UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

THE PROCTER & GAMBLE COMPANY,	:	Case No. 1:12-cv-552
Plaintiff,	:	Judge Timothy S. Black
vs.	:	
TEAM TECHNOLOGIES, INC., *et al.*,	:	
Defendants.	:	

ORDER GRANTING PLAINTIFF'S MOTION FOR PARTIAL SUMMARY JUDGMENT OF NO INVALIDITY (Doc. 88) AND DENYING DEFENDANTS' MOTION FOR SUMMARY JUDGMENT OF INVALIDITY (Doc. 90)

This civil action is before the Court on Plaintiff's Motion for Partial Summary Judgment of No Invalidity (Doc. 88), Defendants' Motion for Summary Judgment of Invalidity (Doc. 90) and the parties' responsive memoranda (Docs. 93, 101, 102, and 105).

I. BACKGROUND

Plaintiff alleges that Defendants are infringing three patents: U.S. Patent No. 5,891,453 ("the '453 Patent"), U.S. Patent No. 5,894,017 ("the '017 Patent"), and U.S. Patent No. 7,122,199 ("the '199 Patent"), which patents concern home tooth whitening products. This civil action was originally brought only against Defendant Team Technologies, Inc. ("Team Tech"). (Doc. 1). Defendant Clio USA, Inc. ("Clio") was added to the suit in September 2012, and Defendant Brushpoint Innovations, Inc. ("Brushpoint") was added in February 2013. (Doc. 10; Doc 42). The Court issued its Order on Claim Construction on November 11, 2013. (Doc. 71).

Asserted claims 1-3 and 7 of United States Patent No. 5,894,017 ("the '017 patent") and asserted claims 2-3, 6-9, 11 and 18 of United States Patent No. 5,891,453 ("the '453 patent") all include limitations related to the flexural stiffness of the strip of material as measured on a Handle-O-Meter per ASTM test method D2923-95 ("the HOM Limitations"). (Doc. 88-1 at 5). Plaintiffs now move for summary judgment of no invalidity as to these asserted claims,[1] alleging that given Defendants' burden of proving invalidity by clear and convincing evidence, they have failed to come forward with sufficient evidence to avoid summary judgment against them as to their allegations that the alleged prior art disclosed the HOM Limitations before P&G's invention. (*Id.*) Defendants concede that the alleged prior art does not explicitly disclose the HOM Limitations, but assert the HOM Limitations are inherently disclosed in the prior art.

Defendants also now move for summary judgment of invalidity as to all asserted claims of the Patents in Suit for anticipation or for obviousness. (Doc. 90 at 5).

II. UNDISPUTED FACTS[2]

A. Plaintiff's Motion for Partial Summary Judgment of No Invalidity

1. Plaintiff is the owner of the'453 Patent, the '017 Patent, and the '199 Patent (collectively, "the Patents-in-Suit"). (Doc. 90-2 at 2, 14, and 22).

2. On July 20, 2012, Plaintiff sued Defendant Team Technologies, Inc. for infringement of the Patents-in-Suit. (Doc. 1).

[1] Plaintiff indicated to the Court on June 4, 2014 that in light of the Supreme Court's recent decision in *Limelight Neworks, Inc. v. Akamai Techs., Inc.*, ___ U.S. ___, Case No. 12-786 (June 2, 2014), it would be withdrawing its infringement contentions as to a number of claims, including claims 8, 9, and 12 of the '017 patent and claim 19 of the '453 patent (previously relevant to these motions).

[2] (*See* Docs. 88-1, 90-1, 93-1, and 101-2).

3. On September 14, 2012, P&G amended its complaint to add Defendant Clio USA, Inc. ("Clio"). (Doc. 10).

4. On February 22, 2013, P&G amended its complaint a second time to add Defendant Brushpoint Innovations, Inc. ("Brushpoint"). (Doc. 42).

5. Asserted claims 1-3, 7-9 and 12 of the '017 patent include the following limitation: "A strip of material having a flexural stiffness less than about 50 grams/centimeter as measured on a Handle-O-Meter per ASTM test method D2923-95."

6. On April 11, 2013, Defendants served invalidity contentions as required by S.D. Ohio Pat. R. 103.4.

7. On May 17, 2013, Defendants amended their invalidity contentions.

8. Defendants did not add any new contentions with respect to the HOM Limitations in their amended invalidity contentions.

