United States District Court,
D. Delaware.

WESLEY JESSEN CORPORATION,
Plaintiff.
v.
BAUSCH & LOMB, INC,
Defendant.

No. CIV.A. 01-294-RRM

June 26, 2002.

Patentee brought infringement action against competitor over invention relating to monomer for making contact lenses and contact lens materials. The District Court, McKelvie, J., held that: (1) phrase "first portion for increasing wettability" was not limited to acrylic structure set out in formula or patent specification; (2) phrase could not be construed as means plus function claim; (3) competitor's products literally infringed on claim; (4) accused substance infringed under doctrine of equivalents; (5) competitor did not willfully infringe upon patent; (6) patent claims were not anticipated by prior art; and (7) permanent injunction would issue to prevent competitor from infringing on patent.

Ordered accordingly.

5,563,184. Cited As Reference.

Andre G. Bouchard, Karen L. Pascale, Bouchard, Margules & Friedlander, Wilmington, Delaware; Raphael V. Lupo, Charles R. Work, Kenneth L. Cage, Thomas P. Steindler, Daniel Bucca, McDermott, Will & Emery, Washington, D.C.; counsel for Wesley Jessen Corporation.

Jack B. Blumenfeld, Morris, Nichols, Arsht & Tunnell, Wilmington, Delaware; Edward W. Remus, Priscilla F. Gallagher, Alejandro Menchaca, Troy A. Groetken, McAndrews, Held & Malloy, Ltd., Chicago, Illinois; counsel for Bausch & Lomb, Inc.

OPINION

MCKELVIE**, District Judge.**

This is a patent case. Plaintiff Wesley Jessen Corporation is a Delaware corporation, with its principal place of business in Des Plaines, Illinois. Wesley Jessen is the owner of U.S. Patent No. 4,711,943 (the "3 patent), which relates to a monomer for making contact lenses and contact lens materials.

Defendant Bausch & Lomb, Inc. is a New York corporation with its principal place of business in Rochester, New York. Bausch & Lomb manufactures and sells an extended wear contact lens under the trade name PureVision.

By a complaint filed on May 3, 2001, Wesley Jessen alleges that by manufacturing and selling its PureVision line of contact lenses Bausch & Lomb is wilfully infringing ten claims of the "3 patent. Bausch

& Lomb answered the complaint by denying infringement, asserting certain affirmative defenses and counterclaiming for a declaratory judgment it does not infringe and that the asserted claims are invalid and unenforceable.

Pursuant to an agreement between the parties, this case was tried to the court, beginning on May 29, 2002. During the trial, Wesley Jessen presented evidence and argument in support of its contention Bausch & Lomb infringed certain claims of the patent either literally or under the doctrine of equivalents, and as a remedy sought injunctive relief and an award of fees and costs based on Bausch & Lomb's alleged willful conduct. Bausch & Lomb responded by presenting evidence and argument in support of its contention that it does not infringe the claims of the patent, either literally or under the doctrine of equivalents, and that the claims of the patent are invalid as anticipated by U.S. Patent No. 4,260,725 issued to Keogh, et al. (the '725 or Keogh patent), and as obvious in light of a number of patents, including Keogh and U.S. Patent Nos. 4,235,985 issued to Tanaka (the '985 or Tanaka patent). Bausch & Lomb also offered evidence and argument in support of its contention that the claims of the "3 patent are invalid for failure to disclose the best mode, for lack of enablement, for lack of utility, and for indefiniteness of the claims. Last, Bausch & Lomb offered evidence and argument in support of its contention the claims of patent should be unenforceable for the inventor's inequitable conduct in failing to disclose material information to the examiner during the prosecution of the patent. Wesley Jessen responded to each of these defenses. The parties completed presenting evidence on June 3, 2002 and submitted closing arguments the following day.

This is the court's post trial opinion.

I. *FACTUAL AND PROCEDURAL BACKGROUND*

The court draws the following facts from the pretrial order and from the evidence presented at trial, including the evidence presented during the April 5, 2002 claim construction hearing.

A. *The Field of the Invention and* the "3 Patent

The application that led to the "3 patent was filed in 1985 and relates to contact lens materials and contact lenses fabricated therefrom that have a combination of properties not achieved prior to the invention. The "3 patent addressed problems experienced in the contact lens industry in the early eighties that related to developing a comfortable contact lens that could be worn for longer periods of time.

As noted in the background section of the "3 patent, the contact lens market in the early 1980s consisted of three basic types of contact lenses: (1) rigid, non-gas permeable lenses, (2) soft hydrogels, and (3) rigid, gas-permeable lenses. As detailed below, each of these contact lenses had certain deficiencies that made them generally unsuitable for extended wear use. Lenses suitable for extended wear must be optically transparent, possess chemical and thermal stability, be wettable to tears, permeable to oxygen, and be comfortable, durable, and easy to handle.

The first contact lenses developed as a substitute for eyeglasses were rigid and non-gas permeable lenses, which were made from materials such as polymethyl methacrylate (PMMA or polyMMA). Rigid PMMA lenses have acceptable surface wettability when used in conjunction with wetting solutions, and excellent durability, but lack sufficient oxygen permeability for extended wear. Because there is a lack of blood vessels within the cornea, the cornea must obtain oxygen directly from the atmosphere. If a contact lens does not have sufficient oxygen permeability, placing it over the cornea will result in corneal swelling and discomfort. Although the PMMA lenses blocked the natural flow of oxygen to the cornea, sufficient oxygen would usually be transported to the wearer's cornea by tear film generated between the lens and the cornea through normal blinking. Oxygen deprivation was a problem, however, when the wearer was asleep and, therefore, not blinking.

In the late 1970's and early 1980's, people in the content lens industry began to develop extended wear contact lenses from soft hydrogel materials, such as poly (2-hydroxyethyl)methacrylate (HEMA). These lenses improved oxygen permeability by significantly increasing the water content of the materials. They also possessed excellent wetting characteristics, which made them very comfortable to wear. However, the high water content caused the lenses to soften, drape, and sag in a way that good optical resolution was difficult, and they tended to tear when handled and were subject to increased protein deposits on the lenses.

People in the industry also sought to develop rigid, gas-permeable lenses made primarily with siloxane-containing components. These lenses were not a commercial success. They would dry and irritate the eye, as the siloxane materials tended to be hydrophobic, which meant water would bead on the lens rather than form a film on its surface.

Thomas B. Harvey, III filed an application with the United States Patent and Trademark Office ("PTO") on April 26, 1985, entitled "Hydrophilic Siloxane Monomers FN1 and Dimers for Contact Lens Materials and Contact Lenses Fabricated Therefrom." Harvey sought to combine the desirable properties of the three aforementioned types of lens materials into one contact lens material that had the dimensional stability of rigid non-gas-permeable lenses, the comfort of silicone hydrogels, and the oxygen permeability of gas-permeable lenses. In his patent application, Harvey reviewed the history of developments relating to contact lenses and limitations that were restricting the uses of extended wear lenses. This history demonstrated that attaining a combination of desirable properties in a single material had been particularly problematic since the addition of one component to improve a desirable property, such as adding a siloxane to improve oxygen permeability, had tended to adversely affect other desirable properties, such as wearer comfort.

FN1. A monomer is a molecule that has the capability of joining with a similar molecule to form a chain. In simplest terms it is a building block. By replicating a monomer one can build a molecule with many units, called a polymer or a macro molecule.

The invention of the "3 patent sought to solve these problems by teaching the making of siloxane-containing hydrogel monomer for making contact lenses having both improved oxygen permeability and dimensional stability. Harvey described his invention as including the use of a monomer that combined a hydrophilic group and a siloxane into a single monomer to form a strong, highly oxygen-permeable silicone hydrogel material that did not depend solely on water content for its oxygen permeability. The hydrophilic group could be an amid or a carbamate. He reported that the invention made it possible to maintain high oxygen permeability without having the high water content of earlier extended wear lenses and the problems of physical deformation that normally accompanied high water content lenses. Harvey characterized his claimed contact lens materials as having a specified range of (i) water content, (ii) oxygen permeability, (iii) tear strength, and (iv) percent elongation.

Harvey summarized the objects of the invention as follows:

An object of the present invention is to provide new and useful hydrophilic siloxane-containing monomers for making contact lenses.

Another object of the invention is to prepare hydrogels from the monomers of the foregoing type which have moderate water contents (about 15-60%), but high oxygen permeabilities [greater than about Dk 25 x 10^{-10} (Dk is measured in units of cm ^{3} (O_2) cm/cm ^{2} sec. cm Hg)].

A further object of the invention is to provide a contact lens having improved wettability, characterized by a receding contact angle of less than that of contact lenses made of polyMMA.

Still another object of the invention is to provide a hydrophilic siloxane copolymer, suitable for the

fabrication of extended wear contact lenses, and having the following characteristics:

(1) moderate water content [about 15-60%];

(2) high oxygen permeability [Dk greater than about $25x10^{-10}$];

(3) tear strength greater than about 1.0 g/mm^2;

(4) percent elongation greater than or equal to about 80%;

(5) wettable; and

(6) minimal protein deposit formation.

"3 patent, col. 3, l. 49-col. 4, l. 8.

B. ***Prosecution History of*** the "3 Patent

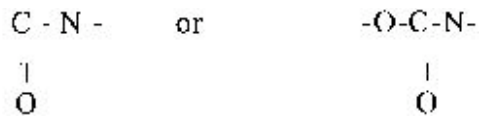
The "3 patent was originally filed as Application Serial No. 06/727,501 on April 26, 1985. The original application, as amended, contained 63 claims, directed to three subclasses or groups, contact lens material, organic compound synthesis, and copolymers.

In an Office Action dated August 22, 1985, the Examiner noted the claims had been incorrectly numbered and required that the applicant elect one of the three groups for prosecution. The applicant elected to prosecute the claims directed to the contact lens material.

Claim 1 read as follows:

1. A contact lens material having improved oxygen permeability and stability; said contact lens material comprising a monomer having:

a first portion for increasing wettability, said first portion being hydrophilic and including a side-chain functionality selected from the group including the following structural formulae:



and
a second portion for increasing oxygen permeability, said second portion including a siloxane.

In an Office Action dated August 23, 1985, the Examiner allowed certain claims and rejected others as being unpatentable over U.S. Patent No. 4,495,361 to Friends et al. ("Friends") either alone or in view of U.S. Patent No. 2,929,829 to Morehouse ("Morehouse"), and as indefinite on the ground that it was not clear whether the claims covered monomers as well as polymers.

Harvey responded by arguing that Friends does not teach monomers that contain a siloxane, a required element of each of the pending claims, and that amino acid compounds of Friends were not contact lens

materials. He sought to distinguish Morehouse on the ground that it does not teach contact lens materials. On the issue of indefiniteness, Harvey responded that the rejected claims covered monomers and added certain new claims to cover the corresponding polymers.

By an Office Action dated March 17, 1986, the Examiner again rejected claims 1 through 14 as indefinite and suggested Harvey amend them to specify that only monomers were encompassed by the claims. The Examiner also rejected certain claims as being anticipated by Newell and other claims as being obvious over Newell, or U.S. Patent No. 3,652,629 to Fort ("Fort"), or U.S. Patent No. 3,249,461 to Te Grotenhuis ("Te Grotenhuis") in view of Friends alone, or together with U.S. Patent No. Re. 31,406 to Gaylord ("Gaylord").

In response, Harvey filed a paper on July 16, 1986, amending claim 1 to clarify that monomers were being claimed to obviate the rejection of indefiniteness. In response to the rejection based on the prior art, Harvey argued that Newell, Fort, and Te Grotenhuis, disclose the use, in one fashion or another, of siloxane compounds having either an amide or carbamate, but were either not directed to contact lens materials or to the hydrophilic siloxane monomer and that the secondary references failed to cure these deficiencies. He also argued that the primary references were concerned with (1) electro-optical light transmitting coatings and adhesives in an industrial environment; (2) lubricants for fibers and plastics; and (3) hydrolyzable siloxanes. Harvey also argued that the secondary references did not provide direction for modifying the primary references to arrive at the pending claims. In particular, he cited Gaylord as an example this, noting that Gaylord teaches the use of a separate co-monomer to provide wettability, whereas his patent application teaches incorporating an amide or urethane (carbamate) moiety in the monomer structure itself.

On September 16, 1986, the Examiner again rejected all the pending claims either as anticipated by Newell or obvious over the previously cited combination of art, noting that the use of the co-monomers in the secondary references with the nitrogen-silicone containing monomers of the primary references would be, *prima facie,* obvious in contact lens manufacture.

Thereafter, the Examiner indicated he would allow claims limited to the physical properties as defined in dependent claim 48 and which distinguish over optical fibers. Applicant then filed a Notice of Appeal and later filed an amendment after the Appeal to amend independent claims: 1, 19, 25, 26, 27, 64, and 82 to distinguish the claims over optical fibers, to include a specified range of oxygen permeability, water content, tear strength, and percent elongation, and to clarify that claim 1 was directed to a polymeric material.

A Notice of Allowance issued on April 23, 1987, and the application matured into U.S. Patent 4,711,943 on December 8, 1987.

C. *The Claims at Issue*

The "3 patent contains 73 claims, 7 of which are independent and 66 of which are dependent. Wesley Jessen is asserting 4 independent claims: 1, 19, 27 and 50, and 6 dependent claims: 11, 14, 54, 57, 60, and 63.

Most of the asserted claims center on: (a) a first portion for increasing wettability; (b) a second portion for increasing oxygen permeability; and (c) four physical properties of the resulting contact lens material or contact lens, including moderate water content (15-60%), good oxygen permeability (Dk greater than or equal to 25×10^{-10}), and good physical stability measured by tear strength and percent elongation. Claims 19, 54 and 57 specifically claim an acrylic structure.

Claims 1, 27, and 50 are independent claims and all cover polymeric material comprising a monomer having a designated hydrophilic first portion (which is a combination of an amide or a carbamate) and a designated siloxane second portion. Claims 2 through 13 are dependent claims that depend from claim 1.

Independent claim 1, a composition of matter claim, recites:

1. A non-fibrous polymeric contact lens material having

improved oxygen permeability and stability, said polymeric contact lens material comprising a monomer having the following structural formula:

first portion for increasing wettability, said first portion being hydrophilic and including a side-chain functionality selected from the group including the following structural formulae:

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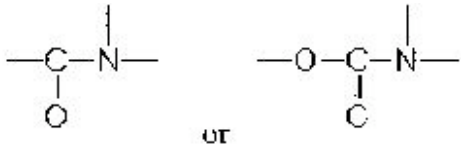


or

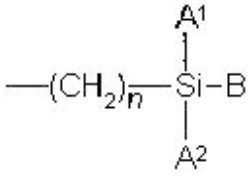
and

and
a second portion for increasing oxygen permeability, said second portion including a siloxane;

wherein: said material has a water content of about 15-60%; Dk greater than or equal to about 25 x 10^{-10}; tear strength greater than or equal to about 1.0 g/mm ^{2}; and percent elongation greater than or equal to about 80%.

Claims 11 and 14 depend from claim 1, claim a composition of matter and article claim respectively. Claim 11 limits the second portion to a particular siloxane structure. Claim 14 is a contact lens made from the material described in claim 1. They read as follows:

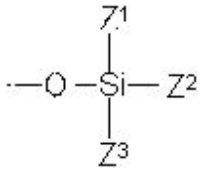
11. The contact lens material of claim 1 wherein said second portion comprises the following structural formula:



wherein:
n is 3;

A ^{1} and A ^{2} are the same or different and are selected from lower alkyl and B groups; and

B has the following structural formula:



wherein:
Z^1, Z^2 and Z^3 are CH_3.

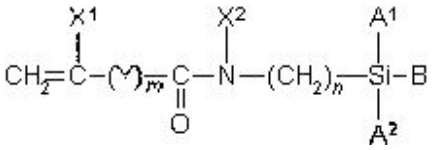
14. A contact lens formed from the contact lens material of claim 1.

Independent claim 19 is not stated in terms of a first and second portion, but rather shows a general chemical structure for a monomer with contains both portions. The general chemical structure is an acrylic, either a (meth)acrylamide or a (meth)acrylcarbamate. This structure is also depicted in Formula III in the patent specification as one of the preferred embodiments of the invention. Formula III is composed of a combination of Formula I and Formula II. *See* "3 patent, col. 6, ll. 60-65. It reads:

19. A non-fibrous polymeric material for making a contact lens

with improved oxygen permeability and stability, said contact lens material comprising

a monomer having the following structural formula:



wherein:
X^1 is CH_3 or H;

X^2 is CH_3 or H;

m is 0 or 1; and

Y is selected from the group consisting of the following structural formulae, the radical shown on the left of each formula being bonded to the carbon shown on the left of Y in the above formula;

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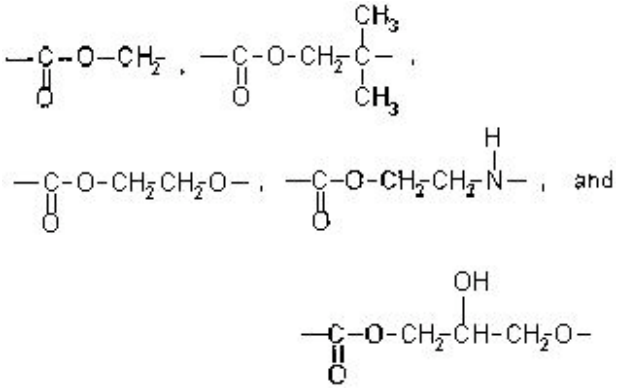
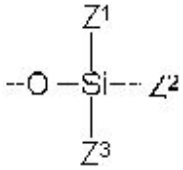


wherein:
n is an integer from 1 to 6;

A^1 and A^2 are the same or different and are selected from lower alkyl and B groups; and

B has the following structural formula:



wherein:
Z^1, Z^2 and Z^3 are the same or different and are selected from the group consisting of lower alkyl, phenyl, benzyl and tri-alkyl-siloxy substituents; and

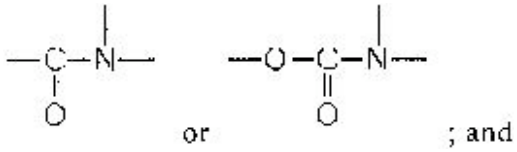
wherein: said material has a water content of about 15-60%; Dk greater than or equal to about 25 x 10^{-10}; tear strength greater than or equal to about 1.0 g/mm^2; and percent elongation greater than or equal to about 80%.

