus, with respect to separate or co-continuous oxyperm or ionoperm phases, the 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. 86 at 20-21.)

The term "phases substantially separate" appears in the '100 Patent claims as follows:

> 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, 50, 51, 53-57.)

Drawing upon the definition of "phase" contained in the patent specification, ('100 Patent col.5 ll. 20-31), and recognizing that the proposals of both parties regarding the meaning of "substantially separate" simply repeat portions of the

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[18] Typographical error in N.D. Ga. Court Order. (See Doc. 86 at 21.)

definition of "phase," the Court construes "phases substantially separate" as follows:

"Phases Substantially Separate"

"Phases substantially separate" means at least two "phases" as "phase" is previously defined.

8. "Pathways" and "Continuous Pathways"

J&J's Proposed Construction	CIBA's Proposed Construction
a pathway has the same meaning as phase. (Doc. 94 at 22) a phase which forms a continuous structure from one surface of an article to another surface of an article. (Doc. 94 at 22)	[N.D. Ga.] a polymer region that extends from one surface of the lens to the opposite surface of the lens, with a continuous pathway for water transmission manifesting itself in a high water or ion permeability and a continuous pathway for oxygen manifesting itself in a high oxygen permeability, as defined above. (Doc. 86 at 21.)

The terms "pathways" and "continuous pathways" are found in a number of patent claims. The claim terms are used as follows:

> wherein said lens allows ion or water permeation via ion or water *pathways* in an amount sufficient to enable the lens to move on the eye . . .

('100 Patent cls. 1, 44, 49-57, 59, 60 (emphasis added));

> 11. An ophthalmic lens of claim 1, wherein said polymeric material comprises a plurality of *co-continuous pathways*, at least one being an ion or water *pathway* and at least one other being an oxygen *pathway*, which *pathways* extend continuously from the inner surface of the lens to the outer surface of the lens.

('100 Patent cl. 11)(emphasis added);

> 12. An ophthalmic lens of claim 11, wherein said co-

> *continuous pathways* include a continuous *phase* of ionoperm polymeric material and a continuous *phase* of siloxane-containing polymeric material.

('100 Patent cl. 12)(emphasis added);

> 1. A method of forming a biocompatible lens having high oxygen permeability and high water permeability, said method comprising the steps of:
>
> (a) forming a polymeric core material including:
>
> (1) at least one *continuous pathway* from front curve to base curve surfaces for oxygen transmission therethrough, and
>
> (2) at least one *continuous pathway* from front curve to base curve surfaces for water transmission therethrough . . . .

('461 Patent cl. 1; see also id. cls. 9-14.)

While the specifications do not define the term "pathways," they do use the term concurrently with "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. . . . 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).)

J&J relies upon the testimony of CIBA inventor Dr. Nicolson before the USPTO on re-examination, at the temporary injunction hearing before this Court, and in deposition in which he agrees that "pathways" refer to "phases" (Docs. 50 at 111; 84-58 (J&J Ex. 53 at 73 (filed under seal)("pathways are the phases"), 90-15 at 5, 8 (J&J Ex. 113 at 67, 73); see also Doc. 90-16 at 3 (J&J Ex. (J&J Ex. 114 at 134 (co-inventor Dr. Judith Riffle: no difference between pathway and phase in this case)), as well as the patent examiner's interpretation of "pathways." (Docs. 84-29 (J&J Ex. 24 at 3 ("the pathways or continuous phases being essential"); 90-8 at 3 (J&J Ex. 106 at 2 (referring to "continuous fluid and oxygen conducting pathways, each pathway corresponding to a resin phase within the lenses").)

CIBA argues the "pathways" does not equate to "phase" and that because the patents do not ascribe any specialized meaning to the words "pathways" or "continuous pathways," they are to be accorded their ordinary meaning. (Docs. 86 at 21; 91 at 29.)

Unlike the term "phase," the patent specifications do not explicitly define the claim terms "pathways" or "continuous pathways." The context in which the term "pathways" is used is more consistent with the term's ordinary meaning and is consistent with the ordinary meaning of "pathways," as being a throughfare or "course." See Webster's Third New International Dictionary 1654-55 (1971)(defining

"pathway" as a "course" or "a way that is or serves as a path" and "path" as "a way or course traversed by something").[19] Thus, "pathways" refers to and defines the function of "phases" as opposed to the chemical composition, which is addressed by the explicit definition of "phase." While it is true that the inventor in testimony in response to questions testified that "pathways" refers to "phases," the language of the claims and specifications do not support a finding that the terms are indeed interchangeable, as urged by J&J.[20] "[T]he ordinary meaning of some claim terms 'may be readily apparent even to lay judges, and claim construction in such cases involves little more than the application of widely accepted meaning of commonly understood words.'" Agfa Corp. v. Creo Prod., Inc., 451 F.3d 1366, 1376 (Fed. Cir. 2006)(citing Phillips, 415 F.3d at 1314). "The words of a claim are generally given the ordinary meaning that they would have to a person of ordinary skill in the field of the

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[19] The Court may "refer to the dictionary to begin understanding the ordinary meaning of . . . claim terms, 'so long as the dictionary definition does not contradict any definition found in or ascertained by a reading of the patent documents.'" Cross Medical Products, Inc. v. Medtronic Sofamor Danek, Inc., 424 F.3d 1293, 1305 (Fed. Cir. 2005)(quoting Phillips, 415 F.3d at 1322-23).

[20] Counsel for J&J at the *Markman* hearing, revealed the the significance of this construction issue when he argued that "[i]f it just says pathway, CIBA will not have to prove a phase is there. If it says phases, they will. And they'll have to meet their definition. . . . [Otherwise] [t]hey can say, Well, something moves from one side to the other. There must be a pathway somehow. But that doesn't mean there's a phase." (Tr. at 192.) The Court, of course, cannot look forward to issues of liability when construing the terms of the claims. Rather, it looks to the claims themselves, specifications, and intrinsic and extrinsic evidence.

invention, (citation omitted) and are read in view of the specification, of which they are a part." Gillespie v. Dywidag Sys. Int'l, No. 501 F.3d 1285, 1291 (Fed. Cir. 2007)(citing Phillips, 415 F.3d at 1312, 1315). J&J has not established that the customary meaning within this field of art in anyway alters the ordinary meaning of the word "pathways" found in the patent claims.

The Court declines to adopt completely the construction made by the Northern District of Georgia to the extent it is uses the phrase "continuous pathway" to define that very phrase. Rather, borrowing from the prior court construction, and relying upon the patent's specification use of the term, the Court construes "pathways" and "continuous pathways" to mean:

"Pathways" and "Continuous Pathways"

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.

9. "Ophthalmically Compatible"

J&J's Proposed Construction	CIBA's Proposed Construction
a material or surface of a material which may be in intimate contact with the ocular environment for an extended period of time without significantly damaging the ocular environment and without significant user discomfort. Thus, an ophthalmically compatible contact lens will not produce significant corneal swelling, will adequately move on the eye with blinking to promote adequate tear exchange, will not have substantial amounts of lipid adsorption, and will not cause substantial wearer discomfort during the prescribed period of wear (Doc. 94 at 24.)	[N.D. Ga.] This term refers to contact lenses which may be in intimate contact with the eye for a prescribed period of extended wear without significantly damaging the eye and without significant user discomfort, which means that the lenses do not produce significant corneal swelling, will adequately move on the eye with blinking to promote adequate tear exchange, will not have substantial amounts of lipid adsorption, and will not cause substantial wearer discomfort. For a lens to be "ophthalmically compatible," it must meet these criteria in a significant number of patients when worn over a substantial period of time." (Doc. 86 at 9.)

The patent specification specifically defines "opthalmically compatible" as follows:

> "Ophthalmically compatible", as used herein, refers to a material or surface of a material which may be in intimate contact with the ocular environment for an extended period of time without significantly damaging the ocular environment and without significant user discomfort. Thus, an ophthalmically compatible contact lens will not produce significant corneal swelling, will adequately move on the eye with blinking to promote adequate tear exchange, will not have substantial amounts of lipid adsorption, and will not cause substantial wearer discomfort during the prescribed period of wear.

('100 Patent col.5, ll.46-56.)

CIBA urges the inclusion of language requiring contact lenses to "meet these [specified] criteria in a significant number of patients when worn over a substantial

period of time," reflective of "research and development" clinical study language, to preclude a competing lens from qualifying as "ophthalmically compatible" by establishing that a so-called "commando" wearer can endure even the most incompatible lens. (Tr. 198-201.) Relying upon extrinsic expert testimony, CIBA contends that clinical studies are routinely used in the contact lens industry and that the studies provide the measure of success for a proposed lens. (See Doc. 87 (CIBA Exs. I at 23-24; L at 23-24 (filed under seal).)

J&J responds that Title 35 does not require that a patented invention be commercially viable absent a claim limitation to that effect. See CMFT, Inc. v. Yieldup Int'l Corp., 349 F.3d 1333, 1338 (Fed. Cir. 2003)(enablement "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"). Further, according to J&J, CIBA relied on a comparison of one of its lenses with one of the Bausch & Lomb lenses in its presentation to the USPTO examiner to establish that prior art was not ophthalmically compatible. J&J contends that the claims refer to a single lens being "ophthalmically compatible" and that the claims do not require that the lens work on a "significant number of patients." (Tr. at 208.)

CIBA's proposed language concerning "significant number of patients" and "substantial period of time" does nothing to further delineate "ophthalmic compatibility" and introduces additional uncertainties to the definition. (Indeed, counsel for CIBA

cited to a "landmark study" listed in the '100 Patent with ten subjects, which he termed "a significant number of patients" (Tr. at 201); the prosecution history cites studies with 32 contact wearers (Doc. 87 (CIBA Ex. K at 37)); and CIBA's expert discusses clinical studies upon 342 subjects and 39 subjects (Doc. 87 (CIBA Ex. L at 23-24 (filed under seal).) The Court rejects CIBA's proposed additional limitation, and construes the term "opthalmically compatible" as set forth by the patent specification:

"Ophthalmically compatible"

> "Ophthalmically compatible", as used herein, refers to a material or surface of a material which may be in intimate contact with the ocular environment for an extended period of time without significantly damaging the ocular environment and without significant user discomfort. Thus, an ophthalmically compatible contact lens will not produce significant corneal swelling, will adequately move on the eye with blinking to promote adequate tear exchange, will not have substantial amounts of lipid adsorption, and will not cause substantial wearer discomfort during the prescribed period of wear.[21]

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[21] J&J, at one point, requested without any explanation, citation or argument, that the claim term "ophthalmic lens" be construed as having the same meaning as "ophthalmically compatible," (Doc. 90-3 at 3 (J&J Ex.101 at 2 ("JJVC'S Requested Markman Rulings")), which was opposed by CIBA which cites the patent's express definition of "ophthalmic lens." (Doc. 86 at 38 (CIBA App. A)(citing '100 Patent col.4 ll.31-39).). J&J appears to have abandoned this position as to the proposed construction of "ophthalmic lens" inasmuch as it is not included in J&J's "Updated Table of Disputed Terms and Constructions." (Doc. 90-4 (J&J Ex. 104).) The Court does not construe the claim term "ophthalmic lens," and refers the parties to the patent's express definition of the term. (See '100 Patent col.4 ll. 31-40.)

10. "Extended Wear"

J&J's Proposed Construction	CIBA's Proposed Construction
Indefinite. (Doc. 90-4 (J&J Ex. 102 at 13).)	The term refers to a method of continuous wear of a contact lens for a period of at least 24 hours, or for such longer period as specified in a particular claim. (Doc. 86 at 39 (App. A); Doc. 91-2 at 10 (Response App. 1).)

This case is about "extended wear" ophthalmic lenses. The term "extended wear" appears in the title of all six patents which are the subject of this action, and throughout the claims and specifications. J&J contends that this term is "indefinite" and thus invalid. J&J offers no argument or support for this position.

In support of its proposed construction of "extended wear," CIBA cites to the "Objects and Summary of the Invention" which says:

> Another object of the invention is to provide an ophthalmic lens capable of extended continuous wear periods of at least 24 hours without substantial adverse impact on ocular health or consumer comfort, and more preferably, to provide a lens capable of continuous wear 4 to 30 days or more without substantial adverse impact on ocular health or consumer comfort.

('100 Patent col.2, ll.44-51.) In this case, both the '100 Patent specifications and prosecution history clearly indicate that the invention is focused on providing extended wear contact lenses for a period from 24 hours to up to thirty days. While the summary is not wholly dispositive, there is nothing in the '100 patent specifications that precludes designation of a time frame for "extended wear," and the prosecution

history provides additional support for this conclusion." See MBO Labs., Inc., 474 F.3d at 1329-30. Further, "the fact that a patent asserts that an invention achieves several objectives does not require that each of the claims be construed as limited to structures that are capable of achieving all of the objectives.'" Phillips, 415 F.3d at 1327 (citation omitted). CIBA's proposed construction of "extended wear" captures the patent's objective without limiting the claims, by acknowledging that a particular claim may specify the length of wear for the lens described. "Where that term appears in a claim preamble, it is 'necessary to give life, meaning, and vitality to the claim,' and may be used as a limitation." MBO Laboratories, Inc., 474 F.3d at 1330 (citation omitted). The Court construes the term "extended wear" as follows:

"Extended Wear"

The term refers to a method of continuous wear of a contact lens for a period of at least 24 hours, or for such longer period as specified in a particular claim, without substantial adverse impact on ocular health or consumer comfort.

