UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

DOME PATENT, L.P.,	)	
Plaintiff,	)	
v.	)	Civil Action No. 07-1695 (PLF)
TERESA STANEK REA, Acting Under Secretary of Commerce for Intellectual Property and Acting Director of the United States Patent and Trademark Office,	)	
Defendant.[1]	)	

OPINION, FINDINGS OF FACT AND CONCLUSIONS OF LAW

Dome Patent L.P. owns United States Patent No. 4,306,042 (the "Neefe Patent"), which was issued on December 15, 1981. The Neefe Patent is entitled "Method of Making a Contact Lens Material With Increased Oxygen Permeability," and it is based on an application filed by Russell A. Neefe. See JTX-1. In 2007, the United States Patent and Trademark Office (the "PTO") found that claim 1 of the Neefe Patent should be cancelled as obvious in light of the prior art. Dome timely filed a civil complaint under 35 U.S.C. §§ 145 and 306, requesting that this Court set aside the PTO's decision. See Compl. ¶ 20. After considering the parties' arguments, the administrative record, the decision of the PTO's Board of Patent Appeals and Interferences, the evidence presented during a three-day bench trial, and the relevant legal authorities, the Court concludes that the process recited in claim 1 of the Neefe Patent is

[1] Pursuant to Rule 25(d) of the Federal Rules of Civil Procedure, the Court substitutes as defendant the acting Under Secretary, Teresa Stanek Rea, for the former Under Secretary, David J. Kappos.

unpatentable, as it would have been obvious to a person of ordinary skill in the art at the time the patent application was filed. The Court therefore will enter judgment in favor of the defendant, Teresa Stanek Rea ("the Director"), Acting Under Secretary of Commerce for Intellectual Property and Acting Director of the PTO.[1]

I. BACKGROUND

A. The Neefe Patent and the Procedural History

The Neefe Patent contains four claims, the first of which is relevant to this action. Claim 1 recites:

[1] The exhibits presented at trial – Joint Trial Exhibits ("JTX") 1-34, Plaintiff's Trial Exhibits ("PTX") 1-6, and Defendant's Trial Exhibits ("DTX") 1-2 – are listed in the appendix to this decision. In addition, the Court reviewed the following papers in connection with this matter: the complaint ("Compl.") [Dkt. No. 1]; defendant's answer [Dkt. No. 4]; plaintiff's trial brief ("Dome's Trial Brief") [Dkt. Nos. 54/52 (sealed/public)]; defendant's response to plaintiff's trial brief ("Director's Trial Brief") [Dkt. Nos. 57/59]; plaintiff's reply trial brief [Dkt. Nos. 65/71]; the parties' joint pretrial statement ("Jt. Pretrial Stmt.") [Dkt. Nos. 61/62]; defendant's motion *in limine* to exclude the testimony of Dr. Melamed pursuant to Fed. R. Evid. 702 [Dkt. Nos. 70/67]; plaintiff's opposition to defendant's motion to exclude the testimony of Dr. Melamed [Dkt. Nos. 76/79]; defendant's reply in support of her motion *in limine* to exclude the testimony of Dr. Melamed [Dkt. Nos. 82/85]; defendant's motion *in limine* to exclude the testimony of Dr. Melamed and portions of the testimony of Dr. Long pursuant to Fed. R. Evid. 401 [Dkt. Nos. 69/66]; plaintiff's opposition to motion *in limine* to exclude the testimony of Dr. Melamed and portions of the testimony of Dr. Long [Dkt. Nos. 77/80]; defendant's reply to opposition to motion *in limine* to exclude the testimony of Dr. Melamed and portions of the testimony of Dr. Long [Dkt. Nos. 83/84]; plaintiff's surreply in opposition to motion *in limine* to exclude testimony of Dr. Melamed and portions of the testimony of Dr. Long [Dkt. Nos. 89, 88]; plaintiff's supplemental trial brief [Dkt. No. 81]; defendant's brief in response to plaintiff's supplemental trial brief [Dkt. No. 87]; plaintiff's reply supplemental trial brief [Dkt. No. 91]; defendant's proposed findings of fact and conclusions of law ("Director's PFF." or "Director's Prop. Concl. of Law," as appropriate) [Dkt. No. 100]; plaintiff's proposed findings of fact and conclusions of law ("Dome's PFF." or "Dome's Prop. Concl. of Law," as appropriate); defendant's response to plaintiff's proposed findings of fact and conclusions of law ("Director's Resp. PFF." or "Director's Resp. Concl. of Law," as appropriate) [Dkt. No. 104]; plaintiff's response to defendant's proposed findings of fact and conclusions of law ("Dome's Resp. PFF." or "Dome's Resp. Concl. of Law," as appropriate) [Dkt. No. 105]; and transcripts of the January 15, 2013 pretrial conference and of the bench trial held from January 28 through January 30, 2013, designated by way of example as "Jan. 28 AM Tr.".

> A method of making an oxygen permeable material for the manufacture of contact lens [sic] by the synthesization of the monomer 1,1,1-tris(methylsiloxy)methacryloxypropylsilane (a siloxanyl alkyl ester) by the following procedures:
>
> (a) a mixture is prepared having the relationship of one mole of methacryloxypropyltrimethoxysilane with three to forty moles of trimethylchlorosilane;
>
> (b) the mixture is then added to water whose volume is from 3 to 10 times that of the mixture;
>
> (c) agitation is maintained for 30 minutes to 48 hours;
>
> (d) then allow the mixture to separate into layers, remove and filter the upper organic layer;
>
> (e) the unwanted by-product (hexamethyldisiloxane) is then removed by vacuum distillation;
>
> (f) forming an oxygen permeable contact lens material by copolymerizing from 5% to 90% by weight of the 1,1,1 tris(trimethylsiloxy)methacryloxypropyl-silane prepared above; 3% to 90% by weight of an ester of acrylic or methacrylic acid; from 0.5% to 90% by weight of a surface wetting agent, from 0.01% to 90% by weight of an oxygen permeable crosslinking agent selected from the class of multifunctional siloxanyl alkyl esters in the presence of a free radical or a photo initiator.

JTX-1 at col.5 lines 38-64 (emphasis added); id., Certificate of Correction. Steps (a) through (e) of this claim recite a process for manufacturing a chemical compound commonly known as "Tris." Step (f) describes a process for synthesizing Tris with three other compounds to create a rigid, gas permeable material suitable for manufacturing a contact lens.[2]

In December 1997, Dome sought to enforce the Neefe Patent in an infringement action against several defendants. See Dome Patent L.P. v. Permeable Technologies, Inc., et al., Civil Action No. 98-6247 (filed in the Western District of New York, after being transferred

[2] The first underlined term refers to a chemical compound commonly known as "Tris." The second underlined term refers to a Tris-type cross-linking agent.

from the Eastern District of California). One of these defendants, Optical Polymer Research, Inc., filed a request with the PTO for reexamination of the Neefe Patent. JTX-34 at 53-95 (Request for Reexamination, Aug. 27, 1998). On May 23, 2002, an examiner at the PTO concluded that claims 2, 3, and 4 of the Neefe Patent should be confirmed, but that claim 1 of the Neefe Patent – recited above – should be cancelled because the method it described "would have been obvious at the time the invention was made to a person having ordinary skill in the art." 35 U.S.C. § 103(a); JTX-34 at 1110-20 (Office Action in Ex Parte Reexamination). Dome timely appealed the examiner's ruling to the Board of Patent Appeals and Interferences (the "Board"). JTX-34 at 1134-35 (Notice of Appeal dated July 12, 2002).[3] On July 31, 2007, the Board issued an order affirming the examiner's decision. JTX-34 at 1270-93 (In re Neefe, Appeal 2007-1366).

On September 24, 2007, Dome timely filed this civil action pursuant to 35 U.S.C. §§ 145 and 306 for review of the Board's decision. Compl.; Jt. Pretrial Stmt. at 3. The Court conducted a three-day bench trial from January 28 through January 30, 2013, during which the parties introduced the expert testimony of Timothy E. Long, Ph.D., Mark A. Melamed, M.D., and William J. Benjamin, O.D., Ph.D., as well as testimony from the patent's author, Robert A. Neefe. Dr. Long, called as a witness by Dome, is a professor of chemistry at the Virginia Polytechnic Institute and State University and an expert in the field of polymer chemistry. Dr. Melamed, also Dome's witness, is an ophthalmologist with a large private practice in which he spends a substantial part of his time prescribing and fitting contact lenses. He also is a Professor of Ophthalmology at New York University School of Medicine. Dr. Melamed is an expert on the use and prescription of rigid gas permeable contact lenses and on the medical benefits of

[3] The Board is now known as the Patent Trial and Appeal Board.

contact lenses with improved oxygen permeability.[4] The Director's expert, Dr. Benjamin, is a Professor of Optometry and Vision Science at the University of Alabama School of Optometry. He is an expert in the measurement of the oxygen permeability of contact lenses and the wettability of rigid contact lenses.[5]

B. The Parties' Positions

As discussed in the Findings of Fact below, many of the relevant facts in this case are undisputed. The parties agree that a usable hard contact lens must be clear, rigid, oxygen permeable, and wettable (*i.e.*, hydro*philic*). The parties also agree that the field of contact lens development witnessed a breakthrough in the 1970's with the advent of rigid gas permeable lenses, which combined the clarity, rigidity, and wettability of one prior technology (PMMA lenses) with the oxygen permeability of another prior technology (soft silicone lenses). One of the lead inventors in this field, Norman Gaylord in New Providence, New Jersey, created the first commercially viable rigid gas permeable lens material using a novel "polymer," composed of

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[4] The Director filed a motion *in limine* to exclude the testimony of Dr. Melamed relating to the commercial success of Bausch & Lomb's Boston IV lens pursuant to Rule 702 of the Federal Rules of Evidence. Because the purpose of Rule 702 and Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579 (1993) is for the judge to serve a gatekeeping role for the jury, see Jacobsen v. Oliver, Civil Action No. 01-1810, 2007 WL 5527513, at *1 (D.D.C. Nov. 2, 2007) (collecting cases), the Court declined to exclude Dr. Melamed's testimony during this non-jury trial. See Jan. 15 AM Tr. at 33:24–34:06. But the Court has given little weight to Dr. Melamed's testimony relating to the reasons for the Boston IV lens' commercial success, as his opinion on this matter is not based on any study, survey, or reliable methodology, but is simply based on his experience with his own patients.

[5] The Court granted Dome's motion during trial to exclude those portions of Dr. Benjamin's testimony relating to the polymer chemistry underlying contact lens production, as this topic does not fall within the scope of Dr. Benjamin's expertise. Goodman v. Harris Cnty., 571 F.3d 388, 399 (5th Cir. 2009) (an expert may not "go beyond the scope of his expertise in giving his opinion"); Sosna v. Binnington, 321 F.3d 742, 746 (8th Cir. 2003) (same).

different "monomers." In making this polymer, Gaylord began by using a silicone-containing monomer called Tris, which is very oxygen permeable but not wettable (that is, it is hydro*phobic*). Gaylord next added other monomers similar to those used in PMMA lenses, which are highly wettable but not oxygen permeable. Gaylord then joined the hydrophobic Tris monomers and the hydrophilic comonomers together, using a hydrophilic cross-linking agent. This material could then be machined into a reasonably usable contact lens. Several other scientists subsequently refined and expanded on Gaylord's invention.

A few years later, a group of scientists led by Kyoichi Tanaka in Japan patented a different rigid gas permeable contact lens material using a non-Tris monomer with a range of cross-linking agents. One of Tanaka's preferred cross-linkers was a hydrophobic multifunctional siloxanyl alkyl ester, which is similar in molecular structure to the Tris monomer.

Less than two years later, Robert Neefe of Big Spring, Texas, combined the monomers used by Gaylord with the cross-linker used by Tanaka to develop a usable rigid gas permeable lens. Neefe's process was patented as claim 1 of U.S. Patent No. 4,306,042, recited above and referred to here as the Neefe Patent.

This case centers on the parties' disagreement as to whether it would have occurred to a person of ordinary skill in the art to do what Neefe did: to combine the first three compounds listed in step (f) of claim 1 of the Neefe Patent – *i.e.*, Gaylord's compounds – with the fourth compound listed in step (f) – *i.e.*, Tanaka's cross-linker. Dome contends that it would not have occurred to a person of ordinary skill to attempt this combination. According to Dome, one with ordinary skill would have been deterred from using both the Tris monomer from Gaylord and the Tris-type cross-linker from Tanaka in the same formulation, out of concern that the resulting compound would be unwettable or otherwise unusable for contact lens production.

See Dome's Trial Brief at 10 ("[U]sing both a hydrophobic Tris monomer and a hydrophobic cross-linker would have been expected to yield a hydrophobic polymer that would be unsuitable as a contact lens material."); id. at 9 ("Neefe offered a novel and counter-intuitive solution to the oxygen permeability problem: a polymer that contains both a hydrophobic Tris monomer **and** a hydrophobic Tris-type cross-linker.") (emphasis in original). Dome also attempts to show that the success of a commercial contact lens made using the Neefe process demonstrates the nonobviousness of that process, supporting its patentability. Id. at 1 (describing evidence of "surprising and counter-intuitive results achieved by the method disclosed and claimed in the Neefe Patent" and "evidence of large scale commercial exploitation and use of the method disclosed and claimed in the Neefe Patent").

The Director disagrees, arguing that it was established that the hydrophobicity of both the Tris monomer and the Tris-type cross-linker could be offset by the hydrophilic monomers suggested by Gaylord, particularly within the broad ranges identified by Neefe. See Director's Trial Brief at 28 ("Any concern about wettability arising from the use of a small amount of Tris (as low as 5% by weight), therefore, easily could be alleviated by use of a wetting agent (up to 90% by weight), while still remaining within the scope of the claim."). And while the Director does not dispute that the contact lens referenced by Dome was commercially successful, she argues that this success cannot be attributed to the Neefe process for several reasons, and therefore any evidence of success is irrelevant to the question of obviousness. See id. at 5-7, 13-14, 16-25.

II. FINDINGS OF FACT

The following findings of fact are based on the evidence submitted by the parties during the bench trial, the administrative record before the Board, the Board's opinion, the parties' stipulations of undisputed facts, and the record as a whole.

A. The Polymer Chemistry of Contact Lens Material Production

a. Properties of Rigid Gas Permeable Contact Lenses

1. Claim 1 of the Neefe Patent recites a process for making material for the manufacture of a rigid gas permeable ("RGP") contact lens. JTX-1 at [57] (Abstract).

2. A material for use in a RGP contact lens should have the following four characteristics: it should be optically clear; it should be hard and rigid; it should be wettable; and it should be oxygen permeable. Jan. 28 AM Tr. at 49:8–50:13 (Long); Jan. 29 AM Tr. at 14:25–16:7, 17:2-21, 100:9-11 (Melamed); Jan. 29 PM Tr. at 48:3-11 (Benjamin).

3. Optical *clarity* is important in order for the material to provide a clear visual image for the user. See Jan. 28 AM Tr. at 49:8-10 (Long); Jan. 29 PM Tr. at 48:3-7 (Benjamin).

4. *Rigidity* is required so that the lens can be machineable into a precise enough shape to provide crisp, consistent visual acuity. Jan. 28 AM Tr. at 49:16-21 (Long); Jan. 29 PM Tr. at 48:3, 48:7-11 (Benjamin).