Independent claim 27 describes a polymeric material comprising a monomer with a first and second portion and with four physical properties as in claim 1, but differs from claim 1 in also claiming a second monomer, a crosslinking agent and a polymerization initiator. It reads:

27. A non-fibrous contact lens material comprising the copolymerization product of:

(a) a first monomer having:

a first portion for increasing wettability, said first portion being hydrophilic and including a side-chain functionality selected from the group consisting of the following structural formulae:



a second portion for increasing oxygen permeability, said second portion including a siloxane;
(b) a second monomer, copolymerizable with said first monomer;

(c) a crosslinking agent; and

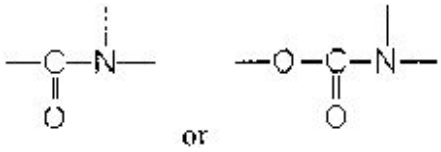
(d) a polymerization initiator; and

wherein: said material has a water content of about 15-60%; Dk greater than or equal to about 25 x 10^{-10}; tear strength greater than or equal to about 1.0 g/mm ^{2}; and percent elongation greater than or equal to about 80%.

Independent claim 50 is similar to claim 1, but claims a material comprising a polymer (rather than a monomer) formed from "at least" a monomer having the first and second portions, with the material having the four physical properties. It reads:

50. A non-fibrous contact lens material having improved oxygen permeability and stability, said contact lens material comprising a polymer formed from at least a monomer having:

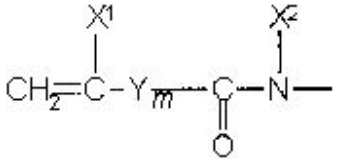
a first portion for increasing wettability, said first portion being hydrophilic and including a side-chain functionality selected from the group including the following structural formulae:



and a second portion for increasing oxygen permeability, said second portion including a siloxane;
wherein: said material has a water content of about 15-60%; Dk greater than or equal to about 25 x 10^{-10}; tear strength greater than or equal to about 1.0 g/mm ^{2}; and percent elongation greater than or equal to about 80%.

Dependent claims 54 depends on claim 50 and limits the first portion of the monomer to acrylics-either a (meth)acrylamide or a (meth)acrylcabamate. It reads:

54. The contact lens material of claim 50 wherein said first portion comprises the following structural formula:

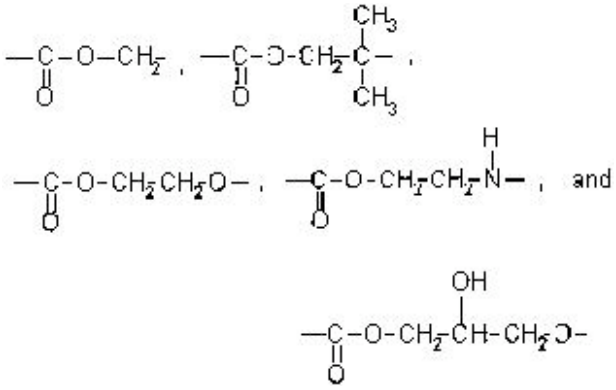


wherein:
X^1 is CH_3 or H;

X^2 is CH_3 or H;

m is 0 or 1; and

Y is selected from the group consisting of the following structural formulae, the radical shown on the left of each formula being bonded to the carbon shown on the left of Y in the above formula:



Claim 57 depends from Claim 54 and limits the second portion to particular siloxane structures. It reads:

57. The contact lens material of claim 50 wherein said first portion comprises the following structural formula:

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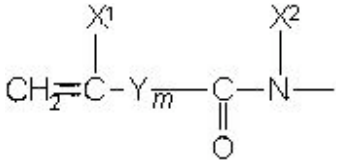
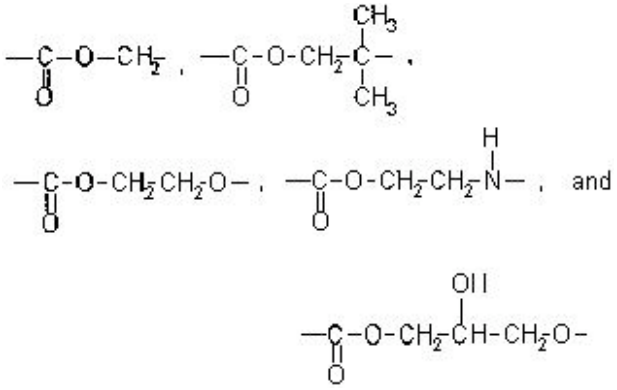


wherein:
X^1 is CH_3 or H;

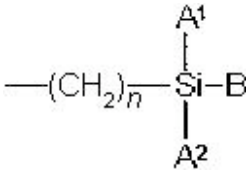
X^2 is CH_3 or H;

m is 0 or 1; and

Y is selected from the group consisting of the following structural formulae, the radical shown on the left of each formula being bonded to the carbon shown on the left of Y in the above formula:



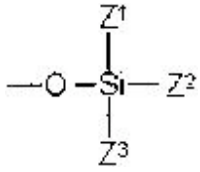
wherein said second portion comprises the following structural formula:



wherein:
n is an integer from 1 to 6;

A^1 and A^2 are the same or different and are selected from lower alkyl and B groups; and

B has the following structural formula:

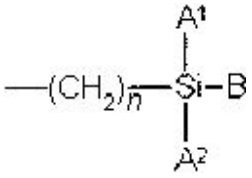


wherein:

Z^1, Z^2 and Z^3 are the same or different and are selected from the group consisting of lower alkyl, phenyl, benzyl and tri-alkylsiloxy substituents.

Claim 60 depends from claim 50 and more narrowly limits the second portion of the monomer to a specific species of siloxane structures. It reads:

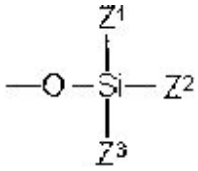
60. The contact lens material of claim 50 wherein said second portion comprises the following structural formula:



wherein:
n is 3;

A^1 and A^2 are the same or different and are selected from lower alkyl and B groups; and

B has the following structural formula:



wherein:
Z^1, Z^2 and Z^3 are CH_3.

Claim 63 is the contact lens made from the material of claim 50. It reads:

63. A contact lens formed from the contact lens material of claim 50.

The specification of the "3 patent contains nine preferred embodiments of the hydrophilic siloxane monomers, five are preferred embodiments of the dimers, and over sixty examples of materials made from two of the preferred monomers, as well as fifteen tables describing the physical properties of each formed material.

D. ***The Bausch & Lomb Accused Products***

Bausch & Lomb's PureVision silicone hydrogel contact lens is made from a non-fibrous polymeric contact lens material called "Balafilcon A." Wesley Jessen contends that Bausch & Lomb's PureVision contact

lenses, as well as Balafilcon A, infringe the asserted claims of the "3 patent.

According to Bausch & Lomb, "Balafilcon A is a copolymer of a silicone vinyl carbamate, N-vinyl-prryolidone, a siloxane cross-linker and a vinyl alanine wetting monomer..." Balafilcon A, and hence PureVision contact lenses, are made by the copolymerization of at least two monomers, one of which is a monomer known as Tris(trimethylsiloxy)silylpropyl vinyl carbamate or TRIS-VC. As is apparent from its complete chemical name, TRIS-VC is a silicone vinyl carbamate monomer.

E. ***The Trial***

During trial, the parties directed their attention to five issues. First, whether, as Wesley Jessen contends, the claims cover a vinyl carbamate such as TRIS-VC, the material in Bausch & Lomb's PureVision lens, or, as Bausch & Lomb contends, the claims are limited to acrylics. Second, whether Wesley Jessen has proved Bausch & Lomb's Balafilcon A monomer has "a first portion for increasing wettability." Third, whether, as Bausch & Lomb contends, Dr. Harvey's invention was anticipated by the Keogh '725 patent or would have been obvious in light of the Keogh '725 patent and the Tanaka '985 patent. Fourth, whether, as Bausch & Lomb contends, Dr. Harvey was never able to demonstrate that his material was suitable for contact lenses and that he failed to disclose to the Patent and Trademark Office the most successful test he did conduct was with an oxygen plasma treatment. It argues these facts suggest the claims of the patent are invalid for lack of enablement and a failure to disclose best mode, or unenforceable due to inequitable conduct. Finally, Wesley Jessen asks the court to draw a negative inference from Bausch & Lomb's failure to disclose an opinion it sought from counsel on whether it infringed the claims of the Harvey Patent and find Bausch & Lomb is willfully infringing the patent.

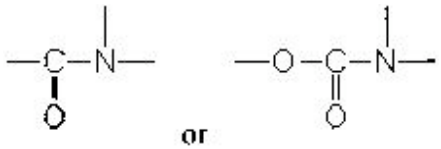
The parties offered the following evidence at trial on these matters.

1. ***Infringement***

a. ***Literal Infringement***

Wesley Jessen called Dr. Harvey to testify in support of its infringement case. Dr. Harvey testified that in June of 1981 he was working at Syntex Ophthalmics when he conceived the idea for and began working on developing a hydrophilic siloxanemonomer for use in contact lens materials. His goal was to improve the hydrophilicity and oxygen permeability of the lens materials. A further object of the invention was to provide a contact lens material with improved wettability. Harvey's idea was to combine the properties of siloxane with the properties of hydrogels in a single monomer that would contain a hydrophilic portion, a siloxane portion, and a polymerizable group. This approach, to develop a hydrophilic siloxane-containing monomer that could be incorporated into a hydrogel, could provide a lens with increased oxygen permeability that does not have a high water content, because the hydrogel would not depend solely on water for its oxygen permeability.

By 1985, Harvey had developed a material he described by a structural formula that is set out in claim 1 of the patent. It has a first portion for increasing wettability. He described and claimed that first portion as: "said first portion being hydrophilic and including a side-chain functionality selected from the group including the following structural formulae":



The monomer also has a second portion that Harvey described and claimed as: "a second portion for increasing oxygen permeability, and said second portion including siloxane." He also characterizes the material as "ha[ving] a water content of about 15-60%, Dk [a measure of oxygen permeability] greater than or equal to about $25x10^{-10}$, tear strength greater than or equal to about 1.0 g/mm(2), and percent elongation greater than or equal to about 80%."

Dr. Harvey reported that in testing the material he needed a proxy to test wettability in the eye and used a test that measured a receding contact angle, which he referred to as a wetting angle or a contact angle. The "3 patent thus characterizes improved wettability as having "a receding contact angle of less than that of contact lenses made of polyMMA [PMMA, the substance used in hard lenses]." "3 patent, col. 3, ll. 59-62.

Wesley Jessen called Dr. Lynn Winterton to testify on tests he performed to establish that Bausch & Lomb's PureVision has "increased wettability," as required by the asserted claims. Dr. Winterton is the analytical group director in surface chemistry and surface modification at Wesley Jessen's corporate parent CIBA Vision. He has a Ph.D. in material science and engineering from the University of Utah. Dr. Winterton concluded, based on his tests, that the PureVision lens material Balafilcon A has "increased wettability" over the material used in rigid non-gas permeable materials, PMMA.

Dr. Winterton testified that in his patent Harvey describes using a test called the Wilhelmy Plate Methodology to measure wettability. Under that test, a sample of material is suspended from an electro-balance and is either lowered into a fluid or the fluid is raised up to it to create a wavefront, from which contact angles can be measured. The smaller the receding contact angle, the more wettable the substance. Harvey used this test on hydrated material and measured a receding contact angle, which would be less than that of a contact lens material made with PMMA. Winterton confirmed that in 1985, receding contact angle measurements were the most accurate methodology to determine wettability using water.

Dr. Winterton explained that the receding contact angles of PMMA is not a fixed number, but depends on the processing history of the sample. Dr. Winterton testified that he performed the Wilhelmy Plate test on hydrated samples of PMMA and determined that PMMA had a receding angle of 46 degrees. He performed the same test on untreated samples of hydrated PureVision material and found that it had a receding angle of 21 degrees. He noted that these results confirm that the non-plasma treated PureVision lenses have a lower contact angle (and thus are more wettable) than PMMA.

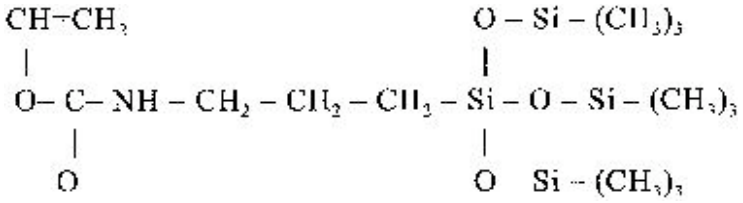
Dr. Winterton next testified as to a Sessile Drop test that he conducted on both untreated PureVision lenses and the treated PureVision commercial product. Under the Sessile drop test, he used a syringe to place water on the samples and then to withdraw that water, while measuring the advancing and receding contact angles. He testified that the results from this test were comparable to the results he obtained using the Wilhelmy Plate method. The Sessile Drop tests also demonstrated that the PureVision material was more wettable than PMMA. While the PMMA had a receding angle of 53 degrees, the untreated PureVision had an average receding angle 17 degrees. The average receding angle for the commercialized product was 11 degrees.

For a third set of tests, Bausch & Lomb brought to CIBA Vision three films characterized as PMMA, TRIS, and TRIS-VC. These films were hydrated prior to Dr. Winterton performing the contact angle measurements. He testified that a dynamic Sessile Drop method was performed as a substitute for the Wilhelmy Plate method because the samples produced by Bausch & Lomb were not amenable to the Wilhelmy Plate technique. Dr. Winterton explained that the "3 patent reports static and dynamic (i.e., advancing and receding) contact angles and that the Wilhelmy Plate method was used to record dynamic contact angles, while the Sessile Drop technique was used to record static contact angles. Dr. Winterton testified that the dynamic sessile mode gives values for receding contact angles that are comparable to the Wilhelmy Plate method and reported that the measurements of the receding contact angles of PMMA

obtained by that method were comparable to the Wilhelmy Plate method. He further reported that the average receding angle for TRIS by the dynamic sessile technique was 64 (deg.), while the average receding angle for TRIS-VC was 40 (deg.). Dr. Winterton concluded that these results show that TRISVC is more wettable than TRIS. He opined that the lower receding contact angle of TRIS-VC as compared to TRIS was due to the presence of the carbamate.

Wesley Jessen called Dr. Murray Goodman as a technical expert. Dr. Goodman is a professor of Chemistry and Biochemistry at the University of California at San Diego. He testified that Dr. Harvey's polymer had "a first portion for wettability," which is made up of a hydrophilic grouping of oxygen, carbon and nitrogen and could be an amid or a carbamate. The first portion of the polymer is complimented by a second portion that is designed to increase oxygen permeability or oxygen transport. This second portion is a hydrophobic oxygen transporting siloxane. The two portions are polymerized, or joined, to make the monomer.

Dr. Goodman described the structure of the Balafilcon A polymer in Bausch & Lomb's PureVision line of contact lenses. It includes a vinyl acrylic tinting agent, dimethiacryl antiquineone, which adds color to the lens, and cross linked chains with a TRIS-VC monomer, a vinyl pyrrolidone, and a vinyloxycarbonyl alanine derivative. The TRIS-VC monomer includes siloxane and a carbamate as side chains. It has the following structure:



Dr. Goodman testified that Balafilcon A meets each of the limitations in the claim 1. It is a non-fibrous contact lens material with improved oxygen permeability and stability. It has a water content between 15 and 60 percent, a Dk greater than or equal to 25 times 10^{-10}, a tear strength greater to or equal to 1 gram per square millimeter, and an elongation greater than or equal to 80 percent. It is a polymeric material comprising a monomer. The TRIS-VC component has a first portion for wettability that is hydrophilic, and a carbamate or amide with a side chain functionality selected as identified in the claim. Dr. Goodman testified that a carbamate is hydrophilic, which has the characteristic of increasing wettability. He further testified that Dr. Winterton's report established that the TRIS-VC is more wettable than TRIS, using the comparison of receding contact angles used to characterize increased wettability in the patent.

In the context of claim construction, Dr. Goodman testified that a person of ordinary skill in the art would be a person holding a Ph.D. or have approximately four years of experience in the field of contact lens research or its equivalent. That person would understand Harvey's invention and the claims as follows. Harvey claims a monomer with a first portion for wettability, which is made up of a hydrophilic grouping, identified in the claim as either an amid or a carbamate, each of which is a specific grouping of oxygen, carbon and nitrogen. This first portion is complimented by a second portion, designed to increase oxygen permeability, that includes a siloxane. He notes that a person of ordinary skill in the art would understand that there needs to be a polymerizable entity appended to make the polymer. In the context of the claim, a person of ordinary skill in the art would understand that, with an appropriate initiator, a vinyl or acrylic would be that polymerizer. Vinyl and acrylic are both C double bond C and they polymerize through a chain growth process by a free radical initiator. They are in many ways interchangeable, as acrylics are a subset of vinyls. While in examples in the patent, Harvey identifies acrylics as the C double bond C polymerizable

group, one of ordinary skill in the art would understand the patent teaches one to use a vinyl.

As noted above, Dr. Goodman relied on certain testing done by Dr. Lynn Winterton, to confirm that the Balafilcon A has improved wettability as claimed in the patent. That is, the patent provides that the improved wettability of the claimed material would be characterized by a receding contact angle of less than that of the contact lenses made from the material used in hard contact lenses, PMMA. He testified that Dr. Winterton's tests showed that the vinyl carbamate group of TRIS-VC was more wettable than TRIS, and attributed that wettability to TRIS-VC containing a hydrophilic carbamate.

Dr. Goodman testified that the TRIS-VC component of Balafilcon A has a second portion for increasing oxygen permeability, with the second portion including a siloxane.

He concluded that, based on this analysis and his understanding of the claims, Bausch & Lomb's Balafilcon A infringes each of the following claims asserted by Wesley Jessen: claims 1, 11, 14, 27, 50, 60 and 63.

Bausch & Lomb responded to Wesley Jessens' evidence on literal infringement with testimony from Dr. George Grobe, III, who questioned Dr. Winterton's tests on wettability and with testimony by Dr. William H. Daly who responded to Dr. Goodman's testimony on literal infringement.

George L. Grobe, III, is a director of materials and surface science at Bausch & Lomb. He testified he had tested dry films of TRIS and TRIS-VC for wettability under a refined Sessile Drop methodology called a Zisman plot, where liquids are placed on a solid surface, and a contact angle can be measured. Under the Zisman methodology, measurements of contact angle made where the probe is inserted are excluded. He reported that by this test, the wetting characteristics of TRIS and TRIS-VC were the same. However, on cross examination he conceded that his test results in Def. Ex. 109 do indicate a difference-TRIS-VC is reported as having a contact angle of 99 (deg.), while TRIS is reported as having a contact angle of 113 (deg.).