11. "Adequate Tear Exchange"

J&J's Proposed Construction	CIBA's Proposed Construction
Indefinite as a Matter of Law. (Docs. 90-3 at 4 (J&J Ex. 101); 90-4 (J&J Ex. 102 at 11).)	[N.D.Ga.] The term "adequate tear exchange" means tear flow between the lens and eye for removing debris, such as foreign particulates or dead epithelial cells, from the tear fluid sufficient to render the lens ophthalmically compatible for a prescribed extended wear period. (Doc. 86 at 12)

A number of independent claims found in the subject patents contain the phrase "adequate tear exchange." (See '100 Patent cls. 1 (set forth above), 44, 49–57, 59, 60; '999 Patent cls. 1, 27-34; '461 Patent cls. 1, 9-14; '811 Patent cls. 1, 24-26, 28; '894 Patent cls. 88, 89.) Typically it appears in conjunction with the term "adequate movement on the eye" as follows: "while having adequate movement on the eye with blinking to promote adequate tear exchange . . . ." The phrase is also found in the specification defining "ophthalmically compatible." ('100 Patent col.5 l.53.) In setting forth the "Background of the Invention," the '100 Patent discusses the "ophthalmical compatibility requirements" for soft contact lenses, as including

> "[T]he consumer must be able to easily remove the lens from the eye for disinfecting, cleaning, or disposal. However, the lens must also be able to move on the eye in order to encourage tear flow between the lens and the eye. Tear flow between the lens and eye allows for debris, such as foreign particulates or dead epithelial cells, to be swept from beneath the lens and, ultimately out the tear fluid. Thus, a contact lens must not adhere to the eye so strongly that adequate movement of the lens on the eye is inhibited.

('100 Patent col.1 ll.44-52.) And on re-examination before the USPTO, CIBA optometrist and head of Global Clinical Affairs Scott R. Robirds declared that

> 12. Adequate on-eye movement of a contact lens is also critical to ophthalmic compatibility. A lens that is immobile will trap normal physiological debris that is generated by the cornea and lead to tear stagnation. Adequate movement allows for adequate tear exchange, which re-supplies the tear cushion between the posterior surface of the contact lens and the cornea.

(Doc. 87 (CIBA Ex. J at ¶ 12.) Indeed, J&J describes its own contact lens product, the ACUVUE®OASYS™ as having "Adequate movement for tear exchange (0.2-0.4mm)." (Doc. 92 (CIBA Ex. CC)(emphasis added).)

While the claim construction of the Northern District of Georgia does not have preclusive effect here, to the extent that patent owner CIBA embraces the B&L case construction, and J&J, while raising an "indefiniteness" defense, cites to no intrinsic and extrinsic evidence to the contrary, the Court will defer to (though slightly edit based upon the patent's specification) the previous construction of the claim term "adequate tear exchange."

"Adequate Tear Exchange"

The term "adequate tear exchange" means tear flow between the lens and eye for removing debris, such as foreign particulates or dead epithelial cells, to be swept from beneath the lens and, ultimately from the tear fluid, sufficient to render the lens ophthalmically compatible for a prescribed period of extended wear.

12. "Substantial Amounts Of Lipid Adsorption"

J&J's Proposed Construction	CIBA's Proposed Construction
amount of lipids on the surface of a lens greater than the amount of lipids found on the surface of a Focus Night & Day lens. (Doc. 94 at 26.)	[N.D.Ga.] [L]ipid deposits in an amount that cause substantial interference with vision or cause substantial wearer discomfort so as to make the lens unsuitable for wear as a contact lens for a prescribed period of extended wear. (Doc. 86 at 12.)

As described by J&J, "[t]his claim limitation refers to the tendency of lipids, or

fat molecules, in the eye to become attached to the lens surface. The limitation requires that there be no 'substantial amounts' of these lipids." (Doc. 94 at 26.)

The term "substantial amounts of lipid adsorption" appears in numerous independent claims in CIBA's patents, including Claim 1 of the '100 Patent set forth above. (See '100 Patent cls. 1, 44, 49-57, 59, 60; '999 Patent cls. 1, 17, 27-34; '461 Patent cls. 1, 9-14; '811 Patent cls. 1, 24-27; '894 Patent cls. 29, 34, 41, 49, 50, 54, 85, 86, 88, 89). The term is found as part of the description of the ophthalmic lens invention and methodology, and also appears in the specification definition of "opthalmically compatible." ('100 Patent col.5 ll.46-56.) The patent examiner, in approving the '100 Patent on reexamination, required amendments to the patent claims to reflect the fact that the claimed ophthalmic lens possesses the property of ophthalmic compatibility that encompasses four criteria: that the lens (a) will not produce significant corneal swelling, (b) will adequately move on the eye with blinking to promote adequate tear exchange, (c) will not have *substantial amounts of lipid adsorption*, and (d) will not cause substantial wearer discomfort over a prescribed period of wear." (Doc.84-6 at 4, 20 (J&J Ex. 4 at 3, 19)(emphasis added).)

In describing the background of the extended wear ophthalmic lens invention, CIBA addressed lipid adsorption in its review of prior art contact lenses, distinguishing prior art lenses with siloxane-containing polymers with high oxygen permeability from its own extended wear lenses: "[P]olysiloxanes are typically highly lipophilic. . . . In

addition, polysiloxane lipidity promotes adhesion to the lens of lipids and proteins in the tear fluid, causing a haze which interferes with vision through the lens." ('100 Patent col.2 ll.9-22.)

J&J contends that the claims and specifications offer no guidance on what amount of lipid adsorption would be "substantial" and states that in 1994-95, when CIBA first submitted the '100 Patent application to the USPTO, there was no standard definition in the art. (Doc. 94 at 26 (citing expert report and 1994 and 1995 articles).) J&J cites to the prosecution history on reexamination, including a 2000 USPTO examiner's interview summary recounting that CIBA alleged and demonstrated "that Lai's [Bausch & Lomb] lens showed relatively greater lipid adsorption than applicants' Focus Day & Night lens." (Doc. 84-36 at 2-3 (J&J Ex. 31).) J&J discounts the Georgia Court's construction of the term, advanced by CIBA here, as being based upon a dictionary definition that was not opposed in that prior litigation by Bausch & Lomb. J&J also contends that CIBA's proposed construction contains equally imprecise terms raising even more uncertainty and is entirely dependent on individual wearer sensibilities. (Docs. 94 at 27-28 (citing CIBA expert statements that wearer comfort is subjective to the wearer); 90 at 20.) See Datamize, LLC v. Plumtree Software, Inc., 417 F.3d 1342, 1350 (Fed. Cir. 2005)(rejecting proposed construction for term "aesthetically pleasing" because Datamize offered no objective definition identifying a standard; "the scope of claim language cannot depend solely on the

unrestrained, subjective opinion of a particular individual purportedly practicing the invention; "[s]ome objective standard must be provided in order to allow the public to determine the scope of the claimed invention").

CIBA objects to J&J's request to limit the term to a commercial embodiment of the CIBA patents, the CIBA Focus® NIGHT & DAY™ lens, based on prosecution history, which it contends is contrary to the Federal Circuit's rule against limiting a patent claim to a specific embodiment. (Doc. 91 at 15-16 (citing Phillips, 415 F.3d at 1322 ("although the specification often describes very specific embodiments of the invention, we have repeatedly warned against confining the claims to those embodiments").) CIBA argues that it never specifically disclaimed or disavowed a level of lipid adsorption which might be greater than that adsorbed by its Focus® NIGHT & DAY™ lens. Rather, CIBA contends the '100 Patent's prosecution history on re-examination supports the more general construction adopted by the Georgia Court. In a July 2000 declaration to the USPTO on re-examination which resulted in the claim amendment to include "substantial amounts of lipid adsorption," CIBA optometrist Scott F. Robirds stated that in order to maintain the health of ocular tissues, "the surfaces of the contact lens must avoid hydrophobic deposits, such as lipids, that disrupt the pre-lens tear layer."

> 8. Maintaining a low level of surface deposition is critical to the determination of ophthalmic compatibility. This is particularly problematic with lipid deposits. As the level of lipid absorption increases within and on the surface of a

> contact lens, the normally smooth nature of the *pre-lens tear layer is disrupted*. As a result, light is scattered upon entering the lense and is less effectively focused onto the retina. This *tear layer disruption due to lipid deposition is noticed by the wearer as a loss of visual clarity*, often times to a significant degree.
>
> 9. When lipid adsorption is at an unacceptable level, the eye care practitioner can observe, through the biomicroscope, a *"beaded" tear layer on the surface of the lens*. The beading of the aqueous tear is caused by the hydrophobic nature of substantial lipid absorption on the lens surface.
>
> 10. The precise amount of lipid deposition necessary to cause the tear layer to be disrupted has not been definitively quantified. However, it is apparent to a skilled optometrist that *when tears are seen to bead up, rather than sheen smoothly off the front surface of the contact lens, there is a substantial amount of lipid adsorption on the lens rendering the lens unsuitable for a contact lens. . . .*

Doc. 87 (CIBA Ex. J at ¶¶ 7-10 (emphasis added).)

Further, CIBA refutes J&J's reliance on CIBA expert testimony concerning subjective wearer comfort levels, noting that the expert testimony reveals that a clinician in the field would be able to determine whether a lens "substantially interferes with vision" by evaluating the surface of a lens with a slit lamp biomicroscope to deterime whether there were deposits on the surface; measuring the patient's visual acuity; and then asking the patient whether he is having difficulty with vision for specific tasks. (Doc. 92 (CIBA Ex. HH at 155-56).)

"'When a word of degree is used the district court must determine whether the

patent's specification provides some standard for measuring that degree.'" Datamize, LLC, 417 F.3d at 1351 (citing Seattle Box Co., Inc. v. Industrial Crating & Packing, Inc., 731 F.2d 818, 826 (Fed. Cir. 1984)). When faced with a purely subjective phrase, "a court must determine whether the patent's specification supplies some standard for measuring the scope of the phrase." Datamize, LLC, 417 F.3d at 1351. Further, "'[w]hen the claim language itself lacks sufficient clarity to ascertain the scope of the claims,' we look to the written description for guidance." Chimie v. PPG Industries, Inc., 402 F.3d 1371, 1377 (Fed. Cir. 2005)(citation omitted). "The term 'substantial' is a meaningful modifier implying 'approximate,' rather than 'perfect.'" Liquid Dynamics Corp. v. Vaughan Co., 355 F.3d 1361, 1368 (Fed. Cir. 2004). In Cordis Corp. v. Medtronic AVE, Inc., 339 F.3d 1352, 1361 (Fed. Cir. 2003), the Federal Circuit declined to impose a precise numeric constraint on the term "substantially uniform thickness," noting that the proper interpretation of this term was "'of largely or approximately uniform thickness, unless something in the prosecution history imposed a 'clear and unmistakable disclaimer.'" Playtex Products, Inc. v. Procter & Gamble Co., 400 F.3d 901, 907 (Fed. Cir. 2005)(discussing Cordis Corp., 339 F.3d at 1361).

In its presentation to the USPTO examiner, CIBA compared its Focus® NIGHT & DAY™ lens with the prior art Lai '461 Patent and established that the Lai lens had more lipid adsorption than the CIBA lens, thus distinguishing the two. Based upon

this demonstration, the USPTO examiner concluded that "the inventive lens' capacity for not having substantial amounts of lipid adsorption as compared to the lens made from Lai's material" supports CIBA's contention that its invention as "exemplified" by the Focus® NIGHT & DAY™ lens is distinct from the Lai prior art. (Doc. 92 (CIBA Ex. FF at 19-20).) The Court finds that CIBA did not "clearly and unmistakeably" disclaim any embodiment of its patents with a higher level of lipid adsorption than the Focus® NIGHT & DAY™ lens. For this reason, J&J's proposed claim construction must be rejected.

The Court does agree, however, that the construction proferred by CIBA does contain some uncertainties which, if further modified by terms found in the prosecution history, would provide direction to the finder of fact. The patent's description of prior art refers to "adhesion to the lens of lipids and proteins in the tear fluid, causing a haze which interferes with vision through the lens." ('100 Patent col.2 ll.9-22.) Moreover, upon reexamination, CIBA disclosed that a "substantial amount of lipid adsorption" rendering the lens unsuitable occurs when, as is apparent to a skilled optometrist, "tears are seen to bead up, rather than sheen smoothly off the front surface of the contact lens" and the pre-lens tear level is disrupted such that the wearer notices a loss of visual clarity. (Doc. 87 (CIBA Ex. J at ¶¶ 8-10.) Accordingly, the Court construes the term "substantial amounts of lipid adsorption" as follows:

"Substantial Amounts of Lipid Adsorption"

Lipid deposits in an amount that the skilled optometrist can observe a "beaded" tear layer on the surface of the contact lens, rather than tears sheening smoothly off the front surface of the contact lens, and that cause tear layer disruption that is noticed by the wearer as a loss of visual clarity, substantially interfering with vision or causing substantial wearer discomfort, so as to make the lens unsuitable for wear as a contact lens for a prescribed period of extended wear.