5. *Wettability*, which is the interaction of water with a surface (such as the surface of a contact lens), is necessary for a contact lens to be comfortable on the eye of the wearer. Jan. 28 AM Tr. at 50:7-13 (Long); Jan. 29 AM Tr. at 15:12–16:7, 17:7-9 (Melamed).

6. Wettability is important because contact lenses do not actually sit on the surface of the cornea of the eye; instead, they float on a thin film of tears on the surface of the cornea. Jan. 29 AM Tr. at 14:12-14 & 15:19-23 (Melamed). Contact lenses must be tolerated in the eye

without eliciting a painful foreign body sensation, so an even coating of tears must be spread across the surface of the lens. Id. at 15:12–16:3 (Melamed).

7. A hydro*phobic* polymer is one that is water repellent, while a hydro*philic* polymer can readily absorb water. Jan. 28 AM Tr. at 10:2 (Long); Jan. 30 AM Tr. at 13:25 (Benjamin).

8. Adequate *oxygen permeability* is necessary to prevent long-term damage to the eye of the wearer. Jan. 28 AM Tr. at 49:22–50:6 (Long); Jan. 29 AM Tr. at 14:25–15:11, 17:2-6, 17:19-21, 100:9-11 (Melamed).

9. Oxygen permeability is important because a constant flow of oxygen to the cornea is essential to avoid degenerative changes in its cells. Jan. 29 AM Tr. at 14:25–15:11 (Melamed). The cornea has no blood supply to bring it oxygen, so it gets its oxygen from the atmosphere, through the open lids of the eye. Jan. 29 AM Tr. at 14:14-17 (Melamed).

10. Anything that covers the cornea – either a contact lens or the eyelid – impedes the flow of oxygen to the cornea. Jan. 29 AM Tr. at 14:17-20 (Melamed). Thus, the oxygen flow to the cornea is impeded during sleep. Id. at 16:10-21 (Melamed).

11. Even with a contact lens in place, oxygen can reach the front surface of the cornea in two ways: (1) it can permeate through the body of the contact lens itself; or (2) it can be carried by tears around the edge of the contact lens. Jan. 29 AM Tr. at 14:20-24 (Melamed).

12. The oxygen permeability of a material is measured in Dk, or "barrers." JTX-4 at 62; Jan. 29 AM Tr. at 25:22-23 (Melamed); Jan. 30 AM Tr. at 35:25 (Benjamin).

13. Ideally, a contact lens material will meet all four criteria: clarity, hardness, oxygen permeability, and wettability. Jan. 28 AM Tr. at 53:21-24 (Long). As Dome's counsel

noted at trial, these criteria can be remembered with the acronym "CHOW." Jan. 28 AM Tr. at 9:7-8; see also Jan. 28 AM Tr. at 48:16-17 (Long).

b. The Polymer Chemistry Behind Contact Lens Manufacturing

14. The technology at issue in this case is the polymer chemistry required to manufacture RGP contact lenses.

15. A RGP contact lens is made from material that permits the passage of oxygen through the lens to the eye of the wearer. Jan. 29 AM Tr. at 40:9-10 (Melamed); JTX-4 at 63.

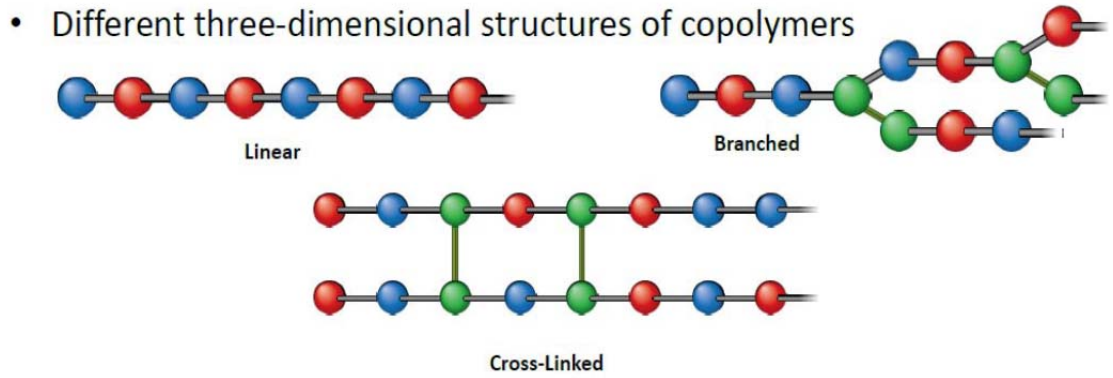
16. A "polymer," also known as a "macromolecule," is a large molecule made up of many smaller units called "monomers." JTX-3 at 3.

17. The process of synthesizing a polymer from monomers is called "polymerization." JTX-3 at 3.

18. A "copolymer" is a type of polymer that is formed from two or more different types of monomers. JTX-3 at 7.

19. The process of synthesizing a copolymer is known as "copolymerization." PTX-4, at tab 2; Director's PFF. 14.

20. Polymers can take different forms, including linear, branched, and cross-linked (*i.e.*, networked). JTX-3 at 8-10. Illustrative examples of these different forms were provided at trial and are reproduced below. See PTX-4 at Tab 3; Jan. 28 AM Tr. at 57:10-63:20 (Long).



21. The materials that make up a polymer can alter the polymer's chemical structure and therefore its physical properties. Jan. 28 AM Tr. at 63:1-20 (Long).

22. For example, the use of one cross-linking agent instead of another can affect the size of the gaps in the polymer's structure, which can affect the polymer's oxygen permeability. Jan. 28 AM Tr. at 62:3-63:20 (Long).

23. Cross-linked polymers can be exceptionally complex; the cross-linking agents may be close together or far apart, short or long, few or plentiful. Jan. 28 AM Tr. at 61:8-22 (Long).

B. The Prior Art: The Comonomers Used by Neefe Were Known in the Prior Art and, When Used in Combination, Could Be Expected to Promote Oxygen Permeability

This case centers on a dispute about whether Neefe's invention would have been obvious to a person of ordinary skill in the art, in light of the technology existing and known in the field at the time of Neefe's invention – *i.e.*, the prior art. Although the facts discussed in the section below are undisputed, the Court makes the following findings relating to the prior art and the Neefe Patent, with the purpose of providing background and context.[6]

[6] Some of the facts in Section B (FF. 24-89) are dismissed by one party or the other as irrelevant or misleading, but there are no genuine disputes as to their factual accuracy.

a. The Prior Art

24. The first practical plastic contact lens was made out of polymethyl methacrylate ("PMMA"), which was first branded commercially as Plexiglas. See Jan. 28 AM Tr. at 50:25-51:1 (Long); Jan. 30 AM Tr. at 12:2-18 (Benjamin).

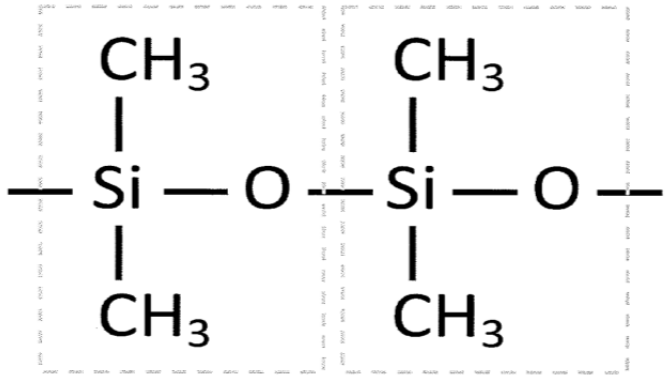
25. PMMA is a rigid, glass-like thermoplastic with relatively little flexibility. Jan. 28 AM Tr. at 51:9-10 (Long), 70:17-18; JTX-4 at 61-62.

26. PMMA is highly wettable, but it also is completely impermeable to oxygen. See Jan. 28 AM Tr. at 51:13-21 (Long); Jan. 30 AM Tr. at 12:2-18 (Benjamin).

27. This lack of oxygen permeability of PMMA lenses led to the development of so-called "contact lens over-wear syndrome" in users. Wearing these lenses for an extended period of time could cause pain, death of nerve endings in the cornea, blurred or filmy vision, glare, and halos around lights. Jan. 29 AM Tr. at 15:2-9 (Melamed); see also JTX-10 at col.1 lines 28-32; Jan. 30 AM Tr. at 16:10-21 (Benjamin); JTX-27 at 279.

28. In response to the problem of contact lens over-wear, many scientists began exploring polymers containing siloxanes for use in contact lens materials. Jan. 28 AM Tr. at 51:22–53:24 (Long); JTX-4 at 7, 60-63.

29. Siloxanes are chemical compounds containing carbon atoms (C), oxygen atoms (O), and silicon atoms (Si), in which two silicon atoms are bonded directly to one oxygen atom in the form –Si–O–Si–. JTX-4 at 60-62. The –Si–O–Si– chain can be thought of as the polymer's backbone, to which other atoms and molecules are attached. Id.



PTX-4 at tab 8.

30. Siloxanes are highly oxygen permeable. They also, however, are hydrophobic – that is, water repellant. In addition, siloxanes are soft and difficult to machine. Jan. 28 AM Tr. at 52:10-25 (Long); Jan. 30 AM Tr. at 13:22-23 (Benjamin); JTX-4 at 17, 61-62; JTX-5 at 272; JTX-13 at col.1 lines 33-34, 40-43.

31. A significant breakthrough in the field of contact lens materials took place in the 1970's, when Norman G. Gaylord had the idea of using a rigid material for a contact lens that still allowed oxygen to pass through the lens to reach the cornea of the eye. Gaylord introduced the first RGP lens, an oxygen permeable contact lens made from a mixture of PMMA and silicone (siloxane). JTX-4 at 17; Jan. 29 AM Tr. at 22:24-25 (Melamed); id. at 53:19-24 (Melamed); see JTX-7; JTX-8.

32. In his invention, Gaylord combined four ingredients: (i) a silicone -based monomer; (ii) an acrylate; (iii) a wetting agent; and (iv) a cross-linking agent. Jan. 28 AM Tr. at 70:18-23 (Long); JTX-4 at 64; JTX-7 at col.1 lines 57-60; JTX-8 at col.1 lines 52-56, col.5 lines 39-46, col.6 lines 3-12; see Board Decision, JTX-16 at F.10.

33. In Gaylord's polymer, the silicone is the chemical compound 1,1,1-tris(trimethylsiloxy)methacryloxypropylsilane, which is commonly known in the contact lens

field as a "Tris" monomer. Jan. 28 AM Tr. at 69:11-70:5 (Long); JTX-1 at col.3 lines 13-14; JTX-4 at 63; JTX-7 at col.2 lines 26-35; JTX-8 at col.2 lines 32-44.

34. After Gaylord, the Tris monomer became the "industry standard" siloxy-methacrylate monomer in the field of RGP contact lenses. JTX-4 at 63.

35. Tris is a siloxanyl alkyl ester compound. Jan. 28 PM Tr. at 66:8 (Long); JTX-1 at col.3 lines 12-14, col.5 lines 40-41.[7]

36. Tris is very hydrophobic, *i.e.*, water repellant. Jan. 28 AM Tr. at 66:2-4, 74:20-21 (Long); JTX-6 at col.1 lines 63-66.

37. In addition to Tris, Gaylord used methyl methacrylate ("MMA," the monomer in PMMA) as the acrylate, and he employed methacrylic acid as the wetting agent. Both MMA and methacrylic acid are hydrophilic: these comonomers therefore increased the wettability of the polymer. Jan. 28 AM Tr. at 67:3-12 (Long); Jan. 28 PM Tr. at 68:14-21 (Long); JTX-7 at col.3 line 29, col.4 lines 50-59; JTX-8 at col.3 line 65, col.5 lines 39-48; see also JTX-4 at 17.

38. The fourth ingredient, which Gaylord used to bind these comonomers together, was a hydrophilic, non-siloxane based cross-linking agent, such as ethylene glycol dimethacrylate. Jan. 28 AM Tr. at 70:9-13 (Long); PTX-4 at Tab 9.

39. Contact lenses manufactured using the Gaylord polymer were introduced into the marketplace in the late 1970's by Syntex, Inc. under the trade name Polycon. Jan. 30 AM Tr. at 40:2-7 (Benjamin); JTX-4 at 17; JTX-10 at col.2 lines 29-32; JTX-12 at 238.

40. The first Polycon lens (Polycon I) had an oxygen permeability of approximately 5 Dk; the second (Polycon II), an oxygen permeability of approximately 10 to 12 Dk. The Polycon

[7] Tris was first disclosed by George J. Quaal in U.S. Patent No. 3,377,371 (issued April 9, 1968). JTX-6 at 1.

lenses thus exhibited much better oxygen permeability than PMMA lenses, which were completely impermeable. JTX-4 at 67; JTX-12 at 238; JTX-27 at 273.

41. Gaylord explains that the reason for the increased oxygen permeability of his lens materials is the inclusion of silicone (*i.e.*, the use of the siloxanyl alkyl ester), which "is highly permeable to oxygen." JTX-8 at col.1 lines 31-32; see generally id. at col.1 lines 19-56.

42. At noted at FF. 30 and 36, although the presence of silicone improves the oxygen permeability of a contact lens material, it detracts from its wettability.

43. Gaylord addresses the issue of wettability in his patent. He states that "[w]hile some of the copolymers [disclosed in his patent] are inherently wettable by human tears, it may be necessary to improve the wettability of others." JTX-8 at col.5 lines 39-41.

44. Gaylord discloses four alternate methods for improving the wettability of these copolymers, including adding hydrophilic monomers to the copolymerization mixture and applying wetting agents to the surface of the contact lenses. JTX-8 at col.5 lines 42-58.

45. Although Gaylord's invention represented a significant improvement in oxygen permeability, the first lenses incorporating Gaylord's polymer still could not be used for prolonged daily wear. See Jan. 29 AM Tr. at 91:13–92:8 (Melamed).

46. After Gaylord's technique was known, several scientists worked to increase the oxygen permeability, wettability, and hardness of Gaylord's formulation. See Jan. 28 AM Tr. at 73:10–79:10 (Long); see, e.g., JTX-9 at col.1 lines 11-41.

47. One pair of scientists – Edward J. Ellis and Joseph C. Salamone at Polymer Technology Corporation in Massachusetts – improved Gaylord's technique by employing Tris but also adding an additional hydrophilic comonomer to improve the material's wettability and

structural integrity. Jan. 28 AM Tr. at 73:20–74:21 (Long); see generally JTX-9. Ellis applied for a patent based on this invention on February 15, 1978. JTX-9 at [22].

48. The Ellis patent was issued on May 1, 1979. It was later used to create the Boston II lens, which had an oxygen permeability of approximately 12 to 14 Dk. JTX-9 at [45]; Jan. 29 AM Tr. at 25:22-25, 54:4-9 (Melamed); Jan. 30 AM Tr. at 69:25–70:2, 75:21-25 (Benjamin); JTX-4 at 66; JTX-12 at 238; JTX-21 at BL8556; JTX-27 at 273.

49. Another scientist, Nick N. Novicky of Wheeling, Illinois, attempted to solve the problems of the Gaylord polymers by replacing the Tris monomer with novel silicones of his own design. Jan. 28 AM Tr. at 75:23-25 (Long); see JTX-11 at col.3 lines 22-23, col.14 lines 37-45, col.18 lines 8-13.