Grobe further testified he had reviewed Dr. Winterton's test under the Sessile Drop method and concluded it was not useful, as the probe Dr. Winterton used influenced and distorted the shape of the drop. Grobe further testified that by his definition, in his testing, fully processed PureVision lenses are hydrophobic, notwithstanding the fact that Bausch & Lomb advertises its PureVision lenses to the world as hydrophilic. *See* Pl.Ex. 733 (PureVision brochure stating that "The Bausch & Lomb PureVision (Balafilcon A) Visibility Tinted Contact Lens is a soft hydrophilic contact lens."). Dr. Grobe testified that a contact angle of 90 (deg.) indicates a hydrophobic lens and that his opinion is consistent with Bausch & Lomb's PureVision Global Training Program, which indicates that the water wetting angle of a completely hydrophobic lens is about 110 (deg.). He conceded, however, that Balafilcon A, the bulk material of PureVision, is defined by the USP Dictionary of USAN International Drug Names (1998) as being hydrophilic.

Dr. Daly, who has a Ph.D. in polymer chemistry and is a Professor of Chemistry at LSU, testified that Bausch & Lomb's material and lenses do not infringe, as TRIS-VC is an vinyl monomer, not an acrylate, and does not correspond to the structural formula in claim 1. He testified that the vinyl groups and the acrylate groups will not behave the same when used to make a copolymer system. To obtain a good contact lens material, one that is clear, one needs to have a good distribution of the co-monomers in a given polymer chain. When one changes from an acrylic as identified by Harvey in the patent to a vinyl monomer, one will not get a good distribution of the co-monomers and will get a poor lens material.

In addition, Dr. Daly looked to Dr. Grobe's tests to confirm that TRIS-VC does not increase wettability. He further testified in support of Bausch & Lomb's position that as used in the patent the term "wettability" means wettable enough to be able to be inserted into the eye without causing discomfort to the patient as it is the wettability in a patient's eye that determines whether a material may be used for contact lenses.

Bausch & Lomb argued that the claims of the "3 patent should be limited to the specific embodiments disclosed in the specification, which are acrylics. Specifically, Bausch & Lomb reads the section at column 5 of the patent titled "Detailed Description of Preferred Embodiments" as describing the first portion as in claim 1 and as reporting that this first portion has the general structure shown in Formula I, which is an acrylic. Bausch and Lomb reaches this conclusion by finding that the applicant adopted this construction when he stated that the first portion for wettability as claimed has the general structure shown in Formula I. Second, it argues that this must be the structure for the first portion as the applicant did not identify any other structure that would justify a broader claim construction. Third, Bausch & Lomb argues that if there is no structure tied to the claims, the "first portion for increasing wettability" is a means-plus-function element and must be limited to the structures disclosed in the specification.

b. ***Infringement Under the Doctrine of Equivalents***

Dr. Goodman also testified for Wesley Jessen on whether the PureVision lens and Balafilcon A infringe under the doctrine of equivalents. Goodman explained that the differences between independent claim 50 and claim 54 (and, by logical extension, claim 57 which depends from claim 54) is that claim 54 specifically claim acrylics for the polymerizable portion of the monomer. As noted above, he opined that one skilled in the art could substitute an acrylic monomer for TRIS-VC (a vinyl monomer) in Balafilcon A and come up with an equivalent material and that one skilled in the art would know that interchangeability of that sort could be accomplished.

Goodman testified that an acrylic is a specific type of vinyl compound. He explained that both vinyls and acrylics have the vinyl grouping CH_2=CH-. Vinyls have an unspecified compound bonded to CH, while in acrylics that compound is C=O. *See* Pl.Ex. 721 (quoting definition of "vinyl compound" from Hawley's Condensed Chemical Dictionary (13th ed.1997)). He also noted that using a material that has a vinyl carbamate group imparts a more wettable, hydrophilic character to the material. To support that general proposition he cited to an article written by Bausch & Lomb witness Jay F. Kunzler. *See* Pl.Ex. 713 (article entitled "Silicone-based Hydrogels for Contact Lens Application," which was published in the August 1999 edition of Contact Lens Spectrum notes that "This vinyl carbamate group is hydrophilic. This direct hydrophilic attachment now gives the silicone significant, hydrophilic character.")

Goodman also noted that the chemical structure of one of the Harvey patent's preferred acrylic monomers differs from TRIS-VC only in that TRIS-VC has a single additional oxygen atom, which is not critical to the claimed invention. In comparing the two monomers, he stated: "Both are vinyl structures. They have C double-bond C at the left side of the structures ... one [the Harvey monomer, TSAA] is linked to a carbonyl. The other [TRIS-VC] is linked to an oxygen ... so that an oxygen is the only additional part in TRIS-VC over TSAA."

Goodman further noted that TRIS-VC is synthesized in a substantially identical fashion to the Harvey monomers via a condensation reaction. *See* Pl.Ex. 722-724. Last, he noted that acrylics and vinyls are interchangeable for purposes of the claimed invention, as acrylics can be copolymerized with vinyls and vice versa. Goodman thus concluded that TRIS-VC is an equivalent structure, that performs substantially the same function in substantially the same way.

With regard to claim 19, which is also directed to an acrylic, Goodman noted that his testimony regarding the interchangeability of acrylics and vinyls as discussed in the context of claim 54 is equally applicable to the whole monomer as described in claim 19. He further stated that the difference between TRIS-VC and the monomers described in claim 19 were insubstantial and that one of ordinary skill would know that TRIS-VC and the monomers described in claim 19 are interchangeable. Goodman testified that there are differences between the manner in which vinyls and acrylics copolymerize, but that these differences are not substantial and that, for the purposes of the invention, vinyls and acrylics are interchangeable. Thus, even if TRIS-VC is not identical to the monomer in the first portion in claims 19, 54 and 57, it is used in

substantially the same way as those monomers, with substantially the same structure, performs substantially the same function and that the differences between them are insubstantial.

As further evidence of the interchangeability of vinyls and acrylics, Wesley Jessen relies on a 1995 Bausch & Lomb document, from its Chemical and Material Development Program entitled "Hi-Dk Program Perspective." That document notes that "a vinyl carbonate or carbamate could be used in place of the methacyrlate group for nearly any currently used monomer." Pl.Ex. 725.

Dr. Daly responded to Dr. Goodman's testimony, by testifying that it was his opinion there was no equivalence, as TRIS-VC does not increase wettability and is a substantially different structure than any monomers listed in the Harvey patent. TRIS-VC also exhibits a substantially different reactivity in a copolymerization process than the TRIS amide that is cited in the Harvey patent. He testified that while the TRIS amide as described in the patent can not react with N-vinyl pyrrolidone, TRIS-VC and N-vinyl pyrrolidone copolymerize very cleanly. And when they do, they produce a cloudy, opaque material. Therefore, any attempt to polymerize TRIS-VC with the monomers in the Harvey patent would result in incompatible copolymers. He testified that Bausch & Lomb's work demonstrated this, as it had to design a whole ensemble of new monomers to carry out the polymerization to make Balafilcon A.

In rebuttal, Dr. Goodman explained that he disagreed with Dr. Daly's conclusion that differences in the reactivities of vinyls and acrylics made vinyls non-equivalent. He noted that while this may be true for very simple "textbook" examples of these types of monomers, the reactivities of the complex monomers at issue here are not very different and there would be no problem getting polymerization to take place.

2. ***Validity***

a. ***Anticipation and Obviousness***

In support of its case on invalidity, Bausch & Lomb called Jay F. Kunzler. Dr. Kunzler is a research fellow at Bausch & Lomb. Kunzler has a Ph.D. in macromolecular science from Case Western Reserve University. He is one of the inventors on the Keogh patent, which discloses a variety of hydrophilic side chains that can be employed on siloxane monomers for hydrogels for contact lens applications.

The Keogh patent, introduced as Def. Ex. 118, is entitled "Hydrophilic Contact Lens Made From Polysiloxanes Which are Thermally Bonded to Polymerizable Groups and Which Contain Hydrophilic Sidechains." The invention relates to "a novel polysiloxane water absorbing contact lens." More specifically, the abstract states the patent discloses "[a] water absorbing, soft, hydrophilic, flexible, hydrolytically stable, biological inert contact lens with the capability of transporting oxygen sufficiently to meet the requirements of the human cornea." The invention comprises "a polysiloxane which is (alpha), (omega) terminally bonded through divalent hydrocarbon groups to polymerizably activated unsaturated groups and which contain[s] hydrophilic sidechains ...." Keogh teaches that the claimed contact lenses are to be prepared "from the polymerization of hydrophilic sidechains containing polysiloxane monomers ... to form polymers in a cross-linked network." '725 patent, col. ll. 9-18.

After setting forth a number of formulae embodying the claimed invention, the Keogh patent lists 33 illustrative examples of how to prepare its preferred embodiments. Example V instructs the reader how to measure a number of the physical properties of the resultant film, including oxygen permeability, percent of water, tensile strength, tensile modulus, and percent elongation. The copolymer prepared in accordance with Example V includes a water content of 18%, an oxygen permeability of 6.7×10^{-10} Dk, a tensile strength of 36 g/mm ^{2}, and percent elongation of 84%. A number of the other examples, including Example XXX, state that after following its instructions "[a] soft, water absorbant, hydrophilic, optically clear film is obtained."

Dr. Kunzler testified that he had recently prepared four sample materials pursuant to Example XXX in the

Keogh patent, after modifying and simplifying the monomer and polymer preparations, and concluded that the amide side-chain siloxane polymers described in the patent can be used to prepare low modulus silicone hydrogels possessing a water content of about 15-60%, oxygen permeability (Dk) of greater than or equal to about 25 x. 10^{-10}, as measured by the coulometric technique, with tear strength greater than or equal to about 1.0 g/mm_2 and percent elongation greater than or equal to about 80%. Dr. Kunzler reported that two of the four formulations he prepared fell within the ranges for the four physical properties required by the claims of the "3 patent.

Dr. Daly followed this testimony with his opinion that based on Dr. Kunzler's recent work, the Keogh patent anticipates all of the claims of the Harvey patent explicitly or inherently, with the exception of claim 19 which discloses the specific structure of the claimed monomer. Example V of the Keogh patent demonstrates the four claimed properties that the copolymer of Keogh was designed to achieve, while examples XXVIII, XXIX, and XXX describe the synthesis of the materials. Daley noted Keogh teaches polysiloxane monomers which include an amide side chain that is hydrophilic. He also testified that Keogh discloses each element of the broader asserted claims, as construed by Wesley Jessen. In particular, Example XXX discloses a monomer having an amide structure, a siloxane structure, and polymerizable groups.

In addition, Dr. Daly testified that a person of ordinary skill in the art (which he defined as a person with a Ph.D. in chemistry or polymer science working in this area) would have found the invention in the Harvey patent obvious, in light of both Tanaka and Keogh. He noted that Keogh identified a method to prepare contact lens material which has a hydrophilic side chain attached to a siloxane structure. Tanaka discloses siloxane monomers having hydrophilic groups that are useful for contact lens materials. The Tanaka monomer discloses the concept of attaching a polymerizable group to a hydrophilic moiety and then further attaching the hydrophilic moiety to the siloxane. Dr. Daly provided no testimony, however, as to what specific teaching there is to combine the Tanaka and Keogh patents.

In response, Wesley Jessen called Dr. Goodman, who testified the Keogh structure is very different from the structure claimed by Harvey in the "3 patent. He testified that Keogh teaches a ladder-shaped polymeric structure in which the siloxane is contained in the rungs of the latter as a cross-linker, while Harvey teaches the hydrophilic siloxane portions as a side chain off of the polymer backbone. He further testified that, as Harvey indicated in col. 2 ll. 25-32 of the "3 patent, Keogh specifically teaches away from monofunctional monomers, such as those claimed in the "3 patent. In addition, he noted that Keogh does not teach or suggest the separate cross-linking agent, as described in claim 27 of the "3 patent, or the four claimed physical properties of the Harvey patent.

Dr. Goodman further testified that the Keogh patent does not teach or suggest the substitutions made by Dr. Kunzler for Example XXX of the Keogh patent. As to Kunzler's tests, Dr. Goodman reported that the changes he made, including substituting DMA, were major deviations from the example in the Keogh patent, and would not have been obvious.

In addition, Wesley Jessen identified a number of alleged deficiencies with Dr. Kunzler's test to support its contention that these tests cannot and do not support a finding of anticipation. First, the material identified in the example used by Dr. Kunzler had not been produced at the time the patent was filed, and perhaps had not been produced before Dr. Kunzler did it for this trial.

Second, the first embodiment that Kunzler prepared directly from Example XXX produced a material that did not meet the four physical properties of the "3 patent, and is not even a hydrogel. Thus it is vastly different from a material produced from the "3 patent claims which disclose "essentially ... a hydrogel, which does not depend solely on water for its oxygen permeability," having the claimed structure, and the four claimed physical properties. Moreover, none of the other samples prepared by Dr. Kunzler are in fact disclosed in the Keogh patent, as he substituted certain constituents in making them, including DMA. Dr. Kunzler acknowledged that none of his other three samples exactly reproduced what was contained in

Example XXX, and that, while the third and fourth samples meet the four properties of the "3 patent, they involve the substitution of DMA for two components listed in Example XXX. He explained that he picked DMA over the other preferred co-monomers listed in the Keogh patent, because he had it available in his laboratory.

Third, Wesley Jessen argues that in selecting DMA from dozens of preferred monomers in the Keogh patent, Dr. Kunzler was simply working backwards from the Harvey patent, where nothing in Keogh suggests that the choice of DMA would work. Dr. Goodman opined that these "fundamental" changes, including the substitution of DMA, were "a belated attempt to make such a major substitution in order to create something that would create a hydrogel, since the replication of Example XXX showed that it was clearly not a hydrogel" and led to "polymers with completely different properties." As further support for this contention, Wesley Jessen points to Dr. Daly's testimony that the reason for substituting DMA in Example XXX of the Keogh patent was because "the objective is to make a hydrophilic gel." Wesley Jessen suggests all of these facts demonstrate Keogh did not anticipate or disclose inherently the Harvey invention.

As for the Tanaka reference, Dr. Goodman testified that Tanaka teaches away from the Harvey invention, as it is directed to contact lens materials "which do not substantially absorb water." He further testified that there was no motivation in the prior art to suggest these two references should be combined to produce hydrophilic siloxane hydrogels. Finally, he noted that it is not physically possible to take the hydrophilic group from Keogh and insert it into Tanaka.

Wesley Jessen also points to a number secondary considerations that suggest the invention in the Harvey patent was not obvious. Wesley Jessen notes that Bausch & Lomb's documents show that upon reading of the Harvey patent, its scientists recognized its importance. Further, Bausch & Lomb has recognized the contribution of the "3 patent by citing it in many of their own patents and publications, including U.S. Patent Nos. 5,563,184; 5,525,691; 5,387,663; 5,387,632; 5,364,918; 5,358,995; 5,336,797; 5,274,008; 5,219,965; 5,177,165; 5,158,717; and 5,135,197.

Finally, Wesley Jessen notes that Keogh and Tanaka are listed as references cited on the front of the "3 patent. Consequently, the Examiner considered these references and was aware of these references when the PTO issued the patent. Moreover, the Harvey patent specifically addresses and distinguishes both Keogh and Tanaka in describing the background of his invention. With regard to Keogh, the "3 patent states that:

Difunctional acrylic siloxanes are at the heart of what is called the B & L (Bausch & Lomb) technology, exemplified by [a number of patents including the Keogh '725 patent]. There, a variety of polysiloxanes, end-capped with polymerizable, unsaturated groups, are shown to be useful for manufacturing contact lenses without the use of "fillers" such as cross-linking agents. The specifications of such patents suggest (but no specific teaching or example is provided showing) incorporation of an acrylamido group adjacent to each polymerizable and unsaturated group of the difunctional monomers and specifically teach away from use of monofunctional monomers, as requiring such "fillers." Moreover, even in the disclosed difunctional embodiments ... the ... dimers of the present invention are not shown or suggested.

"3 patent, col. 2, ll. 16-35. With regard to Tanaka, the "3 patent states that while "[c]opolymerization of a variety of hydrophobic siloxane monomers ... with a hydrophilic monomer (such as N-vinyl pyrrolidone or dimethyl acrylamide) ..., a cross-linking agent, and an initiator, are described in a series of patents to Tanaka," including the Tanaka '985 patent, the Tanaka references "do not teach or suggest the acrylamide sidechain siloxane monomers and polymers of the present invention." Id. at col. 1, ll. 67-col. 2, ll. 9.

b. *Best Mode and Enablement*

On the issues of best mode and enablement, Bausch & Lomb offered the testimony of Dr. Daly who testified that the documents relating to Dr. Harvey's development of his material show that he was not

successful in ever actually having the material work as a contact lens in a human eye, and that the most success he did have was when he used a plasma treated lens, which a patient was able to keep in his eye for a few minutes. As Dr. Harvey failed to disclose that plasma treatment for his lens he had failed to disclose his best mode of practicing the invention.

In response to these contentions, Wesley Jessen relied on the testimony of Dr. Harvey. He confirmed that he never did successfully commercialize the material for a contact lens. He then reviewed his development of the material and his attempts to test it in humans.

Dr. Harvey reported that in an initial test on a volunteer a lens made from the material caused sufficient stinging that the volunteer could not keep it in his eye long enough to evaluate his vision through the lens. Dr. Harvey then modified the material by removing methanol in a process called methanol extraction. He then placed the lens in the volunteer's eye and confirmed they had eliminated the stinging. The methanol extraction caused surface drying on the lens, which meant that when the lens was place in a volunteer's eye it removed layers of epithelium from the corneal area. Dr. Harvey then sought to solve the drying problem by treating the lens with an oxygen plasma surface treatment. During a follow up test with the plasma treatment, the volunteer found that the lens fit and visual acuity was good.

Dr. Harvey testified that he understood that the plasma treatment would not last well. It was generally understood in the contact lens field at that time that the effect of plasma treatment was short-lived. Dr. Harvey explained that while he believed that the use of plasma treatment could be a valuable tool with which to test the properties of the lens, he did not believe plasma treatment to be his best mode because of its short term effect. This belief is corroborated by Harvey's statement in the Background of Invention section of the "3 patent, where he stated that "surface treatments ... have a tendency to be short lived in their effectiveness due to normal wear and tear on the surface." "3 patent, col. 1, ll. 62-66.