13. "Adequate Movement On The Eye With Blinking"

J&J's Proposed Construction	CIBA's Proposed Construction
at least 0.5 mm of vertical lens movement during the routine blink. (Doc. 94 at 28.)	[N.D. Ga.] The term "adequate movement" means movement of the contact lens on the eye sufficient, upon blinking, to permit tear exchange between the lens and eye so as to permit the lens to be safely and effectively worn for (and removed after) the prescribed extended wear period. (Doc. 86 at 11.)

The term "adequate movement on the eye with blinking" is found in multiple independent claims, including Claim 1 set forth above. (See '100 Patent, cls. 1, 44, 49-57, 59, 60; '999 Patent cls. 1, 17, 27-34; '461 Patent cls. 1, 9-14; '811 Patent cls. 1, 24-26, 28; '894 Patent cls. 49, 50, 54, 89.) It is also found in the patent specification defining "ophthalmically compatible." ('100 Patent col.5 ll.51-56.) Significantly, the phrase was an amendment upon reexamination as one of four criteria for ophthalmic compatibility and reads, in its entirety: "will adequately move on

the eye with blinking to promote adequate tear exchange."[22]

Claim 1 of the '100 Patent further describes "adequate movement" as follows:

> wherein said lens allows ion or water permeation via ion or water pathways in an amount sufficient to enable the lens to move on the eye such that corneal health is not substantially harmed and wearer comfort is acceptable during the period of extended, continuous contact with ocular tissue and ocular fluids.

('100 Patent cl. 1.) The patent specifies that "the lens must also be able to move on the eye in order to encourage tear flow between the lens and the eye [allowing for] . . . debris, such as foreign particulates or dead epithelial cells, to be swept from beneath the lens and, ultimately, out of the tear fluid." ('100 Patent, col. 1, ll. 44-51.) See (Doc. 87 (CIBA Ex. J. ¶ 12.) CIBA's Practitioner's Fitting Guide "directs the clinician to look for adequate lens movement during the normal blink of 0.1 - 0.5 mm. Movement less than 0.1 may lead to the problems associated with binding, and movement greater than 0.5 mm may lead to discomfort." (Doc. 87 (CIBA Ex. J at ¶ 13)(citations omitted); see also Doc. 84-38 at 46 (J&J Ex. 33 at 39 (CIBA 2000 response to USPTO on re-examination discloses Practitioner's Guide which "directs the clinician to look for adequate lens movement during the normal blink of 0.1 - 0.5 mm.").) Based on these representations, the USPTO examiner required patent claim amendments to include the criteria for ophthalmic compatibility, including "adequate

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[22] The Court has already construed "adequate tear exchange."

movement on the eye with blinking."

Arguing that the patent does not offer a definition of the term, J&J takes issue with the Georgia district court's construction as being based not on any patent claim or specification, but rather on an unopposed definition proposed by CIBA in that litigation. (Tr. at 214.) J&J contends that the "established ordinary meaning to those skilled in the art in 1995, when the patent application was filed" of movement of extended-wear hydrogel contact lenses is 0.5 to 1 mm, as set forth in textbooks dating to 1995, and according to expert testimony. (Doc. 94 at 28; see also Tr. at 216; Docs. 84-54 at 4 (J&J Ex. 49 at 54); 84-73 at 3 (J&J Ex. 68 at 261); 84-77 at 32 (J&J Ex. 72 at 412); 84-61 (J&J Ex. 56 at 788185)(filed under seal); 84-82 at 5 (J&J Ex. 77 at W119906); 84-83 at 2 (J&J Ex. 78 at 513); 84-84 at 3 (J&J Ex. 79 at W115991).)[23]

CIBA contends that the intrinsic evidence in the patent itself defines "adequate movement" functionally and in non-numeric terms, in connection with the discussion

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[23] J&J's citation to Intellectual Prop. Dev., Inc. v. UA-Columbia Cablevision, 336 F.3d 1308 (Fed. Cir. 2003) as support for the proposition that it can substitute a numeric definition of "adequate movement" based upon the "ordinary meaning" of that term for hydrogel lens is called into question. In Intellectual Prop. Dev., the Federal Circuit invoked the "ordinary meaning" of the term "high frequency" as that frequency set forth in a dictionary definition because the construing court "could properly look to dictionary definitions for 'ordinary meaning' before consulting written description or prosecution history to determine the meaning of a patent claim term." The Federal Circuit has since receded from and clarified its position, confirming that intrinsic evidence in the form of patent descriptions, specifications and prosecution history take precedence when construing claim terms. See Phillips, 415 F.3d at 1317-18.

of "adequate tear exchange." (Tr. 212-13.) CIBA argues that J&J's proposed numeric limitation of the term is based on extrinsic evidence and that it relates to movement not of silicone hydrogel lenses such as CIBA's Focus® NIGHT & DAY™ lens, but to prior art conventional hydrogel lenses that were not as efficient in allowing oxygen through the lens to the corneal surface, and thus required more movement with blinking to oxygenate the eye. (Doc. 91 at 15 n. 11; Tr. 213.) J&J acknowledges that because there were no silicone hydrogel lenses on the market in 1995, the date of CIBA's patent application, the "ordinary meaning" of "adequate movement" would not have encompassed "adequate movement" of a silicone hydrogel lens such as CIBA's patent, but says that because the literature at the time defined "adequate movement" as .5 to 1 millimeter, CIBA's patent should be so construed. (Tr. at 216-17.)[24]

"'When a claim term is expressed in general descriptive words, [the court] will not ordinarily limit the term to a numerical range that may appear in the written description or in other claims.'" Conoco, Inc., 460 F.3d at 1358 (citation omitted). "It is usually incorrect to read numerical precision into a claim from which it is absent,

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[24] J&J argues that CIBA cannot rely upon representations made during prosecution upon re-examination five years hence, citing Biogen, Inc. v. Berlex Labs., Inc., 318 F.3d 1132, 1140 (Fed. Cir. 2003). In Biogen, the court held that "[r]epresentations during prosecution cannot enlarge the content of the *specification*" and that the district court was correct in relying upon the specification in analyzing the claims. Biogen, Inc., 318 F.3d at 1140 (emphasis added). Here, the patent specification does not specifically define the claim term "adequate movement on the eye with blinking" except by referring to it functionally.

particularly when other claims contain the numerical limitation." Modine Mfg. Co. v. U.S. Int'l Trade Comm'n, 75 F.3d 1545, 1551 (Fed. Cir. 1996), abrogated on other grounds sub nom. by, Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd., 234 F.3d 558 (Fed. Cir. 2000)(en banc); cf. W.L. Gore & Assocs., Inc. v. Garlock, Inc., 842 F.2d 1275, 1280 (Fed. Cir. 1988)(a term such as "about" is not subject to precise construction but is dependent on the factual situation presented); Seattle Box Co., Inc. v. Indus. Crating & Packing, Inc., 731 F.2d 818, 829 (Fed. Cir. 1984)(imprecise phrase such as "substantially equal to" has a fact-dependent meaning). Here, J&J draws its numbers not from a specification or even an embodiment that appears in the patent, but rather from extrinsic evidence of textbooks in 1995 that discuss different technology and expert testimony, while attempting to discount prosecution history. The Court rejects J&J's proffered construction.

The most important indicator of the meaning of "adequate movement" is its usage and context within the claim itself. Middleton, Inc. v. Minn. Mining and Mfg. Co., 311 F.3d 1384, 1387 (Fed. Cir. 2002). Further, the prosecution history of the CIBA patents does not clearly and unambiguously disclaim "adequate movement" of less than 0.5 mm; quite the contrary, it embraces movement between 0.1 and 0.5 mm., prompting the USPTO examiner to require inclusion of various criteria for ophthalmic compatibility, including "adequate movement on the eye with blinking." While this prosecution history might suggest a numeric construction of the claim term,

the Court is counseled by the dictates of the Federal Circuit and refrains from limiting the claim term that is expressed in general descriptive words. Therefore, the Court adopts the Georgia Court's definition.

"Adequate Movement On The Eye With Blinking"

Movement of the contact lens on the eye sufficient, upon blinking, to permit tear exchange between the lens and eye so as to permit the lens to be safely and effectively worn for (and removed after) the prescribed extended wear period.

14. "Significant Corneal Swelling"

J&J's Proposed Construction	CIBA's Proposed Construction
corneal swelling greater than 8% (Doc. 94 at 30.)	[N.D.Ga.] The term significant corneal swelling means swelling of the cornea to such a degree as to cause significant harm to the cornea or significant wearer discomfort during a prescribed extended wear period. (Doc. 86 at 14.)

This term appears in numerous independent patent claims, including the '100 Patent claim 1 appearing above. Avoidance of "significant corneal swelling" is a criterion for the ophthalmically compatible extended wear hydrogel contact lens ('100 Patent cls. 1, 26, 44, 49-57, 59, 60); '999 Patent cls. 1, 17, 27-34; '461 Patent cls. 1, 9-14; '811 Patent cls. 1, 24-27; '894 cls. 49, 50, 54, 88, 89.)[25] An "ophthalmically compatible" lens is one "in intimate contact with the ocular environment for an

[25] The term "substantial corneal swelling" appears in '894 Patent claims. ('894 cls. 29, 34, 65, 70, 85, 86.)

extended period of time without significantly damaging the ocular environment and without significant user discomfort. Thus, an ophthalmically compatible contact lens will not produce significant corneal swelling . . . ." ('100 Patent col.5 ll.47-52.)

> One ophthalmic compatibility requirement for contact lenses is that the lens must allow oxygen to reach the cornea in an amount sufficient for long-term corneal health. . . If sufficient oxygen does not reach the cornea, corneal swelling occurs. Extended periods of oxygen deprivation causes the undesirable growth of blood vessels in the cornea.

('100 Patent col.1; ll.29-42.)

Thus, the '100 Patent specifies that

> a preferred extended-wear contact lens will produce, after wear of about 24 hours, including normal sleep periods, corneal swelling of less than about 8%, more preferably less than about 6%, and most preferably less than about 4%. A preferred extended-wear contact lens will produce, after wear of about 7 days, including normal sleep periods, corneal swelling of less than about 10%, more preferably less than about 7%, and most preferably less than about 5%.

('100 Patent col.6 ll.59-76.)

Claim 3 of '811 Patent is dependent on claim 1, specifying an ophthalmic lens that "produces, after wear of about 24 hours, including normal sleep periods, less than about 8% corneal swelling." '811 Patent cl.3. Dependent Claim 4 provides for: "less than 6% corneal swelling"; Claim 5: "less than 4% corneal swelling" after 24 hours of wear. Dependent claims 6 through 10, relating to ophthalmic lenses worn four or seven days, require corneal swelling "less than" about 5%, 7%, or 10%. ('811 Patent,

cls 6-10; see also '999 Patent cls. 11-16)(claiming lenses worn between 24 hours and seven days with corneal swelling of less than about 4% to 10%).) Likewise, independent Claim 1 of the '894 Patent describes a method for producing an extended wear contact lens worn for a continuous period of at least 24 hours "with corneal swelling of less than about 8%." ('894 Patent, cl. 1.; see also cls. 8,13, 23, 37, 61, 68, 73, 83 ("less than about 8% corneal swelling"), 14, 38, 74 ("less than about 4% corneal swelling"), 24, 84 ("less than about 6% corneal swelling"), 32 ("less than about 7% corneal swelling").)

Contending that the term "significant corneal swelling" is invalid as indefinite, J&J nevertheless offers a proposed construction of the term that "by an objective standard, and its ordinary meaning would require corneal swelling greater than 8%." (Doc. 94 at 30.) J&J seeks to limit all claims expressing the term to corneal swelling greater than 8%, a preferred embodiment.

As set forth above, "'[W]hen a claim term is expressed in general descriptive words, [the court] will not ordinarily limit the term to a numerical range that may appear in the written description or in other claims.'" Conoco, Inc., 460 F.3d at 1358 (citation omitted). "A patent applicant is free to recite features of [an invention] either structurally or functionally. . . . '[T]here is nothing intrinsically wrong with [defining something by what it does rather than what it is] in drafting patent claims.'" In re Schreiber, 128 F.3d 1473, 1478 (Fed. Cir. 1997)(citation omitted); see generally Eibel

Process Co. v. Minn. & Ontario Paper Co., 261 U.S. 45, 66 (1923)("[e]xpressions quite as indefinite as 'high' and 'substantial,' in describing an invention or discovery, in patent specifications and claims, have been recognized by this court as sufficient").