50. Like Tris, the novel monomer employed by Novicky contains a methacrylate component and a tris(trimethylsiloxy) component. Jan. 28 AM Tr. at 76:22–77:9 (Long); JTX-11 at col.3 lines 49-53, col.3 lines 64-67, col.4 lines 25-39 (general formula), col.18 lines 28-39 (formula in claim 1).

51. Unlike Tris, the Novicky monomer contains an additional siloxane unit. JTX-11 at col.4 lines 25-39, col.18 lines 28-39; Jan. 28 AM Tr. at 76:1-4, 77:7-9 (Long).

52. This additional siloxane unit makes the novel Novicky monomer even more hydrophobic than Tris. Jan. 28 AM Tr. at 75:22-76:12 (Long).

53. In addition to the novel monomer, Novicky's polymer also contains hydrophilic wetting agents and hydrophilic MMA. JTX-11 at col.3 lines 44-48, col.6 line 65, col.7 line 27, col.18 lines 66-68, col.19 lines 1-3.

54. The Novicky polymer uses the same type of hydrophilic cross-linker used by Gaylord and Ellis; as noted *supra* at FF. 38, this cross-linker does not contain a siloxane group. JTX-11 at col.7 lines 15-24; Jan. 28 AM Tr. at 77:12-18 (Long).

55. The Novicky patent was issued on August 5, 1980. JTX-11 at [45].

56. RGP contact lenses incorporating the Novicky polymer reportedly were marketed by Fused Contacts as the Sil-O2-Flex lens. JTX-10 at col.8 line 23, col.8 line 38; JTX-12 at 238.

57. The Sil-O2-Flex lens had an oxygen permeability level of approximately 5 to 8 Dk. JTX-10 at col.8 line 38; JTX-12 at 238.

58. On September 22, 1978, a group of scientists led by Kyoichi Tanaka in Japan applied for a patent based on a novel polymer to be used for making an RGP contact lens. JTX-13 at [57].

59. Tanaka discloses that his copolymers have an excellent oxygen permeability and a good hydrophilic property (*i.e.*, they are wettable). Jan. 28 PM Tr. at 79:17-19 (Long).

60. Tanaka departed from Gaylord (and Ellis) in two ways. First, rather than using the Tris monomer, Tanaka employed a novel non-Tris silicone monomer containing siloxanylalkyl ester groups, which are hydrophobic, and internal glycerol or polyether groups, which are hydrophilic. Tanaka's novel monomer thus was "amphiphilic," and had a higher affinity for water – *i.e.*, was less water repellant – than the Tris monomer used by Gaylord and Ellis. Jan. 28 PM Tr. at 5:5-8, 5:13-14, 6:11-7:3, 9:14-21 (Long). Strands were then formed by polymerizing this novel non-Tris monomer and MMA as comonomers. Jan. 28 PM Tr. at 5:3-8, 7:7-10 (Long); JTX-13 at col.7 lines 39-41.

61. Second, Tanaka proposed a variety of cross-linking agents, including some cross-linkers that were not employed by Gaylord and Ellis. Although Tanaka stated that a cross-linker

used by Gaylord, ethylene glycol dimethacrylate, could be used in his polymer, JTX-13 at col.8 lines 2-14, Tanaka's "preferred" cross-linking agents were multifunctional siloxanyl alkyl esters having a siloxane bond (which he described as formula [IV] cross-linkers) and multifunctional siloxanyl alkanol esters, also having a siloxane bond (formula [V] cross-linkers). JTX-13 at col.8 lines 11-46; see also Jan. 28 PM Tr. at 77:25–78:22 (Long); JTX-16 at 5 (Board Finding No. 26).

62. Tanaka says that these cross-linking agents are preferred because the siloxane bonds provide increased oxygen permeability to the cross-linked copolymer:

> Since these cross-linking agents of the general formulas [V] and [VI] have siloxane bonds in their molecules, the oxygen permeability of the obtained cross-linked copolymers is high and, therefore, they are preferably employed in the present invention.

JTX-13 at col.8 lines 35-39; see Jan. 28 PM Tr. at 77:25–78:16 (Long); JTX-16 at 5-6 (Board Finding 27).

63. Tanaka states that the novel siloxanyl *alkynol* esters of formula [V] are "particularly useful" because they contain hydrophilic hydroxyl groups. That is, not only do these cross-linkers promote a material's oxygen permeability, but they also promote its wettability. JTX-13 at col.8 lines 39-46.

64. The multifunctional siloxanyl *alkyl* esters referenced by Tanaka had been known in the field of polymer chemistry since at least 1958, and had been disclosed in the Mercker Patent, see PTX-1; Jan. 28 PM Tr. at 107:8-23 (Long), but there is no evidence that it had been purposely employed in contact lens production prior to Tanaka. See Jan. 28 PM Tr. at 107:8–108:6.

65. Tanaka's patent was issued on November 25, 1980. JTX-13 at [45].

b. The Neefe Invention

66. Beginning around 1977, Russell Neefe undertook to create a rigid gas permeable material suitable for contact lenses. Jan. 29 PM Tr. at 6:18-22 (Neefe).

67. At some point between 1977 and 1980, Neefe had the idea to cross-link the silicone-containing Tris monomer not with the cross-linkers used by Gaylord, Ellis, or Novicky, but with a cross-linking agent based on Tris. Jan. 29 PM Tr. at 15:16-23 (Neefe). This type of cross-linking agent – a multifunctional siloxanyl alkyl ester – was one of the agents preferred by Tanaka. See FF. 61-62.[8]

68. The initial material created by Neefe using the process of claim 1 had a Dk value of 14. Jan. 29 PM Tr. at 19:15-20:1 (Neefe).

69. On September 8, 1980, Russell Neefe submitted his application for the patent at issue in this suit. A patent was issued to Neefe on December 15, 1981. JTX-1 at [45].

70. The Neefe Patent is entitled "Method of Making a Contact Lens Material With Increased Oxygen Permeability." JTX-1.

71. The Summary of Invention in the Neefe Patent specification states that the "primary object of this invention is to provide a novel contact lens material which is prepared from a combination of monomers so as to have high oxygen, carbon dioxide permeability, and a hydrophilic surface." JTX-1 at col.1 lines 61-64.

72. The Neefe Patent contains four claims, three of which were not subject to reexamination because the PTO found no substantial question of patentability as to those claims. JTX-34 at 1112.

[8] *Multi*functional siloxanyl alkyl esters (which can serve as cross-linking agents) are distinct from *mono*functional siloxanyl alkyl esters such as Tris (which cannot). See infra at FF. 128 n.11.

73. As noted *supra* at 3, claim 1 of the Neefe Patent outlines a six-step process for making a rigid gas permeable contact lens material, labeled (a) through (f). JTX-1 at col.5 lines 38-64.

74. The first five steps of the claim (steps (a)-(e)) recite a process of making 1,1,1-tris(trimethylsiloxy)methacryloxypropylsilane, or "Tris." JTX-1 at col.5 lines 44-54; JTX-16 at 2 (Board Findings 4-6); Jan. 28 AM Tr. at 69:1-70:5 (Long). There is no dispute that Tris was known in the prior art. Director's PFF. 34; Dome's Resp. PFF. 34.

75. Step (f) of the claim instructs that four chemical ingredients, including Tris, are combined to form "an oxygen permeable contact lens material." JTX-1 at col.5 lines 55-64.

76. The four ingredients combined in step (f) are as follows: (1) "from 5% to 90% by weight" of the Tris monomer; (2) from "3% to 90% by weight of an ester of acrylic or methacrylic acid;" (3) "from 0.5% to 90% by weight of a surface wetting agent;" and (4) "from 0.01% to 90% by weight of an oxygen permeable crosslinking agent selected from the class of multifunctional siloxanyl alkyl esters." JTX-1 at col.5 lines 55-64; id., Certificate of Correction.

77. The first three ingredients listed in step (f) of claim 1 of the Neefe patent were previously disclosed by Gaylord. The only significant difference between the contact lens material taught by Gaylord and the contact lens material in claim 1 of the Neefe Patent is the fourth ingredient: Gaylord's material includes a hydrophilic cross-linking agent rather than the hydrophobic multifunctional siloxanyl alkyl ester used by Neefe. JTX-8 at col.6 lines 3-12; JTX-1 at col.2 lines 43-44 at col.5 lines 61-63; Jan. 28 PM Tr. at 16:3-5, 16:12-13, 17:4-10, 18:2, 70:15-20 (Long).

78. As noted *supra* at FF. 61-63, Tanaka suggested the use of a siloxanyl alkyl ester cross-linker in order to promote oxygen permeability, although Tanaka suggested its use with a different (non-Tris) monomer.

79. Four years later, Neefe created another material using the process of claim 1 of the Neefe Patent, which was commercialized and sold under the trade name TransAire. Jan. 30 AM Tr. at 79:25–80:4, 83:3-5 (Neefe). The TransAire polymer had a Dk value of 45. Jan. 30 AM Tr. at 81:15-18 (Neefe); JTX-27 at 273.

c. An Artisan of Ordinary Skill Would Have Known That Tris Monomer and a Siloxanyl Alkyl Ester Cross-Linker (like Tris Dimer or Trimer) Could Be Combined to Form an Oxygen Permeable Polymer

80. A person of ordinary skill in the art of making RGP contact lens materials, as of September 8, 1980, would have had at least an undergraduate degree – and very likely a graduate degree or some graduate training – in chemistry, coupled with experience in the development, manufacture and use of polymers suitable for the manufacture of RGP contact lenses. Jan. 28 PM Tr. at 60:15-19 (Long).

81. The person having ordinary skill in the art was aware of the reasons for and desirability of high oxygen permeability in contact lens materials. JTX-16 at 8 (Board Finding 50); see Director's PFF. 46; Dome's Resp. PFF. 46.

82. A person of ordinary skill in the art would have fully understood the copolymerization chemistry used to make contact lens materials, including the mechanism involved in cross-linking different comonomers. JTX-16 at 8:10-23; see Director's PFF. 47; Dome's Resp. PFF. 47; Dome's PFF. 69; Director's Resp. PFF. at 3, 5-6.

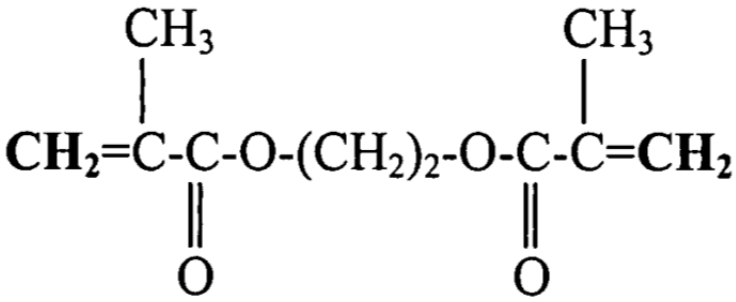
83. The person having ordinary skill in the art also would have understood and been familiar with the processes and chemistry for making the comonomers that are copolymerized in

making contact lens materials. JTX-16 at 8 (Board Finding 53); see Director's PFF. 49; Dome's Resp. PFF. 49.

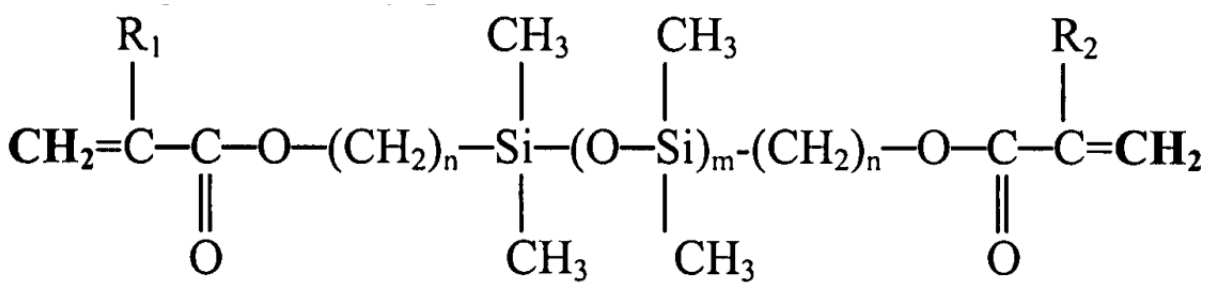
84. One having ordinary skill in the art would have been familiar with the properties of Tris and the chemistry necessary to make it. JTX-16 at 8 (Board Finding 54); see Director's PFF. 50; Dome's Resp. PFF. 50.

85. One having ordinary skill in the art would have understood that cross-linking takes place through terminal unsaturated carbon bonds. JTX-16 at 8, 16; see Director's PFF. 48, 84; Dome's Resp. PFF. 48, 84.

86. One having ordinary skill in the art would have understood that ethylene glycol dimethacrylate, described as a cross-linker by both Gaylord and Tanaka, may be represented by the following formula showing terminal unsaturated carbons (=CH2):



One having ordinary skill in the art would have understood that Tanaka's preferred oxygen permeable cross-linkers similarly have terminal unsaturated carbons (=CH2). For example, the multifunctional siloxanyl alkyl esters employed by Tanaka include those represented by the following general formula:



JTX-16 at 15 n.5; Director's PFF. 83; Dome's Resp. PFF. 83.

87. A person of ordinary skill in the art would have expected that these multifunctional siloxanyl alkyl ester cross-linking agents, having terminal unsaturated carbons (=CH2), would be effective cross-linking agents with the comonomers suggested by Gaylord. See JTX-16 at 16.

88. The person having ordinary skill in the art would have recognized that the oxygen permeability of Tanaka's lens material was due in part to the use of Tanaka's preferred cross-linking agents, which contain siloxane bonds. See JTX-13 at col.8 lines 35-39; Jan. 28 PM Tr. at 79:15-16 (Long); see also JTX-16 at 6, 14.

89. A person of ordinary skill in the art would reasonably expect that combining the comonomers suggested by Gaylord and the multifunctional siloxanyl alkyl ester cross-linking agent suggested by Tanaka would likely yield positive results in terms of oxygen permeability. See JTX-16 at 6 (Board Finding 28); Director's PFF. 78-86; Dome's Resp. PFF. 78-86 (asserting that an artisan of ordinary skill would have been deterred from combining Gaylord's and Tanaka's compounds for other reasons, but not disputing that such artisan would know that these materials could be combined to promote oxygen permeability); Dome's Trial Brief at 4 ("It was known that incorporating a type of chemical called a 'silicone' (of which Tris is an example) in the contact lens material would improve its oxygen permeability.").

C. A Person of Ordinary Skill in the Art Would Not Be Deterred, Because of Concern about Wettability or Opacity, from Using the Siloxanyl Alkyl Ester Monomor Suggested by Gaylord (Tris) with the Siloxanyl Alkyl Ester Cross-Linker Suggested by Tanaka

As noted, a person of ordinary skill in the art would have known that the multifunctional siloxanyl alkyl ester cross-linking agent referenced by Tanaka could be used with the Tris monomer, and that such combination would promote oxygen permeability. See FF. 89. Nevertheless, Dome maintains that the artisan of ordinary skill would have been dissuaded from using these materials together, due to the hydrophobic properties of both. See Jan. 30 PM Tr. at 8:2–9:18, 10:6-20 (Dome closing argument). The Director disagrees, arguing that the artisan of ordinary skill would know that she could offset the hydrophobicity of the two compounds by adding hydrophilic comonomers within the broad ranges identified by Neefe. Jan. 30 PM Tr. at 17:2-7; 18:14–20:6 (Director closing argument).