The invention in the "3 patent was never commercialized at Syntex. Commercialization was hindered by the sale of the company and diversion of resources away from the project. Harvey reported that when the company was sold, he stopped his work on the lens and it was never commercialized. While he pursued the patent, he did not disclose the plasma treatment in the patent application, because he did not consider it a best mode and never did come to a conclusion as a best mode of practicing the invention. Harvey subsequently left Syntex in 1989.

c. ***Utility and Indefiniteness***

In its papers, Bausch and Lomb sets out two additional arguments in support of its contention that the claims of the Harvey patent are invalid. First, Bausch & Lomb contends the claims are invalid for lack of utility. Second, it contends the claims are indefinite, arguing that the second portion for increasing oxygen permeability is indefinite because in most instances the claims fail to describe a complete chemical formula for the second portion. In its post trial filing, Bausch & Lomb supplemented its indefiniteness defense, by further arguing that the claims were indefinite for a second reason: a person of ordinary skill in this art would not be able to determine whether a potentially infringing material has "increased wettability" because the PMMA standard identified in the patent is unreliable.

3. ***Inequitable Conduct***

Bausch and Lomb also argues that the claims are unenforceable and that Dr. Harvey engaged in inequitable conduct by failing to disclose the oxygen plasma treatment to the Patent and Trademark Office, and in suggesting to the PTO that his material possessed all of the wettability necessary for contact lenses. In its post trial briefing, Bausch & Lomb supplemented this defense by also arguing that Dr. Harvey had mislead the PTO in two other statements. First, Harvey distinguished U.S. Patent No. Re. 31,406 to Gaylord by writing "Gaylord teaches a separate monomer that must be copolymerized to achieve greater wettability,

whereas applicant herein teaches putting the amide and urethane moieties in the monomer structure." Defendant contends this statement was misleading as it in effect tells the PTO that it was not necessary to use copolymerization to produce a lens with adequate wettability, because wettability is introduced by the amide and the urethane moieties in the siloxane structure. Second, Bausch & Lomb reports Harvey's statement in the specification at Column 1, lines 59 to 66 that surface treatments of contact lenses have a tendency to be short lived in their effectiveness is not supported by his contemporaneous notebooks and reports.

Bausch & Lomb asks the court to award it attorneys fees based on this alleged inequitable conduct.

4. ***Willful Infringement***

In support of its claim for attorneys fees, Wesley Jessen offered evidence to establish that Bausch & Lomb's infringement was willful. That evidence included testimony by Bausch & Lomb scientist Gary Friends that he and fellow scientists Joe McGee, David Seelye, and Ron Bambury were aware of the Harvey patent in early 1988 and evidence that they thought the material claimed in Harvey was sufficiently close to the material Bausch & Lomb was working on that they sought and obtained an opinion from Christopher Blank, an internal patent attorney for Bausch & Lomb. Blank issued his opinion on April 28, 1989 to Bambury, Friends, and Seelye. Bausch & Lomb continued to develop its PureVision product after receiving this attorney opinion.

Bausch & Lomb has declined to produce a copy of that opinion, withholding it on the basis of attorney-client privilege. Wesley Jessen asks the court to draw an adverse inference that the opinion was negative, that Wesley Jessen is willfully infringing the claims of the Harvey patent and seeks an award of attorneys fees.

In response to Wesley Jessen's case on willfulness, Bausch & Lomb called witnesses, Seelye and McGee, to testify to its decision to abandon its work on an acrylic monomer after it learned of the Harvey patent, to its independent development of the TRIS-VC monomer, to its expenditure of over $60 million dollars on research and development in independently developing its Balafilcon A material and its PureVision lens and its decision to add vinyl to its product to improve its wettability.

Seelye testified that he first synthesized the TRIS-VC monomer on July 22, 1987 and that when he first made the TRIS-VC monomer, he had no knowledge of any work by Dr. Harvey. Seelye reported that he first learned of the "3 patent in August of 1988. He explained, however, that he believed that the "3 patent was not directed to vinyl carbonates or vinyl carbamates and that therefore he concluded that the teaching of the "3 patent were completely unrelated to his work on the TRIS-VC monomer.

Bausch & Lomb offered McGee's testimony as evidence of its diligence and respect for the intellectual property rights of others. McGee testified that he was working on monomers disclosed in the "3 patent when the "3 patent came to Bausch & Lomb's attention. In light of the "3 patent, McGee discontinued his work with those materials.

II. ***DISCUSSION***

A. ***Claim Construction***

1. ***Principles of Claim Construction***

[1] [2] The construction of claims in a patent is a matter left to the province of the court. Markman v. Westview Instruments, Inc., 517 U.S. 370, 391, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996). In interpreting a

claim, "the court should look first to the intrinsic evidence of record, i.e., the patent itself, including the claims, the specification, and, if in evidence, the prosecution history." Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed.Cir.1996) (further noting that "[s]uch intrinsic evidence is the most significant source of the legally operative meaning of the disputed claim language").

[3] [4] Among the three types of intrinsic evidence, the court "look[s] first to the claim language itself to define the scope of the patented invention." Bell Atlantic Network Servs., Inc. v. Covad Communications Group, Inc., 262 F.3d 1258, 1267 (Fed.Cir.2001). The court must give claim terms their ordinary and accustomed meaning as understood by one of ordinary skill in the art at the time of the invention. Multiform Desiccants, Inc. v. Medzam, Ltd., 133 F.3d 1473, 1477 (Fed.Cir.1998).

[5] [6] After looking to the claims themselves, the court considers the remaining intrinsic evidence presented, including the patent's specification and its prosecution history. Interactive Gift Express, Inc. v. Compuserve Inc., 256 F.3d 1323, 1331 (Fed.Cir.2001). If the claim language is clear on its face, then the court's consideration of the rest of the intrinsic evidence is restricted to determining if a deviation from the clear language of the claim is specified. *Id*. As the Federal Circuit explained in *Interactive Gift,*

A deviation may be necessary if "a patentee [has chosen] to be his own lexicographer and use terms in a manner other than their ordinary meaning." Vitronics, 90 F.3d at 1582, 39 USPQ2d at 1576. A deviation may also be necessary if a patentee has "relinquished [a] potential claim construction in an amendment to the claim or in an argument to overcome or distinguish a reference." Elkay Mfg. Co. v. Ebco Mfg. Co., 192 F.3d 973, 979, 52 USPQ2d 1109, 1113 (Fed.Cir.1999).

Id. If, however, the claim language is not clear on its face, the court's consideration of the remainder of the intrinsic evidence "is directed to resolving, if possible, the lack of clarity." *Id*.

[7] The patent specification is helpful in construing the claims because it is the patentee's written description of the invention. There are two general guidelines for the use of the patent specification in claim construction: "(a) one may not read a limitation into a claim from the written description," or limit a claim to a preferred embodiment described in the specification, "but (b) one may look to the written description to define a term already in a claim limitation, for a claim must be read in view of the specification of which it is a part." Renishaw PLC v. Marposs Societa' per Azioni, 158 F.3d 1243, 1248 (Fed.Cir.1998); *see also* Comark Communications, Inc. v. Harris Corp., 156 F.3d 1182, 1186-87 (Fed.Cir.1998) (recognizing that "there is sometimes a fine line between reading a claim in light of the specification, and reading a limitation into the claim from the specification[,]" and stating that courts should look "to the specification to ascertain the meaning of the claim term as it is used by the inventor in the context of the entirety of his invention," but not to limit a claim term); *cf*. Toro Co. v. White Consolidated Indus., Inc., 199 F.3d 1295, 1302 (Fed.Cir.1999) (the terms of a claim will be limited to specific embodiments in the specification where "the invention is described throughout the specification as it is claimed"); SciMed Life Sys. v. Advanced Cardiovascular Sys., Inc., 242 F.3d 1337, 1339-40 (Fed.Cir.2001) (limiting claims to specific embodiments disclosed in patent because, in part, "[the language of the specification] ... 'leaves no doubt that a person skilled in the art would conclude that the inventor envisioned only one design.' "); C.R. Bard, Inc. v. U.S. Surgical Corp., 102 F.Supp.2d. 199, 209, 215 (D.Del.2000) ("Claims should be interpreted consistently with the specification, which provides content for the proper construction of the claims because it explains the nature of the patentee's invention." "[C]laims should not be construed to encompass embodiments beyond those that are described and enabled in the specification.")

[8] [9] After reviewing the specification, the court should also examine the prosecution history of the patent. "The prosecution history limits the interpretation of the claim terms so as to exclude any interpretation that was disclaimed during prosecution." Southwall Techs., Inc. v. Cardinal IG Co., 54 F.3d 1570, 1576 (Fed.Cir.1995). The court should examine the patent's prosecution history to determine whether the patentee limited the scope of the claims in this manner.

[10] [11] [12] If the meaning of the patent claims cannot be discerned from the intrinsic evidence of record, the court may resort to extrinsic evidence. Vitronics, 90 F.3d at 1584; Markman v. Westview Instruments, Inc., 52 F.3d 967, 980 (Fed.Cir.1995) (en banc) (quoting Seymour v. Osborne, 78 U.S. (11 Wall.) 516, 546, 20 L.Ed. 33 (1871)) ("The court may, in its discretion, receive extrinsic evidence in order to 'aid the court in coming to a correct conclusion' as to the 'true meaning of the language employed' in the patent."). "Extrinsic evidence consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises." Markman, 52 F.3d at 980. Such evidence "may be helpful to explain scientific principles, the meaning of technical terms, and terms of art that appear in the patent and prosecution history." *Id*. Extrinsic evidence, however, may only be used to help the court to come to the proper understanding of the claims; "it may not be used to vary or contradict the claim language." Vitronics, 90 F.3d at 1584; *see also* Interactive Gift Express, Inc., 256 F.3d at 1332.

2. *The Parties' Positions*

a. *Bausch & Lomb*

The central dispute in this case concerning claim construction concerns the meaning of the phrase "first portion for increasing wettability." This phrase is found in asserted independent claims 1, 27, and 50, but not in asserted independent claim 19.

Bausch & Lomb's principal argument is that the claims of the "3 patent are limited to materials and lenses derived from specific monomers in the specification, which are (meth)acrylamides and (meth)acrylcarbamates, both acrylics. To reach this conclusion, Bausch & Lomb contends that "a first portion for increasing wettability" does not have a "common meaning understood by those skilled in the art" reading the patent claims, and that it is necessary to turn to the specification to determine the meaning of this claim term. The specification states that:

The monomer molecule has a first portion for increasing wettability and a second portion for increasing oxygen permeability as compared with presently existing contact lenses and materials therefor.

The first portion is hydrophilic; it includes a side-chain functionality of the structural formula [depicted as that of an amide or a carbamate] *and has a general structure shown below in Formula I*.

"3 Patent, col. 5, ll. 3-4 (emphasis added). Formula I is a formula for an acrylic, which includes both acrylamides and acrylcarbamates. Bausch & Lomb contends that since Formula I is part of the definition of the "first portion," the claim term "a first portion for increasing wettability," as used in claims 1, 27, and 50, must be limited to acrylics.FN2 As further support for its definition, Bausch & Lomb also points out that all of the specific monomers disclosed in the exemplary embodiments in the specification are acrylics. Thus, Bausch & Lomb contends, the invention of the "3 patent is limited to materials that include an acrylic, and the claims should be so construed. Since TRIS-VC, the component in Bausch & Lomb's Balafilcon A material and PureVision contact lenses which gives rise to the infringement allegations in this case, is a vinyl carbamate monomer-a "vinyl" rather than an "acrylic," Bausch & Lomb argues that the accusedproducts are not covered by the claims of the "3 patent.

FN2. It should be noted that the acrylic structures of Formula I are expressly claimed in claim 19, which includes Formula I in the generalized monomer structure that is claimed.

In the alternative, Bausch & Lomb contends that the phrase "a first portion for increasing wettability" is a means-plus-function limitation, whose structure is limited to include acrylics, in that the structure of Formula I is the only corresponding structure.

b. ***Wesley Jessen***

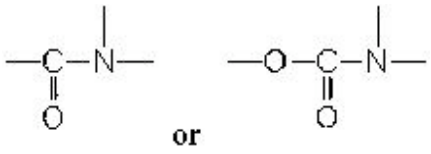
In response, Wesley Jessen contends that "a first portion for increasing wettability" is not limited to acrylics in independent claims 1, 27, and 50 of the "3 patent. Instead, that term is expressly defined by the words that follow it in the claims themselves, which require only that the "said first portion" be "hydrophilic" and include a "side-chain functionality" selected from one of two shown structural formulae, which are an amide and a carbamate. Thus, while Wesley Jessen concedes that each of the examples in the specification uses an acrylic as the first portion, it contends that Harvey claimed his invention more broadly in independent claims 1, 27, and 50 than the specific embodiments of the specification. Wesley Jessen argues that the language and structure of those claims provide a readily understandable definition of the meaning of this claim term.

In response to Bausch & Lomb's alternative argument that the claim term is a means-plus-function limitation, Wesley Jessen contends that it is not drafted in means-plus-function format and that there is no reason to construe it as such.

3. ***The Court's Construction***

[13] To determine the meaning of the claim term "a first portion for increasing wettability," the court begins by looking to the language of the claims themselves. Bell Atlantic Network Servs., Inc., 262 F.3d at 1267. The claims recite a monomer having:

a first portion for increasing wettability, said first portion being hydrophilic and including a side-chain functionality selected from the group including the following structural formulae:



Thus, the phrase "a first portion for increasing wettability" is given a specific definition by the words that follow in the claims themselves. The claims precisely define what "a first portion for increasing wettability" means, and this meaning does not include the acrylic formula referenced in the specification. Rather the claims state, more broadly, that the "first portion" must be "hydrophilic" and include a "side-chain functionality" selected from one of two shown structures, which are an amide and a carbamate. In other words, the "first portion" must be hydrophilic and include an amide functional group or a carbamate functional group as a side chain extending from the backbone of the polymer.

[14] Bausch & Lomb argues that "a first portion" does not have a common meaning that is recognized and understood by those in the art, and that therefore the court must examine the specification to define the term. But where, as here, the claims specifically define the term at issue, it is unnecessary to import a more restrictive definition from the specification. Consideration of the specification is instead restricted to determining if "a deviation from the clear language of the claims is specified." Interactive Gift Express, Inc., 256 F.3d at 1331. No such deviation is found in the specification.

Bausch & Lomb nonetheless argues that the claims of the "3 patent should be limited to the specific embodiments (acrylics) disclosed in the specification, on the theory that where the invention is described in limited terms in the specification, the claims are equally limited. *See* Toro Co., 199 F.3d at 1302; SciMed,

242 F.3d at 1339-40. In *Toro Co.,* the court construed the claims for a hand-held convertible vacuum/blower for yard work to require that a "restriction ring" must be permanently attached to the device's cover, as described in the specification. The court noted that the specification "describes the advantages of the unitary structure as important to the invention" and that the specification "stressed" that the ring and cover are one part. 199 F.3d at 1301. Stating that this was not a case of limiting the claims to a preferred embodiment, *id.,* the court found "the invention is described throughout the specification as it is claimed," *id.* at 1302, and therefore construed the claims as described in the specification. In *SciMed,* the Federal Circuit affirmed the district court's narrow claim construction, because the abstract explicitly limited the patents to particular lumen catheters, the patents distinguished the prior art on the basis of such catheters, and the "Summary of Invention" portion of the specification characterized the invention as having that type of catheter. *SciMed,* 242 F.3d at 1347.

Here, unlike the *Toro* and *SciMed* cases, no explicit or express disclaimer of monomers other than acrylics exists in the "3 patent or its prosecution history. Given the absence of any disclaimer of broader coverage, Bausch & Lomb's proposed construction would impermissibly import a narrowing limitation from the specification to the claims. Renishaw, 158 F.3d at 1248.

This is a case where the patentee has claimed his invention more broadly in independent claims 1, 27, and 50 than in the specific exemplary embodiments of the specification. *See* Rexnord Corp. v. Laitram Corp., 274 F.3d 1336, 1344 (Fed.Cir.2001) (citing SRI Int'l v. Matsushita Elec. Corp. of America, 775 F.2d 1107, 1121 (Fed.Cir.1985) (en banc)) ("If structural claims were to be limited to devices operated precisely as a specification-described embodiment is operated, there would be no need for claims. Nor could an applicant, regardless of prior art, claim more broadly than the embodiment"). As the meaning of "a first portion for increasing wettability" can be determined by a person of ordinary skill in the art from the language of the claims themselves, there is no reason to limit that meaning to a narrower embodiment in the specification. Moreover, the "3 patent claims the specific acrylic embodiments of the specification in dependent claims; the independent claims are more broadly claimed. If the patentee intended to limit his invention to acrylics, he would not have claimed his invention in this manner.

Neither does the specification necessarily require that the "first portion" of the invention be limited to the acrylics of Formula I. While certain language, such as that in the Summary of Invention indicates that the claimed material has the "generalized structure" of Formula I, other language indicates a broader scope of invention. For example, the Abstract, like the claim language, defines the invention in broad terms, noting only that the first portion includes a side-chain functionality of an amide or carbamate and that it be hydrophilic; it does not limit the first portion to the Formula I structure. *See* Hill-Rom Co. v. Kinetic Concepts Inc., 209 F.3d 1337, 1341 (Fed.Cir.2000) (noting that courts frequently looks to the abstract to determine the scope of the invention).

[15] As for the references Bausch & Lomb cites from the "Detailed Description of the Preferred Embodiments," they are just that-preferred embodiments. They do not purport to define the entire invention. For example, the reference to the Formula I structure that Bausch & Lomb relies upon, states at the outset that it is describing " *A* monomer embodying the principles of the present invention ...." "3 patent, col. 5, l. 42 (emphasis added). The fact that the specification provides a wealth of teaching about the preferred embodiments does not mean that the claims are limited to those preferred embodiments.

Again, the court comes back to claims such as claim 1, which do not mention a limitation involving Formula I. This clearly indicates that the scope of invention was intended to be broader than one that is limited to acrylics.

The prosecution history also confirms that both the Examiner and the applicant considered the claims to be broader than Formula I. During the prosecution of the patent application that led to the "3 patent, the Examiner imposed a rejection of claims 25-53 as being obvious over Fort in view of Friends alone or

together with Gaylord. Fort teaches vinyl and allyl carbamates, neither of which are acrylics. Specifically, Fort relates to carbamate-containing polysiloxane copolymers useful as emulsifiers, dispersing agents, lubricants, surface active agents, and coagulants. *See* U.S. Patent No. 3,652,629, col. 1, ll. 16-18. Fort describes making these copolymers by reacting ethylenically unsaturated carbamates, such as vinyl and allyl carbamates, with the polysiloxanes. *See, e.g.,* id. at col. 3, ll. 4-30. Thus, Fort teaches vinyl and allyl carbamates, and does not teach or describe any "acrylic" amides or carbamates.