Agreeing with the claim construction by the Northern District of Georgia in the B&L case, the Court construes the term as follows:

"Significant Corneal Swelling"

swelling of the cornea to such a degree as to cause significant harm to the cornea or significant wearer discomfort during a prescribed extended wear period.

15. "Without Causing Substantial Wearer Discomfort"

J&J's Proposed Construction	CIBA's Proposed Construction
Too indefinite to construe (Doc. 94 at 30.)	[N.D. Ga.] The term "substantial wearer discomfort" means a clinically unacceptable level of wearer discomfort during a prescribed extended wear period. (Doc. 86 at 13.)

Citing "consumer comfort" as an objective ('100 Patent col.1 ll.54-66 ("Background Of The Invention"), the CIBA patent discloses that

> Another object of the invention is to provide an ophthalmic lens capable of extended continuous wear periods of at least 24 hours without substantial adverse impact on ocular health or consumer comfort . . . .
>
> . . .
>
> A further object of the invention is to provide an ophthalmic lens capable of extended continuous wear periods of at least 24 hours without substantial corneal swelling or consumer discomfort . . . .

('100 Patent col.2 ll.44-55.) This object is reflected in numerous independent claims, including '100 Patent claim 1 set forth above, by the phrase "without causing substantial wearer discomfort" ('100 Patent cls. 1, 44, 49-57, 59, 60; '999 Patent cls. 1, 17, 28-34; '461 Patent cls. 1, 9-14; '811 Patent cls. 1, 24-26, 28; '894 Patent cls. 54, 89),[26] and the specifications which provide that an "ophthalmically compatible" lens "will not cause substantial wearer discomfort during the prescribed period of wear." ('100 Patent, col. 5, ll. 54-56.)

On reexamination in 2000, CIBA optometrist Robirds stated to the USPTO that:

> 14. Another key indicator of ophthalmic compatibility is lens comfort. This is the primary efficacy endpoint that integrates a number of elements of the contact lens, such as overall lens design, surface characteristics, edge profile and oxygen permeability. If any of the listed attributes are not compatible with the wearer's eyes then satisfactory comfort is not achieved.

(Doc. 87 (CIBA Ex. J at ¶ 14).)

J&J argues that because the claim term "substantial wearer discomfort" is totally subjective, as it says was conceded by CIBA's corporate designee and expert, (Docs. 84-53, 84-54 (J&J Exs. 48 at 34, 49 at 195-97)(exhibits filed under seal)), the term is indefinite and further construction is not possible or helpful, rendering the

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[26] Claims in two patents contain the phrase: "corneal health is not substantially harmed and wearer comfort is acceptable during a period of extended, continuous contact with ocular tissue and ocular fluid." ('631 Patent cl. 1; '894 Patent cls. 10, 34, 41, 49, 77, 86.)

patent invalid as a matter of law. (Doc. 94 at 30.) Further, J&J contends that CIBA's proposed construction is "impermissibly subjective and functional since determining what is 'clinically unacceptable' varies from clinician to clinician and is based on the subjective responses of individuals," and also because the "patents disclose no clinical results for comfort." (Doc. 94 at 31.) The Court has deferred ruling on the question of indefiniteness and proceeds to determine claim construction.

CIBA responds that its proposed construction derives from the patent specification's definition of "ophthalmically compatible," and that the clinical nature of the term is suggested by the patent's repeated references to "consumer comfort." (Doc. 86 at 13.)

J&J offers no proposed construction for the term "without causing substantial wearer discomfort." CIBA proposes that the term be construed with reference to "clinically unacceptable level of wearer discomfort." The Court agrees that inasmuch as an object of the invention is to achieve "consumer comfort," the term "substantial wearer discomfort" must be measured by more than one wearer. Accordingly, the Court construes the term as follows:

"Without Causing Substantial Wearer Discomfort"

a clinically unacceptable level of wearer discomfort during a prescribed extended wear period.

16. "Oxygen Permeability" ("Dk")

J&J's Proposed Construction	CIBA's Proposed Construction
the rate at which oxygen passes through a material, which does not depend on lens thickness (Doc. 94 at 31.)	the rate at which oxygen will pass through a material (Doc. 86 at 15.) Oxygen permeability is measured in accordance with the coulemetric method described in the CIBA patents, without any corrections, and can vary with thickness. (Doc. 91-2 at 3 (Response App.1 at 3).)

The phrase "oxygen permeability" appears in multiple independent claims as "high oxygen permeability."[27] For example, the term appears in Claim 1 of the '100 Patent to describe the CIBA invention as follows:

> . . . said lens comprising a polymeric material which has a high oxygen permeability and a high ion permeability . . . .

The term "oxygen permeability" appears unmodified by the word "high" in several claims (e.g. '100 Patent cl. 58), and the phrase "oxygen permeation" appears in other claims. ('631 Patent cl. 1; '894 Patent cl. 77.)

The patent specifically defines "oxygen permeability" as follows:

> 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.

('100 Patent col.4 ll.58-60.) Noting that "[o]xygen permeability is conventionally expressed in units of barrers," the patent specifies that "[f]or example, a lens having

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[27] The parties request a claim construction of the term "high oxygen permeability," focusing on the term "high."

a Dk of 90 barrers ('oxygen permeability barrers') and a thickness of 90 microns (0.090 mm) would have a Dk/t of 100 barrers/mm ("oxygen transmissibility barrers"/mm)." ('100 Patent col.4 ll.66-67 - col.5 ll.102.)

An early amendment to the '100 Patent, filed by CIBA with the USPTO in 1998 states that

> The present claims have been amended to include recitations of oxygen permeabilities (D_k). In contrast, prior applications, which have been allowed, included recitations of oxygen transmissibilities (D_k/t). The oxygen permeabilities have been calculated from preferred oxygen transmissibilities and preferred thicknesses.

(Doc. 84-28 at 5 (J&J Ex. 23 at 4).)

CIBA argues that the patent specifies that the coulometric method of measurement is to be used to determine oxygen permeability, ('100 Patent col.15 l. 25-col.16 ll.11), and that, according to its expert, "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 that is immediately adjacent to the lenses called a boundary layer] is taught." (Doc. 92 (CIBA Ex. UU at ¶¶ 5, 7, 8).) CIBA cites to prosecution history statements made by CIBA which it contends reflect that the coulometric method used to measure oxygen permeability was uncorrected for the boundary layer. The first citation is to a 1997 declaration comparing the oxygen permeabilities in three prior art lenses which CIBA

says were tested using the uncorrected coulometric method. (Doc. 87 (CIBA Ex. M at 12.) Further, on reexamination, CIBA co-inventor Winterton stated that the oxygen permeability was determined using the coulometric method, and that "wet and dry measurements of oxygen permeability differ greatly." (Doc. 87 (CIBA Ex. N at 18).)

J&J's proposed construction mirrors the patent specification. J&J explains that "oxygen permeability" is a physical property of the material, and is not a function of the shape or thickness of the sample material. (Tr. at 152.) J&J refers to textbooks in the field as setting forth the "ordinary meaning" of "oxygen permeabilty" ("Dk"), which confirm that the measurement of Dk is not dependent upon lens thickness. (Doc. 84-78 at 6 (J&J Ex. 73 at 225(relationship between sample thickness and Dk)), 84-80 at 5 (J&J Ex. 75 at 16 ("permeability is independent of the thickness of the membrane")), 84-85 at 7 (J&J Ex. 80 at 970 ("[p]ermeablity coefficients are independent of the membrane thickness")), 84-97 (J&J Ex. 92 at 1 ("[o]xygen permeability is a physical property of the material. It is not a function of the shape or thickness of the material sample").) Indeed, CIBA inventor Winterton, in a paper entitled "Coulometric Method for Measuring Oxygen Flux and Dk of Contact Lenses and Lens Materials," published in 1987, stated that it is improper to infer that Dk varies with thickness. (Doc. 90-21 (J&J Ex. 119 at V111932).)

Here, the patent specification defining "oxygen permeability" provides a specific definition for the term which is consistent with the ordinary meaning of the term to

persons of ordinary skill in the art at the time of the invention. Phillips, 415 F.3d at 1313, 1316. Furthermore, the patent specifies how oxygen permeability ("Dk"), expressed in barrers, when calculated with thickness, yields "oxygen transmissibility barrers." ('100 Patent col.4 ll.66-67 - col.5 ll.1-2.) CIBA would have the Court graft the patent's description of measurement onto the term and alter its definition in accordance with its expert's view of the measurement technique described. The Court does not find this necessary. Indeed, CIBA confirms that though the definition for "oxygen permeability" as independent of thickness "is true mathematically," "the actual measurement *technique* taught in the patents does depend on thickness because a liquid boundary layer is present and no regression analysis is taught. . . . Any uncertainty regarding the *method* to employ is eliminated by reference to the prosecution history." (Doc. 91 at 21)(emphasis added).) The Court construes the term as it is defined by the patent's specification. Phillips, 415 F.3d at 1315.

"Oxygen Permeability" ("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.

17. "High Oxygen Permeability"

J&J's Proposed Construction	CIBA's Proposed Construction
Indefinite for claims that do not set forth a specific value for "high oxygen permeability." (Doc. 94 at 32.) *[if construed]* a value of 100 "barrers" and as a property that "does not depend on lens thickness" (Doc. 90 at 25.)	[N.D. Ga.] This term refers to a lens having an oxygen permeability that allows sufficient oxygen to pass through the lens to reach the cornea for safe and comfortable wear during the prescribed extended wear period, the oxygen permeability being at least about 70 barrers, as measured in accordance with the coulometric method described in the CIBA patents ('100 Patent col.15, beginning at line 56). (Doc. 86 at 15.)

As set forth above, the term "high oxygen permeability" appears in numerous independent claims. ('100 Patent cls. 1, 44, 50-57, 59, 60; '999 Patent cls.1, 27, 29, 31, 33; '461 Patent cls. 1, 9-14; '894 Patent cls. 1, 5, 17, 25, 41, 49, 50, 54, 60, 61, 65, 70, 77.) A number of the claims recite "high oxygen permeability" levels expressed in units of barrers[28] such as "equal to or greater than" or "at least" 69 barrers ('100 Patent cls. 50, 52; '999 Patent cls. 27, 29, 33; '461 Patent cls. 9. 10; '894 Patent cls. 25, 41, 60); 70 barrers ('894 Patent cls. 70); 72 barrers ('100 Patent cls. 51, 53; '999 Patent cl. 31; '461 Patent cls. 11, 12, 14); and 77 barrers ('894 Patent

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[28] The patent teaches that "[o]xygen permeability is conventionally expressed in units of barrers, where 'barrer' is defined as:

$((cm^3 \text{ oxygen})(mm)/(cm^2)(sec)(mm\ Hg))\times 10^{-10}$."

('100 Patent col.4 ll. 60-63.)

cls. 5, 17.)[29]

CIBA cites to various patent specifications as supportive of its proposed construction. First, the oxygen permeability must be sufficient to promote healthy and comfortable wear for the extended wear duration:

> The previously described ranges for oxyperm polymerizable materials, ionoperm polymerizable materials, and TRIS are offered to enable the reader to better comprehend the invention. However, it should be noted that the specific weight or volume percentages of oxyperm and ionoperm polymerizable materials are not the most critical factors to consider in preparing a good extended-wear ophthalmic lens. More importantly, the lens must have sufficient ion permeability for good on-eye movement and *sufficient oxygen permeability for good corneal health during the extended wear period.*

('100 Patent col.8 ll.5-15 (emphasis added).)

During the prosecution history before the USPTO and in response to a Patent Office action, CIBA expert Richard Baron submitted to the USPTO a declaration in which he distinguished prior art saying that "all of these oxygen permeabilities are less than a preferred range of above about 70 (See page 22 of the Specification). Accordingly, none of the references teach lenses which would allow sufficient oxygen to pass through the lens to reach the cornea, which is required for a safe and

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[29] A number of other claims contain the unmodified phrase "oxygen permeability" and specify oxygen permeability in terms of "equal to or greater than" or "at least" 69, 77, 81, 90, 105, 112.5, 130.5, 140, 150, or 174 barrers.

comfortable extended wear lens." (Doc. 87 (CIBA Ex. M at 13).)[30] As noted above, the patent teaches that oxygen permeability is determined by the coulometric method. CIBA inventor Winterton, in a declaration to the USPTO on reexamination, explained that "[t]he coulometric method was chosen because unlike other methods, . . . the coulometric method can accurately measure permeabilities above 70 barrers (Dk units)." (Doc. 87 (CIBA Ex. N at ¶ 78).)