Upon consideration of the entire record, the Court finds as follows:

90. A person of ordinary skill in the art at the time of the invention would understand that any candidate material for making RGP contact lenses must simultaneously achieve design goals that are often in tension with one another. Jan. 28 PM Tr. at 61:5-10 (Long).

91. Tanaka teaches that polymers "consisting essentially of" a siloxanyl alkyl ester (such as Tris) and having no hydrophilic groups have very strong water repelling properties and therefore are unsuitable for contact lenses. JTX-13 at col.3 lines 10-23.

92. Tanaka teaches that the water repelling nature of polysiloxanyl alkyl ester monomers can be repressed by reducing the number of hydrophobic alkylsiloxy groups in the polymer. Such reduction, however, will lead to a reduction in oxygen permeability:

> In case of such a polysiloxanylalkyl ester monomer, when the water repelling property is repressed by reducing the number of the alkylsiloxy groups in the obtained polymer, the oxygen permeability becomes low, and then the oxygen permeability is

> raised by increasing the number of the alkylsiloxy groups in the obtained polymer, the water repelling property becomes strong. In any case, there cannot be obtained a polymer suited for preparing a contact lens which can be comfortably worn continuously for a long period of time.

JTX-13 at col.3 lines 41-51; see also Jan. 28 PM Tr. at 8:13–9:8 (Long).

93. Tanaka also warns that a polysiloxanyl alkyl ester monomer such as Tris could become opaque when combined with hydrophilic monomers.

> [T]he polysiloxanylalkyl ester monomer may be copolymerized with a hydrophilic monomer to provide the obtained copolymer with a proper hydrophilic property, but since it is hard to copolymerize with the hydrophilic monomer, the copolymer is liable to become opaque. This is a fatal defect for use as contact lens materials. Therefore, the polymerization ratio of the hydrophilic monomer to the polysiloxanylalkyl ester monomer is limited to produce a transparent copolymer, and it is very difficult to decrease the water repelling property by copolymerizing with a hydrophilic monomer.

JTX-13 at col.3 lines 23-41.

94. Tanaka sought to create a continuous wear lens (*i.e.*, an extended or overnight wear lens), not a daily wear lens or a prolonged daily wear lens. JTX-13, Abstract (describing invention as contact lenses that "can be comfortably worn continuously for a long period of time"); id. at col.1 lines 9-10; id. at col.1 lines 31-32; id. at col.3 lines 50-51; id. at col.3 lines 60-63; id. at col.11 lines 4-5; id. at col.11 lines 13-14; id. at col.11 lines 50-52; id. at col.27 lines 43-65 (noting that Tanaka contact lenses "were worn on rabbit eyes continuously for 21 days," and "could be continuously worn without change in eyes").[9]

[9] Dome disputes the Director's assertion that Tanaka sought to create a continuous or extended wear lens, noting that Tanaka never used the phrase "continuous wear" or "extended wear" in his patent. See Dome's Resp. PFF. 103. After reviewing the record, however, and in particular the patent specification language cited above at FF. 94, the Court agrees that Tanaka's invention is directed towards a continuous wear lens.

95. "Continuous wear" is a term that is analogous to "extended wear," where the individual continues to wear the same lens without interruption for several days, even while sleeping. Jan. 30 AM Tr. at 10:20–11:1 (Benjamin); see also Jan. 29 AM Tr. at 28:10-12 (Melamed).

96. The oxygen permeability of a contact lens worn in extended wear or continuous wear needs to be much greater than the oxygen permeability of a lens to be worn for daily wear. Jan. 30 AM Tr. at 21:20-24 (Benjamin).

97. Although Tanaka warned that it could be difficult to increase a Tris-based polymer's wettability simply by adding hydrophilic monomers, prior references in the art taught that hydrophilic monomers could be used, within limits, to offset hydrophobic monomers such as Tris.

98. For example, Gaylord discloses that other ingredients can be added to a siloxanyl alkyl ester to materially affect the basic properties of a contact lens material. Specifically, Gaylord discloses using from 30 to 90 parts by weight acrylic or methacrylic acid ester, JTX-8 at col.4 lines 14-16, both of which are hydrophilic. Jan. 28 PM Tr. at 64:11-19 (Long).

99. Gaylord also explains that, even if the resulting contact lens material is not sufficiently wettable on its own, "several alternate methods" can be used "to improve the wettability of" contact lenses. JTX-8 at col.5 lines 39-58.

100. For example, "wettability can be imparted to the copolymer by the addition of from about 0.1% to about 10% by weight of one or more hydrophilic monomers." JTX-8 at col.5 lines 42-45.

101. Gaylord also states that "the wettability of the surface of contact lenses made from the copolymers can be improved by the application of a wetting agent[,] . . . by exposure of

the surface to a corona discharge or by chemical treatment of the surface with a strong oxidizing agent such as nitric acid." JTX-8 at col.5 lines 51-58.

102. Gaylord further describes that those methods are effective at yielding a wettable material – a lens made with 55 parts Tris (which is hydrophobic), 45 parts methyl methacrylate (which is hydrophilic), and 2 parts methacrylic acid (which is a hydrophilic wetting agent) "is readily wetted with a wetting agent solution." JTX-8 at col.8 lines 5-19.

103. Gaylord also states that these materials will yield a "transparent" material, JTX-8 at col.8 lines 5-22, and thus Gaylord teaches that Tris can be copolymerized with hydrophilic monomers like MMA and surface wetting agents without making the copolymer opaque.

104. In addition, Gaylord teaches that a material can contain relatively high amounts of hydrophobic monomers and still be wettable. For example, Gaylord discloses that lenses with as much as 70 parts by weight of Tris are wettable, even though Tris is hydrophobic. See JTX-8, Abstract; id. at col.1 lines 17-18; id. at col.12 line 50 (claiming material that is up to 70 parts by weight of Tris); id. at col.7 line 21 (disclosing material of 55 parts Tris); id. at col.7 line 38 (disclosing material of 60 parts Tris).

105. Claim 1 of the Neefe Patent permits as little as 0.01% of the hydrophobic cross-linking agent, along with 5% of Tris, which is hydrophobic, so it permits as much as 94.99% of hydrophilic comonomers. JTX-1 at col.5 lines 55-64. The prior art does not teach that a material composed 5% of Tris, .01% of a hydrophobic cross-linking agent, and 94.99% of hydrophilic comonomers would be unwettable. See FF. 102, 104.

106. Dr. Long states that as of September 8, 1980, a person of ordinary skill in the art would not have reasonably expected that the siloxanyl alkyl ester cross-linker preferred by Tanaka could be used with a Tris-based polymer in order to create a contact lens. See Jan. 28

PM Tr. at 108:1-6. But this conclusion is not consistent with other evidence presented at trial. See FF. 90-105.

107. Dr. Long testified that he did not know what continuous wear or extended wear lenses are, and that such knowledge was beyond the scope of his synthetic polymer chemistry skills. Jan. 28 PM Tr. at 81:14-21 (Long). This lack of knowledge may have affected and limited Dr. Long's understanding of Tanaka and his teachings.

108. In light of Findings of Fact 90 through 107, the Court finds that even if the Tanaka patent "teaches away" from the use of hydrophobic compounds such as Tris, it only discourages using such compounds when seeking to make a material that "can be comfortably worn continuously for a long period of time." It did not teach away from using such compounds for daily wear or prolonged daily wear.

109. In light of Findings of Fact 90 through 108, the Court finds that a person of ordinary skill in the art would not be deterred, out of concerns about wettability or opacity, from using the Tris monomer suggested by Gaylord along with the siloxanyl alkyl ester cross-linker preferred by Tanaka to create a daily wear or prolonged daily wear contact lens, provided that other, hydrophilic comonomers also were employed.

D. Dome's Evidence of Secondary Considerations

Dome argues that the process recited in claim 1 of the Neefe Patent satisfied a long-felt need for a contact lens that could be worn throughout the entire day. Dome notes that a variety of first generation lenses (such as Polycon II and Boston II) based on prior art could not be comfortably worn from when the wearer woke up in the morning until she went to bed in the evening. By contrast, the Boston IV lens, a second generation lens that Dome contends embodies claim 1 of the Neefe Patent, could be worn without interruption from morning until

evening. The Boston IV lens achieved considerable commercial success as compared to its predecessor, the Boston II lens, which Dome asserts was not manufactured in accordance with claim 1. Dome argues that the positive results achieved in the Boston IV lens and the ensuing commercial success provides objective evidence of the nonobviousness of claim 1. See Jan. 30 PM Tr. at 12:6–13:10.

The Director maintains that many of the assumptions underlying Dome's arguments are flawed. To begin with, the Director takes issues with Dome's assertion that the Boston IV lens embodies claim 1 of the Neefe Patent, since the Boston IV process does not strictly comply with the sequence of steps for making Tris as specified in claim 1. Therefore, according the Director, the popularity of Boston IV cannot be used to shed light on the novelty of claim 1. The Director next argues that the success of the Boston IV lens was attributable to a number of factors, only one of which possibly relates to the Neefe Patent. Finally, the Director contends that the positive, commercially desirable properties of the Boston IV lens are unlikely to be present in other embodiments falling within the claim's broad range. Thus, even if the success of the Boston IV lens suggests that the process for the Boston IV lens was not obvious, the evidence is irrelevant to the obviousness of other processes falling within the range of claim 1.

The parties' disagreements turn both on questions of law and questions of fact. The factual disputes center on how a person of ordinary skill in the art would interpret the language of claim 1 of the Neefe Patent; whether a person of ordinary skill in the art would view certain steps in the Boston IV and Boston II processes as equivalent to steps specified in claim 1; and the reasons for Boston IV's success. Upon consideration of the entire record, the Court finds as follows:

a. The Boston II and Boston IV Lenses

110. As noted *supra* at FF. 47-48, on May 1, 1979, a patent was issued for the invention of Edward J. Ellis and his colleague, working at the Polymer Technology Corporation ("PTC"), which is owned by Bausch & Lomb. JTX-9 at [54], [75], [45], [73].

111. Similar to the Gaylord polymer, the Ellis polymer used the hydrophobic Tris monomer, a hydrophilic MMA monomer, a hydrophilic methacrylic acid as a wetting agent, and traditional, hydrophilic cross-linking agents. Jan. 28 AM Tr. at 73:25–74:2 (Long); 75:1-11; JTX-9 at col.3 line 68, col.4 lines 24-27, col.5 line 4, col.10 lines 28-33.

112. The Ellis polymer differed from the Gaylord polymer, however, in that Ellis added an additional hydrophilic monomer called itaconate in order to improve the stability and the wettability of the polymer. Jan. 28 AM Tr. at 73:10-16, 74:2-14 (Long); JTX-4 at 64; JTX-9 col.10 lines 28-33.

113. Contact lenses incorporating the Ellis polymer were introduced into the marketplace in 1983 by PTC as the Boston II lens. JTX-10 at col.2 lines 48-51; PTX-3 at BL5513; see also JTX-4 at 64, 66.

114. A year later, in 1984, PTC introduced the Boston IV lens as part of a "second generation" of RGP contact lenses. Jan. 29 AM Tr. at 23:12-15, 55:5-7 (Melamed); Jan. 29 AM Tr. at 43:16–44:22.

115. Both the Boston II contact lens and the Boston IV contact lens are made from an oxygen permeable material formed by a process that includes the copolymerization of Tris by procedures specified in Bausch & Lomb manufacturing protocols. JTX-21 at BL8556-57. Both procedures begin with the synthesis of TX-91, a specific formulation of Tris. Jan. 28 PM Tr. at 56:4-7 (Long); JTX-17 at BL31.

116. As discussed in FF. 117 to FF. 129, the five step process used to formulate TX-91 corresponds to steps (a) through (e) of the Neefe Patent.[10]

b. Formulation of TX-91

117. *First*, the production of TX-91, a specific formulation of Tris, begins by mixing 600 mL methacryloxypropyltrimethoxysilane ("MPS") and 1200 mL trimethylchlorosilane ("TMCS"), for a molar ratio of TMCS to MPS of 3.75 to 1, in a 3 liter round bottom flask. JTX-18 at BL3, Step 7.1.2.

118. This process is performed in the exact manner as set forth in step (a) of claim 1 of the Neefe Patent. Jan. 28 PM Tr. at 27:20-28:2 (Long); JTX-1 at col.5 lines 38-64.

119. *Second*, the mixture of MPS and TMCS is added to one-third volume of water and cooled with an external ice/water bath. JTX-18 at BL4, step 7.1.3-7.1.4.

120. This combined use of one-third volume of water (which catalyzes the hydrolysis reaction) and an external ice/water bath (which acts as a heat sink to absorb the excess heat produced in the exothermic reaction) is not performed in the exact manner as any step recited in the Neefe Patent. See JTX-1 at col.5 lines 38-64. This combined use performs substantially the same functions, however, as the 3 to 10-fold excess volume of water recited in step (b) of claim 1 of the Neefe Patent (*i.e.*, catalyzing the hydrolysis reaction and absorbing excess heat), in substantially the same way (*i.e.*, by providing the water needed for incorporation during the chemical reaction and serving as a heat buffer), to achieve substantially the same result (*i.e.*, forming Tris and limiting the formation of undesired by-products that can form under conditions

[10] The parties introduced no evidence at trial suggesting that the Boston II or the Boston IV processes were intentionally based on the Neefe Patent.

of excessive heat). JTX-18 at BL4, step 7.1.3-7.1.4; Jan. 28 PM Tr. at 33:16-34:20 (Long); see also JTX-6 at col.1 lines 52-54.

121. *Third*, the mixture of MPS, TMCS, and water is stirred slowly for 12 to 16 hours. Jan. 28 PM Tr. at 36:1-14 (Long); JTX-18 at BL4, Step 7.1.5.

122. This process is performed in the exact manner as set forth in step (c) of claim 1 of the Neefe Patent. Jan. 28 PM Tr. at 36:21-37:1 (Long); JTX-1 at col.5 lines 38-64.

123. *Fourth*, the mixture of MPS, TMCS, and water is transferred to a separatory funnel, allowed to separate, and the upper organic layer is retained. Jan. 28 PM Tr. at 37:21-25, 38:1-5 (Long); JTX-18 at BL4, Step 7.1.6.

124. *Fifth*, volatiles (including the unwanted by-product hexamethyldisiloxane) are then removed under vacuum using a rotary evaporator or its equivalent. Jan. 28 PM Tr. at 39:17–40:1 (Long); JTX-18 at BL4, Step 7.1.9. The mixture is then filtered. Jan. 28 PM Tr. at 38:9-17 (Long); JTX-18 at BL5, Step 7.2.2. See generally JX-18.

125. The separation step and the vacuum distillation and filtration steps correspond to steps (d) and (e) of claim 1 of the Neefe Patent. The order in which each action is performed, however, differs from the sequence described in claim 1, which requires that the upper organic layer of the mixture is "remove[d] and filter[ed]" in step (d), and that the hexamethyldisiloxane "is *then* removed by vacuum distillation" in step (e). JTX-1 at col.5 lines 51-54 (emphasis added).