The Examiner reasoned that the primary references (including Fort) disclose monomers having "nitrogen and silicone groups," and the secondary references show the use of co-monomers. Thus, the Examiner concluded, the choice of the applicant's claimed co-monomers would have been obvious. This rejection makes clear that the Examiner considered the applicant's claims to cover vinyl and allyl carbamates, and thus that the claims were not limited to acrylics. The applicant argued against this rejection in his July 16, 1986 response. Therein the applicant distinguished Fort, not by disclaiming vinyl carbamates, but by arguing that Fort's compounds were emulsifiers and were unusable as contact lens materials. In distinguishing Friends and Gaylord, the applicant argued that his claims required the amide or carbamate structure, and that the secondary references failed to teach siloxane monomers having an amide or carbamate. He did not specify that the first portion was limited to acrylics or that acrylics were an important or necessary aspect of his claimed monomer structure.

In sum, at no time in the prosecution history did the applicant disclaim vinyl monomers or assert that his invention is limited to acrylics. If the applicant intended to disclaim vinyls or limit his claim to acrylics, such a disclaimer would have been an appropriate basis upon which to distinguish Fort. That no such disclaimer was made, supports the court's interpretation that the claims are not limited to acrylics.

[16] [17] Last, construing the phrase "a first portion for increasing wettability" as not being limited to acrylics is also supported by the doctrine of claim differentiation. The doctrine of claim differentiation provides that because each claim is presumed to have a different scope, it is presumptively unreasonable to construe one claim so as to render another claim superfluous. Beachcombers, Int'l v. WildeWood Creative Prod., Inc., 31 F.3d 1154, 1162 (Fed.Cir.1994); Intel Corp. v. Broadcom Corp., 172 F.Supp.2d. 478, 496 (D.Del.2001) ("In interpreting claims, it is improper for courts to read into an independent claim a limitation that is explicitly set forth in another [dependent] claim"); *see also* Intermatic Inc. v. Lamson & Sessions Co., 273 F.3d 1355, 1364 (Fed.Cir.2001) (noting that this presumption is "strengthened" when there is a dispute over whether "a limitation found in a dependent claim should be read into an independent claim, and that limitation is the only meaningful difference between the two claims"); *cf.* Wenger Mfg. v. Coating Machinery Sys., 239 F.3d 1225, 1233 (Fed.Cir.2001) (noting that the doctrine of claim differentiation is a guideline and not a hard and fast rule and that claim differentiation cannot be relied upon to broader claims beyond their correct scope). While the court realizes that claim differentiation is a guide and not a strict rule, the guidance provided by this doctrine strongly supports the court's construction.

Bausch & Lomb asserts that the term "a first portion for increasing wettability" is limited to those structures that have the chemical structure of an acrylic (as shown in Formula I of the specification). The structural limitations that Bausch & Lomb would have the court read into the "first portion" of independent claims 1, 27, and 50 are found in the dependent claims of the patent. For example, claim 5, which depends from claim 1, recites the specific structure found in Formula I for the first portion of the monomer. Similarly, claim 2, which also depends from claim 1, claims "the contact lens material of claim 1 wherein said first portion comprises an acrylamide or a methylacrylamide." Under the doctrine of claim differentiation, however, reading the limitation of the specific acrylic structure into claim 1 would render dependent claim 5 superfluous, which is presumptively unreasonable. Beachcombers, 31 F.3d at 1162. This presumption is heightened here, since the acrylic structure limitation is the only meaningful difference between claim 1 and claim 5.FN3

FN3. A Similar analysis can be applied to independent claims 27 and 50, in light of dependent claims 41

and 54, respectively.

[18] [19] Neither does the court agree with Bausch & Lomb's alternative contention that the claim term must be construed as a means-plus-function claim. First, no "means" language is present in the phrase. The failure to include the word "means" creates a presumption that s. 112, para. 6 does not apply. Personalized Media Communications L.L.C. v. Int'l Trade Comm'n, 161 F.3d 696, 703-04 (Fed.Cir.1998). This presumption may only be rebutted where the properly construed claim does not "recite[ ] sufficiently definite structure to avoid the ambit of s. 112, para. 6." *Id*. at 704. In this case, the claims do recite a structure that corresponds to the specified function of increasing wettability, the amide or carbamate side-chain functionality. As Dr. Goodman testified, amides and carbamates are both hydrophilic and perform the function of increasing wettability. Because there is sufficient structure shown to perform the function of increasing wettability, the claim cannot be construed as being in means-plus-function format.

In conclusion, for the reasons stated above, the phrase "first portion for increasing wettability" is not limited to the acrylic structure set out in Formula I or the "3 patent specification. It covers structures that are hydrophilic and include carbamate or amide sidechain functionality. This includes both vinyls and acrylics.

B. ***Infringement Analysis***

[20] [21] [22] [23] A patent infringement analysis involves two steps: the proper constructionof the asserted claims and a comparison of the claims, as construed, to the accused product to determine whether the accused product infringes the properly construed asserted claims. Vitronics, 90 F.3d at 1581-82. Infringement occurs where the alleged infringer's product contains every element of at least one claim of the patent exactly or by substantial equivalent. Panduit Corp. v. Dennison Mfg. Co., 836 F.2d 1329, 1330 n. 1 (Fed.Cir.1987); Johnston v. IVAC Corp., 885 F.2d 1574, 1577 (Fed.Cir.1989). Where the accused product contains every element of the patented invention, infringement is established, regardless of whether the accused product contains additional elements above and beyond those claimed. *See* DiscoVision Assocs. v. Disc Mfg., Inc., 25 F.Supp.2d 301, 334 (D.Del.1998) ("Infringement may not be avoided by simply adding features or components not required by the claims."). Both literal infringement and infringement under the doctrine of equivalents are issues of fact that Wesley Jessen must prove by a preponderance of the evidence. Advanced Cardiovascular Systems, Inc. v. Scimed Life Systems, Inc., 261 F.3d 1329, 1336 (Fed.Cir.2001).

Having construed the disputed claim terms of the "3 patent above, the court now turns to the second determination of whether Bausch & Lomb's PureVision or Balafilcon A infringes those claims. The court will separate its analyses into literal infringement and infringement under the doctrine of equivalents.

1. ***Literal Infringement***

[24] Wesley Jessen asserts literal infringement of claims 1, 11, 14, 27, 50, 60, and 63. Of those claims, claims 1, 11, 27, 50, and 60 claim "contact lens materials," while claims 14 and 63 claim "a contact lens formed from [the claimed] contact lens material."

Bausch & Lomb manufactures and sells a line of contact lenses in the United States, which it markets under the trade name, "PureVision." Bausch & Lomb's PureVision contact lenses are made from a material designated as Balafilcon A, which is admitted to be a non-fibrous polymeric material that can be used to make contact lenses. The parties agree that the Balafilcon A material is made from the following components: (i) TRIS-VC (55 parts by weight); (ii) V_2 D_{55} (15 parts by weight); (iii) VINAL (1 part by weight); (iv) N-vinyl pyrrolidone or NVP (30 parts by weight); (v) Nonanol (15 parts by weight); (vi) Darocur 1173 (0.5 parts by weight); and (vii) Reactive Blue 246 (0.015 parts by weight).

According to Bausch & Lomb, the function of each of these components is as follows. The TRIS-VC is in

the polymer for oxygen transmissibility. The V_2 D_{55} is a cross-linking agent and also provides additional oxygen transmissibility. The Vinal was added to add wettability to the surface properties of the Balafilcon A. The NVP is provided to increase water content. The Nonanol facilitates curing of the polymer, but is removed in processing and does not appear in the final product. The Reactive Blue 246 component is a visibility tint put in the lens so that it can be easily seen. The Darocur 1173 is a UV photo initiator used to initiate the polymerization.

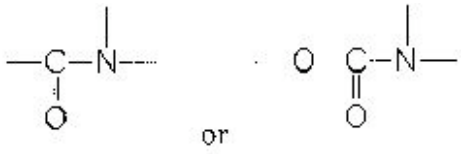
The court will begin its infringement analysis by comparing claim 1, which it reproduces below, to the Balafilcon A (PureVision) material. The chemical structure of the Balafilcon A material is depicted in full in Pl.Ex. 702.

Claim 1 recites:

1. A non-fibrous polymeric contact lens material having improved

oxygen permeability and stability, said polymeric contact lens material comprisinga monomer having the following structural formula:

first portion for increasing wettability, said first portion being hydrophilic and including a side-chain functionality selected from the group including the following structural formulae:



or

and

and
a second portion for increasing oxygen permeability, said second portion including a siloxane;

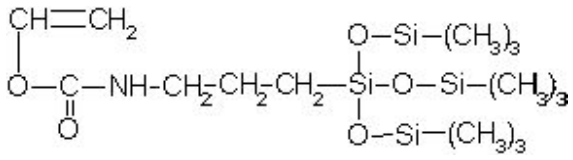
wherein: said material has a water content of about 15-60%; Dk greater than or equal to about 25 x 10^{-10}; tear strength greater than or equal to about 1.0 g/mm ^{2}; and percent elongation greater than or equal to about 80%.

As noted above, Bausch & Lomb does not dispute that Balafilcon A is a non-fibrous polymeric contact lens material. *See* Pre-Trial Order, Statement of Admitted Facts, para. 9. It is also undisputed that the Balafilcon A material and PureVision contact lenses have a water content of about 15-60%; Dk greater than or equal to about 25 x 10^{-10}; tear strength greater than or equal to about 1 g/mm ^{2}; and percent elongation greater than or equal to about 80%. *See* id. at para.para. 9, 11-20. Thus, Balafilcon A material and the PureVision lenses meet the parameters of each of the four physical properties of the claims.

The focus of the parties' dispute centers on whether the accused materials have the required "first portion for increasing wettability." Wesley Jessen asserts that the TRIS-VC monomer in Balafilcon A is a hydrophilic siloxane monomer having a "first portion for increasing wettability, said first portion being hydrophilic and including a side-chain functionality selected from the group including the following structural formulae [for an amide or a carbamate]...." In response, Bausch & Lomb argues that TRIS-VC does not have the required "first portion," and does not "increase wettability." Its first argument flows from its proposed claim

construction that "first portion for increasing wettability" must include Formula I from the specification. The second argument is based on the testimony of Dr. Grobe and Dr. Daley, both of whom conclude that TRIS-VC does not "increase wettability."

TRIS-VC is a monomer having the following structural formula, which includes a siloxane:



Bausch & Lomb's first argument is that TRIS-VC does not have a structure that corresponds to Formula I of "3 specification. This is true. However, the court's claim construction does not require the claimed "first portion" to have this structure. Instead, all that is required is that the "first portion" is "hydrophilic" and include"a side-chain functionality" selected from an amide or carbamate functional group. Dr. Goodman's testimony establishes that these two requirements are present in the TRIS-VC monomer. First, TRIS-VC contains vinyl carbamate. The carbamate of TRIS-VC is a hydrophilic structure of side chain functionality which contributes to wettability. In the "3 patent, Harvey expressly defined "increased wettability" in terms of decreased relative receding contact angle and not in terms of wettability in the eye. As noted by Dr. Goodman, the receding contact angle tests performed by Dr. Winterton, which are the same tests described in the patent, establish that TRIS-VC is more wettable than TRIS and PMMA. Both Drs. Winterton and Goodman concluded that the increased wettability in TRIS-VC is attributable to the presence of the carbamate in TRIS-VC. This demonstrates that the carbamate performs the function of increasing wettability.

The testing results of Dr. Grobe do not convince the court that TRIS-VC does not perform the function of increasing wettability. First, Dr. Winterton performed tests using multiple methodologies and his results consistently indicated that TRIS-VC had a lower receding contact angle, and hence increased wettability, when compared to either PMMA, the material used in hard lenses, or TRIS, the TRIS-VC monomer without the vinyl carbamate portion. Second, unlike Dr. Winterton's testing, the testing performed by Dr. Grobe on a dry surface was not the same testing methodology as that described in the "3 patent. The "3 patent teaches that wettability is to be measured on hydrated lenses, by receding contact angle. *See* "3 patent, col. 37, ll. 31-37 and col. 3, ll. 59-64. Third, neither Dr. Grobe's testimony nor the testimony of Dr. Winterton on cross-examination convince that court that the Sessile Drop method is an inadequate or necessarily inaccurate method to measure contact angles. Fourth, Dr. Grobe's conclusions regarding the hydrophobicity of the material are inconsistent with both Bausch & Lomb literature and established treatises. Fifth, the results of Dr. Grobe's test do indicate that TRIS-VC and TRIS are significantly different in terms of receding contact angle, with TRIS-VC showing increased wettability that logically is attributable to the presence of the hydrophilic carbamate. Last, the court notes that the fact that Bausch & Lomb uses additional steps to provide wettability in the eye, such as surface treatment and other co-monomers such as NVP, does not alter the conclusion that TRIS-VC also increases wettability, as defined by the "3 patent. Thus, the court concludes that Balafilcon A has a "first portion for increasing wettability."

The testimony of Dr. Goodman establishes, in addition, that the TRIS-VC monomer also has a "second portion for increasing oxygen permeability," in that it includes a siloxane portion, which is recognized in organic chemistry to facilitate oxygen transport.

Balafilcon A meets each of the elements of claim 1 of the "3 patent: It is a non-fibrous polymeric contact

lens material with improved oxygen permeability and stability. It is a polymeric contact lens material comprising a monomer that has the required first portion for increasing wettability that is hydrophilic and includes side-chain functionality selected from an amide or carbamate and second portion for increasing oxygen permeability that includes a siloxane. Last, the accused material has a water content of about 15-60%; Dk greater than or equal to about 25 x 10^{-10}; tear strength greater than or equal to about 1 g/mm ^{2}; and percent elongation greater than or equal to about 80%. Therefore, based on the court's above analysis, Balafilcon A and PureVision contact lenses literally infringe claim 1 of the "3 patent.FN4

FN4. The court notes that Bausch & Lomb also argues that there is no literal infringement of claims 1, 11, 14, 19, because those claims require a material "comprising a monomer." It contends that because the monomers cease to exist as independent monomers once they are polymerized, the Balafilcon A material and PureVision cannot literally infringe. *See* Exxon Corp. v. Lubrizol Corp., 64 F.3d 1553 (Fed.Cir.1995) (finding no infringement where the patentee showed that the accused infringer started with claimed ingredients, but failed to show that those ingredients were in fact present in final product). Where, as here, the patent uses terms such as "first portion," "second portion," and "monomer" to refer to the building blocks that are part of the claimed structure, the court does not agree that, merely because the material is no longer a monomer after it is polymerized, this avoids infringement.

The court will now turn to the remainder of the claims that Wesley Jessen contends are literally infringed. As further described below, each of these claims deviates from claim 1 by adding limitations that are also met by the Balafilcon A material. Therefore the court concludes that each of these claims is also literally infringed.

Claim 11 is a dependent claim that adds the limitation that the second portion comprises a specific structural formula for the siloxane. The structure of the siloxane in TRIS-VC is undisputed. *See* Pre-Trial Order, Statement of Admitted Facts, para. 10. Dr. Goodman's testimony establishes that the TRIS-VC monomer has the identical siloxane structure required by the claim. Therefore, Balafilcon A and PureVision contact lenses literally infringe claim 11 of the "3 patent.

Claim 14 adds the limitation that the contact lens material of claim 1 is in the form of a contact lens. It is undisputed that PureVision contact lenses are in the form of a contact lens. Therefore, PureVision contact lenses literally infringes claim 14.

Claim 27 adds the further requirement that the contact lens material be the copolymerization product of a first monomer with the four required characteristics, having a first portion for increasing wettability ... and a second portion for increasing oxygen permeability ...[,] a second monomer copolymerizable with the first, a crosslinking agent, and a polymerization initiator. It is undisputed that Balafilcon A is the copolymerization product of TRIS-VC, which is a monomer (the first monomer) NVP (a vinyl), a crosslinking agent, and an initiator. *See* Pretrial Order, Statement of Admitted Facts para. 9. Therefore, as the court has already found that TRIS-VC has the required "first portion" and "second portion" elements, PureVision contact lenses literally infringes claim 27.

Claim 50 differs from claim 1 in that it claims a "polymer formed from at least a monomer" having the identical elements as claim 1, the specific "first portion" and "second portion," and the four claimed properties of the material. As Balafilcon A is a "polymer formed from at least a monomer," the remainder of the infringement analysis is identical to that for claim 1. Accordingly, Balafilcon A and PureVision contact lenses literally infringe claim 50.

Like claim 11, claim 60 adds the limitation that the second portion of the monomer comprises a specific structural formula for the siloxane. Claim 60 depends not on claim 1, but on claim 50. As the court has noted above, TRIS-VC has the identical siloxane structure covered by claim 60, *see* Pre-Trial Order,

Statement of Admitted Facts, para. 9., and therefore Balafilcon A and PureVision contact lenses literally infringe claim 60.

Last, claim 63 adds the limitation that the contact lens material of claim 50 is in the form of a contact lens. It is undisputed that PureVision contact lenses are in the form of a contact lens. Therefore, PureVision contact lenses literally infringes claim 63.

2. ***Infringement Under the Doctrine of Equivalents***

[25] Wesley Jessen contends that claims 19, 54, and 57 are infringed under the doctrine of equivalents.FN5 These three claims relate to contact lens materials. Each of these claims differ from the claims that Wesley Jessen contends are literally infringed in that they claim a specific chemical structure that expressly includes Formula I, an acrylic, instead of more generally claiming a first portion for increasing wettability and a second portion for increasing oxygen permeability in a manner that does not limit the chemical structure to one including the acrylic structure of Formula I. As Bausch & Lomb's PureVision and Balafilcon A material does not contain an acrylic, but instead contains a vinyl, it does not literally infringe these claims.