9. With respect to the claims that include the HOM Limitations, Dr. Gaffar alleged that the following prior art references and combinations either anticipate or render obvious those claims:

Patent / Claim	Defendants' Contention	Citation
'453 Patent, Claim 2	Saffir discloses using a "thin sheath of cellulosic film or the like" and further describes it as similar to "Scotch Tape." Such materials inherently have the flexural stiffness of "of less than about 5 grams/centimeter" as described by Claim 2.	SJA 0409; SJA 0413; SJA 0418
'453 Patent, Claim 2	Schiraldi: The polyethylene film of Schiraldi in view of its compliant and flexibility characteristics inherently meets the flexural stiffness characteristic of this claim. (*See* Examples 2-5)	SJA 0422; SJA 0426; SJA 0432
'453 Patent, Claim 2	Shapiro: The thin flexible film of Shapiro in view of its compliant and flexibility characteristics inherently meets the flexural stiffness characteristic of this claim. (*See* 2:61-3:9)	SJA 0438
'017 Patent, Claim 1	Saffir: discloses using a "thin sheath of cellulosic film or the like" and further describes it as similar to "Scotch Tape." Such materials inherently have the flexural stiffness of "of less than about 5 grams/centimeter" as described by Claim 2.	SJA 0443; SJA 0447
'017 Patent,	Schiraldi: The polyethylene film of Schiraldi in	SJA 0453;

Patent / Claim	Defendants' Contention	Citation
Claim 1	view of its compliant and flexibility characteristics inherently meets the flexural stiffness characteristic of this claim. (*See* Examples 2-5)	SJA 0457
'017 Patent, Claim 1	Shapiro: The thin flexible film of Shapiro in view of its compliant and flexibility characteristics inherently meets the flexural stiffness characteristic of this claim. (*See* 2:61-3:9)	SJA 0462
'017 Patent, Claim 8	Saffir: discloses using a "thin sheath of cellulosic film or the like" and further describes it as similar to "Scotch Tape." Such materials inherently have the flexural stiffness of "of less than about 5 grams/centimeter" as described by Claim 2.	SJA 0444; SJA 0449
'017 Patent, Claim 8	Schiraldi: The polyethylene film of Schiraldi in view of its compliant and flexibility characteristics inherently meets the flexural stiffness characteristic of this claim. (*See* Examples 2-5)	SJA 0454; SJA 0459
'017 Patent, Claim 8	Shapiro: The thin flexible film of Shapiro in view of its compliant and flexibility characteristics inherently meets the flexural stiffness characteristic of this claim. (*See* 2:61-3:9)	SJA 0464

10. Dr. Gaffar alleges only that each of Schiraldi, Saffir, and Shapiro inherently discloses the HOM Limitations.

11. With respect to the '017 patent, Dr. Gaffar provided the following argument regarding the HOM Limitations:

> 143. With respect to Claim 1, the only additional limitation that is not already explained above with respect to Claim 1 of the '453 Patent is the particular flexural stiffness limitation. This limitation, too, is met by Schiraldi. The outer protective layer described in Schiraldi consists of a polymer mixture of, e.g., hydroxypropyl cellulose, ethyl cellulose and polyethylene. The bioadhesive film can be fabricated to a final product of flexible tapes. The thickness of the protective layer is 0.025.
>
> 144. The flexural stiffness is not measured in Schiraldi. However, it is a material property that is a function of a combination of strip thickness, width and material modulus of elasticity and would necessarily be present in a thin film, like the backing layer of Schiraldi film even prior to being wet. In view of its compliant and flexibility characteristics, the thickness of 0.025-0.25 mm, and the material for the protective layer of hydroxypropyl cellulose, ethylcellulose, polyethylene etc., the protective layer would inherently have a flexural stiffness less than 50 g/cm (as supported by the Koch reference) for cellulose films and the fact that polyethylene is one of

the materials used for the strip of material in the ’017 Patent.

12. With respect to the ’017 patent, Dr. Gaffar provides the following argument regarding the HOM Limitations:

    Shapiro does not measure the flexural stiffness of the thin, flat disposable film. However, the film is made of polyethylene, the same material as the strip of material in the ‘017 patent, and the thickness of the film is 0.0245 mm, at minimum, and thus Shapiro film would necessarily have a flexural stiffness less than 50 g/cm when it is measured by the claimed standard.