126. Nevertheless, a person of ordinary skill in the art would view filtration followed by vacuuming as equivalent to vacuuming followed by filtration. Jan. 28 PM Tr. at 40:12-15, 54:23-25, 87:8-9, 94:14-15 (Long). The Court bases this finding on the following facts:

a. Both the filtration process and the vacuum distillation process are used to purify the desired Tris by removing unwanted materials. Jan. 28 PM Tr. at 54:7-14 (Long).

b. Dr. Long testified that the presence of insoluble impurities or by-products will not alter the way in which the vacuum distillation process works, or its effectiveness in removing soluble materials. Jan. 28 PM Tr. at 54:7-14, 54:23-25 (Long). He also testified that the presence of unwanted soluble, organic impurities or byproducts will not alter the way in which the filtration process works, or its effectiveness in removing particulate materials. Jan. 28 PM Tr. at 54:7-14, 54:23-25 (Long).

c. No evidence was presented at trial indicating that the effectiveness of the filtration process depends on whether the filtration occurs before or after vacuum distillation; nor was any evidence presented that the effectiveness of the vacuum distillation process depends on whether distillation occurs before or after filtration.

127. After the five steps described above are completed, the resulting solution is TX-91. TX-91 consists of at least 85% Tris monomer; the remaining percentage is Tris dimer or trimer. JTX-17 at BL 31; Jan. 28 PM Tr. at 23:8-16 (Long).

128. Tris dimer and Tris trimer are both in the class of multifunctional siloxanyl alkyl esters required for step (f) of claim 1 of the Neefe Patent. Jan. 28 PM Tr. at 58:6–59:1 (Long).[11]

[11] Although the parties did not introduce extensive evidence at trial about the nature of Tris dimer and trimer, they appear to agree that the term multifunctional signifies that the monomer has two or more ends that can react and join with other comonomers. It is this property that enables a multifunctional compound – such as Tris dimer (two ends) or trimer (three ends) – to serve as a cross-linking agent. By contrast, a Tris *mono*mer (one end) can be

129. TX-91 is the first ingredient used in both the Boston II manufacturing process and the Boston IV process. See generally JX-18; Jan. 28 PM Tr. at 56:4-13 (Long); Jan. 28 PM Tr. at 56:4-7 (Long). From this point, however, the Boston II process and the Boston IV process diverge.

c. The Boston II Lens

130. As noted, the first compound used in the Boston II copolymerization process is TX-91. Jan. 28 PM Tr. at 56:4-13 (Long).

131. TX-91, as prepared in steps (a) through (e) above, comprises approximately 41.7% by weight of the Boston II copolymer. JTX-17 at BL24, BL31. The main component of TX-91, the Tris monomer, therefore comprises 35.5% to 41.7% by weight of the Boston II copolymer. Jan. 28 PM Tr. at 56:14-15 (Long); JTX-17 at BL24, BL31.

132. This percentage of Tris falls within the range specified for this reactant in step (f) of claim 1 of the Neefe Patent. Jan. 28 PM Tr. at 56:18–57:1 (Long); JTX-1 at col.5 lines 38-64.

133. The second comonomer used in the copolymerization process is an ester of acrylic or methacrylic acid. Jan. 28 PM Tr. at 57:2-8 (Long).

134. An ester of acrylic or methacrylic acid comprises 21.8% by weight of the copolymer. JTX-17 at BL24, BL31.

135. This percentage of an ester of acrylic or methacrylic acid falls within the range specified for this reactant in step (f) of claim 1 of the Neefe Patent. Jan. 28 PM Tr. at 57:2-12 (Long); JTX-1 at col.5 lines 38-64.

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cross-linked, but it cannot itself serve as a cross-linker. See Jan. 30 PM Tr. 5:14-18 (Dome closing arg.); Director's Trial Brief at 10.

136. The third class of comonomers used in the copolymerization process are the surface wetting agents tetraethyleneglycol dimethacrylate ("CL") and N-Nvinylpyrrolidone ("NVP"). Jan. 28 PM Tr. at 58:1-3 (Long).

137. Together, these surface wetting agents comprise 9.9% by weight of the copolymer. JTX-17 at BL24, BL31 (CL is 8.4% by weight; NVP is 1.5% by weight).

138. This percentage of surface wetting agents falls within the range specified for this reactant in step (f) of claim 1 of the Neefe Patent. Jan. 28 PM Tr. at 58:1-5 (Long); JTX-1 at col.5 lines 38-64.

139. No additional multifunctional siloxanyl alkyl esters are added to this mixture for the Boston II process. JTX-17 at BL 24, 31.[12]

140. Multifunctional siloxanyl alkyl esters nevertheless are often present in the mixture used to create the Boston II lens. This is because, as noted *supra* at FF. 127-128, TX-91 consists of up to 15% Tris dimer or trimer, each of which is an example of the multifunctional siloxanyl alkyl ester called for in step (f) of claim 1. JTX-17 at BL 31; Jan. 28 PM Tr. at 23:8-16, 24:19-23, 98:18–99:3 (Long).

141. Neefe himself disclosed embodiments using Tris dimer or trimer as the cross-linking agent. Examples II and IV in the Neefe Patent specification employ a dimer of Tris. Jan. 28 PM Tr. at 17:24-18:2, 19:1-5 (Long); see also JTX-1 at col.3 lines 30-40, 62. Example VI of the Neefe Patent employs a trimer of Tris. JTX-1 at col.4 lines 36-37.

142. Because TX-91 makes up 41.7% of the Boston II lens by weight (JTX-17 at BL 24; Jan. 28 PM Tr. at 56:10-11 (Long)), the Boston II lens can be comprised up to 6.2% by

[12] Other compounds were present in the Boston II lens as well, including dimethyl itaconate. See JTX-17 at 24, 31.

weight of Tris dimer and trimer (*i.e.*, 41.7% (percentage of TX-91 in the lens) multiplied by 15% (maximum percentage of Tris dimer and trimer in TX-91)). See Director's PFF. 149; Dome Resp. PFF. 149.

143. PTC sought to minimize the presence of dimers and trimers in at least one of its formulations of Tris. JTX-19 at BL 68, 70. There is no evidence, however, that the amount of Tris dimer or trimer was minimized below .01% by weight. In fact, PTC calculated that the Boston II lens contained approximately 1.3 mole percent of Tris dimer and trimer. JTX-21 at 8557, 8577.[13]

144. If Tris dimer and trimer are present in TX-91, then they will be cross-linked in the copolymer. Jan. 28 PM Tr. at 97:18–98:6 (Long).

145. As noted *supra* at FF. 76, step (f) of claim 1 of the Neefe Patent requires that at least .01% of the hydrophobic cross-linking agent – such as Tris dimer or Tris trimer – be copolymerized with the Tris, the ester of acrylic or methacrylic acid, and the surface wetting agent. JTX-1 at col.5 lines 55-64.

146. The maximum amount of Tris dimer and trimer permitted in the Boston II lens – 6.2% – falls well within the "0.01% to 90%" range of siloxanyl alkyl ester cross-linking agent required in Step (f) of claim 1 of the Neefe Patent. See JTX-1 at col.5 lines 55-64.

147. The minimum amount of Tris dimer and Tris permitted in the Boston II lens – 0% – falls narrowly outside of the "0.01% to 90%" range of siloxanyl alkyl ester cross-linking agent required in Step (f) of claim 1 of the Neefe Patent. See id.

148. As noted *supra* at FF. 48, the oxygen permeability of the Boston II lenses consistently was reported to be approximately 12 to 14 Dk. Jan. 29 AM Tr. at 25:22-25, 54:4-9

[13] The parties have neither defined mole percent nor have they testified as to how to convert mole percent to percent by weight for this copolymer.

(Melamed); Jan. 30 AM Tr. at 69:25-70:2, 75:21-25 (Benjamin); JTX-4 at 66 (12-14 Dk); JTX-12 at 238 (12.6 Dk); JTX-21 at BL8556 (14.6 Dk); JTX-27 at 273 (12 Dk); PTX-2 at BL4760 (14.6 Dk); but see JTX-20 at BL8328 (16.4 Dk).

d. The Boston IV Lens

149. Like the Boston II lens, the first compound employed in the Boston IV copolymerization process is TX-91. Jan. 28 PM Tr. at 56:4-7 (Long); JTX-17 at BL31.

150. Sufficient amounts of TX-91 are used so that the Tris monomer comprises 38.3% to 41.0% by weight of the copolymer. JTX-17 at BL31; Jan. 28 PM Tr. at 56:14-15 (Long).

151. This percentage of Tris monomer falls within the range specified in step (f) of claim 1 of the Neefe Patent. Jan. 28 PM Tr. at 56:18–57:1 (Long).

152. As in the Boston II process, the second comonomer employed in the copolymerization set forth in the Boston IV process is an ester of acrylic or methacrylic acid. Jan. 28 PM Tr. at 57:2-8 (Long).

153. An ester of acrylic or methacrylic acid comprises 19.7% by weight of the copolymer used for the Boston IV process. JTX-17 at BL24, BL31.

154. This amount of ester of acrylic or methacrylic acid falls within the range specified in step (f) of claim 1 of the Neefe Patent. Jan. 28 PM Tr. at 57:2-12 (Long).

155. As in the Boston II process, the third class of comonomers employed in the copolymerization set forth in the Boston IV process are the surface wetting agents tetraethylene glycol dimethacrylate and N-Nvinylpyrrolidone. Jan. 28 PM Tr. at 58:1-3 (Long).

156. Together, these surface wetting agents comprise 8.1% by weight of the copolymer. JTX-17 at BL24, BL31 (CL is 2.9% by weight; NVP is 5.5% by weight).

157. This percentage of surface wetting agents falls within the range specified for this reactant in step (f) of claim 1 of the Neefe Patent. Jan. 28 PM Tr. at 58:1-5 (Long).

158. Unlike in the Boston II process, in the Boston IV process TX-91 is modified to become TX-82. TX-82 is prepared by adding substantial quantities of Tris dimer and Tris trimer to the TX-91 formulation produced through steps (a) through (e), so as to increase the percentage of Tris dimer to between 19.5 and 21 percent and Tris trimer to between 3 and 9.5 percent. Jan. 28 PM Tr. at 24:5-18, 58:20–59:1 (Long); JTX-17 at BL24, BL31; JTX-21 at BL8599-8603.

159. As noted *supra* at FF. 128, Tris dimer and trimer are each an "oxygen permeable crosslinking agent selected from the class of multifunctional siloxanyl alkyl esters" as specified in step (f) of claim 1 of the Neefe Patent. Jan. 28 PM Tr. at 58:6-24 (Long).

160. These percentages of Tris dimer and trimer fall within the range specified for this reactant in step (f) of claim 1 of the Neefe Patent. Jan. 28 PM Tr. at 58:15-59:1, 59:25–60:7 (Long); JTX-1 at col.5 lines 38-64.

161. The reported oxygen permeability of the Boston IV lens was 19 to 28 Dk, depending on the measurement technique used. Jan. 29 AM Tr. at 26:1-2, 56:1-4 (Melamed); Jan. 30 AM Tr. at 37:24, 66:12-13 (Benjamin); JTX-4 at 66; JTX-21 at BL8556, BL8578; JTX-22 at BL8739; JTX-23; JTX-27 at 273; PTX-2 at BL4760, BL4776; PTX-3 at BL5507.[14]

e. Boston II versus Boston IV

162. The only substantial difference between the Boston II and the Boston IV manufacturing processes was that the Boston IV process involved the purposeful addition of Tris dimer and trimer. One internal Bausch & Lomb document stated that the final concentration of

[14] As with the Boston II lens, other compounds were present in the Boston IV lens, including dimethyl itaconate. See JTX-17 at 24, 31.

Tris dimer and trimer in the Boston IV lens was 3.9 mole percent, three times that of the Boston II lens (1.3 mole percent). JTX-21 at BL8557, BL8577.

163. There was at least a 50% increase in the oxygen permeability of the Boston IV polymer over the Boston II polymer without impairment of wettability. Jan. 29 AM Tr. at 26:1-4, 62:11-13 (Melamed); JTX-4 at 66; PTX-3 at BL5513.

164. When calculating how much oxygen passes through an actual lens, one considers its oxygen *transmissibility*, which takes into account the material's thickness. Jan. 29 AM Tr. at 63:21-22 (Melamed); Jan. 30 AM Tr. at 23:18-19 (Benjamin); JTX-4 at 62.

165. Oxygen transmissibility is expressed as Dk/L, where Dk is the oxygen permeability and L is the thickness of the given polymer. Jan. 29 AM Tr. at 65:11-14 (Melamed); JTX-4 at 62.

166. The Dk/L of a contact lens must be approximately 18 to 20 to prevent damage to the cornea over the course of a prolonged wearing day. JTX-26 at 11.3 ("To produce virtually no change in corneal thickness under daily wear conditions, a lens must provide an equivalent oxygen percentage (EOP) of no less than 10%. Theoretically, this requires a Dk/L of approximately 18-20."). Jan. 29 AM Tr. at 91:13-21 (Melamed).

167. The oxygen transmissibility of the Boston IV lens is approximately 18.7 Dk/L, and thus the lens is suitable for prolonged daily wear. JTX-4 at 206; Jan. 29 AM Tr. at 65:15-17, 76:7-20 (Melamed); JTX-26 at 11.3-11.4. By contrast, the oxygen transmissibility of the Boston II lens is approximately 8.0 to 9.3 Dk/L, and thus the Boston II is not suitable for prolonged daily wear. PTX-2 at BL4760; JTX-4 at 66, 206; Jan. 29 AM Tr. at 75:22-76:3 (Melamed); see also Dome's PFF. 291-96; Director's Resp. PFF. at 14.

168. The Boston IV lens was an improvement over the Boston II lens because of increased oxygen permeability and oxygen transmissibility. Jan. 29 AM Tr. at 27:8-13 (Melamed).

169. The Boston IV lens largely displaced sales of the Boston II lens. Jan. 29 AM Tr. at 45:7-16 (Melamed); PTX-3 at BL5513; JTX-31 at BL8309.

170. By 1988, the Boston IV lens commanded 65% of Bausch & Lomb's total material sales distribution, while the Boston II lens accounted for 10% of sales. JTX-31 at BL8309.

171. The Boston IV lens is still widely available today. Jan. 29 AM Tr. at 46:12-13 (Melamed); JTX-4 at 17.

172. Other factors in addition to increased oxygen permeability likely contributed to the Boston IV lens' commercial success: (*i*) patients could easily get a replacement lens for the Boston IV lens because they were "consistent and readily reproducible" (Jan. 29 AM Tr. at 68:11-24 (Melamed)); (*ii*) patients were attracted to the Boston IV lens because it was durable and lasted a long time (id. at 68:25 – 69:10 (Melamed)); (*iii*) the long-term costs of purchasing the Boston IV lens were low for the consumer, so economics was an additional attractive feature of the lens (id. at 71:3-12 (Melamed)); and (*iv*) Bausch & Lomb heavily promoted the Boston IV lens, but not other lenses with higher oxygen permeability (*e.g.*, the Boston Equalens lens) (id. at 80:8-23 (Melamed)).

f. Other Embodiments of Claim One of the Neefe Patent

173. The ranges identified in step (f) of the Neefe Patent are very broad. For example, as noted *supra* at FF. 104, claim 1 of the Neefe patent permits as little as 0.01% of the hydrophobic cross-linking agent, along with 5% of Tris, which is hydrophobic, so it permits as much as 94.99% of hydrophilic comonomers. JTX-1 at col.5 lines 55-64.