J&J argues that the term "high oxygen permeability" is too indefinite to construe, and if it is to be construed, it should reflect 100 barrers. J&J cites CIBA inventor Juergen F. Vogt, who testified in deposition that "[w]ith a contact lens of a hundred micrometer thickness, the Dk/t value is exactly the same as the Dk value of the material; and, . . . we were shooting for a decent value, which is around 90 or a hundred." (Doc. 84-62 (J&J Ex. 57 at 149)(filed under seal).) Another inventor, Bronwyn Glenice Laycock, testified that "[a]s we understood it at the time, high Dk was of the order of 85 to 90 barrers. . . . My memory of it was that that was . . . the general target at the beginning of the project." (Doc. 84-56 (J&J Ex. 51 at 40)(filed

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[30] J&J contends that "page 22 of the Specification" refers to oxygen transmissibilities and not oxygen permeabilities. J&J cites to the 1995 patent application where CIBA stated that "[a] preferred ophthalmic lens material will have an oxygen transmissibility, Dk/t, of at least 70 (cm^3 oxygen)(mm)/mm-cm^2 × (sec/mm Hg) × 10^{-9} or [barrers/mm], more preferably at least 75 barrers/mm, and most preferably at least 87 barrers/mm." (Doc. 84-23 at 29 (J&J Ex. 18 at 22).)

under seal).)[31]

Given that the barrer numbers are provided in the patent itself and the prosecution history in which the USPTO was informed that oxygen permeability of at least 70 barrers is sufficient to promote corneal health during extended wear of contact lenses, the Court accepts CIBA's proposed construction, which imports the limitation of 70 barrers into the construction of the term "high oxygen permeability." Those claims teaching specific oxygen permeability barrers amounts, ranging from "at least" or "equal to or greater than" 69 barrers to 77 barrers, are limited to the measurement expressed. The Court adopts the construction for the term "high oxygen permeability" made by the Northern District of Georgia.

"High Oxygen Permeability"

Oxygen permeability that allows sufficient oxygen to pass through the lens to reach the cornea for safe and comfortable wear during the prescribed extended wear period, the oxygen permeability being at least about 70 barrers, as measured in accordance with the coulometric method described in the CIBA patents ('100 Patent col.15, beginning at line 56).

[31] J&J's citation (Doc. 90 at 24) to a segment of a 1994 Patent Office document in connection with patent application No. 08/301,166 rejecting claims as "obvious" under 35 U.S.C. § 103 and stating "[e]ach of these three [prior art] references discloses high oxygen permeabilities of above 100 barrers or about 100 barrers" (Doc. 90-6 at 10 (J&J Ex. 104 at 9)) does not serve to define or construe "high oxygen permeability" as used in the CIBA patents before the Court.

18. "Oxygen permeability from said inner to said outer surface sufficient to prevent substantial corneal swelling"

J&J's Proposed Construction	CIBA's Proposed Construction
an oxygen permeability level in which corneal swelling would not be greater than 8%. (Doc. 90-3 at 4 (J&J Ex. 101).)	[N.D. Ga.] This term refers to a lens property which permits oxygen to pass (i.e. diffuse) through the lens in amounts such that significant corneal swelling (as defined above) is prevented during a prescribed extended wear period. (Docs. 86 at 18, 34; 91-2 at 3-4.)

This term appears in independent Claim 1 of the '811 Patent, which describes an ophthalmic lens that includes the property:

> (a) an oxygen permeability from said inner to said outer surface sufficient to prevent substantial corneal swelling during a period of extended wear.

('811 Patent, cl. 1.) Several claims ultimately dependent upon Claim 1 specify an amount of corneal swelling. See '811 cl. 3 ("less than about 8% corneal swelling); cl. 4 ("less than about 6% corneal swelling"); cl. 5 ("less than about 4% corneal swelling"); cl.8 ("less than about 10% corneal swelling"); cl. 9 ("less than about 7% corneal swelling); cl. 10 ("less than about 5% corneal swelling").)[32]

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[32] A form of the term appears in Claim 28 of the '811 Patent which describes an ophthalmic lens as follows:

> . . . (a) an oxygen permeability equal to or greater than about 72 barrers from said inner to said outer surface sufficient to prevent substantial corneal swelling during a period of extended wear . . . .

('811 Patent cl. 28.)

CIBA cites to the patent's specified definition of "oxygen permeability," which states that it is "the rate at which oxygen will pass through a material" ('100 Patent col.4 ll.59-60), and to a phrase which appears in the "Background" introduction to the patent, which states that for lenses to be opthalmically compatible, "the lens must allow oxygen to reach the cornea in an amount which is sufficient for long-term corneal health. . . . Thus, soft contact lenses must allow oxygen to diffuse through the lens to reach the cornea." ('100 Patent col.1 ll.30-40.) CIBA attempts to merge the two statements and to inject the word "diffuse" into the '811 Patent term in dispute, such that oxygen will "diffuse through the lens."

The Court rejects CIBA's interpretation; the patent specifically states that "[o]xygen will diffuse predominantly through the oxyperm polymer, while the ionoperm polymer provides a higher barrier to oxygen diffusion." ('100 Parent col.8 ll.40-48.) Further, the Court sees no need to specify a degree of corneal swelling, as proposed by J&J.

Inasmuch as the term incorporates several other terms that are construed by the Court, the Court does not believe that any further claim construction is required.

19. "Oxygen permeation in an amount sufficient to maintain corneal health"

J&J's Proposed Construction	CIBA's Proposed Construction
Indefinite. (Docs. 90-3 at 4 (J&J Ex. 101); 90-4 at 12 (J&J Ex. 102)..)	[N.D. Ga.] a lens property which permits oxygen to pass (i.e. diffuse) through the lens in amounts such that the wearers' corneas are not substantially harmed during a prescribed extended wear period. (Doc. 86 at 19.)

As noted by CIBA in its brief, (Doc. 86 at 19), this phrase[33] is nearly synonymous with the previous phrase, the only substantive difference being "corneal health" versus "corneal swelling." The Court also agrees that the patent specifications make clear that "corneal swelling" is a manifestation of poor "corneal health." See '100 Patent col.15 ll.31-33 ("[o]ne result of the cornea receiving an inadequate amount of oxygen is that the cornea will swell"). Indeed, the patent claims state that the patented "lens allows oxygen permeation in an amount sufficient to maintain corneal health and wearer comfort during the period of extended, continuous contact with ocular tissue and ocular fluids." '100 Patent cl.1. For the reasons stated above, the Court declines to adopt the Northern District of Georgia's and CIBA's construction of this phrase which states that oxygen "diffuses through the lens." The Court has construed "significant corneal swelling" to mean: the "swelling of the cornea to such

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[33] The phrase "oxygen permeation in an amount sufficient to maintain corneal health" is found in '100 Patent cls. 1, 44, 49-57, 59, 60; '999 Patent cls. 1, 27, 29, 31, 33; '461 Patent cls. 1, 9-14; and '894 Patent cl. 49.

a degree as to cause significant harm to the cornea or significant wearer discomfort during a prescribed extended wear period." Thus, "corneal health" is adequately addressed and defined by the patent specifications and this Court's construction of patent claims.

20. "Substantially harmed"

J&J's Proposed Construction	CIBA's Proposed Construction
Indefinite. (Doc. 90-3 at 5 (J&J Ex. 101).)	[N.D. Ga.] refers to clinically material injury to the cornea such that the lens is not ophthalmically compatible for a prescribed extended wear period. (Doc. 86 at 38 (App. A).)

In context, the claim term "substantially harmed" appears as follows:

> wherein said lens allows ion or water permeation via ion or water pathways in an amount sufficient to enable the lens to move on the eye such that corneal health is not *substantially harmed* and wearer comfort is acceptable during the period of extended, continuous contact with ocular tissue and ocular fluids . . . .

('100 Patent cl. 1 (emphasis added).)[34] CIBA's proposed construction reflects verbatim the construction made by the Northern District of Georgia in the B&L case. (See Doc. 87 (CIBA Ex. G at 5).) J&J argues that the phrase is "indefinite." The parties provided no briefing or argument to guide the Court on this term and the

[34] The term also appears in the following claims: '100 Patent cls. 1, 44, 49-57, 59, 60; '999 Patent cls. 1, 17, 27-34; '461 Patent cls. 1, 9-14; '631 Patent cls. 1, 27-34; '894 Patent cls. 17, 41, 49, 70, 77. Some of the claims state that the "corneal health is not substantially harmed and wearer comfort is acceptable during said extended wear."

Northern District of Georgia cites to no authority or reasoning for its claim construction. The Court has deferred ruling on the question of indefiniteness.

"The term 'substantial' is a meaningful modifier implying 'approximate,' rather than 'perfect.'" Liquid Dynamics Corp. v. Vaughan Co., Inc., 355 F.3d 1361, 1368 (Fed. Cir. 2004). Both parties have embraced the term "substantially" or "substantial" as an appropriate word to define claims. (See Docs. 86 at 9, 12, 19, 20- 21; 90 at 13; 94 at 24.) Referring to the specifications, the term "substantially" as used here, is a term of magnitude, describing the extent of the harm to the cornea. See Deering Precision Instruments, L.L.C. v. Vector Distribution Sys., 347 F.3d 1314, 1323-24 (Fed. Cir. 2003). Further, the patent and its specifications make clear that "harm" to the cornea means "injury." There being no opposition by J&J to the construction adopted by the Northern District of Georgia, the Court adopts the construction of "substantially harmed" proffered by CIBA.

"Substantially harmed"

"Substantially harmed" refers to clinically material injury to the cornea such that the lens is not ophthalmically compatible for a prescribed extended wear period.

21. "Oxygen Transmissibility"

J&J's Proposed Construction	CIBA's Proposed Construction
Indefinite. (Doc. 94 at 33.)	[N.D. Ga.] [T]he 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 measured by the coulometric method disclosed in the CIBA patents ('100 Patent Col 15, beginning at line 56), without any corrections. (Doc. 86 at 16-17.)

The term "oxygen transmissibility" appears in numerous claims and is expressed in terms of the measurement "barrers/mm" or Dk/t. For example, Claim 1 of the '100 Patent describes an ophthalmic lens "wherein said ophthalmic lens has an *oxygen transmissibility* of at least about 70 barrers/mm . . . ." ('100 Patent cl.1 (emphasis added).) The method patent, '999 Patent, describes as a step in the method of screening an opthalmic lens for utility as an extended-wear lens,

> (d) selecting said lens as an extended-wear lens if said *oxygen transmissibility* factor and said water or ion permeability factor are both above predetermined limits which are established to ensure good corneal health . . . .

('999 Patent cl.17.)

The patent specifically defines "oxygen transmissibility" as follows:

> The "oxygen transmissibility" of a lens, as used herein, is 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 and "barrer" is defined as:

$$((cm^3 \text{ oxygen})(mm)/(cm^2)(sec)(mm\ Hg))\times 10^{-9}$$

('100 Patent col.4 ll.51-57.)

Oxygen transmissibility is Dk (permeability) divided by thickness (*t*). (Tr. at 159.) Thus, the equation Dk/t is equal to oxygen transmissibility. J&J concedes that transmissibility does depend on thickness (in contrast to permeability); thus, if a material is thick it is more difficult for oxygen to pass through it. (Tr. at 150, 160.) J&J attacks the definition of "oxygen transmissibility" as being "indefinite," because it contends that the applicable unit of measurement, "barrers," is defined inconsistently in the patent. (See Doc. 84-41 at 9 (J&J Ex. 36 at 38).)

Specifically, when defining "oxygen permeability," "'barrer' is defined as:

$$((cm^3 \text{ oxygen})(mm)/(cm^2)(sec)(mm\ Hg))\times 10^{-10}"$$

('100 Patent col.4 ll.60-63; Doc. 84-41 at 7-9 (J&J Ex. 36).) When defining "oxygen transmissiblity," the '100 Patent states that "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 and 'barrer' is defined as:

$$((cm^3 \text{ oxygen})(mm)/(cm^2)(sec)(mm\ Hg))\times 10^{-9}"$$

('100 Patent col.4 ll.53-57.) Within the context of the patent's discussion of "Oxygen Transmissibility and Permeability," ('100 Patent col.15 l.42 to col.16 l.12; Doc. 94 at 33), the patent states that "D_k is expressed in units of barrers, i.e.,

$$((cc \text{ oxygen})(mm)/(cm^2)\times(sec/mm\ Hg)\times 10^{-10}"$$

('100 Patent col.16 ll. 8-11.)

J&J cites a pair of 1997 e-mails between the CIBA patent inventors identifying a "technical" and "slight" problem with patent having two definitions for the term "barrer," calling the discrepancy "bad science." Inventor John Court concluded that the concern was "nullified" by "suitable Double Speak." (Doc. 90-10 (J&J Ex. 108).) J&J states that "[t]he two definitions differ by a factor of 10." (Doc. 94 at 33.)

CIBA responds that because "the patents provide that Dk values are to be measured according to the coulometric method without any corrections for the effect of a boundary layer," the construction of the term "oxygen transmissibility" should include reference to the method of measurement. (Doc. 86 at 17.)

The Northern District of Georgia apparently addressed (without explanation) this alleged inconsistency by including reference to the coulometric method of measurement in its construction of both "oxygen permeability" and "oxygen transmissibility." However, measurement of "oxygen transmissibility," and specifically, measurement of Dk (oxygen permeability) need not be resolved at the claim construction phase of these proceedings; only the *meaning of the claim language* is before the Court for construction. Issues of indefiniteness and validity will be determined later. See Phillips, 415 F.3d at 1327 (validity analysis not a regular component of claim construction). Consistent with and taking into consideration the Court's construction of the term "oxygen permeability," which eliminates reference to

the coulometric method of measurement, the Court construes "oxygen transmissibility" as follows:

"Oxygen Transmissibility"

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.