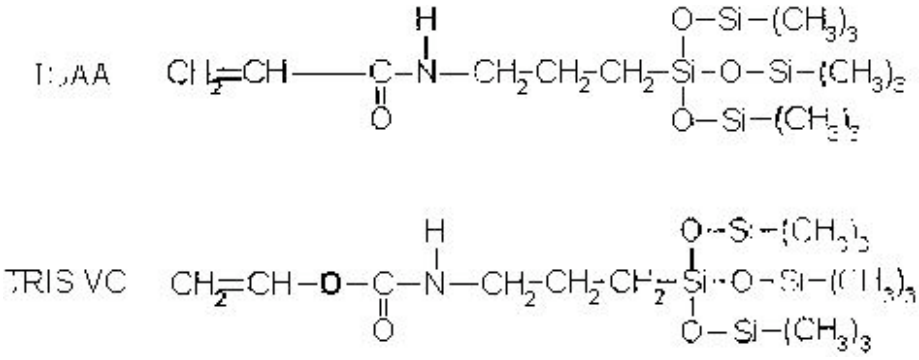
FN5. Alternatively, Wesley Jessen contends that, even if the court adopted Bausch & Lomb's claim construction limiting the remaining asserted claims to acrylics, Bausch & Lomb's Balafilcon A material still infringes all of the asserted claims under the doctrine of equivalents. Given that the court's claim construction does not adopt Bausch & Lomb's more limiting construction, there is not need to consider whether all of the claim infringe under the doctrine of equivalents; the court will therefore limit its discussion of doctrine of equivalents to claims 19, 54, and 57.

Wesley Jessen contends, however, that the first portion of TRIS-VC, whose polymerizable group is a vinyl, is equivalent to the first portion of the claimed hydrophilic siloxane monomers of the "3 patent that are limited to acrylics. It argues that this vinyl portion performs substantially the same function of increasing wettability as the claimed acrylic portion. Also, like the claimed acrylic "first portion for increasing wettability," the vinyl portion of TRIS-VC increases wettability in substantially the same way by including a carbamate functional group having a hydrophilic portion with side-chain functionality. Last, TRIS-VC achieves substantially the same result as the claimed material in that it is a hydrophilic siloxane monomer that increases the oxygen permeability of the contact lens material by having a first portion for increasing wettability and a second portion for increasing oxygen permeability. Therefore, Wesley Jessen argues that although Bausch & Lomb's PureVision does not infringe claims 19, 54, and 57 literally, it infringes those claims under the doctrine of equivalents.

In further support of this proposition, Wesley Jessen first notes that acrylics and vinyls are closely related, as acrylics are simply a subset of vinyls. Next, Wesley Jessen relies on the testimony of its expert, Dr. Goodman, who noted that the interchangeability of vinyls and acrylics was well known in the art.

As further proof of the equivalence of TRIS-VC to the "3 monomers, Dr. Goodman compared the chemical structure of TRIS-VC to the structure one of the Harvey preferred monomers, TSAA, and concluded that the structures differ only in that TRIS-VC has a single additional oxygen atom that is not critical to the claimed invention. The addition of an oxygen atom to the amide of TSAA results in the identical carbamate structure of TRIS-VC:

***388**



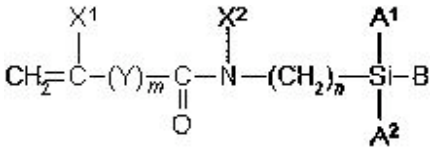
In response, Bausch & Lomb argues that TRIS-VC is substantially different from the monomers disclosed in the "3 patent, such as TSAA, and that it does not perform the function of increasing wettability or a substantial equivalent. According to Bausch & Lomb, TRIS-VC is substantially different from the monomers disclosed in the "3 patent, because it has different reactivity in the copolymerization process when it is polymerized with the TRIS amides cited in the patent. Therefore, the TRIS-VC monomer is incompatible with the co-monomers disclosed in the "3 patent and that any attempted copolymerization of those monomers would result in a material that could not be used as a contact lens material. Bausch & Lomb further notes that in order to get TRIS-VC to copolymerize to form a polymer that will provide visual acuity, it had to design a whole ensemble of new monomers for copolymerization with TRIS-VC. Therefore, because of these differences Bausch & Lomb contends, it cannot infringe claims 19, 54, and 57 under the doctrine of equivalents.

[26] An accused product "that does not literally infringe upon the express terms of the patent claim, may nonetheless be found to infringe if there is 'equivalence' between the elements of the accused product ... and the claimed element of the patented invention." Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 21, 117 S.Ct. 1040, 137 L.Ed.2d 146 (1997). Over time, courts have described the doctrine of equivalents in several ways. The Supreme Court has suggested that the inquiry is "whether under the circumstances the change was so insubstantial" that the doctrine should apply. Graver Tank & Mfg. Co. v. Linde Air Prods. Co., 339 U.S. 605, 610, 70 S.Ct. 854, 94 L.Ed. 1097 (1950). This test has been dubbed the "insubstantial differences" test. It has also described the inquiry as whether the accused product "performs substantially the same function in substantially the same way to obtain the same result." Machine Co. v. Murphy, 97 U.S. 120, 125, 24 L.Ed. 935 (1877) (describing the test now known as the "triple identity" test). More recently, in *Warner-Jenkinson,* the Court indicated that the "particular linguistic framework used" is not important, so long as it addresses the "essential inquiry: Does the accused product or process contain elements identical to or equivalent to each claimed element of the patented invention?" 520 U.S. at 40, 117 S.Ct. 1040. The Court emphasized that "[t]he determination of equivalence should be applied as an objective inquiry on an element-by-element basis." *Id; see also* Athletic Alternatives, Inc. v. Prince Mfg., Inc., 73 F.3d 1573, 1581, 37 USPQ2d 1365, 1373 (Fed.Cir.1996) (noting that the doctrine of equivalents "is not a license to ignore or erase structural and functional limitations of the claim").

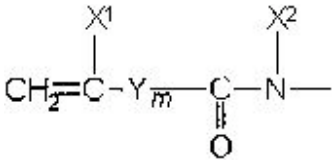
In determining whether PureVision and Balafilcon A infringes claims 19, 54, and 57 under the doctrine of equivalents, the sole issue before the court is whether the TRIS-VC monomer in the accused materials is equivalent to the claimed chemical structure element in those claims.FN6

FN6. All of the other elements of the claims are literally present in the accused materials. As noted earlier, it is undisputed that the contact lens material made from TRIS-VC, meets all four of the physical properties required by the claims, is a non-fibrous contact lens material comprising a polymer formed from at least one monomer (i.e., is a polymeric material), and has improved oxygen permeability and stability.

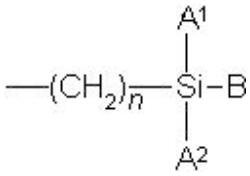
The chemical structure disclosed in claim 19 is:



Claim 54 is further directed at the "first portion" of that structure:



Claim 57, which depends from claim 54, is directed at the "second portion" of that structure.



This "second portion" of the general structure set forth in claim 19 is literally present in the TRIS-VC monomer. Therefore, the inquiry on equivalents for all of these claims reduces to whether TRIS-VC contains a portion that is equivalent to the "first portion" of that structure.

Wesley Jessen has marshaled convincing evidence to support its doctrine of equivalents case. This includes the testimony of Dr. Goodman regarding the relation between acrylics and vinyls, the knowledge of those skilled in the art regarding the interchangeability of acrylics and vinyls for the purposes of the claimed invention, and testimony explaining the sole insubstantial difference between TRIS-VC and the "3 patent's TSAA monomer.

This evidence establishes the following. TRIS-VC includes a carbamate, which has the required side-chain functionality. The carbamate is hydrophilic, and performs the function of increasing wettability. Tests performed by Wesley Jessen demonstrate that contact lens material made from TRIS-VC are more wettable than materials made from TRIS. The first portion of TRIS-VC, whose polymerizable group is a vinyl, is functionally equivalent to the first portion of the claimed hydrophilic siloxane monomers of the "3 patent that are limited to acrylics. It is also substantially equivalent structurally, with the sole difference between TRIS-VC and the claimed monomer being the presence of an additional oxygen atom. The presence of this

oxygen atom provides no meaningful distinction between the claimed structure and that of TRIS-VC in light of the purpose of the invention. The second portion of TRIS-VC includes a siloxane, and performs the function of increasing oxygen permeability.

As a whole, this evidence establishes both that the differences between the claimed acrylic structure and the vinyl carbamate structure of TRIS-VC are insubstantial and that the "first portion" of the TRIS-VC monomer, which contains the carbamate functional group, performs substantially the same function as the correspondingstructure in the claims at issue, in substantially the same way, to accomplish the same result. Accordingly, the court concludes that Balafilcon A infringes claims 19, 54, and 57 under the doctrine of equivalents.

3. *Willfulness*

[27] Wesley Jessen next contends that Bausch & Lomb's infringement of the "3 patent was willful. Although it does not seek damages as part of its remedy, electing instead to pursue only an injunction,FN7 if successful on its willfulness case, Wesley Jessen requests that the court deem this an exceptional case and order Bausch & Lomb to pay to its attorneys' fees incurred in connection with this case. *See* 35 U.S.C. s. 285; *see, e.g.,* Advance Transformer Co. v. Levinson, 837 F.2d 1081, 1085 (Fed.Cir.1988).

FN7. Counsel for Wesley Jessen informed the court that this election was made in the interest of moving the case to trial quickly, in light of the small amount of time left before the expiration of the Harvey patent.

[28] [29] [30] Willfulness is a question of fact. SRI Int'l v. Advanced Tech. Lab, Inc., 127 F.3d 1462, 1465 (Fed.Cir.1997). In a willfulness inquiry, "the primary consideration is whether the infringer, acting in good faith and upon due inquiry, had sound reason to believe it had the right to act in the manner that was found to be infringing." Id. at 1464-65. A finding of willful infringement requires clear and convincing evidence that based on the totality of circumstances, an infringer lacked a reasonable basis to believe that its product was not within the scope of any valid claim of the patent-in-suit. Transmatic, Inc. v. Gulton Indus., Inc., 53 F.3d 1270, 1279 (Fed.Cir.1995); Amstar Corp. v. Envirotech Corp., 823 F.2d 1538, 1544-47 (Fed.Cir.1987).

[31] One factor to consider in the willfulness inquiry is whether the infringer obtains and follows competent legal advice, in the form of an opinion of counsel, after having knowledge of the patent. SRI Int'l, 127 F.3d at 1465. Where, as here, the defendant obtains an opinion of counsel, but asserts the attorney-client privilege with respect to the opinion and therefore does not disclose its content, the Federal Circuit has held that the court may draw an adverse inference that the opinion was "contrary to the infringer's desire to initiate or continue its use of the patentee's invention." Fromson v. Western Litho Plate & Supply Co., 853 F.2d 1568 (Fed.Cir.1988).

Bausch & Lomb's wilfulness case rests on two facts. First, Bausch & Lomb became aware of the "3 patent in 1988, but nonetheless proceeded to develop and sell its PureVision product. Second, Bausch & Lomb obtained an opinion of counsel regarding the "3 patent, but has withheld this opinion on privilege grounds. As a result, Wesley Jessen asserts it is entitled to an adverse inference that the opinion was negative. Fromson, 853 F.2d at 1568.

Bausch & Lomb responds that its infringement was not willful because it was reasonable in its belief that it did not infringe. In support, it cites to the testimony of Seelye and McGee to establish that while Bausch & Lomb knew about the "3 patent and stopped working on monomers that it reasonably believed would infringe that patent, it did not discontinue work on its TRIS-VC project or on the development of PureVision lenses, because it believed that those materials were outside the scope of the "3 patent. Bausch & Lomb also points to its $60 million investment in the development of the PureVision line of contact lenses to corroborate the fact that Bausch & Lomb reasonably believed that it did not infringe the "3 patent.

[32] In consideration of the evidence raised by both parties, the court must determine whether Bausch & Lomb lacked a reasonable basis to believe that it did not infringe. While its failure to produce its opinion of counsel indicates that a negative inference may be drawn, this is one factor to be weighed; it is not the end of the court's inquiry on willfulness. Rather, the court must make its willfulness determination in view of the totality of the circumstances. Central Soya Co. v. Geo. A. Hormel & Co., 723 F.2d 1573, 1577 (Fed.Cir.1983). Applying this standard, the court concludes that Wesley Jessen has not met its burden in proving willfulness.

Bausch & Lomb's position on claim construction and throughout the case was that the "3 patent was limited to acrylics and excluded vinyl carbamate. While the court has disagreed with Bausch & Lomb's construction in this opinion, it was not a position that was "unreasonable." Moreover, the employee testimony provided by Bausch & Lomb indicates that it did not believe that its materials infringed the "3 patent for the same reasons Bausch & Lomb has asserted in its claim construction briefing and non-infringement case. The court finds this testimony to be credible. The fact that Bausch & Lomb spent $60 million to develop its PureVision line of lenses also counsels in favor of a finding that its infringement was not willful. It corroborates the Bausch & Lomb employee testimony that Bausch & Lomb believed it had designed a material that was outside the scope of the invention of the "3 patent. In addition, there is no evidence that Bausch & Lomb deliberately copied the invention of the "3 patent. Seelye testified that he developed TRIS-VC before becoming aware of the "3 patent. This too counsels against a finding of wilfulness. *See,* Crystal Semiconductor Corp. v. TriTech Microelectronics Intern., Inc., 246 F.3d 1336, 1352 (Fed.Cir.2001) (citing Advanced Display Sys., Inc. v. Kent State Univ., 212 F.3d 1272, 1285 (Fed.Cir.2000)) (stating that evidence of copying is relevant to a determination of willfulness).

In light of this evidence, the court finds its more likely that when Bausch & Lomb became aware of the "3 patent and evaluated its own project, it reasonably believed it had designed around the material claimed in the "3 patent. While in the end, this belief was incorrect, that belief was reasonable enough to merit a conclusion that its infringement was not willful.

Therefore, the court finds that Bausch & Lomb's infringement of the "3 patent was not willful. Accordingly, it declines to award attorneys' fees to Wesley Jessen pursuant to 35 U.S.C. s. 285.

C. ***Validity Analysis***

1. ***Invalidity Based on the Prior Art***

a. ***Anticipation***

[33] Bausch & Lomb contends that the claims of "3 patent are anticipated by U.S. Patent No. 4,260,725 to Keogh, et al. (the "Keogh patent" or "the '725 patent"). The Keogh patent was issued on April 7, 1981, and is thus prior art to the "3 patent.

[34] [35] Anticipation is determined by a simple comparison of the literal language of the claim at issue with a single prior art reference. Lindemann Maschinenfabrik v. American Hoist & Derrick, 730 F.2d 1452, 1458 (Fed.Cir.1984). A patent claim is anticipated, and therefore invalid, if every feature of the claim is found, either expressly or inherently, in a single prior art reference. Scripps Clinic Research Found. v. Genentech, Inc., 927 F.2d 1565, 1576 (Fed.Cir.1991); *see also* Telemac Cellular Corp. v. Topp Telecom, Inc., 247 F.3d 1316, 1327 (Fed.Cir.2001) ("A prior art reference must disclose every limitation of the claimed invention, either explicitly or inherently, to infringe").

[36] "If the prior art reference does not expressly set forth a particular element of the claim, that reference

still may anticipate if that element is 'inherent' in its disclosure." In re Robertson, 169 F.3d 743, 745 (Fed.Cir.1999). To establish inherency, the evidence must make clear that the missing descriptive matter is "necessarily present" in the material described in the reference, and that it would be so recognized by persons of ordinary skill in the pertinent art. Continental Can Co. v. Monsanto Co., 948 F.2d 1264, 1268 (Fed.Cir.1991); In re Robertson, 169 F.3d at 745 (noting that inherency cannot be established by probabilities or possibilities).

[37] As patents are presumed to be valid, *see* 35 U.S.C. s. 282, an accused infringer seeking to prove that a patent is anticipated and therefore invalid must do so by clear and convincing evidence. WMS Gaming Inc. v. Int'l Game Tech., 184 F.3d 1339, 1355 (Fed.Cir.1999). The Federal Circuit has pointed out that meeting this "burden is especially difficult when the asserted prior art was before the PTO examiner during the prosecution of the application." *Al-* Site Corp. v. VSI Int'l Inc., 174 F.3d 1308, 1323 (Fed.Cir.1999); *see also* Central Soya, 723 F.2d at 1577 (the burden is "most formidable when the parties asserting invalidity relies upon prior art" that was considered by the PTO).

Wesley Jessen asserts that part of the novelty of the claimed invention was that Harvey was the first to recognize and claim a material that combined the four claimed physical parameters for water content, oxygen permeability, tear strength, and percent elongation in a contact lens material. It contends that these four physical properties are neither expressly nor inherently described in the teachings of the Keogh patent, and that therefore Keogh cannot anticipate the "3 patent. Wesley Jessen also noted that the Keogh patent teaches a different polymeric structure than that of the "3 patent; the Keogh patent teaches a ladder-shaped polymeric structure in which the siloxane is contained in the "rungs" of the ladder as a cross-linker, while the "3 patent teaches the hydrophilic and siloxane portions as a side-chain off of the polymer backbone.

In attempting to meet its burden in proving anticipation, Bausch & Lomb relies on the test of Dr. Kunzler and the opinion testimony of Dr. Daly. It contends that Example XXX of the Keogh discloses a monomer having an amide structure, a siloxane structure, and polymerizable groups as required by the Harvey claims. While the four physical properties claimed in each of the asserted claims of the "3 patent are not specifically taught, Bausch & Lomb asserts that they are inherently disclosed. In support, Bausch & Lomb points out that when the co-polymers of Example XXX were prepared by Dr. Kunzler and the physical properties of the resulting material were determined, they corresponded to the four claimed properties of the Harvey material in that it possessed a water content of about 15-60%, oxygen permeability of greater than or equal to $25x10^{-10}$ Dk, tear strength greater than 1 g/mm ^{2}, and percent elongation greater than about 80%. Therefore, Bausch & Lomb asserts that Keogh renders the "3 patent invalid by anticipation.

As noted above, the Keogh '725 patent does not expressly describe the limitation of a polymeric contact lens material having the combination of four physical properties identified in independent claims 1, 27, and 50 of the "3 patent. Accordingly, the Keogh patent only anticipates the "3 patent, if at all, under the doctrine of inherency. In re Robertson, 169 F.3d at 745. Bausch & Lomb contends that the embodiments which it made from Example XXX of the Keogh patent demonstrate that the Keogh patent inherently anticipates the "3 patent.

Of the four materials that Dr. Kunzler made, the embodiment made directly from Example XXX produced a material that does not meet the four physical properties of the "3 patent. *See* Def. Ex. 107 (Report of Jay Kunzler). Dr. Kunzler's report notes that the water content of the first sample he prepared had an oxygen permeability below $25x10^{-10}$ Dk, a water content below 15%, and a percent elongation well below 80%. Kunzler then made three additional materials by substituting different components for the preferred components identified in Example XXX.