13. The Patent Trial and Appeal Board (“PTAB”) stated:

    Clio’s evidence does not persuade us that Saffir’s regenerated cellulose film backing necessarily has a flexural stiffness less than about 50 g/cm as measured on a Handle-O-Meter per ASTM test method D2923-95. Saffir describes the film as merely physically resembling “Scotch tape.” If we accept, for the sake of argument, that “Scotch tape” is Cellophane tape, it does not follow that Saffir discloses the use of Cellophane tape; at most, it discloses the use of something that resembles Cellophane tape. But even if we accept, further, that Saffir does disclose the use of Cellophane tape, and that the Cellophane tape has a thickness in the range specified in Kellgren, it does not follow from Koch and Morton that Cellophane tape necessarily has the claimed flexural stiffness. Neither Koch nor Morton discloses the thickness of the regenerated cellulose films they tested, nor do they identify them by the term “Cellophane.” Instead, they each report the weight per unit area of the regenerated cellulose films in grams per square meter (g/m2). Clio does not explain how the weight per unit area of a sheet of regenerated cellulose is indicative of the sheet’s thickness. Although Koch and Morton may support a contention that some regenerated cellulose sheets have a flexural stiffness of less than 50 g/cm, they do not establish that those regenerated cellulose sheets having the thickness of Cellophane tape (as evidenced by Kellgren) possess the claimed flexural stiffness.

14. The Board further stated:

    P&G argues that Clio has not established that Schiraldi’s cellulosic film or polyethylene film necessarily has the claimed flexural stiffness. Prelim. Resp. 45- 46. We agree with P&G, for reasons similar to those explained, above, with regard to the challenges based on Saffir. Clio has not explained how either Koch or Morton discloses the thickness of the materials tested in those references. Morton’s Fig. 8, like Fig. 7 discussed above, identifies the films tested by weight per unit area, not by thickness.

Clio has not established that any of the films tested in Koch or Morton have Schiraldi's thickness. For this reason, Clio has not established that Schiraldi's hydroxypropyl cellulose and polyethylene films necessarily possess the claimed flexural stiffness.

15. The Board also stated:

Clio cites no evidence to support its assertion that Shapiro's film would have the required flexural stiffness. The evidence Clio puts forward elsewhere regarding flexural stiffness of polyethylene sheets is unpersuasive because it does not establish that polyethylene sheets of the thickness Shapiro describes have the flexural stiffness required by the claims.

B. Defendants' Motion for Summary Judgment of Invalidity

1. The '453 Patent was issued on April 6, 1999. (Doc. 90-2 at 2).

2. The '453 Patent claims priority on its face to a filing on June 6, 1997. (*Id.*)

3. The '453 Patent has 22 total claims. (*Id.*)

4. Plaintiff asserts that the Defendants infringe Claims 1-3, 6-8, 9, 11, 18, and 21 of the '453 Patent. (*Id.* at 39).

5. The original claims of the '453 patent were rejected for obviousness under 35 USC § 103(a) over Schiraldi in view of secondary and tertiary references. (Doc. 90-5 at 3, 6).

6. The '017 Patent was issued on April 13, 1999. (Doc. 90-2 at 14).

7. The '017 Patent has 21 total claims. (*Id.*)

8. Plaintiff asserts that the Defendants infringe Claims 1-3 and 7 of the '017 Patent. (*Id.* at 39).

9. The original claims of the '017 patent were rejected for obviousness under 35 USC § 103(a) over Schiraldi in view of secondary and tertiary references. (Doc. 90-9 at 2, 5).

10. The '199 Patent was issued on Oct. 17, 2006. (Doc. 90-2 at 22).

11. On its face, the '199 patent claims priority to US Patent Application No.

10/321,252, filed December 17, 2002, now US Patent No. 6,884,426, which is a continuation of US Patent Application No. 09/864,640, filed May 24, 2001, now abandoned, which is a continuation of US Patent Application No. 09/268,185, filed March 15, 1999 now abandoned, which is a continuation-in-part of US Patent Application No. 09/040,000, filed March 17, 1998, now US Patent No. 5,891,453, which is a continuation-in-part of US Patent Application No. 08/870,330, filed June 6, 1997, now US Patent No. Pat. No. 5,879,691. (*Id.*)

12. The '199 Patent has 31 total claims. (*Id.*) [Exhibit 3]

13. Plaintiff asserts that the Defendants infringe Claims 17, 20, 23-26, and 28-30 of the '199 Patent. (*Id.* at 39).

14. The continuation in part application filed on March 15, 1999 was published as U.S. Patent Publication No. 2002/0018754. (*Id.* at 46).