174. Dome did not introduce any expert evidence showing that a contact lens made from ingredients in the amounts at the ends of those ranges would be sufficiently oxygen permeable or wettable.

175. For example, Dome's expert, Dr. Long, did not know whether a contact lens material that is 5% by weight Tris monomer, 90% by weight MMA, 4.99% by weight surface wetting agent, and 0.01% by weight a multifunctional siloxanyl alkyl ester would be sufficiently oxygen permeable, even though such a lens material would fall within the scope of claim 1 of the Neefe Patent. Jan. 28 PM Tr. at 86:7-23 (Long).

176. Nor did Dr. Long know whether a lens material that is 90% by weight Tris monomer, 3% by weight MMA, 0.5% by weight surface wetting agent, and 6.5% by weight Tris dimer as a cross-linker would be wettable, even though such a lens material would fall within the scope of claim 1 of the Neefe patent. Jan. 28 PM Tr. at 85:20–86:6 (Long).

177. Based on the evidence introduced at trial regarding the Boston II lens, a person of ordinary skill in the art would expect that a contact lens material comprised 35.5% to 41.7% by weight of Tris monomer, 21.8% by weight of ester of acrylic or methacrylic acid, 9.9% by weight of surface wetting agents tetraethyleneglycol dimethacrylate and N-Nvinylpyrrolidone, and between .01% and 6.2% by weight of Tris dimer and trimer, and manufactured in accordance with claim 1, would be wettable and would have an oxygen permeability of approximately 12 to 14 Dk. See FF. 131, 134, 137, 140, 142, 144, 148.

178. As noted *supra* at FF. 68, the initial material created by Neefe using the process of claim 1 had a Dk value of 14. The parties did not introduce any evidence at trial about how much of each ingredient (Tris monomer, MMA, surface wetting agent, and multifunctional siloxanyl alkyl ester) was used in the manufacturing process of that material.

179. As noted *supra* at FF. 79, the TransAire polymer, which was based on claim 1 of the Neefe patent, had a Dk value of 45. The parties did not introduce any evidence at trial about how much of each ingredient (Tris monomer, MMA, surface wetting agent, and multifunctional siloxanyl alkyl ester) was used in the TransAire manufacturing process.

III. CONCLUSIONS OF LAW

A. Legal Standards

1. Burden of Proof

Once the PTO has determined that "a substantial new question of patentability" is raised by a request for reexamination, the PTO initiates a reexamination proceeding. In re Swanson, 540 F.3d 1368, 1375 (Fed. Cir. 2008) (quoting 35 U.S.C. § 303(a)). In a reexamination proceeding, as in the initial examination of a patent application, the patent examiner bears the initial burden of showing by a preponderance of the evidence that the invention is unpatentable as obvious. See Rambus Inc. v. Rea, 731 F.3d 1248, 1255 (Fed. Cir. 2013) ("In reexamination proceedings, 'a preponderance of the evidence must show nonpatentability before the PTO may reject the claims of a patent application.'") (internal quotation omitted); In re Etter, 756 F.2d 852, 856 (Fed. Cir. 1985) (en banc). Once a *prima facie* showing of obviousness is made, however, the burden shifts to the patent holder to demonstrate nonobviousness. In re Giannelli, 739 F.3d 1375, 1379 (Fed. Cir. 2014); In re Glaug, 283 F.3d 1335, 1338 (Fed. Cir. 2002).

Dome objects to the application of this legal standard here, arguing that claim 1 of the Neefe Patent may be cancelled only if the Director proves obviousness under a clear and convincing evidence standard. In support of its position, Dome points to the standard of proof in patent infringement proceedings initiated under 35 U.S.C. § 282. See Dome's Prop. Concl. Law

11 (citing Microsoft Corp. v. i4i Limited Partnership, 131 S. Ct. 2238 (2011)). In Section 282 proceedings, a party accused of infringement may claim, as an affirmative defense, that the relevant patent is invalid due to obviousness. To prevail on this defense, the accused infringer must show obviousness by clear and convincing evidence. Section 282 is a fundamentally different context than the present one, and the burdens of proof governing those proceedings are inapplicable here. See In re Swanson, 540 F.3d at 1377 (noting that PTO examination and reexamination proceedings "have distinctly different standards, parties, purposes, and outcomes" than Section 282 infringement proceedings); In re Etter, 756 F.2d at 855-59; cf. Sciele Pharma Inc. v. Lupin Ltd., 684 F.3d 1253, 1260 (Fed. Cir. 2012) (noting that the clear and convincing standard applicable in Section 282 proceedings is rooted in a "necessary deference to the PTO") (internal quotation omitted).

The Court therefore considers whether the Director has shown by a preponderance of the evidence that claim 1 of the Neefe Patent is *prima facie* obvious, and, if so, whether Dome has rebutted this initial showing.

2. Standard of Review

A party subject to an adverse reexamination decision by the Board may seek review of that decision in this Court under 35 U.S.C. § 145, or it may appeal the decision directly to the Federal Circuit pursuant to 35 U.S.C. § 141.[15] Unlike a Section 141 appeal, a Section 145

[15] 35 U.S.C. § 141 was amended on November 29, 1999, to provide the Federal Circuit with exclusive jurisdiction of any challenge to the Board's final decision in a reexamination proceeding. 35 U.S.C. § 141; see generally Teles AG v. Kappos, 846 F. Supp. 2d 102, 111 (D.D.C. 2012). 35 U.S.C. § 145 was amended on September 16, 2011, changing the venue for Section 145 actions from this Court to the United States District Court for the Eastern District of Virginia. See Kappos v. Hyatt, 132 S. Ct. 1690, 1694 n.1 (2012). Neither amendment

proceeding in district court is a "unique 'hybrid of an appeal and a trial *de novo*.'" Alberts v. Kappos, 917 F. Supp. 2d 94, 104 (D.D.C. 2013), aff'd sub nom., Alberts v. Lee, 552 F. App'x 986 (Fed. Cir. 2014). In a Section 145 action, the parties may present new evidence that was not presented to the PTO, and in so doing, are restricted only by the Federal Rules of Evidence and the Federal Rules of Civil Procedure. Kappos v. Hyatt, 132 S. Ct. 1690, 1694 (2012). Where new evidence is presented on a disputed question of fact, "[t]he district court must assess the credibility of new witnesses and other evidence, determine how the new evidence comports with the existing administrative record, and decide what weight the new evidence deserves." Id. at 1700. The Court then "must make *de novo* factual findings that take account of both the new evidence and the administrative record before the PTO." Id. at 1701. Where no new evidence is presented at all or with respect to certain facts found by the Board, the Court "must [instead] apply the APA's substantial evidence standard to Patent Office fact findings." Hyatt v. Kappos, 625 F.3d 1320, 1336 (Fed. Cir. 2010) (en banc), aff'd, 132 S. Ct. 1690 (2012). Because new evidence was presented on every significant, contested factual issue in this case, the Court's factual findings are largely *de novo*. Questions of law also are reviewed *de novo*. Cytologic, Inc. v. Biopheresis GmbH, 682 F. Supp. 2d 1, 12 (D.D.C. 2010).

B. Analysis

1. The Director Has Made a *Prima Facie* Showing of Obviousness

"Whether a claim would have been obvious under 35 U.S.C. § 103(a) is a legal conclusion based on underlying factual determinations." Rambus Inc. v. Rea, 731 F.3d at 1251-52 (citing In re Kotzab, 217 F.3d 1365, 1369 (Fed. Cir. 2000)). These factual

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is retroactive or applicable here, as the request for reexamination in this case was filed on August 27, 1998.

determinations "include (1) the scope and content of the prior art; (2) the differences between the claims and the prior art; (3) the level of ordinary skill in the art; and (4) objective evidence of nonobviousness." Id. at 1251 (citing Graham v. John Deere Co. of Kansas City, 383 U.S. 1, 17-18 (1966)). The inquiry into obviousness "entails 'an expansive and flexible approach.'" Sciele Pharma Inc. v. Lupin Ltd., 684 F.3d at 1259 (quoting KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 415 (2007)). If any embodiment within the scope of the claim is determined to be obvious, then the entire claim is unpatentable for obviousness, regardless of whether other embodiments are nonobvious. See ArcelorMittal France v. AK Steel Corp., 700 F.3d 1314, 1325 (Fed. Cir. 2012) ("'[C]laims which are broad enough to read on obvious subject matter are unpatentable even though they also read on nonobvious subject matter.'") (quoting Muniauction, Inc. v. Thomson Corp., 532 F.3d 1318, 1328 n.4 (Fed. Cir. 2008)).

It is undisputed that each of the compounds recited in claim 1 of the Neefe Patent – the Tris monomer, the ester of acrylic or methacrylic acid, the surface wetting agent, and the siloxanyl alkyl ester cross-linking agent – was known in the prior art. This fact alone, however, does not establish obviousness. KSR Int'l Co. v. Teleflex Inc., 550 U.S. at 418-19 ("[A] patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art."); see also Stryker Spine v. Biedermann Motech GmbH, 750 F. Supp. 2d 107, 122 (D.D.C. 2010). Where all of the elements of a claim are known in the prior art, as is the case here, the obviousness inquiry generally will turn on two factual questions:

> (1) whether the prior art would have suggested to those of ordinary skill in the art that they should make the claimed composition or device, or carry out the claimed process; and
>
> (2) whether the prior art would also have revealed that in so making or carrying out, those of ordinary skill would have a reasonable expectation of success.

Medichem, S.A. v. Rolabo, S.L., 437 F.3d 1157, 1164 (Fed. Cir. 2006) (quoting Velander v. Garner, 348 F.3d 1359, 1363 (Fed. Cir. 2003)); see also In re Rosuvastatin Calcium Patent Litig., 703 F.3d 511, 518 (Fed. Cir. 2012) ("[I]n cases involving new chemical compounds, it remains necessary to identify some reason that would have led a chemist to modify a known compound in a particular manner to establish prima facie obviousness of a new claimed compound.") (internal quotation marks omitted). A court "need not seek out precise teachings directed to the specific subject matter of the challenged claim," KSR Int'l Co. v. Teleflex Inc., 550 U.S. at 418, as the analysis "can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." Id.

In this case, the Director has demonstrated both the reason for combining the compounds recited in claim 1 of the Neefe Patent and a reasonable expectation of success. A person of ordinary skill in the art would have known that the ideal contact lens would have a relatively high level of oxygen permeability, and would be motivated to combine comonomers and cross-linkers to create an oxygen permeable polymer. See FF. 8-11, 81. This artisan also would have known that the siloxanyl alkyl ester cross-linkers discussed by Tanaka promoted oxygen permeability, as these cross-linkers contained a siloxane bond. FF. 61-62. And the artisan would have known that the siloxanyl alkyl ester cross-linkers could effectively cross-link the comonomers used by Gaylord and Ellis. FF. 80-88. It therefore would have been obvious to a person of ordinary skill in the art that these materials, when combined with traditional hydrophilic comonomers and wetting agents, could potentially be used to create an oxygen permeable contact lens. FF. 89. The Director has established a *prima facie* case of obviousness, and the burden shifts to Dome to prove nonobviousness.

2. The Prior Art Does Not Teach Away from Combining the Elements in Claim 1 of the Neefe Patent

A patentee may rebut a *prima facie* showing of obviousness by demonstrating that the prior art "teaches away" from the claimed invention in any material respect. In re Peterson, 315 F.3d 1325, 1331 (Fed. Cir. 2003); see KSR Int'l Co. v. Teleflex Inc., 550 U.S. at 416 ("[W]hen the prior art teaches away from combining certain known elements, discovery of a successful means of combining them is more likely to be nonobvious."). Dome has taken this tack, arguing that while it may have been apparent that both Tris monomer and siloxanyl alkyl ester cross-linker promote oxygen permeability, the prior art "taught away" from attempting this combination.

"A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant." In re Gurley, 27 F.3d 551, 553 (Fed. Cir. 1994) (collecting cases). The degree to which a reference teaches away will depend on the particular facts, but the basic question is whether the reference "suggests that the line of development flowing from the reference's disclosure is unlikely to be productive of the result sought by the applicant." Id. "What a reference teaches and whether a person of ordinary skill in the art would have been motivated to combine the teachings of separate references are questions of fact." Pregis Corp. v. Kappos, 700 F.3d 1348, 1353 (Fed. Cir. 2012). When considering apparently conflicting references in the prior art, the fact-finder must weigh each reference "for its power to suggest solutions to an artisan of ordinary skill . . . consider[ing] the degree to which one reference might accurately discredit another." Medichem, S.A. v. Rolabo, S.L., 437 F.3d at 1165 (quoting In re Young, 927 F.2d 588, 591 (Fed. Cir. 1991)).

As discussed above, see FF. 90-109, the prior references of Tanaka did not teach away from combining Tris with a siloxanyl alkyl ester cross-linking agent, at least for daily wear and prolonged daily wear lenses. Granted, Tanaka warned that in constructing a lens that "can be comfortably worn continuously for a long period of time," it was difficult, when using the Tris monomer, to achieve high levels of oxygen permeability, clarity, and wettability, and that a highly hydrophobic solution could not always be made wettable by simply adding high levels of hydrophilic monomer – there were limits. FF. 91-94. But other references in the prior art taught that Tris *could* be used effectively in the manufacturing of contact lenses, so long as hydrophilic comonomers were used to offset the water-repellant properties of Tris. See, e.g., FF. 42, 97-104 (discussing Gaylord's patent, which taught that Tris could be synthesized with hydrophilic monomers like MMA and surface wetting agents without making the copolymer opaque); FF. 47- 48 (discussing Ellis's patent, which combined Tris and hydrophilic comonomers).[16] Indeed, Tanaka himself recognized that the hydrophobic properties of Tris could be successfully repressed – within limits – by the addition of hydrophilic compounds. To the extent that Tanaka teaches away from using Tris altogether, the Court finds that such teaching can be fairly read as confined to continuous wear lenses, see FF. 94, not to daily wear or prolonged daily wear lenses, and that the teaching is outweighed by the teachings of Gaylord and Ellis.

[16] Dome correctly points out that the Board twice suggested, erroneously, that a multifunctional siloxanyl alkyl ester would be hydrophilic. See JTX-16 at 5:20-23 (describing hydrophilic formula [V] as a multifunctional siloxanyl alkyl ester); id. at 16:6-8 (describing hydrophobic "polyfunctional siloxanyl ester cross-linking agents" as hydrophilic). Dome argues that this factual error infected the Board's analysis. After reviewing the evidence presented to the Board *de novo*, along with the evidence presented at trial, the Court is convinced that the Board's errors do not affect the correctness of the Board's result.

The Court therefore concludes that Dome has not rebutted the *prima facie* case of obviousness by demonstrating that the prior art taught away from the method recited in claim 1.[17] As the Board found, a person of ordinary skill in the art would have had a reasonable expectation of success in combining the comonomers suggested by Gaylord and Ellis with the cross-linking agents suggested by Tanaka.