22. "At least about 70 barrers/mm"

J&J's Proposed Construction	CIBA's Proposed Construction
Indefinite. (Doc. 90-3 at 4 (J&J Ex. 101).)	[N.D. Ga.] oxygen transmissibility (as defined above) of at least 70 barrers/mm taking into account a measurement error of 5%. (Doc. 86 at 17.)

The patent claims describe an extended-wear opthalmic lens with "an oxygen transmissibility of at least about 70 barrers/mm . . . ." (See e.g. '100 Patent cl. 1.) Other independent claims recite lenses with oxygen transmissibility "of at least 75 barrers/mm" ('999 Patent cls. 29, 33) and "at least 81 barrers/mm." ('999 Patent cls. 31.) Dependent claims provide for ophthalmic lenses with oxygen transmissibility rates of "at least about" 75, 80 or 87 barrers/mm. ('100 Patent cls. 4, 5, 45, 46, 61, 62; '461 Patent cl. 2; '811 Patent cls. 20, 27.) The patent teaches that "[t]he oxygen transmissibility (Dk/t) of the lens is preferably at least 70 barrers/mm, more preferably at least 75 barrers/mm, and most preferably at least 87 barrers/mm." ('100 Patent

col.6 ll. 42-45.)

CIBA urges that the Court adopt the claim construction by the Northern District of Georgia which imports into the claim "a measurement of error of 5%," (see Doc. 87 Ex. G at 6), arguing that because the specification differentiates between Dk/t values of 70 and 75, the variation contemplated by "about 70 barrers/mm" must be less than 5 (or 7%). "The 5% error range is consistent with this requirement." (Doc. 86 at 18.)[35] Thus, according to CIBA's proffered construction, the oxygen transmissibility "of at least about 70%" could range between 66.5 barrers/mm and 73.5 barrers/mm.[36]

CIBA argues that the prosecution history also supports its proffered construction. During reexamination, CIBA inventor Winterton stated that when using the coulometric method of measurement of oxygen permeability, "[i]ntra-lab variances of 1-3 percent and inter-lab differences of from 3-5 percent are expected and validated." (Doc. 87 (CIBA Ex. N at ¶ 79).) Notably, this statement was made in the context of discussing accurate measurement of oxygen permeability (Dk units) which is stated in terms of "barrers" as opposed to transmissibility (Dk/t) which is stated in

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[35] J&J does not address this term in its papers or in argument, stating without explanation that the term is "indefinite." The Court is unable to discern the basis for J&J's position, whether it is based upon the claim term "about" or upon the reference to "barrers."

[36] CIBA is silent as to whether the other approximated transmissibility barrers/mm levels found in other claims (75, 80, 81, 87) would also be accorded a 5% measurement error, which if so, would mean that the claims would overlap as to oxygen transmissibility levels.

in units of "barrers/mm," and thus is not helpful to the determination of oxygen transmissibility.

"'[T]he word "about" does not have a universal meaning in patent claims, . . . the meaning depends upon the technological facts of the particular case.'" Ortho-McNeil Pharm., Inc. v. Caraco Pharm. Labs., 476 F.3d 1321, 1326 (Fed. Cir. 2007)(citation omitted).

> The use of the word "about," avoids a strict numerical boundary to the specified parameter. Its range must be interpreted in its technological and stylistic context. We thus consider how the term . . . was used in the patent specification, the prosecution history, and other claims. It is appropriate to consider the effects of varying that parameter, for the inventor's intended meaning is relevant. Extrinsic evidence of meaning and usage in the art may be helpful in determining the criticality of the parameter . . . .

Id., 476 F.3d at 1326 (quoting Pall Corp. v. Micron Separations, Inc., 66 F.3d 1211, 1217 (Fed. Cir. 1995)). Such extrinsic evidence "may be received from the inventor and others skilled in the field of the invention." Pall Corp., 66 F.3d at 1217.

Patent claims may be drafted "using terminology that is not as precise or specific as it might be, [a]s long as the result complies with the statutory requirement to 'particularly point[ ] out and distinctly claim[ ] the subject matter which the applicant regards as his invention,' 35 U.S.C. § 112, para. 2." PPG Indus. v. Guardian Indus. Corp., 156 F.3d 1351, 1355 (Fed. Cir. 1998).

> That does not mean, however, that a court, under the rubric of claim construction, may give a claim whatever additional

> precision or specificity is necessary to facilitate a comparison between the claim and the accused product. Rather, after the court has defined the claim with whatever specificity and precision is warranted by the language of the claim and the evidence bearing on the proper construction, the task of determining whether the construed claim reads on the accused product is for the finder of fact.

Id.

The patent appears to be silent about the exactitude of oxygen transmissibility contemplated by "at least about 70 barrers/mm" (at least the parties are silent), and CIBA cites to no intrinsic evidence that relates to barrers/mm measurement of DK/t. Further, the parties offer no extrinsic evidence in the form of expert testimony to enlighten the Court as to the meaning and usage of the term "at least about" in the art as it applies to the technology of "barrer/mm" measurement of oxygen transmissibility. Hence, there is no basis in the record supporting CIBA's assertion that a 5 percent measurement error is appropriate. It could well be argued that "about" requires a narrow construction encompassing a measurement error of less than 5 percent so as to avoid the possibility of different claims having overlapping oxygen transmissibility levels. However, because the Court is unable, on this record, to make an exact determination of the proper variable, its construction of the term "at least about 70 barrers/mm" is subject to the receipt of further evidence. See Acumed LLC v. Stryker Corp., 483 F.3d 800, 806 (Fed. Cir. 2007)("a sound claim construction need not always purge every shred of ambiguity"); see generally W.L. Gore & Assocs., Inc. v.

Garlock, Inc., 842 F.2d 1275, 1280-81 (Fed. Cir. 1988).

Based on the record before it, the Court determines there is no need to construe this term.

23. "High Ion Permeability"

J&J's Proposed Construction	CIBA's Proposed Construction
ion permeability in the amounts identified as threshold levels in the patent specification, characterized by an Ionoton Ion Permeability Coefficient of above 0.008×10^{-3} cm^2/sec (Doc. 94 at 34.)	[N.D. Ga.] ion permeability in the amounts identified as threshold levels in the patent specification. (Doc. 86 at 19.)

Claim 1 describes an ophthalmic lens "comprising a polymeric material which has a high oxygen permeability and a *high ion permeability* . . . . ('100 Patent cl.1 (emphasis added).) High ion permeability is important because "above a certain threshold of ion permeability through a lens, from the inner surface of the lens to the outer, or vice versa, the lens will move on the eye, and below the threshold the lens will adhere to the eye." ('100 Patent col.9 l.64-col.10 l.3; Tr. 225-26.)

While agreeing with the Georgia court's construction of this term, which is submitted by CIBA, J&J urges the claim be limited and that "only the threshold Ionoton Ion Permeability Coefficient values . . . set forth below Table E in the patents, may be used [as threshold values of 'high ion permeability'], because the Ionoton measurement is the only method for ion permeability a person skilled in the art would use." (Doc. 94 at 34 (citing '100 Patent col.64 Table E.) Citing to thirteen examples,

the patent states:

> Considering Examples E-1 through E-13 of Table E, the lowest value of Ionotone Ion Permeability Coefficient for which a lens moves on the eye is 0.25×10^{-3} cm^2/sec. The highest value of Ionoton Ion Permeability Coefficient for a lens which bound on the eye is 0.008×10^{-3} cm^2/sec. Thus, *a contact lens preferably has an Ionoton Ion Permeability Coefficient greater than about 0.008×10^{-3} cm^2/sec.*, more preferably greater than about 0.25×10^{-3} cm^2/sec.

('100 Patent col.64 ll.48-55 (emphasis added).) Because the patent states that Ionoton coefficients measure ion permeability, "Ionoton coefficients are appropriate values for referring to high ion permeability," according to J&J. (Doc. 94 at 34.)

CIBA contends that the patent claims define two methods for measuring ion permeability - the Ionotone method, and the Ionoflux method - and objects to J&J's proposed construction because it relies upon the Ionoton technique alone. Second, CIBA opposes J&J's attempt to limit the Ionotone value of ion permeability to that of a preferred example in the patent, contending that the so-called threshold level can be lower than that cited by J&J. (Tr. 227-29.) CIBA argues that the patent has 60 examples, some of which "don't work," and that J&J is in error by focusing on one example. (Tr. 230.)

Some of the patent claims refer to <u>both</u> techniques, claiming ion permeability "characterized either by (1) an Ionoton Ion Permeability Coefficient of greater than about 0.2×10^{-6} cm^2/sec or (2) an Ionoflux Diffusion Coefficient of greater than about 1.5×10^{-6} mm^2/min. wherein said ion permeability is measured with respect to sodium

ions." ('100 Patent cls.1, 44, 49-51.) Other claims refer solely to an Ionoton Ion Permeability Coefficient ('100 patent cls.14, 15, 37, 41, 52-54, 59) or solely to an Ionoflux Diffusion Coefficient ('100 Patent cls.16, 17, 38, 42, 47, 55-57, 60) when speaking of ion permeability. The patent specifications define the Ionoflux and Ionoton measurement techniques. J&J contends that the Ionoflux diffusion coefficient and Ionoton permeability coefficient, though related, are two entirely different concepts representing different properties - diffusion and permeability - of a material., and that the Ionoflux Diffusion Coefficient cannot be used to measure ion permeability. (Doc. 94 at 34 (citing expert Freeman (Doc. 84-42 at 5-8, 9 (J&J Ex. 37 at ¶¶ 184-89, 199).) Further, J&J argues that the patent is inherently confusing as to the Ionoflux measurement technique, citing to Table F of the patent discussing various embodiments and referring to the "Ionoflux Ion *Permeability* Coefficient." (See '100 Patent col. 67 ll.40-67 (emphasis added).)

While Table F of the patent ('100 Patent col. 67 ll.40-67) refers to an "Ionoflux Ion Permeability Coefficient" as opposed to an "Ionoflux Ion Diffusion Coefficient," CIBA inventor Winterton on reexamination informed the Patent Office that each expression was a coefficient defined by units of mm^2/min "and is used to identify the rate of 'ion permeability' through a lens," and that the terms were used interchangeably. (Doc. 84-39 at 21-22 (J&J Ex. 34 ¶ 83); see also Doc. 84-60 at 4 (J&J Ex. 55 at 223)("I'm confident they are the same").) The Patent Office approved

the patent containing the different terms.[37]

The patent claims and specifications recognize that ion permeability may be characterized by either the ionoton measurement technique or the ionoflux measurement technique. Further, the Court declines to limit the claim term "high ion permeability" to a numerical measurement found in a particular embodiment. See Phillips, 415 F.3d at 1323 ("athough the specification often describes very specific embodiments of the invention, we have repeatedly warned against confining the claims to those embodiments"). The term is construed as follows:

"High Ion Permeability"

ion permeability in the amounts identified as threshold levels in the patent specification.

[37] The Court declines to rule at this time whether "Ionoflux Diffusion Coefficient," "Ionoflux Ion Permeability Coefficient" and "Ion Permeablity Characterized . . . By . . . An Ionoton Permeability Coefficient" are indefinite as a matter of law, as requested by J&J. (Doc. 94 at 36.)

24. "Wherein said lens is autoclaved without lowering either said oxygen permeability or said ion permeability below levels sufficient to maintain good corneal health and on-eye movement"

J&J's Proposed Construction	CIBA's Proposed Construction
Indefinite as a Matter of Law. (Doc. 90-3 at 5 (J&J Ex. 101).)	the contact lens is autoclaved without lowering its oxygen permeability and ion permeability to levels where the lens is no longer ophthalmically compatible in that it causes significant damage to the eye and/or lacks adequate on-eye movement. (Doc. 86 at 27-28.)

CIBA argues that its proffered construction of this phrase (see '100 patent cls. 56, 60; '999 Patent cls. 27, 28, 29; '811 cl. 25 cf '461 Patent cls. 13, 14 (describing method of "autoclaving said lens")) is understood by a person of ordinary skill in the art. (Doc. 86 at 28.) CIBA cites to the patent specification discussing methods of manufacturing which states:

> An essential feature of the manufacturing methods of the present innovative lenses is that a balance of high oxygen permeability and ion permeability is achieved. Manufacturing techniques and conditions which result in lowering either the oxygen permeability or the ion permeability below levels sufficient to maintain good corneal health and on-eye movement during periods of extended wear are unacceptable . . . .

('100 Patent col.45 ll.37-46), as the basis for its proposed construction.

J&J summarily contends that the term is "indefinite," which the Court is not addressing at this time.

The Court finds no need to construe this claim.