15. Each of the asserted claims of the '199 Patent include a claim element of "b) folding a second portion of the strip of material and tooth bleaching composition about the incisal edges of the plurality of adjacent teeth." (*Id.* at 34, 39).

16. The Schiraldi reference ("Schiraldi") issued as U.S. Patent No. 4,713,243 on Dec. 15, 1987, entitled "Bioadhesive Extruded Film For Intra-Oral Drug Delivery And Process." (Doc. 90-3 at 2).

17. The Saffir reference ("Saffir"), entitled "Means for treating teeth," issued as U.S. Patent 2,835,628 on May 20, 1958. (*Id.* at 10).

18. Saffir describes a delivery system for applying medicaments to a given area of a tooth, including to sound portions thereof. (*Id.*)

19. The Saffir adhesive at normal atmospheric conditions is tacky and pressuresensitive so that it secures good adherence of itself and the backing film to surfaces upon which it is pressed in use. (*Id.*; Doc. 90-10 at ¶ 35).

20. The Gaglio reference issued as U.S. Patent No, 5,326,685 on July 5, 1994, entitled "Viscous Fluid Dispensing Apparatus." (Doc. 90-4 at 2).

21. Gaglio describes an applicator for dispensing viscous fluids such as tooth whitening gels. (*Id.*; Doc. 90-10 at ¶ 42).

22. The Gaglio applicator comprises two layers, a first flexible backing material of a closed-cell structure and a second flexible dispensing material of an open-celled material carried by the flexible backing material. (*Id.*)

23. The Biegajski reference issued as U.S. Patent No. 5,700,478 ("Biegajski") on Dec. 23, 1997. (Doc. 90-4 at 15).

24. The Biegajski reference claims on its face to priority based on a 102(e) date of August 3, 1995. (*Id.*)

25. The Biegajski reference also was published as WO95/05416 on Feb. 23, 1995, according to the face of Biegajski. (*Id.*)

26. The Fischer reference ("Fischer") issued as U.S. Patent No. 5,376,006 on Dec. 27, 1994, entitled "Dental Bleaching Compositions and Methods for Bleaching Teeth Surfaces." (*Id.* at 51).

27. Fischer describes high viscosity tooth bleaching dental compositions. (*Id.*; Doc. 90-10 at ¶ 72).

28. Fischer sets forth seven bleaching substance formulation examples. (Doc. 90-4 at 62; Doc. 90-10 at ¶ 73).

29. Each of the formulation examples in Fischer is based on the inclusion of cabamide peroxide as the bleaching agent and sodium hydroxide as a pH adjustment agent. Doc. 90-4 at 62-63; Doc. 90-10 at ¶ 73).

30. The resultant compositions are described as sustained release dental bleaching compositions. (Doc. 90-4 at 62; Doc. 90-10 at ¶ 73).

31. The Shapiro reference issued as U.S. Patent 5,462,067 on Oct. 31, 1995, entitled "Device for Hygienic Protection of The Teeth and Gums." (Doc. 90-4 at 75).

32. Shapiro describes a thin polymeric film (such as polyethylene) for use as a disposable shield device to be worn upon the teeth and gums during chewing of food to prevent food particles from lodging between the teeth. (*Id.*; Doc. 90-10 at ¶ 76).

33. The Court issued a claim construction order in this case on November 22, 2013. (Doc. 71).

34. The Court construed "without permanent deformation" as it appears in Claims 1 and 21 of the '453 patent and in Claim 1 of the '017 Patent to mean "without permanently conforming to the shape of the teeth." (*Id.* at 3, 6-8).

35. The adopted construction of "without permanent deformation" was the

construction proposed by and argued for by P&G. (*Id.* at 6-8).

36. In adopting the Plaintiff's proposed construction of "without permanent deformation," the Court cited Plaintiff's argument that "When a user applies the claimed delivery system to the teeth, the strip of material is not permanently molded into the shape of the surface of the teeth being treated, like a strip made of wax or putty might be." (*Id.* at 6).

37. Plaintiff argued for this construction based in part on the idea "that the '017 patent explains that the purpose of this limitation was to distinguish the invention from prior moldable devices, such as wax- or putty-based systems, that required pressure to permanently deform the strip into the shape of the teeth." (*Id.*)

38. The court construed "almost unnoticeable when worn/substantially unnoticeable when worn" as those terms appear in Claim 1 of the '453 patent and in Claim 1 of the '017 Patent to mean "not readily apparent to others when worn." (*Id.* at 3, 13).