3. Dome's Evidence of Secondary Considerations Does Not Indicate Nonobviousness.

Dome also attempts to rebut the Director's *prima facie* case using evidence of secondary considerations, and in particular, evidence of commercial success. Secondary considerations, "[s]uch as commercial success, long felt but unsolved needs, failure of others, etc.," often can "give light to the circumstances surrounding the origin of the subject matter sought to be patented." KSR Int'l Co. v. Teleflex Inc., 550 U.S. at 406 (quoting Graham v. John Deere Co. of Kansas City, 383 U.S. at 17-18). Evidence that a patented invention attained significant commercial success may provide an independent basis for inferring that the invention was not obvious, "because the law presumes an idea would successfully have been brought to market sooner, in response to market forces, had the idea been obvious to persons skilled in the art." Merck & Co., Inc. v. Teva Pharm. USA, Inc., 395 F.3d 1364, 1376 (Fed. Cir. 2005); see also 3 MOY'S WALKER ON PATENTS § 9:62 (4th ed. 2013). Commercial success of an invention over the prior art also implies that the difference between an invention and the prior art is significant or substantial. 3 MOY'S WALKER ON PATENTS § 9:62. Although secondary considerations must be taken into account, they do not necessarily control the obviousness

[17] This question alternatively can be viewed as part of the inquiry into whether a person of ordinary skill attempting the patented combination would have had a reasonable expectation of success. Assuming *arguendo* that it is the Director's burden of showing that success would be reasonably expected despite the hydrophobicity of both the Tris monomer and the siloxanyl alkyl ester cross-linking agent, the Court concludes that such burden has been satisfied.

conclusion. Pfizer, Inc. v. Apotex, Inc., 480 F.3d 1348, 1372 (Fed. Cir. 2007) (citing Newell Cos., Inc. v. Kenney Mfg. Co., 864 F.2d 757, 768 (Fed. Cir. 1988)); see Wyers v. Master Lock Co., 616 F.3d 1231, 1246 (Fed. Cir. 2010) ("[S]econdary considerations of nonobviousness . . . simply cannot overcome a strong prima facie case of obviousness.").[18]

Dome asserts that an embodiment of claim 1 achieved unexpected results that led to substantial commercial success. Dome also argues, with less force, that this embodiment satisfied a long felt but unsolved need. See, e.g., Dome's PFF. 351-402; Dome's Prop. Concl. Law at 36-40, 52; Dome Resp. Prop. Concl. Law 159, 194-95, 199, 229-30. The Director contends that the evidence presented by Dome is irrelevant and unpersuasive.

a. Unexpected Results Leading to Commercial Success

Dome focuses on the commercial success of the Boston IV lens, which, according to Dome, was manufactured using the process recited in claim 1 of the Neefe Patent. It is undisputed that the Boston IV lens achieved significant commercial success over prior Bausch & Lomb RGP lenses. See FF.169-71. But this success is only relevant to the obviousness inquiry if Dome can establish the following: *first*, that the Boston IV lens embodies claim 1 of the Neefe Patent – that is, that the lens is made in accordance with claim 1 of the Neefe Patent, see Brown & Williamson Tobacco Corp. v. Philip Morris Inc., 229 F.3d 1120, 1130 (Fed. Cir. 2000); *second*, that the success of the Boston IV lens was the *result* of the novel feature claimed in the Neefe Patent, and not the result of some feature in the prior art, or some unrelated feature such as increased marketing, see Tokai Corp. v. Easton Enterprises, Inc., 632 F.3d 1358, 1369 (Fed. Cir.

[18] Secondary considerations are often referred to as objective evidence of nonobviousness. See Demaco Corp. v. F. Von Langsdorff Licensing Ltd., 851 F.2d 1387, 1391 (Fed. Cir. 1988) ("The rationale for giving weight to the so-called "secondary considerations" is that they provide objective evidence of how the patented device is viewed in the marketplace, by those directly interested in the product.").

2011); and *third*, that other embodiments of claim 1 could be expected to exhibit the same commercially beneficial properties exhibited by the Boston IV lens, see MeadWestVaco Corp. v. Rexam Beauty & Closures, Inc., 731 F.3d 1258, 1264-65 (Fed. Cir. 2013).

As discussed below, the Court agrees with Dome that there is a product – the Boston IV lens – that embodies claim 1 of the Neefe Patent and that achieved some commercial success. But the Court also finds that Dome has failed to present persuasive evidence that the success of the Boston IV lens is the result of the novel feature claimed in the Neefe Patent, or that other embodiments of claim 1 could be expected to exhibit the same commercially beneficial properties as those possessed by the Boston IV lens. The Court discusses each of these points in turn.[19]

i. The Boston IV lens Falls Within the Scope of Claim 1

Although neither Neefe nor Dome created the Boston IV lens, the success of this product nevertheless may shed light on the obviousness (or nonobviousness) of Neefe's invention, so long as Dome shows that the Boston IV lens "embodies the claimed features" of the patented invention – *i.e.*, that it is made in accordance with claim 1 of the Neefe Patent. Brown & Williamson Tobacco Corp. v. Philip Morris Inc., 229 F.3d at 1130.

As noted *supra* at FF. 149-159, the Boston IV lens is manufactured using the following materials: 38.3% to 41.0% by weight of Tris; 19.7% of an ester of acrylic or methacrylic acid; 8.1% of surface wetting agents (tetraethylene glycol dimethacrylate and N-Nvinylpyrrolidone); and 19.5 to 21% and 3 to 9.5%, respectively, of Tris dimer and Tris

[19] The Director moved to exclude testimony relating to the differences between the Boston II and the Boston IV lens as irrelevant, based on a purported lack of nexus and commensurateness. See Director's Mot. *in Limine* to Exclude the Testimony of Dr. Melamed and Portions of the Testimony of Dr. Long Pursuant to Rule 401 of the Federal Rules of Evidence, Dkt. No. 66 (filed under seal, Dkt. No. 69) (Oct. 23, 2012). The Court declined to rule on the motion at trial, but now will deny it.

trimer. These ranges fall within the ranges recited in claim 1 of the Neefe Patent, which calls for from 5% to 90% by weight of Tris; from 3% to 90% of an ester of acrylic or methacrylic acid; from .5% to 90% of a surface wetting agents; and from .01% to 90% of a siloxanyl alkyl ester cross-linker, such as Tris dimer or trimer. See FF. 76. But as the Director points out, there are two ways in which the synthesis of these compounds in the Boston IV lens process appears to deviate from the process recited in claim 1.

First, as discussed in FF. 123-125, the manufacture of the Boston IV lens requires that two steps – the vacuuming and the filtration of unwanted byproducts – occur in a different order than the order recited in claim 1 of the Neefe Patent. Generally speaking, however, a claim is not restricted to the performance of its steps in the order recited where sequence is not a clear limitation in the claim, and where neither logic nor any aspect of the specification or prosecution history requires a limiting construction. See Altiris, Inc. v. Symantec Corp., 318 F.3d 1363, 1370-71 (Fed. Cir. 2003); cf. Loral Fairchild Corp. v. Sony Corp., 181 F.3d 1313, 1322 (Fed. Cir. 1999) ("Although not every process claim is limited to the performance of its steps in the order written, the language of the claim, the specification and the prosecution history support a limiting construction in this case."). Although the ordering of the steps and the use of the word "then" suggests an order, neither logic nor anything in the specification or prosecution history suggests that the order of these steps would matter. See FF. 126. The Court therefore finds that the vacuuming and filtering elements recited in claim 1 are literally present in the Boston IV lens, and that the sequence of these steps is not a separate limitation of the claim. The variation in sequence does not take the Boston IV lens outside the scope of claim 1.

Second, claim 1 of the Neefe Patent requires at step (b) that the mixture of methacryl-oxypropyltrimethoxysilane and trimethylchlorosilane is added to water whose volume

is from 3 to 10 times that of the mixture. See JTX-1 at col.5 lines 38-64. By contrast, the Boston IV manufacturing process calls for the addition of one-third volume of water to this mixture of methacryloxypropyltrimethoxysilane and trimethylchlorosilane, followed by an external ice/water bath. See FF. 119. Both parties agree that this step of the Boston IV process is different from step (b) of claim 1; the water addition element of claim 1 thus is not literally met by the Boston IV process. See Dome PFF. 308-11; Director's Resp. PFF. 308-11. The parties also agree that the addition of one-third volume of water in the Boston IV step, followed by an ice/water bath, is substantially equivalent to claim 1's step (b). See Dome PFF. 308-11; Director's Resp. PFF. 308-11. The Director asserts that this technical departure from the claim 1 process establishes that the Boston IV lens falls outside the scope of claim 1. Dome disagrees, maintaining that the Boston IV lens falls within the scope of claim 1 under the doctrine of equivalents, and therefore can inform the obviousness inquiry.

The doctrine of equivalents arose in the context of infringement disputes, and it "grow[s] out of a legally implied term in each patent claim that 'the claim extends to the thing patented, however its form or proportions may be varied.'" Warner-Jenkinson Co., Inc. v. Hilton Davis Chemical Co., 520 U.S. 17, 35 (1997); see also Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 535 U.S. 722, 733 (2002) ("The doctrine of equivalents allows the patentee to claim those insubstantial alterations that were not captured in drafting the original patent claim but which could be created through trivial changes."). To evaluate whether a product or process infringes under the doctrine of equivalents, the court asks "whether an asserted equivalent represents an 'insubstantial difference' from the claimed element, or 'whether the substitute element matches the function, way, and result of the claimed element.'" Deere & Co. v. Bush

Hog, LLC, 703 F.3d 1349, 1356 (Fed. Cir. 2012) (quoting Warner-Jenkinson Co. v. Hilton Davis Chemical, 520 U.S. at 40)).

Although neither party has pointed to any case directly addressing this question, the Court is persuaded that the commercial success of a product that infringes a patent claim under the doctrine of equivalents can inform whether the patent claim is obvious. To begin with, the Director's contention that a process that infringes by equivalence is *outside* the scope of a claim is inconsistent with the established principle that "[t]he scope of a patent is not limited to its literal terms but instead embraces all equivalents to the claims described." Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 535 U.S. at 732. In this vein, courts have considered the commercial success of a competitor's infringing product or process as a secondary consideration, without distinguishing between literal infringement or infringement by equivalence. See, e.g., Brown & Williamson Tobacco Corp. v. Philip Morris Inc., 229 F.3d at 1130. Moreover, fact-finders in patent cases are instructed to take an "expansive and flexible approach" when considering obviousness. KSR Int'l Co. v. Teleflex Inc., 550 U.S. at 415. Where the differences between the process used to create a successful product and the process claimed in the patent are insignificant, and where all evidence indicates that a product manufactured in strict accordance with the claim language would be identical to the successful, equivalent product, the commercial success of the equivalent product can shed light on the patent's obviousness. The Court therefore finds that the Boston IV lens falls within the scope of claim 1 for purposes of the obviousness inquiry.

ii. Nexus Between Commercial Success and Claim 1

In order to rely on the commercial success of the Boston IV lens as evidence of nonobviousness, Dome must show a legally and factually sufficient connection – a "nexus" –

between the merits of claim 1 of the Neefe Patent and the evidence of the Boston IV lens' commercial success. Tokai Corp. v. Easton Enterprises, Inc., 632 F.3d at 1369; Wyers v. Master Lock Co., 616 F.3d at 1246; Demaco Corp. v. F. Von Langsdorff Licensing Ltd., 851 F.2d 1387, 1392 (Fed. Cir. 1988). "A prima facie case of nexus is generally made out when the patentee shows both that there is commercial success, and that the thing (product or method) that is commercially successful is the invention disclosed and claimed in the patent." Demaco Corp. v. F. Von Langsdorff Licensing Ltd., 851 F.2d at 1392; see also Ormco Corp. v. Align Tech., Inc., 463 F.3d 1299, 1312 (Fed. Cir. 2006) ("[W]hen a patentee can demonstrate commercial success, usually shown by significant sales in a relevant market, and that the successful product is the invention disclosed and claimed in the patent, it is presumed that the commercial success is due to the patented invention.") (internal quotation omitted); but see In re Huang, 100 F.3d 135, 140 (Fed. Cir. 1996) (requiring additional proof that increased sales "were a direct result of the unique characteristics of the claimed invention"). Where the evidence shows that the commercial success derived from some aspect of the prior art, or was the result of "economic and commercial factors unrelated to the quality of the patented subject matter," evidence of commercial success will not be sufficient to demonstrate nonobviousness of a claimed invention. In re DBC, 545 F.3d 1373, 1384 (Fed. Cir. 2008); see also Tokai Corp. v. Easton Enterprises, Inc., 632 F.3d at 1369-70.

As discussed in the preceding subsection, the Boston IV lens falls within the scope of claim 1 of the Neefe patent. And as noted, the parties do not dispute that the Boston IV lens achieved significant commercial success over prior Bausch & Lomb rigid contact lens products. See FF. 169-171. Dome therefore is entitled to a presumption that this commercial success relates to claim 1 of the Boston IV lens. Demaco Corp. v. F. Von Langsdorff Licensing

Ltd., 851 F.2d at 1392. But several factors undercut the persuasiveness of the evidence offered at trial.

First, the evidence of commercial success in the market is not particularly strong. Although Dome introduced evidence that the Boston IV lens achieved significant commercial success over prior *Bausch & Lomb* products, there is little evidence in the record of this product's success as compared to *competitors'* products. Rather, other RGP lenses with comparable or improved oxygen permeability levels came on the market at or near the same time, and there is no evidence that the Neefe process was used in developing these lenses. See JTX-4 at 206; JTX-26 at 11.3-11.4; JTX-27 at 23. Dome puts forth a narrative that could be compelling – artisans struggling in vain to create an extended wear lens, a problem finally solved by Neefe, to great commercial advantage – but provides no market data to support this narrative.

Second, on the issue of nexus, Dome has done little more than show that the Boston IV lens falls within the scope of claim 1 and achieved some commercial success. To bolster its nexus argument, Dome introduced the testimony of Dr. Mark Melamed, who explained why oxygen permeability would be a desirable property, and the Court has no doubt that increased oxygen permeability was one of the reasons for the Boston IV's popularity. See FF. 8-13, 81, 168. But Dr. Melamed's suggestion that oxygen permeability drove Boston IV's success is not reliable expert testimony, as such statements are outside the scope of his medical expertise. Moreover, Dr. Melamed himself indicated that at least some of the commercial success of the Boston IV lens is due to factors other than the lens' oxygen permeability – factors such as the lenses' durability, the ease of replacing them, and low long-term costs, as well as heavy marketing by Bausch & Lomb. See FF. 172.

Dome also attempted to show a nexus by contrasting the successful Boston IV lens, which falls within claim 1, with the less successful Boston II lens, which, according to Dome, does not. For the reasons described below – reasons that intersect with the commensurateness requirement – this evidence is not persuasive.

iii. Commensurateness with the Scope of Claim 1

For evidence of secondary considerations such as commercial success to be persuasive, the evidence "must be commensurate in scope with the claims which the evidence is offered to support." MeadWestVaco Corp. v. Rexam Beauty & Closures, Inc., 731 F.3d at 1264-65 (internal quotation omitted). Evidence of secondary considerations "is not commensurate with the claims if the claims are broader than the scope" of such evidence. Joy Technologies, Inc. v. Manbeck, 751 F. Supp. 225, 229 (D.D.C. 1990) aff'd, 959 F.2d 226 (Fed. Cir. 1992). "The claims are broader in scope than the objective evidence if a limitation or element recited in the claim is broader than the limitation or element in the objective evidence . . . or if the objective evidence contains limitations or elements not recited in the claims." Id. at 229-30 (citations omitted).