In addition, according to the testimony of Dr. Goodman, the first sample prepared in accordance with the teachings of Example XXX is not a hydrogel material. While two of the three additional prepared materials

do meet the four properties of the "3 patent, the Keogh patent does not teach or suggest the substitutions made by Bausch & Lomb to produce those samples. The fact that Example XXX can be substantially altered to achieve materials that sometimes fall within the "3 patent does not establish anticipation. *See* In re Oelrich, 666 F.2d 578, 581 (CCPA 1981) ("Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient."). These substitutions, which included the substitution of DMA, a Harvey preferred monomer, made with the benefit of hindsight, would not be recognized by persons of ordinary skill as "necessarily present in the Keogh patent." Continental Can Co., 948 F.2d at 1268.

Therefore the court concludes that Bausch & Lomb has not met its burden of proving by clear and convincing evidence that the asserted claims of the "3 patent are anticipated by the Keogh patent.

b. ***Obviousness***

[38] Bausch & Lomb contends that to the extent that the claims of the "3 patent are not anticipated by the Keogh '725 patent, they are obvious based on a combination of the Keogh patent and U.S. Patent No. 4,235,985 to Tanaka et al. ("the Tanaka '985 patent"). It contends that the claims of the "3 patent is obvious in light of these references, because Keogh teaches two specific hydrophilic groups present in the "3 patent-one of which is an amide-and Tanaka discloses siloxane monomers having hydrophilic groups that are useful for contact lenses. It contends that a person skilled in the art would recognize that either of the two hydrophilic groups could be used in a siloxane monomer, such as disclosed in Tanaka.

[39] [40] A patent is invalid for obviousness if "the difference between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." 35 U.S.C. s. 103. Whether a patent is invalid for obviousness is a question of law that is based on underlying factual issues. McGinley v. Franklin Sports, Inc., 262 F.3d 1339, 1349 (Fed.Cir.2001). These underlying factual issues include: (1) the scope and content of the prior art; (2) the differences between the claims and the prior art; and (3) the level of ordinary skill in the pertinent art. Graham v. John Deere Co., 383 U.S. 1, 18, 86 S.Ct. 684, 15 L.Ed.2d 545 (1966); *see also* In re Lee, 277 F.3d 1338, 1342 (Fed.Cir.2002). In addition, secondary considerations such as "commercial success, long felt but unresolved need, failure of others, etc." may be used to shed light on the obviousness determination. Graham, 383 U.S. at 17, 86 S.Ct. 684.

[41] When considering the obviousness or non-obviousness of a claim, the court should adhere to the following guidelines. First, the claimed invention must be considered as a whole. *Id*. Second, the references must be considered as a whole and must suggest the desirability and thus obviousness of making the combination. *See* Ashland Oil, Inc. v. Delta Resins & Refractories, Inc., 776 F.2d 281, 295 n. 17 (Fed.Cir.1985) (noting that a reference must be considered for all it teaches, including disclosures that teach away from the invention as well as disclosures that point toward the invention). Third, the references must be viewed without hindsight vision afforded by the claimed invention. Thus, when obviousness is based on multiple references there must be a showing of some teaching, suggestion, reason to combine the references. ACS Hosp. Sys. v. Montefiore Hosp., 732 F.2d 1572, 1577 (Fed.Cir.1984); *see* Brown & Williamson Tobacco Corp. v. Philip Morris, Inc., 229 F.3d 1120, 1124-25 (Fed.Cir.2000) ("a showing of a suggestion, teaching, or motivation to combine the prior art references is an 'essential evidentiary element of an obviousness holding' "); In re Dembiczak, 175 F.3d 994, 999 (Fed.Cir.1999) ("the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for showing of the teaching or motivation to combine prior art references."); In re Lee, 277 F.3d at 1343 (noting that "precedent [requiring inquiry into motivation to combine] has been reinforced in myriad decisions, and cannot be dispensed with").

[42] As with anticipation, because patents are presumed to be valid, *see* 35 U.S.C. s. 282, an accused

infringer seeking to prove that a patent is obvious and therefore invalid must do so by clear and convincing evidence. WMS Gaming, Inc. v. Int'l Game Tech., 184 F.3d 1339, 1355 (Fed.Cir.1999). As noted above, meeting this burden is "most formidable when the party asserting invalidity relies upon prior art" that was considered by the PTO. Central Soya, 723 F.2d at 1577; *see also Al-* Site Corp., 174 F.3d at 1323.

The Tanaka patent does not teach or suggest the claim elements from the "3 patent that the Keogh patent lacks. As noted above, the Keogh patent does not expressly or inherently teach the four claimed physical properties of the "3 patent. It also teaches a different polymeric structure and fails to suggest a separate cross-linker that would be necessary to produce the material claimed by Harvey.

The Tanaka patent does not teach materials that have the four claimed properties of the Harvey patent. In addition, the Tanaka patent teaches away from hydrogels in that it is directed to contact lens materials "which do not substantially absorb water." '985 patent, col. 1, ll. 6-8. Tanaka, therefore, does not suggest the use of amides and carbamates, as disclosed in the claims of the Harvey patent. In addition, the court concludes that there is no convincing evidence of any motivation to combine these two references in a manner that would produce the hydrophilic siloxane hydrogels of the "3 patent.

There is also one secondary consideration of non-obviousness that is relevant to the obviousness inquiry. Bausch & Lomb has recognized the importance of the invention of the Harvey patent by citing it in many of their own patents and publications. *See* Gambro Lundia AB v. Baxter Healthcare Corp., 110 F.3d 1573, 1579 (Fed.Cir.1997) (noting that infringer's recognition of importance of invention is objective evidence of non-obviousness). Included within this group of patents is U.S. Patent No. 5,563,184, which credits the "3 patent with "blurring the distinction between rigid-gas permeable lenses and hydrogel lenses." '184 patent, col. 1, ll. 39-46.

For these reasons, the court finds that the combination of the Keogh and Tanaka references, both of which were before the PTO when it issued the "3 patent, does not render the "3 patent obvious.

2. *Invalidity for Failure to Disclose Best Mode*

[43] Bausch & Lomb further contends that the "3 is rendered invalid by Harvey's failure to disclose the best mode of his invention. Based on evidence of Harvey's preliminary testing of the material that he patented, Bausch & Lomb contends that oxygen plasma treatment was Harvey's best mode of practicing his invention because it was the only successful attempt to increase the wettability of the lens in the eye and allow the user to comfortably wear the lens. Bausch & Lomb asserts that because Harvey did not disclose oxygen plasma treatment to the PTO, the "3 patent should be declared invalid.

[44] The first paragraph of section 112 of Title 35 requires that a patent specification "set forth the best mode contemplated by the inventor of carrying out his invention." 35 U.S.C. s. 112. "The best mode requirement creates a statutory bargained-for-exchange by which a patentee obtains the right to exclude others from practicing the claimed invention for a certain time period, and the public receives knowledge of the preferred embodiments for practicing the claimed invention." Eli Lilly and Co. v. Barr Laboratories, Inc., 251 F.3d 955, 963 (Fed.Cir.2001). Therefore, patents that fail to meet this "best mode" requirement are invalid. *See, e.g.,* United States Gypsum Co. v. National Gypsum Co., 74 F.3d 1209 (Fed.Cir.1996); Spectra-Physics, Inc. v. Coherent, Inc., 827 F.2d 1524, 1535 (Fed.Cir.1987).

[45] [46] To determine whether a patent complies with the best mode requirement, a court, as the finder of fact in this case, must undertake a two-prong inquiry. Nobelpharma AB v. Implant Innovations, Inc., 141 F.3d 1059, 1064 (Fed.Cir.1998). First, the fact finder must determine "whether, at the time the inventor filed his patent application," he had a best mode, i.e. "he knew of a mode of practicing his invention that he considered to be better than any other." Chemcast Corp. v. Arco Indus. Corp., 913 F.2d 923, 927-28 (Fed.Cir.1990). Second, if the inventor possessed a best mode, whether "the disclosure is adequate to enable

one skilled in the art to practice the best mode." *Id*. The first prong involves a subjective inquiry, focusing on the inventor's state of mind at the time he filed his patent application. Eli Lilly, 251 F.3d at 963; *see also* Mycogen Plant Science, Inc. v. Monsanto Co., 61 F.Supp.2d. 199, 252 (D.Del.1999) (noting that section 112 requires disclosure of the best mode "contemplated by the inventor, not the best mode in any absolute or ideal sense"). The second prong involves an objective inquiry, focusing on the scope of the claimed invention and the level of skill in the art. Eli Lilly, 251 F.3d at 963.

The first part of the best mode inquiry is wholly subjective and involves determining "whether, at the time the inventor filed his patent application, he knew of a mode of practicing his invention that he considered to be better than any other." Chemcast, 913 F.2d at 927-28. Dr. Harvey testified that he did not believe oxygen plasma treatment was the best mode to practice his invention, because he did not believe oxygen plasma treatment would be an effective long-term approach for improving wettability in the eye. He viewed oxygen plasma treatment only as a short term fix for the wettability issue, given its known propensity to be short lived in its effectiveness. Dr. Harvey indicatedas much in the background section of the "3 patent, where he pointed out that the use of surface treatments to address wettability had a tendency to be short-lived in their effectiveness. *See* "3 patent, col 1. ll. 59-66. Dr. Harvey's testimony strongly supports Wesley Jessen's position that because Dr. Harvey did not consider oxygen plasma treatment to be his best mode, his failure to disclose it as part of his invention should not invalidate the "3 patent on best mode grounds.

Bausch & Lomb nonetheless argues that oxygen plasma treatment must have been the best mode because it was the only technique used in the preliminary testing that produced workable results. The court concludes, however, that the mere fact that it was the only technique applied in preliminary testing FN8 that allowed for good visual acuity and comfortable wearing in the eye does not compel the conclusion that oxygen plasma treatment was Dr. Harvey's the best mode. The single test did not establish that plasma treatment would be a necessary part of a successful lens, nor did it establish that oxygen plasma treatment was effective as a long term solution. Thus, although plasma treatment was effective as a short term stop-gap, there is no evidence that Harvey considered this technique to be the optimal way to practice his invention. To the contrary, he considered this technique to be an inferior solution to the problem he sought to solve, because he understood that the effectiveness of surface treatments was short lived.FN9 As corroborated by the disclosure of the "3 patent, in Dr. Harvey's mind, his invention did not include such surface treatments.

FN8. After this preliminary test, no further clinical testing was performed. As noted earlier, Harvey's invention was never commercialized at Syntex. He left the company soon after filing for his patent.

FN9. The court notes that Bausch & Lomb did not challenge that it was then understood that the effectiveness of surface treatments to provide wettability was only temporary. In fact, that this view of surface treatments existed at the time that Harvey filed his patent and thereafter is corroborated by one of Bausch & Lomb's patents (the '369 patent issued to Valint), which cites an earlier patent as stating that "although exposing the surface of an object to plasma discharge with oxygen is known to enhance the wettability or hydrophilicity or such surface, such treatment is only temporary." See '369 patent, col. 2, ll. 6-9.

[47] As the best mode requirement does not obligate an inventor to disclose a technique that the inventor did not believe was the best way of carrying out his invention, the court finds that Harvey did not breach the best mode requirement.

3. *Invalidity for Failure to Provide Utility or Enable the Invention*

[48] As additional grounds to invalidate the "3 patent, Bausch & Lomb next challenges the utility of the invention of the "3 patent and contends that the "3 patent does not enable persons skilled in the art to make

a contact lens that could be worn, without pain, on the human eye. The crux of its position on both issues is that the claims of the "3 patent simply do not work to produce a wearable contact lens. Although Bausch & Lomb's post-trial papers state their position in terms of enablement, under this set of circumstances, where the defendant argues that the claimed invention simply does not work, the utility and enablement inquiries are closely related.

[49] The enablement requirement of 35 U.S.C. s. 112, para. 1, mandates that the specification adequately discloses to one skilled in the relevant art how to make the claimed invention without "undue experimentation." Process Control Corp. v. HydReclaim Corp., 190 F.3d 1350, 1358 (Fed.Cir.1999); In re Wright, 999 F.2d 1557, 1561 (Fed.Cir.1993). As the Federal Circuit has stated, "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable .... Tossing out the mere germ of an idea does not constitute enabling disclosure." Genentech, Inc. v. Novo Nordisk A/S, 108 F.3d 1361, 1366 (Fed.Cir.1997).

[50] Similarly, the utility requirement of 35 U.S.C. s. 101, mandates that the claimed invention provide some identifiable benefit, Brenner v. Manson, 383 U.S. 519, 534, 86 S.Ct. 1033, 16 L.Ed.2d 69 (1966), and not be "totally incapable of achieving a useful result." Brooktree Corp. v. Advanced Micro Devices, Inc., 977 F.2d 1555, 1571 (Fed.Cir.1992). In order to be useful, "the subject matter of the claim must be operable." Process Control Corp., 190 F.3d at 1358.

[51] [52] Thus, while the enablement and utility inquiries are distinct, they are closely related. Where the "claimed subject matter is inoperable, the patent may indeed be invalid for failure to meet the utility requirement of s. 101 and the enablement requirement of s. 112." Brooktree Corp., 977 F.2d at 1571; Process Control Corp., 190 F.3d at 1358 (noting that the questions of whether a specification provides an enabling disclosure under s. 112, para. 1, and whether an application satisfies the utility requirement of s. 101 are closely related, because if the claims fail to meet the utility requirement because the invention is inoperative, they also fail to meet the enablement requirement because a person skilled in the art cannot practice the invention); *see also* Raytheon Co. v. Roper Corp., 724 F.2d 951, 956 (Fed.Cir.1983) (discussing the utility and enablement inquiries). Both non-enablement and lack of utility are questions of law that must be proved by clear and convincing evidence. *Northern Telecom, Inc.,* 908 F.2d at 941.

Bausch & Lomb contends that the "3 patent is non-enabling, because following the teachings of the "3 patent does not enable one to produce a contact lens that would be satisfactory for someone to wear with comfort and with visual clarity. It states in its post-trial submissions, that "[w]ithout further years of development and undue experimentation, the Harvey material when made as disclosed in the "3 patent and shaped into a contact lens is merely a 'hunk of plastic' with no real use because its placement on the eye would result in severe damage to the eye."

In response Wesley Jessen asserts that the fact that Bausch & Lomb spent many years improving its silicone hydrogel product so that it would be sold commercially as a 30-day extended wear contact lens should not obscure that Dr. Harvey had produced a successful and novel silicone hydrogel contact lens material. The focus of the inquiry is not how long it took for Bausch & Lomb to make improvements to the material, or whether the Harvey material is able to be worn as a 30-day extended wear product like PureVision, but whether the material and corresponding contact lens are sufficiently enabled by the "3 patent.

Wesley Jessen contends that Harvey's clinical test established that the claimed material could be successfully used as a contact lens in the eye. That test shows that when first placed in the eye, the lens caused stinging, and could only be worn for ten seconds. This problem was alleviated by methanol extraction, a process that was known in the art at the time, and disclosed in the "3 patent. After extraction, the lenses could be worn comfortably, but did not give good visual acuity. Thereafter, the lenses were subjected to oxygen plasma treatment, and gave excellentvisual acuity. It is Wesley Jessen's position that oxygen plasma treatment too, was known in the art at that time. The deposition testimony of two Bausch &

Lomb witnesses, Mr. Karutz and Mr. Daly, establishes that as of the early 1980's the use of oxygen plasma treatment to improve wettability of contact lenses was well-known. In addition, as noted above, the background of invention section of the patent also refers to use of oxygen plasma treatment, but notes that its limitation is that its effectiveness is short-lived. After the oxygen plasma treatment, the lenses were worn comfortably and with good visual acuity for several hours. Thus, according to Wesley Jessen, Dr. Harvey produced his novel material as taught in the "3 patent, molded it into a contact lens, and made it comfortable and able to provide good visual acuity by using two techniques (extraction and oxygen plasma treatment) which were known in the art at the time. As these two techniques were known in the art, the failure to disclose or claim the oxygen plasma treatment does not make the "3 patent not enabled, because those skilled in the art would know that they could apply such treatments to Dr. Harvey's invention. *See, e.g.*, Spectra-Physics, Inc., 827 F.2d 1524 ("A patent need not teach, and preferably omits, what is well-known in the art"); In re Gay, 50 C.C.P.A. 725, 309 F.2d 769, 774 (CCPA 1962) ("Not every last detail is to be described, else patent specifications would turn into product specifications, which they were never intended to be").

The asserted claims of the "3 patent are directed to either a contact lens material or to a contact lens made from the material that is comprised from hydrophilic siloxane monomers having a specified combination of water content, oxygen permeability, tear strength, and elongation. Of the ten asserted claims, two of the claims, claims 14 and 63, are directed at contact lenses, while the remaining eight are directed at contact lens materials. The patent's specification teaches numerous preferred embodiments of hydrophilic siloxane monomers and dimers, and over sixty example of materials made from two of the preferred monomers, as well as including tables describing the physical properties of each of the formed materials.

[53] While the claims cover materials that are used to fabricate extended wear contact lenses, the claims do not require the limitation of extended wear. FN10 Thus, whether the patent enables an extended wear contact lens is not the relevant inquiry. The patent only must enable what is claimed. The claims all specify "contact lens" or "contact lens material." Thus, to be enabled, the claimed material must be able to be inserted in the eye as a contact lens or used to fabricate a contact lens. Moreover, the enablement and utility standards do not require that the claimed material perform optimally in the sense that it is a usable sellable commercially fit contact lens; it is enough that the material provides some benefit and works well enough to meet at least one of its objectives.

FN10. Using the material to fabricate extended wear contact lenses is only one objective of the invention. The other three objectives were to provide "new and useful hydrophilic siloxane-containing monomers for making contact lenses," to "prepare hydrogels from [those monomers] which have moderate water content (about 15-60%), but high oxygen permeabilities (greater than about Dk 25 x 10^{-10})," and to "provide a contact lens having improved wettability, characterized by a receding contact angle of less than that of contact lenses made of polyMMA [PMMA]."

[54] The "3 patent enables one to make a material which, when treated with oxygen plasma treatment, works as a contact lens. Prior to the oxygen plasma treatment, however, testing indicated that the lens caused stinging and irritation in the eye, or, if this was treated with methanol extraction, poor visual acuity (i.e., the lens was cloudy and opaque). The inquiry at hand boils down to this: if oxygen plasma treatment was well-known in the art at the time of invention, there is no need for the "3 patent to disclose its use in order to provide an enabling invention. Applying known techniques to solve common problems with the material is not "undue experimentation." If, however, the use of oxygen plasma treatment was not well-known in the art, and it was not possible to create a material that could be effective as a contact lens using the disclosures of the "3 patent without additional "undue experimentation," the disclosure is lacking and non-enabling.