25. "Oxyperm Polymerizable Materials"

J&J's Proposed Construction	CIBA's Proposed Construction
None offered.	This term 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, with the resultant polymers referred to as "oxyperm polymers. Oxyperm polymerizable materials include a wide range of materials, including siloxane-containing macromers and monomers, and macromers or monomers containing hydrophilic groups. Doc. 86 at 39 (App. A); Doc. 91-2 at 10 (Response App. 1).)

CIBA addresses this proposed construction in an appendix chart, providing only a citation to a patent specification and an expert report. (Doc. 86 at 44.) J&J did not address the term in its papers.

The patent specification defines the term "oxygen polymerizable materials:"[38]

> A "polymerizable material which is capable of polymerizing to form a polymer having a high oxygen permeabililty" 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

[38] The term "Oxyperm Polymerizable Materials" appears in a number of claims. (See '100 Patent cls. 1, 49-57; '999 Patent cls. 1, 27, 29, 31, 33; '631 Patent cl.1; '894 Patent cls. 1, 25, 29, 34, 41, 49, 60, 61, 65, 70, 77, 86, 91.)

> 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.) The patent teaches that

> [o]xyperm polymerizable materials include a wide range of materials which may be polymerized to form a polymer displaying a relatively high oxygen diffusion rate therethrough. In addition, these materials must be relatively ophthalmically compatible. These oxyperm polymerizable materials include, without limitation thereto, siloxane-containing macromers and monomers, flourine-containing macromers and monomers, and carbon-carbon triple bond-containing macromers and monomers. The oxyperm macromer or monomer may also contain hydrophilic groups.
>
> Preferred oxyperm polymers are those formed from a siloxane-containing macromer. . . .

(‘100 Patent col.6 ll.23-34.) CIBA offers no explanation why the additional limitations contained in the patent specification should be omitted from the construction of the claim term “oxygen polymerizable materials.” The Court finds this term is sufficiently defined; there is no need to construe it.

26. "Ionoperm Polymerizable Materials"

J&J's Proposed Construction	CIBA's Proposed Construction
None offered.	This term 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, with the resultant polymers referred to as ionoperm polymers. Ionoperm polymerizable materials include a wide range of materials, including 2-hydroxyethyl methacrylate (HEMA) and dimethylacylamide (DMA) and mixtures therof. Doc. 86 at 39-40 (App. A); Doc. 91-2 at 11 (Response App. 1).)

The patent specifications define "ionoperm polymerizable materials"[39] as follows:

> 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.) Further, the patent specifies that

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[39] The term "ionoperm polymerizable materials is found in a number of claims. (See '100 Patent cls. 1, 49-57; '999 cls. 1, 27, 29, 31, 33; '631 cl.1; '894 cls. 1, 25, 29, 34, 41, 49, 60, 61, 65, 70, 77, 86.)

> Ionoperm polymerizable materials include a wide range of materials which may be polymerized to form a polymer displaying a relatively high ion diffusion rate therethrough. In addition, these materials must be relatively ophthalmically compatible. These ionoperm polymerizable materials include, without limitation thereto, acrylates and methacrylates, such as 2-hydroxyethyl methacrylate [HEMA], acrylamide, methacrylamide, and dimethylacrylamide [DMA]; poly (alkylene glycols), such as poly(ethylene glycol); N-vinyl pyrrolidones such as N-vinyl-2-pyrrolidone; and the like and mixtures thereof. Other ionoperm materials are disclosed in the specific embodiments of Materials A-D, described below."

('100 Patent col.7 ll.8-20.)

Again, CIBA, without explanation, eliminates some of the possible materials encompassed by the term as set forth in the patent specifications. The Court finds the term sufficiently defined and determines that no further construction is necessary.

27. "Wherein said ionoperm polymerizable material, if polymerized alone would form a hydrophilic polymer having a water content of at least 10 weight percent upon full hydration"

J&J's Proposed Construction	CIBA's Proposed Construction
ionoperm polymerizable material, if polymerized alone, *i.e.,* without the addition of a crosslinker, would form a hydrogel having a determinable water content of at least 10 weight percent upon full hydration. Such an ionoperm polymerizable material would be water swellable but not water soluble (Doc. 94 at 38.)	wherein said ionoperm polymerizable material, if polymerized alone would form a hydrophilic polymer having a water content of at least 10 weight percent upon full hydration, which includes water soluble polymers. (Doc. 86 at 27.)

The parties have a "major dispute" over the proper construction of this term.

(Tr. 238.) J&J contends that the term refers to a hydrogel which absorbs water and cannot refer to a material that is soluble (or dissolves) in water, and that its position is supported by the prosecution history, expert testimony and dictionary definitions about the chemistry involved. CIBA counters that it specifically declined to limit the "hydophillic polymer having a water content of at least 10 weight percent upon full hydration" to hydrogels; that the hydrophilic polymer formed could include water soluble polymers, and that a number of the embodiments set forth in the patent would be eliminated if this term were limited to hydrogels. (Tr. 234-47.)

This term, which is known as the "10 percent limitation" (Tr. at 234), appears in a number of independent claims.[40] According to J&J, this term is limited to hydrogels. "Hydrogels, or water-containing gels, are polymers characterized by hydrophilicity[41] and insolubility in water. In water, they swell to equilibrium volume, but preserve their shape." (Docs. 84-99 at 3 (J&J Ex. 94 (Concise Encyclopedia of Polymer Science and Engineering)); 94 at 39.)

J&J frames this issue as "whether 'a hydrophilic polymer having a water content of at least 10 weight percent upon full hydration' encompasses water-soluable

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[40] (See '100 Patent cls. 1, 49-57; '999 Patent cls. 1, 27, 29, 31, 33.)

[41] "Hydrophilicity" is defined as "[h]aving an affinity for water; readily absorbing or dissolving in water," The American Heritage® Dictionary of the English Language (2006), and as "of, relating to, or having a strong affinity for water." Merriam-Webster's Online Dictionary, www.merriam-webster.com/dictionary/hydrophilicity.

polymers." (Doc. 90 at 27.) In support for its position that it does not, J&J cites to the prosecution history in which the USPTO examiner, in a handwritten note in 1997 on reexamination of the patent, described "the general nature of what was agreed to" as being that "claim language should include critical limits (1) that the ion permeable phase, standing alone in water, forms a hydrogel." (Doc. 84-24 at 2 (J&J Ex. 19).) J&J contends that CIBA's patent amendment that included the language "having a water content of at least 10 weight percent upon full hydration" was made "[i]n accordance with the hydrogel language referenced in the Interview Summary" and thus was CIBA's way of saying that the material formed was a hydrogel. (Docs. 84-25 at 9 (J&J Ex. 20); 84-26 at 8 (J&J Ex. 21 at 7).) Thus, argues J&J, "any materials *not* forming a hydrogel when standing alone in water would not be encompassed by this claim limitation." (Doc. 94 at 39 (emphasis in original).) J&J also asserts that the claim term should be construed to include "crosslinker," citing CIBA's expert who in response to a deposition question, agreed that the term "polymerized alone" means "without a cross linker." (Docs. 94 at 39; 84-57 at 4 (J&J Ex. 52 at 56).)

CIBA urges a literal reading of the claim term. Additionally, as support for its position that the patent makes clear that ionoperm polymerizable materials include materials which are water soluble, CIBA cites the claim specification which provides

> *A comonomer (a) present in the novel polymer can be hydrophilic or hydrophobic or a mixture thereof*. Suitable comonomers are, in particular, those which are usually used in the production of contact lenses and biomedical

> materials. A *hydrophobic comonomer* (a) is taken to mean a monomer which typically gives a homopolymer which is insoluble in water and can absorb less than 10% by weight of water. Analogously, a *hydrophilic comonomer* (a) is taken to mean a monomer which typically gives a homopolymer which is soluble in water *or* can absorb at least 10% by weight of water.

('100 Patent col.26 ll.19-29 (emphasis added); see also Doc. 91 at 37.)

CIBA's expert Mays, who interprets the claim phrase to mean that "[t]he ionoperm polymerizable material is thus hydophilic (i.e., water loving) and is expected to form a hydrophilic polymer when polymerized alone," states that two preferred hydrophilic polymers listed in the patent are consistent with the definition of an ionoperm polymerizable material. (Doc. 87 (CIBA Ex. F at 11 ¶¶ 26, 27 (citing '100 Patent col.27 ll. 27-32)(2-hydroxyethyl methacrylate (HEMA) and N,N-dimethylacrylamide (DMA)); see also construction of "ionoperm polymerizable material".) One of these materials, DMA, when polymerized alone, dissolves in water upon full hydration, according to CIBA expert Mays. (Doc. 87 (CIBA Ex. Q at 3-4 ¶ 11).)[42] CIBA expert Mays states that DMA is specifically identified in the patent as an ionoperm polymerizable material and that "many" of the patent examples disclose the

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[42] This is consistent with the Bausch & Lomb challenge to the '100 Patent, prompting its reexamination, in which Bausch & Lomb contended that "N,N-dimethylacrylamide [DMA], polymerized alone, would be water soluble" and that "a polymer made by polymerizing N,N-dimethylacrylamide [DMA] alone would be a hydrophilic polymer having a water content of at last 10 weight percent upon full hydration." (Doc. 92 (CIBA Ex. SS at 16 ¶¶ 40-43).)

use of DMA. Mays concludes that based upon the intrinsic evidence, "this claim limitation is met by an ionoperm polymerizable material (such as DMA) which, when polymerized alone, dissolves in water." (Doc. 87 (CIBA Ex. Q at 4 ¶¶ 11, 12).) CIBA argues that "[a] person of skill in the art would readily understand that many of these materials, including, for example, DMA [which is used in "many" embodiments and is listed among preferred hyrophilic comonomers], form water soluble polymers." (Doc. 91 at 37.)

As to the "agreement" with the Patent Office examiner, CIBA responds that it declined to amend the claim term to limit it to hydrogels. (Tr. at 245; Doc. 91 at 38 (citing Gerber Garment Tech., Inc. v. Lectra Sys., Inc., 916 F.2d 683, 688 n.3 (Fed. Cir. 1990)("[a]n applicant is at liberty to resist any such suggestion" by the examiner).) Thus the term "hydrogel" was specifically excluded from the claim term and should not now be read into it, argues CIBA.

In response, J&J contends that the specification defines the term "hydrophilic comonomer" in two parts: "'a monomer which typically gives a homopolymer which is [i] soluble in water *or* [ii] can absorb at least 10% by weight of water,'" and that "CIBA's patents claim only the second part." (Doc. 90 at 27 (citing '100 Patent col.26 ll.26-29 (emphasis added).)

Importing limitations onto a claim from the specification is "fraught with danger." MBO Labs., Inc., 474 F.3d at 1333; Phillips, 415 F.3d at 1323. "Limiting claims from

the specification is generally not permitted absent a clear disclosure that the patentee intended the claims to be limited as shown." MBO Labs., Inc., 474 F.3d at 1334 (citing Phillips, 415 F.3d at 1323). While "there is sometimes a fine line between reading a claim in light of the specification, and reading a limitation into a claim from the specification," Comark Commc'ns, Inc., 156 F.3d at 1186, when the claim addresses only some of the features disclosed in the specification, it is improper to limit the claim to other unclaimed features. Phillips, 415 at 1327.

To assess whether a patentee relinquished a particular claim construction (here that the "hydrophilic polymer" formed includes "water soluble polymers") the Court must assess the totality of the prosecution history, including amendments to the claims and arguments made to overcome or distinguish references, not the individual segments of the presentation made to the patent examiner. Rheox, Inc. v. Entact, Inc., 276 F.3d 1319, 1327 (Fed. Cir. 2002). To establish that the prosecution history limits the interpretation of claim terms so as to exclude any interpretation that was disclaimed during prosecution, the disclaimer "must be effected with 'reasonable clarity and deliberateness.'" Springs Window Fashions LP v. Novo Inds., Inc., 323 F.3d 989 (Fed. Cir. 2003)(citation omitted).

Furthermore, an interpretation of a claim term that would exclude a preferred embodiment of the invention "'is rarely, if ever correct and would require highly persuasive evidentiary support'" to establish that a patent's prosecution history

excludes some but not all of the preferred embodiments. Rheox, Inc., 276 F.3d at 1319 (citation omitted); see also Nat'l Steel Car, Ltd. v. Canadian Pac. Ry., Ltd., 357 F.3d 1319, 1337 (Fed. Cir. 2004)("[c]laim interpretations that do not read on the preferred embodiment are 'rarely, if ever, correct and would require highly persuasive evidentiary support'" (citation omitted)). Only when there is a "clear disclaimer during the prosecution history, . . . may [it] be appropriate to read out the preferred embodiments." Revolution Eyewear, Inc. v. Aspex Eyewear, Inc., 175 Fed. Appx. 350, 356 (Fed. Cir. 2006)(citations omitted).