At least two rationales underlie the commensurateness requirement. First, a claim can be patented only if it is nonobvious *throughout the range* of the patent claim. Evidence of nonobviousness of one embodiment in a broad claim is of limited value, as it leaves open the question of whether other embodiments were obvious. See, e.g., Therasense, Inc. v. Becton, Dickinson & Co., 593 F.3d 1325, 1336 (Fed. Cir. 2010) (rejecting evidence that claimed invention solved a longstanding problem, where claims were broad enough to cover both devices that solved the problem and devices that did not); In re Clemens, 622 F.2d 1029, 1036 (C.C.P.A. 1980) (finding narrow range of data could not "be reasonably extended to prove the

unobviousness of a broader claimed range"); In re Tiffin, 448 F.2d 791, 792 (C.C.P.A. 1971) ("the objective evidence of non-obviousness is not commensurate with the scope of claims 1-3 and 10-16, reciting 'containers' generally, but establishes non-obviousness only with respect to 'cups' and processes of making them"). Second, evidence that commercially desirable properties are not commensurate with the patent claim suggests that the commercial success of one particular embodiment results from something different (or more specific) than the claim. In other words, if one embodiment of Neefe claim 1 has desirable properties, but another one does not, claim 1 does not necessarily *cause* those desirable properties. Viewed this way, the commensurateness requirement bears on the nexus inquiry, and has occasionally been described as such. See Regent Lighting Corp. v. FL Indus., Inc., 60 F.3d 840, 1995 WL 331122, at *5 (Fed. Cir. 1995) (unpublished table disposition); Joy Technologies, Inc. v. Manbeck, 751 F. Supp. at 229.

As a general matter, the requirement that evidence of secondary considerations be reasonably commensurate with the scope of the claim "does not mean that an applicant is required to test every embodiment within the scope of his or her claims." In re Kao, 639 F.3d 1057, 1068 (Fed. Cir. 2011); In re DBC, 545 F.3d at 1384 ("[A] patentee need not show that all possible embodiments within the claims were successfully commercialized in order to rely on the success in the marketplace of the embodiment that was commercialized.") (internal quotation omitted). The Federal Circuit has recognized that it is "unlikely that a company would sell a product containing multiple, redundant embodiments of a patented invention." In re Glatt Air Techniques, Inc., 630 F.3d 1026, 1030 (Fed. Cir. 2011). Thus, "[i]f an applicant demonstrates that an embodiment has an unexpected result *and provides an adequate basis to support the conclusion that other embodiments falling within the claim will behave in the same manner*, this

will generally establish that the evidence [of secondary considerations such as unexpected results and commercial success] is commensurate with scope of the claims." In re Kao, 639 F.3d at 1068 (emphasis added). Where it appears that commercially desirable properties appear only in a subset of a patent's embodiments, however, a court may not extend evidence of commercial success to the entire patent range. See In re Peterson, 315 F.3d at 1331 (affirming finding of obviousness where patent applicant claimed alloy with 1% to 3% rhenium and presented unexpected results only for alloy with 2% rhenium, where evidence suggested that alloy with 3% rhenium possessed inferior properties). Dome's evidence of commercial success falls into the latter category, as there are several reasons to doubt that other embodiments of claim 1 will behave in the same manner – *i.e.*, achieve the same commercially desirable levels of oxygen permeability – as the Boston IV lens.

First, it is undisputed that the material first manufactured by Neefe in accordance with his patent had a Dk value of 14. This level is only marginally better than the oxygen permeability levels obtained by the Polycon II lens based on Gaylord's patent, and is in the range obtained by the Boston II lens based on Ellis's patent. See FF. 40 (noting the 10 to 12 Dk for Polycon II lenses); FF. 148 (12-14 Dk for Boston II lenses). Dome agrees that this oxygen permeability level would be insufficient for prolonged daily wear and would not drive commercial success. See Dome Prop. Concl. Law 400 (discussing how the Boston II lens, with a Dk value of 12 to 14, accounted for only 10% of Bausch & Lomb's total material sales distribution).

Second, as noted *supra* at FF. 177, the evidence indicates that a contact lens material comprised of 35.5% to 41.7% by weight Tris monomer, 21.8% by weight ester of acrylic or methacrylic acid, 9.9% by weight surface wetting agents tetraethyleneglycol

dimethacrylate and N-Nvinylpyrrolidone, and between .01% and 6.2% by weight Tris dimer and trimer – all amounts falling within the range specified in claim 1 of the Neefe Patent – and manufactured in accordance with that claim would have an oxygen permeability around 12 to 14 Dk. See FF. 131, 134, 137, 140, 142, 144, 148. This expectation would be reasonable because the Boston II lens, which has this composition, see FF. 131, 134, 137, 140, 142, has an oxygen permeability of 12 to 14 Dk, see FF. 148. Dome notes that the Boston II lens differs from the claim 1 process in that a Tris-based cross-linker is not deliberately added to the Boston II material – rather, it is a byproduct created during the process of making the Tris monomer, and it simply remains in the mixture. But the evidence indicates that this distinction is not a meaningful one in terms of the end result. As Dr. Long explained, Tris dimer and trimer will serve as cross-linking agents regardless of when they are created or added. FF. 144.[20]

Third, Dome provides minimal evidence that other successful products could be manufactured with Neefe's ingredients at other amounts within the ranges disclosed by Neefe, despite the fact that the disclosed ranges are very broad. See FF. 76 (calling for (1) "from 5% to 90% by weight" of Tris, (2) from "3% to 90% by weight of an ester of acrylic or methacrylic acid;" (3) "from 0.5% to 90% by weight of a surface wetting agent;" and (4) "from 0.01% to 90% by weight of an oxygen permeable crosslinking agent selected from the class of multifunctional siloxanyl alkyl esters"). Other than the Boston IV lens, Dome presented evidence of only one other highly oxygen permeable lens manufactured under claim 1 – the

[20] The Director argues that the Boston II lens therefore falls within the scope of claim 1 of the patent, arguing that step (f) should be construed as being satisfied so long as Tris dimer and trimer were present in the TX-91 formula. Although the Court finds that the inclusion of some amount of Tris dimer and trimer through the TX-91 formula, rather than the purposeful addition of the same amount later, is unlikely to affect the end result, the Court is hesitant to provide a definitive construction of step (f) or its equivalence without further expert evidence or briefing. And it is unnecessary to do so to resolve the issue of obviousness in this case.

TransAire lens invented in 1984, with a Dk value of 45 – and did not introduce evidence on how that lens was manufactured. See FF. 79. Dome's expert, Dr. Long, could not provide an opinion on whether polymers containing comonomers in amounts at the outer ends of the ranges identified by Neefe would have high oxygen permeability. FF. 173.

Although the Boston IV lens had increased oxygen permeability and achieved commercial success, there is not "an adequate basis to support the conclusion that other embodiments falling within [claim 1 of the Neefe Patent] will behave in the same manner." In re Kao, 639 F.3d at 1068. That is, there is no basis for inferring that other embodiments throughout the range of claim 1 will demonstrate high levels of oxygen permeability or achieve commercial success. Dome has thus failed to present evidence of commercial success that is commensurate with the broad scope of claim 1 of the Neefe Patent.

b. Satisfaction of Long-Felt Need and Failure of Others

Although Dome focuses mainly on evidence of commercial success, Dome also argues that the Court should consider evidence of a long-felt, unsatisfied need for a contact lens suitable for prolonged daily wear, which Dome asserts was ultimately obtained through the claim 1 process, in the form of the Boston IV lens. Dome's PFF. 279-302; Dome's Prop. Concl. Law 52. Specifically, Dome points to the inventions of Novicky and Ellis as evidence that other scientists struggled to create an oxygen permeable contact lens that could be worn comfortably throughout the day. Novicky's polymer had an oxygen permeability of 5 to 8 Dk, Ellis's

polymer had an oxygen permeability of 12 to 14 Dk, and both were unsuitable for prolonged daily wear.[21]

Dome's arguments are undermined by the same commensurateness defect that limits its evidence of commercial success. Although the record indicates that the Boston IV lens satisfied the need for a lens suitable for a prolonged wearing day, the record is also clear that other embodiments of claim 1 would fail to satisfy the long-felt need identified by Dome.[22]

c. Dome's Evidence of Secondary Considerations Is Not Sufficient To Overcome the *Prima Facie* Case of Obviousness.

Even where evidence of commercial success and other secondary considerations is clear and commensurate with a patent claim, it may be insufficient to outweigh a strong *prima facie* case of obviousness. See Tokai Corp. v. Easton Enterprises, Inc., 632 F.3d at 1370 ("Even if [the patentee] could establish the required nexus, a highly successful product alone would not overcome the strong showing of obviousness.") (internal quotation omitted); Wyers v. Master Lock Co., 616 F.3d at 1246 (collecting cases). Given that the evidence of secondary considerations in this case is neither compelling nor commensurate with the patent claim, the Court concludes that Dome has not rebutted the Director's strong *prima facie* showing of obviousness.

[21] Dome also presented limited evidence relating to the process developed by Donald J. Ratkowski and Ping-Chang Lue, which led to a patent issued on December 6, 1983. See JTX-10; Jan. 28 AM Tr. at 77:19–79:22 (Long).

[22] The Court also notes that while the need for a highly oxygen permeable contact lens was indisputably long-felt, only a relatively short amount of time passed between the relevant teachings in the prior art and the introduction of the process recited in claim 1: Neefe applied for his patent less than two years after Tanaka submitted his application.

IV. CONCLUSION

For the foregoing reasons, the Court finds that the differences between the process recited in claim 1 of the Neefe Patent and the prior art "are such that the claimed invention as a whole would have been obvious" before September 8, 1980 (the filing date of the Neefe Patent application) "to a person having ordinary skill in the art" of the polymer chemistry of contact lens material. 35 U.S.C. § 103. Accordingly, the decision of the Board of Patent Appeals and Interferences will be upheld. An appropriate Order will issue this same day.

/s/
PAUL L. FRIEDMAN
United States District Judge

DATE: July 1, 2014

APPENDIX – TRIAL EXHIBITS

A. Joint Trial Exhibits 1-34

1. U.S. Patent No. 4,306,042 to Neefe, issued December 15, 1981.
2. Curriculum Vitae of Timothy E. Long, Ph.D.
3. POLYMER CHEMISTRY: AN INTRODUCTION (Malcolm P. Stevens, ed., 3d ed. 1999) (Excerpts - title pages and pp. 3-1 0).
4. CONTACT LENSES (Anthony J. Phillips and Lynne Speedwell, eds., 5th ed. 2007) (Excerpts - title pages and pp. 17-18, 60-64, 66-67, 206).
5. FITTING GUIDE FOR RIGID AND SOFT CONTACT LENSES: A PRACTICAL APPROACH (Harold L. Stein, et al., eds., 4th ed. 2002) (Excerpts - title pages and pp. 167-68, 272).
6. U.S. Patent No. 3,377,371 to Quaal, issued April 9, 1968.
7. U.S. Patent No. 3,808,178 to Gaylord, issued April 30, 1974.
8. U.S. Patent No. 4,120,570 to Gaylord, issued October 17, 1978.
9. U.S. Patent No. 4,152,508 to Ellis et al., issued May 1, 1979.
10. U.S. Patent No. 4,419,505 to Ratkowski et al., issued December 6, 1983.
11. U.S. Patent No. 4,216,303 to Novicky et al., issued August 5, 1980.
12. FITTING GUIDE FOR RIGID AND SOFT CONTACT LENSES: A PRACTICAL APPROACH (Harold L. Stein, et al., eds., 2d ed. 1984) (Excerpts - title pages and p. 238).
13. U.S. Patent No. 4,235,985 to Tanaka et al., issued November 25, 1980.
14. U.S. Patent No. 4,153,641 to Deichert, issued May 8, 1979.
15. U.S. Patent No. 4,189,546 to Deichert, issued February 19, 1980.
16. Decision of the Board of Patent Appeals and Interferences in Ex parte Neefe, dated July 31, 2007.
17. "Boston Product Information." (Excerpt - BL24, BL31).
18. "Manufacturing of TX-91 Monomer." (BL 1-23).
19. "Synthesis of Methacrylate/Siloxane Monomer," dated November 17, 1978. (BL67-73).
20. Polymer Technology Corporation, PMA 820065 - Boston Lens II, Volumes 7, 9 and 11. (Excerpts - BL8325-29, BL8344-48, and BL8478-8512).
21. Polymer Technology Corporation, Special Supplement to PMA 820065 - Boston Lens II. (Excerpts - BL8553-57, BL8576-82, and BL8599-8603).
22. Polymer Technology Corporation, Premarket Approval Application for the Boston Equalens. (Excerpts - BL8732-BL8742).
23. "Introducing the Boston Lens IV." (BL4303).
24. Curriculum Vitae of Mark A Melamed, M.D.
25. 3 CUNNINGHAM'S MANUAL OF PRACTICAL ANATOMY (14th ed. 1979). (Excerpt - title pages and p. 152).
26. CONTACT LENS FITTING, A CLINICAL TEXT ATLAS. (Frank J. Weinstock, ed., 1989). (Excerpt - title pages and pp. 11.1-11.16).

27. FITTING GUIDE FOR RIGID AND SOFT CONTACT LENSES: A PRACTICAL APPROACH (Harold L. Stein, et al., eds., 4th ed. 2002) (Excerpt - title pages and pp. 167-68, 271-79).
28. CONTACT LENSES: A GUIDE TO SELECTION, FITTING AND MANAGEMENT OF COMPLICATIONS (Susan Stenson, ed., 1987). (Excerpt - title pages and p. 48).
29. CONTACT LENSES: A TEXTBOOK FOR PRACTITIONER AND STUDENT (Anthony J. Phillips and Janet Stone, 3d ed., 1989). (Excerpt - title pages and p. 761).
30. Letter dated October 17, 1984 from Harold A. Stein, M.D. to Patrick J. Caroline of Polymer Technology Corp.
31. Annual Report for the period of November 1987 to June 1988, Volume II. (Excerpt - BL8282, BL8309).
32. Curriculum Vitae of William J. Benjamin, O.D., Ph.D.
33. Prosecution history of U.S. Patent No. 4,306,042 including references of record therein
34. Reexamination history of U.S. Patent 4,306,042 (Control No. 90/005,090)

B. Plaintiff's Trial Exhibits 1-6

1. U. S. Patent No. 2,793,223, issued May 21, 1957.
2. Excerpt of Boston Product Guide (BL4760, BL4776) (1999)
3. Excerpt of Polymer Technology Consultants Reference Manual, *Boston Lenses Physical Properties* (BL5507, BL5513) (1992)
4. Demonstrative Exhibit - Notebook tabs 1, 2,3, 9, 10, 11, 12, 13, 16, 18, 19
5. Demonstrative Exhibit - Flip Chart by Dr. Long
6. Demonstrative Exhibit Board

C. Defendant's Trial Exhibits 1-2

1. William J. Benjamin & Quido A. Cappelli, *Oxygen Permeability (Dk) of Thirty-Seven Rigid Contact Lens Materials*, 79 OPTOMETRY AND VISION SCIENCE 103 (2002).
2. Excerpts from Dr. Long's deposition testimony (pp. 1-2, 94-122).