The testimony of Dr. Harvey, the deposition testimony of Mr. Karutz and Dr. Daley, the facts surrounding

the clinical tests of the "3 material, and the specification of the "3 patent establish that oxygen plasma treatment was a known technique in the early 1980's. Therefore, Dr. Harvey's failure to detail its use in one successful early clinical test of his material does not make his patent non-enabling. The teachings of the "3 patent are extensive and detailed. Following the teaching of his patent, those skilled in the art could produce a novel hydrophilic siloxane-containing monomer that, in conjunction with known techniques, could be used as a material with which to make contact lenses. As measured against the patent's objectives, this is a largely successful contact lens material. Accordingly, the "3 patent is not invalid for failure to enable or for lack of utility.

4. ***Invalidity for Indefiniteness***

[55] Bausch & Lomb also asserts that the "3 patent is invalid on the ground that it is indefinite. The court discerns two theories of indefiniteness that Bausch & Lomb has pursued during the course of the trial. First, during claim construction, Bausch & Lomb argued that the "second portion for increasing oxygen permeability" is indefinite because in most instances the claims fail to describe a complete chemical formula for the second portion, instead defining it as "including a siloxane." FN11 Bausch & Lomb does not appear to have pursued this theory in its post-trial papers, but the court briefly will address it below. Second, Bausch & Lomb contends that the claims of the "3 patent are indefinite, because they do not provide a fixed definition for the term "increased wettability."

FN11. This argument does not apply to claims 11, 19, 57, or 60, as each of these claims contain a specific structural formula for the second portion of the monomer.

[56] Patents are required to "conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention." 35 U.S.C. s. 112. "Whether a claim is invalid for indefiniteness requires a determination whether those skilled in the art would understand what is claimed when the claim is read in light of the specification." Morton Int'l, Inc. v. Cardinal Chem. Co., 5 F.3d 1464, 1470 (Fed.Cir.1993); *see also* Mycogen Plant Science, Inc., 61 F.Supp.2d. at 255 ("If the claims, read in light of the specification, reasonably apprise those skilled in the art both of utilization and scope of the invention, and if the language is as precise as the subject matter permits, the courts can demand no more.").

[57] [58] The indefiniteness determination is made as a matter of law. Personalized Media, 161 F.3d at 705. The party seeking to prove indefiniteness bears the burden of showing by clear and convincing evidence that one of ordinary skill in the art would not understand what is included within the claims of the "3 patent. Mycogen Plant Science, Inc., 61 F.Supp.2d. at 255.

Bausch & Lomb has not successfully proved either of its indefiniteness theories. The court first will turn to Bausch & Lomb's argument that the claim language describing "the second portion for increasing oxygen permeability" as "including a siloxane" is indefinite. This language is indefinite only if those skilled in the art would not understand what is meant by "second portion ... including a siloxane." Testimony from the Markman hearing confirms that this is not the case.

There, Dr. Nicolson explained that earlier rigid gas permeable lenses were made from siloxane monomers and that the chemistries of siloxanes were well-understood. There is no evidence to the contrary. Moreover, patents describing siloxane monomers date back to at least U.S. Patent. No. Re. 31, 406 to Gaylord issued in 1974. In addition, the concept of monomers with a siloxane portion was also known in the prior art. As one example, the Keogh '725 patent specifically recites a "siloxane portion." Finally, it is well established that a chemical compound can be claimed by claiming a partial chemical structure. *See, e.g., Manual of Patent Examining Procedure,* 2173.05(t) ("A claim to a chemical compound is not indefinite merely because structure is not presented or because a partial structure is presented."); In re Fisher, 57 C.C.P.A. 1099, 427

F.2d 833, 838 (CCPA 1970). Thus, the term a "siloxane portion" is not indefinite to one of skill in the art.

[59] Next the court will address Bausch & Lomb's contention that "increased wettability" is an indefinite term. As discussed at length above, the "3 patent states that an object of the invention is to provide a contact lens with improved wettability, characterized by a receding contact angle of less than that of contact lenses made of PMMA. This feature is claimed in the language "first portion for increasing wettability." Bausch & Lomb points out, however, that Dr. Winterton explained that the receding contact angle of PMMA is not a fixed number, but instead depends on how the PMMA was produced, how long it was hydrated, and a host of other issues. Thus, depending on all these factors, the receding contact angle for any sample of PMMA can vary dramatically. As evidence of this, Bausch & Lomb underscores that the "3 patent reports a receding contact angle for PMMA of 22 (deg.), Dr. Grobe reported an angle of 60 (deg.), and Dr. Winterton reported an angle of 46 (deg.). Based on this, Bausch & Lomb reasons that a person of ordinary skill would not be able to determine whether his material has "increased wettability," because the PMMA standard identified by the "3 patent is unreliable and not reproducible.

Differences in the receding contact angles of PMMA do not make the "first portion for increasing wettability" indefinite. Testing the receding contact angle of a material and comparing it to that of PMMA is a *relative test*. Both samples are treated in the same manner, hydrated for the same amount of time, and then tested using the same procedures. Despite the variances in the receding contact angles of PMMA, a potential infringer can definitively assess whether a given potentially infringing material has "increased wettability" by comparing its receding contact angle to the receding contact angle of a similarly treated sample of PMMA. Therefore, the court cannot conclude that the asserted claims are indefinite in this regard.

D. ***Enforceability Analysis-Inequitable Conduct***

[60] Bausch & Lomb raises two theories in support of its next contention that Dr. Harvey engaged in inequitable conduct that renders the "3 unenforceable. First, Bausch & Lomb asserts that Dr. Harvey engaged in inequitable conduct by failing to disclose that oxygen plasma treatment had been used successfully in clinical testing, and misrepresented the success of oxygen plasma treatment by disparaging the use of such known surface treatments in the background section of the "3 patent. Second, Bausch & Lomb contends that Dr. Harvey further engaged in inequitable conduct by representing to the PTO Examiner that his invention differed from the prior art, which required an additional monomer to introduce wettability, and that his claimed monomers did not intrinsically possess all of the wettability necessary to allow the contact lenses to be sufficiently wettable in the eye.

[61] It is well-established that "[p]atent applicants are required to prosecute patent applications with candor, good faith, and honesty." Semiconductor Energy Lab. Co. v. Samsung Elecs. Co., 204 F.3d 1368, 1373 (Fed.Cir.2000); *see also* 37 C.F.R. s. 1.56(a). Specifically, patent applicants and their patent attorneys have a duty to disclose to the PTO known information material to the examination of the application. *See* 37 C.F.R. s. 1.56(a).

[62] An applicant breaches the duty of candor when he affirmatively misrepresents a material fact, fails to disclose material information, or submits false material information to the Examiner. Perseptive Biosystems, Inc. v. Pharmacia Biotech, Inc., 225 F.3d 1315, 1318 (Fed.Cir.2000); Molins PLC v. Textron, Inc., 48 F.3d 1172, 1178 (Fed.Cir.1995). Prior to 1992, "materiality" was defined as whether "there was a substantial likelihood that a reasonable examiner would have considered the information important in deciding whether to allow the application to issue as a patent." Molins PLC, 48 F.3d at 1179 n. 8. Since the application for the "3 patent was filed in 1985, this standard applies to Bausch & Lomb's inequitable conduct theories raised this case.

[63] [64] A breach of the duty of candor, when coupled with an intent to deceive or mislead the PTO, constitutes inequitable conduct, which, when proven, renders the patent unenforceable. Li Second Family

Ltd. P'ship. v. Toshiba Corp., 231 F.3d 1373, 1381 (Fed.Cir.2000); *see also* Molins PLC, 48 F.3d at 1182 (explaining that "[o]ne who has engaged in inequitable conduct has inflicted damage on the patent examining system, obtaining a statutory period of exclusivity by improper means, and on the public, which must face an unlawfully granted patent"). Thus, a successful proof of inequitable conduct requires clear and convincing evidence of (1) information that is material, (2) knowledge chargeable to the patent applicant of such information and its materiality; and (3) the applicant's failure to disclose or misrepresentation of such information as a result of an intent to mislead the PTO. FMC Corp. v. Manitowoc Co., Inc., 835 F.2d 1411, 1415 (Fed.Cir.1987); Key Pharmaceuticals v. Hercon Labs. Corp., 161 F.3d 709, 719 (Fed.Cir.1998). Once materiality and intend have been established, "the court conducts a balancing test and determines whether the scales tilt to the conclusion that 'inequitable conduct' occurred." Critikon, Inc. v. Becton Dickinson Vascular Access, Inc., 120 F.3d 1253, 1256 (Fed.Cir.1997).

[65] Based on the evidence presented, the court concludes that Bausch & Lomb has failed to prove either of its inequitable conduct theories. The first, concerning Dr. Harvey's failure to disclose his success with oxygen plasma treatment is based on the same set of facts as its contentions regarding best mode. The court concludes here, as the court concluded with regard to that theory, that Dr. Harvey did not breach any duty of candor owed to the PTO by failing to disclose the plasma treatment as a viable mechanism to practice his invention. The test does not establish that plasma treatment was necessary to achieve a successful lens, nor did it establish that oxygen plasma treatment was effective as along term solution, given its known propensity to have limited effectiveness. Moreover, because plasma treatment was known to those skilled in the art at the time of the filed application, a reasonable examiner would not have considered it important in determining patentability. Therefore, the fact that oxygen plasma treatment had been used successfully in a single clinical test was not material to the Examiner's determination regarding patentability of the invention. Nor is there any evidence that Dr. Harvey had any intent to mislead the PTO. Dr. Harvey did not hide the existence of plasma treatment; he truthfully disclosed that he did not believe plasma treatment to be an effective solution. For these reasons, the court concludes that Dr. Harvey did not engage in inequitable conduct by failing to disclose his successful plasma treatment test results.

[66] Bausch & Lomb's second argument regarding inequitable conduct is based on an erroneous construction of Harvey's statement to the Examiner. Dr. Harvey distinguished the Gaylord reference on grounds that Gaylord "teaches a second monomer that must be copolymerized to achieve greater wettability whereas applicant herein teaches putting the amide and urethane moieties in the monomer structure." Bausch & Lomb contends this statement is a false representation by Dr. Harvey that *all* of the wettability of the contact lens material in the "3 patent must be achieved by putting a hydrophilic group (the amide) into the first monomer. Dr. Harvey's statement does not go so far. He did not state that wettability may not also be provided by specific co-monomers, such as DMA and NVP, which were included in the original claims before the Examiner. Rather, Dr. Harvey simply was distinguishing his invention as teaching an incorporation of an amide or carbamate into the monomer itself to produce increased wettability, while Gaylord achieves increased wettability by use of a separate monomer. This statement is true, and not misleading, and therefore cannot provide the basis for a finding of inequitable conduct.

For the foregoing reasons, Bausch & Lomb has not shown by clear and convincing evidence that Dr. Harvey engaged in inequitable conduct during the prosecution of the "3 patent.

E. *Remedy*

1. *Injunction*

[67] [68] Wesley Jessen does not seek damages in this case. It seeks a permanent injunction to prevent Bausch & Lomb from infringing the "3 patent. Pursuant to 35 U.S.C. s. 283, the court is authorized to "grant injunctions in accordance with the principles of equity to prevent the violation of any right secured by patent, on such terms as the court deems reasonable." Because a patent is, at its heart, the right to exclude

another from making the patented invention, *see* U.S. Const. art. 1, s. 8, cl. 8, as a general rule, "an injunction will issue when infringement has been adjudged, absent a sound reason for denying it." Richardson v. Suzuki Motor Co., 868 F.2d 1226, 1247 (Fed.Cir.1989); *see also* W.L. Gore & Assoc. v. Garlock, Inc., 842 F.2d 1275, 1281-83 (Fed.Cir.1988) ("although the district court's grant or denial of an injunction is discretionary depending on the facts of the case ... injunctive relief against an adjudged infringer is usually granted.").

[69] Thus, the decision to grant an injunction upon the successful proof that the claims of a patent are infringed, not invalid, and enforceable, is ordinarily quite straightforward. In this case, there was more discussion about the issuance of an injunction than in most. That is perhaps because this case has a few aspects that distinguish it from many patent cases. First, the patentee seeks only an injunction and no damages. Second, the patentee never commercialized a product from its patent, while the infringer spent much time and effort in its effort to commercialize an extended wear contact lens. FN12

FN12. One interesting corollary issue apparent from this is that issuing an injunction sometimes harms the party that has worked harder towards commercializing the product. Here, the infringer, Bausch & Lomb has invested a lot of money in producing a commercial product that works well as an extended wear lens. Wesley Jessen, on the other hand, has not commercialized the invention of the "3 patent, yet seeks to exclude Bausch & Lomb from the market.

Of course it is well-settled that a patentee need not commercialize his invention to successfully sue for patent infringement, and that a patent at its core is the right to exclude. This is the bargain at the heart of our patent system. The patentee, Wesley Jessen, contributes to the public by disclosing its novel ideas. In exchange, it may exclude others from practicing that idea for the period of its patent. *See* Smith Int'l, Inc. v. Hughes Tool Co., 718 F.2d 1573, 1577-78 (Fed.Cir.1983) (explaining the basis for granting injunctive relief in patent cases and explaining that "without the right to obtain an injunction, the right to exclude granted to the patentee would have only a fraction of the value it was intended to have, and would no longer be as great an incentive to engage in the toils of scientific and technological research")
There is one noteworthy consequence of Wesley Jessen's choice to seek "only" an injunction and no damages. If a damages case were put on, Bausch & Lomb could have brought in evidence to try to minimize the amount of damages by proving that the contribution of the patented feature of their product was relatively small. In other words, although their product contains the patented material, Bausch & Lomb could have attempted to prove that the patented material alone was of limited value, because it took years of development and $60 million investment to commercialize a viable contact lens from the material.FN13 Because Wesley Jessen is seeking only an injunction, however, Bausch & Lomb such arguments have no place in the case. The remedy is either an injunction or nothing; there is no in between point depending on the relative value of the patented feature. This is of course true for both parties. If this court does not enter an injunction after finding the claims of the patent infringed, enforceable and not invalid, it would leave Wesley Jessen without any remedy.

FN13. In making this theoretical argument, the court does not suggest that the invention of the "3 patent is not valuable. Of course there are many good arguments in favor of the proposition that the "3 patent was not just "a small step on the road to defendant's market position," but was instead a giant step and a launching off point in that it was the first to suggest using a specific type of material with specific parameters in contact lenses. The court is simply pointing out that it heard no evidence in this regard and that there seems to be no place for such evidence in an injunction-only case.

In this case, during closing arguments, the court explored the equities of issuing an injunction in a dialogue with counsel. The court queried whether, if it concluded that the patent was infringed and not invalid, Bausch & Lomb had any further arguments that it could levy against granting an injunction. The parties addressed this issue in post-trial briefing that was submitted to the court shortly thereafter.

Therein, Wesley Jessen maintains that it is entitled to a permanent injunction. It notes that only on the rarest of occasions, where an injunction would harm the public interest, do courts decline to grant injunctive relief in patent cases where such relief is sought and infringement is successfully proved. *See* City of Milwaukee v. Activated Sludge, 69 F.2d 577 (7th Cir.1934) (denying injunction because an injunction would leave entire community without any means to dispose raw sewage other than by running it into Lake Michigan, thereby polluting its waters and endangering the health and lives of those in the community); Hybritech, Inc. v. Abbott Labs., 4 U.S.P.Q.2d. 1001, 1987 WL 123997 (C.D.Cal.1987), *aff'd,* 849 F.2d 1446 (Fed.Cir.1988) (denying injunction because it would stop the supply of medical test kits). Wesley Jessen contends that no such circumstances apply to this case as contact lenses are not a medical necessity, the lack of which would harm the public, and there are numerous alternatives to the PureVision product, including its corporate parent CIBA Vision's 30-day extended wear lenses, and market substitutes such as weekly wear lenses, daily wear lenses, eye glasses, and even laser surgery.

In reply, Bausch & Lomb does not dispute the case law cited by Wesley Jessen. It does contend, however, that the parties should be permitted further discovery on the factual issues that underlie Wesley Jessen's contention that the exclusion from the market of Bausch & Lomb's PureVision product would not harm the public.

After considering the parties' arguments, the court concludes that it is proper to enter an injunction in this case. Wesley Jessen has proved infringement and Bausch & Lomb has failed to prove that the patent is invalid or unenforceable. Further, there is no "sound reason" for denying Wesley Jessen's request for injunctive relief.

[70] While issuing an injunction that prevents a party from making and selling any product arguably harms the public in some way, the standards applied to determine when to deny a request for an injunction in a patent case, where the injunction is the remedy inherent in the patentee's right to exclude, are far higher. In patent cases, courts only exercise their discretion to deny injunctive relief when the harm to the public from granting the injunction is so severe that it outweighs the patentee's individual right to exclude. *See, e.g.,* City of Milwaukee, 69 F.2d 577; Hybritech, Inc., 4 U.S.P.Q.2d. 1001. In those cases where courts have decline to grant an injunction, the issuance of injunction would have had severe medical or environmental consequences. That is simply not the case here.

Nor is there any need for "further discovery" on this matter. Injunctive relief was requested in the complaint. Now that the discovery period and the trial are over, the time for additional discovery has long passed.

The court will grant Wesley Jessen's request for injunctive relief.

2. *Exceptional Case-Attorney's Fees*

As the court has concluded that Bausch & Lomb's infringement was not willful, *see* supra II.B.3, there is no basis for a determination that this is an "exceptional case," under 25 U.S.C. s. 285. Accordingly, as noted above, it declines to award attorneys' fees to Wesley Jessen.

III. *CONCLUSION*

The court concludes that Bausch & Lomb's Pure Vision products infringe claims 1, 11, 14, 19, 27, 50, 54, 57, 60, and 63 of the "3 patent. Claims 1, 11, 14, 27, 50, 60, and 63 are literally infringed. Claims 19, 54, and 57 are infringed under the doctrine of equivalents. Bausch & Lomb's infringement, however, is not willful.

Further, the court finds that the claims of the "3 patent are not invalid by reason of anticipation,

obviousness, indefiniteness, non-enablement, lack of utility, or failure to disclose best mode. The court also finds that the "3 patent is enforceable, as Bausch & Lomb did not successfully prove that Wesley Jessen engaged in inequitable conduct.

The court will grant the injunctive relief requested by Wesley Jessen, but, in line with its finding of no willfulness, declines to award attorneys' fees.