The language of the claim term speaks to the formation of "a hydrophilic polymer having a water content of at least 10 weight percent upon full hydration." The patent specification states that for purposes of the contact lens invention, "a *hydrophilic comonomer* (a) [present in the novel polymer] is taken to mean a monomer which typically gives a homopolymer which is soluble in water *or* can absorb at least 10% by weight of water." ('100 Patent col.26 ll.26-29 (emphasis added).) Thus, the conundrum. At the *Markman* hearing the Court questioned CIBA how a material - here, a hydophilic polymer - could absorb water (to "at least 10 weight percent upon full hydration") and dissolve in water (be a "water soluable polymer") at the same time. In other words, may something that is soluble in water have any water content at all? Counsel for CIBA responded that "something that dissolves in water has at least ten percent water content" and that "persons of

ordinary skill in the art would understand that having at least ten percent water includes materials that are soluble in water." (Tr. 244-45, 247.)

J&J bases its argument to limit the claim term to "hydrogels" in large part upon an "agreement" between CIBA and the patent office examiner on reexamination that the material formed would constitute a hydrogel. However, the amended patent claims including this term indicate that the term was *not* changed from the original claim (see '100 Patent cl. 1; '999 Patent cl. 1), dispelling J&J's argument that CIBA "complied" with the hydrogel "agreement" by including the phrase "having a water content of at least 10 percent upon full hydration" in the amended claims, and confirming CIBA's contention that it did not follow the patent examiner's "agreement." (See Tr. at 241, 245.) See Sorenson v. Int'l Trade Comm'n, 427 F.3d 1375, 1379 (Fed. Cir. 2005)(it is the applicant and not the examiner who must "'give up or disclaim subject matter'" (citation omitted)).

Particularly in light of the fact that the language of the patent claims was not *amended* to include the hydrogel limitation sought by J&J, the Court determines that J&J has failed to cite to a clear disclosure that CIBA intended to limit this claim term to hydrogels or to establish with highly persuasive evidentiary support that CIBA intended that the claim term be construed to exclude DMA-containing preferred

embodiments of the invention set forth in the patent.[43] The Court construes the term as follows.

"Wherein said ionoperm polymerizable material, if polymerized alone would form a hydrophilic polymer having a water content of at least 10 weight percent upon full hydration"

wherein said ionoperm polymerizable material, if polymerized alone would form a hydrophilic polymer having a water content of at least 10 weight percent upon full hydration, which includes water soluble polymers.

28. "An ionoperm polymerizable material comprising at least one of 2-hydroxyethyl methacrylate or N,N-dimethylacrylamide"

J&J's Proposed Construction	CIBA's Proposed Construction
J&J does not believe that this term needs to be construed. (Doc. 90-4 at 3 (J&J Ex. 102).)	This term refers to an ionoperm polymerizable material of at least one of 2-hydroxyethyl methacrylate (also known as HEMA) or N,N dimethylacrylamide (also known as DMA). (Doc. 86 at 40 (App. A); Doc. 91-2 at 11 (Response App. 1).)

The Court adopts CIBA's construction incorporating abbreviations "HEMA" and "DMA" for the chemicals 2-hydroxyethyl methacrylate and N,N-dimethylacrylamide in the context of these patents,[44] and construes the term "comprising" as being "of." J&J does not dispute that "[t]he terms are chemical names for specific polymerizable

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[43] The Court reaches the same conclusion with respect to inclusion of a limitation "without the addition of a crosslinker."

[44] While the chemicals are referred to throughout the patent, the specific claim term herein construed is found in the '894 Patent, cl. 89.

materials." (See Doc 87 (CIBA Ex. F at 9).)

"An ionoperm polymerizable material comprising at least one of 2-hydroxyethyl methacrylate or N,N-dimethylacrylamide"

This term refers to an ionoperm polymerizable material of at least one of 2-hydroxyethyl methacrylate (also known as HEMA) or N,N dimethylacrylamide (also known as DMA).

29. "Wherein said oxyperm polymerizable material comprises at least one of a siloxane containing macromer or a siloxane containing monomer"

J&J's Proposed Construction	CIBA's Proposed Construction
J&J does not believe that this term needs to be construed. (Doc. 90-4 at 4 (J&J Ex. 102))	This term refers to an oxyperm polymerizable material of at least one of a siloxane containing macromer or a siloxane containing monomer. A siloxane containing macromer is a polymerizable material containing a siloxane having a molecular weight of at least 800 grams/mol and a siloxane containing monomer is a polymerizable material containing a siloxane and having a molecular weight of less than about 800 grams/mol. (Doc. 86 at 40 (App. A); Doc. 91-2 at 12 (Response App. 1).)

CIBA's proposed construction of the claim term: "wherein said oxyperm polymerizable material comprises at least one of a siloxane containing macromer or a siloxane containing monomer" (see '894 Patent cl. 91) incorporates the patent's definitions of "macromer" and "monomer" ('100 Patent col.5 ll.13-19) and reflects that and an oxyperm polymerizable material includes siloxane-containing macromers and monomers. ('100 Patent col.6 ll.22-37; see Doc. 87 (CIBA Ex. F at ¶ 24 (CIBA expert

Mays' report at 9).) The claim term is adequately addressed in the patent's specifications; it requires no further interpretation or construction.

Summary

In summary, these are the Court's constructions:

Agreed Constructions

1. "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. (Docs. 94 at 19-20; 86 at 20; Tr. 176 (emphasis added).)

2. “Co-continuous Phases”

“Co-continuous Phases” refers to at least two regions, each of substantially uniform composition which differs from the other, and each of which forms a continuous pathway from one surface of an article to another surface of an article. However, each “phase” need not be a chemically pure substance, but merely connotes that certain bulk properties differ significantly from the properties of another phase within the material. Thus, with respect to co-continuous oxyperm and ionoperm phases, the 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. (Docs. 94 at 22; 86 at 22 (emphasis added).)

3. “Polyvinylpyrrolidone”

a homopolymer that is produced by the polymerization of N-vinylpyrrolidone.

4. “Biocompatible”

“Biocompatible” has the same meaning as “ophthalmically compatible.”

5. “High Water Permeability”

the rate of water permeation through the lens, from one surface to another, of greater than about 0.2 x 10^{-6} cm^2/sec

Disputed Constructions

1. "Surface Treatment Process"

"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.

2. Whether All Claims Require Surface "Surface Modification" and "Co-Continuous Phases"

No further construction needed.

3. "Altering the surface of said core material to produce a surface which is more hydrophilic than said core material"

   "Altering the surface of said core material to produce a surface which is more hydrophilic than said core material by a surface treatment process"

No further construction needed.

4. "Region of Substantially Uniform Composition"

No further construction needed.

5. "Distinct and Physically Separate Portion of a Heterogeneous Polymeric Material

No further construction needed.

6. “Essentially Only Ionoperm Polymer” and “Essentially Only Oxyperm Polymer”

No further construction needed.

7. “Phases Substantially Separate”

“Phases substantially separate” means at least two “phases” as “phase” is previously defined.

8. “Pathways” and “Continuous Pathways”

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.

9. “Ophthalmically Compatible ”

“Ophthalmically compatible”, as used herein, refers to a material or surface of a material which may be in intimate contact with the ocular environment for an extended period of time without significantly damaging the ocular environment and without significant user discomfort. Thus, an ophthalmically compatible contact lens will not produce significant corneal swelling, will adequately move on the eye with blinking to promote adequate tear exchange, will not have substantial amounts of lipid adsorption, and will not cause substantial wearer discomfort during the prescribed period of wear.

10. “Extended Wear”

The term refers to a method of continuous wear of a contact lens for a period of at least 24 hours, or for such longer period as specified in a particular claim, without substantial adverse impact on ocular health or consumer comfort.

11. “Adequate Tear Exchange”

The term “adequate tear exchange” means tear flow between the lens and eye for removing debris, such as foreign particulates or dead epithelial cells, to be swept from beneath the lens and, ultimately from the tear fluid, sufficient to render the lens ophthalmically compatible for a prescribed period of extended wear.

12. “Substantial Amounts Of Lipid Adsorption”

Lipid deposits in an amount that the skilled optometrist can observe a “beaded” tear layer on the surface of the contact lens, rather than tears sheening smoothly off the front surface of the contact lens, and that cause tear layer disruption that is noticed by the wearer as a loss of visual clarity, substantially interfering with vision or causing substantial wearer discomfort, so as to make the lens unsuitable for wear as a contact lens for a prescribed period of extended wear.

13. “Adequate Movement On The Eye With Blinking”

Movement of the contact lens on the eye sufficient, upon blinking, to permit tear exchange between the lens and eye so as to permit the lens to be safely and effectively worn for (and removed after) the prescribed extended wear period.

14. “Significant Corneal Swelling”

swelling of the cornea to such a degree as to cause significant harm to the cornea or significant wearer discomfort during a prescribed extended wear period.

15. “Without Causing Substantial Wearer Discomfort”

a clinically unacceptable level of wearer discomfort during a prescribed extended wear period.

16. “Oxygen Permeability” (“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.

17. “High Oxygen Permeability”

Oxygen permeability that allows sufficient oxygen to pass through the lens to reach the cornea for safe and comfortable wear during the prescribed extended wear period, the oxygen permeability being at least about 70 barrers, as measured in accordance with the coulometric method described in the CIBA patents (‘100 Patent col.15, beginning at line 56).

18. “Oxygen Permeability from said inner to said outer surface sufficient to prevent substantial corneal swelling”

No further construction needed.

19. “Oxygen permeation in an amount sufficient to maintain corneal health”

No further construction needed.

20. “Substantially harmed”

“Substantially harmed” refers to clinically material injury to the cornea such that the lens is not ophthalmically compatible for a prescribed extended wear period.

21. “Oxygen Transmissibility”

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.

22. “At least about 70 barrers/mm”

No further construction needed.

23. “High Ion Permeability”

ion permeability in the amounts identified as threshold levels in the patent specification.

24. “Wherein said lens is autoclaved without lowering either said oxygen permeability or said ion permeability below levels sufficient to maintain good corneal health and on-eye movement”

No further construction needed.

25. “Oxyperm Polymerizable Materials”

No further construction needed.

26. “Ionoperm Polymerizable Materials”

No further construction needed.

27. “Wherein said ionoperm polymerizable material, if polymerized alone would form a hydrophilic polymer having a water content of at least 10 weight percent upon full hydration”

wherein said ionoperm polymerizable material, if polymerized alone would form a hydrophilic polymer having a water content of at least 10 weight percent upon full hydration, which includes water soluble polymers.

28. “An ionoperm polymerizable material comprising at least one of 2-hydroxyethyl methacrylate or N,N-dimethylacrylamide”

This term refers to an ionoperm polymerizable material of at least one of 2-hydroxyethyl methacrylate (also known as HEMA) or N,N dimethylacrylamide (also known as DMA).

29. “Wherein said oxyperm polymerizable material comprises at least one of a siloxane containing macromer or a siloxane containing monomer”

No further construction needed.

Conclusion

This case involves six patents relating to extended wear contact lenses. The technological detail is exhaustive. As noted by counsel for one of the parties, “[t]his patent [one of the six patents, the ‘100 Patent] has a massive teaching. It’s got 69 columns of chemistry in it. It’s got 60 different examples.” (Tr. at 230.) The parties submitted some 40 claim terms to construe, often without accompanying argument

or citation to intrinsic or extrinsic evidence or to legal precedent. Often, the parties presented their proposed constructions (or in the case of J&J's assertion that a particular term is "indefinite as a matter of law") in a summary appendix, list or chart, with no accompanying discussion. (See Docs. 86 at 32, 90-3, 90-4, 91-2.) The parties at times each offered more than one claim construction for a claim term; slightly altered the term to be construed which added to the total number; and requested construction of terms found within an agreed-to claim construction. Confronted with this morass of material, the Court was required to extensively prepare for a day-long *Markman* hearing. At the *Markman* hearing, the parties agreed to the claim construction of five terms and dropped their request to construe other terms, leaving 29 distinct terms to be construed. However, this still left much work before the Court could issue this opinion.

Without question, the parties, with knowledge of the ultimate comparison of the products, made partisan presentations of claim constructions so as to position their respective inventions favorably for the ultimate determination on the merits. However, the Court is asked to construe these terms in a relative vacuum, without regard to the claim construction's impact upon the ultimate questions presented in this case. In other words, the Court is apparently not allowed to ask "What difference does it make?" Though the judicial labor necessitated by this project has been extraordinary, the Court has endeavored to construe (or not construe as the

case may be) the claim terms presented as warranted. One can only hope, if this case proceeds further, that the parties will hone their presentations and focus upon only those essential matters truly needing adjudication.

It is hereby

ORDERED:

1. Absent further Order, further proceedings will be consistent with this Order.

2. No later than **February 21, 2008**, any party may file a motion for reconsideration of this Order, pointing out any error of fact or law it believes the Court has made. The motion will be limited to ten (10) pages, 13-point font and no footnotes. If a motion is filed, the opposing party may respond by **March 10, 2008** with the identical page and formatting limitations. This Order will become final following the Court's ruling on any motion for reconsideration.

3. No later than **March 10, 2008**, the parties will file a joint status report detailing their plans for further proceedings and scheduling of this case.

DONE AND ORDERED at Jacksonville, Florida, this 4th day of February, 2008.

jl.
Copies to:
Counsel of Record