39. The court construed "folding a second portion of the strip of material and tooth bleaching composition about the incisal edges of the plurality of adjacent teeth" as it appears in Claim 17 of the '199 patent to have its "plain and ordinary meaning (no construction necessary)." (*Id.* at 3, 16).

40. The court construed "gel" as it appears in Claim 6 of the '453 patent and in Claim 2 of the '017 Patent to mean "a material ranging from near-liquid to near-solid that resists flow in the steady state." (*Id.* at 3, 18-20).

III. STANDARD OF REVIEW

A. Summary Judgment

A motion for summary judgment should be granted if the evidence submitted to the Court demonstrates that there is no genuine issue as to any material fact, and that the movant is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c). *See Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986); *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247-48 (1986). The moving party has the burden of showing the absence of genuine disputes over facts which, under the substantive law governing the issue, might affect the outcome of the action. *Celotex*, 477 U.S. at 323. All facts and inferences must be

construed in a light most favorable to the party opposing the motion. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986).

A party opposing a motion for summary judgment "may not rest upon the mere allegations or denials of his pleading, but . . . must set forth specific facts showing that there is a genuine issue for trial." *Anderson*, 477 U.S. at 248 (1986).

B. Patent Invalidity

A determination that a patent is invalid as being anticipated under 35 U.S.C. § 102 requires a finding that each and every limitation is found either expressly or inherently in a single prior art reference. *Transclean Corp. v. Bridgewood Servs., Inc.*, 290 F.3d 1364, 1370 (Fed. Cir. 2002). Because a patent issued by the U.S. Patent and Trademark Office ("USPTO") is presumed to be valid, 35 U.S.C. § 282, the evidentiary burden to show facts supporting a conclusion of invalidity is clear and convincing evidence. *Id.* at 1370. Thus, a court must uphold the validity of a patent if at least one limitation in the claim distinguishes the claimed invention from the prior art. When a prior art reference does not expressly disclose each and every limitation in the patent claim, the reference may still anticipate if the missing limitation is inherently present in the prior art reference. However, "[a]nticipation by inherent disclosure is appropriate only when the reference discloses prior art that must necessarily include the unstated limitation[.]" *Id.* at 1373. Inherency may not be established by "probabilities or possibilities." *Mentor H/S, Inc. v. Med. Device Alliance, Inc.*, 244 F.3d 1365, 1376 (Fed. Cir. 2001).

Under the applicable version of the statute, a patent is invalid for obviousness "if the differences between the subject matter sought to be patented and the prior art are such

that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." 35 U.S.C. § 103(a). An obviousness determination must be based on four factual inquiries: (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 indicia of nonobviousness. *KSR Int'l Co. v. Teleflex Inc*., 550 U.S. 398, 406 (2007) (citing *Graham v. John Deere Co*., 383 U.S. 1, 17-18 (1966)).

IV. ANALYSIS

A. Plaintiff's Motion for Partial Summary Judgment of No Invalidity

Dr. Gaffar concedes that none of the references cited in his expert report explicitly disclose the HOM Limitations; rather, Dr. Gaffar alleges that each of Schiraldi, Saffir, and Shapiro inherently discloses the HOM Limitations. (Doc. 92-9 at 133) ("The flexural stiffness is not measured in Schiraldi. However, it … would necessarily be present in a thin film, like the backing layer of Schiraldi film"); *id*. at 135 ("The flexural stiffness of the backing is not measured in Saffir, however the limitation is inherently met by Saffir"); *id*. at 214 ("Shapiro does not measure the flexural stiffness of the thin, flat disposable film. However, … Shapiro film would necessarily have a flexural stiffness less than 50 g/cm when it is measured by the claimed standard").

1. Shiraldi

With respect to the '453 patent, Dr. Gaffar provides a single sentence regarding Schiraldi's alleged disclosure of the HOM Limitations: "The polyethylene film of Schiraldi inherently meets the flexural stiffness characteristic of this claim, in view of its

compliant and flexibility characteristics." (Doc. 92-9 at 117). Dr. Gaffar also provides a footnote citation to Examples 2-5 of Schiraldi. (*Id*.) Dr. Gaffar has provided *no* evidence supporting his conclusion with respect to the '453 patent and has not shown that the alleged prior art reference necessarily discloses the claim limitation. Aside from a vague, unexplained citation to Examples 2-5 of Schiraldi, Dr. Gaffar does not provide any citations to Schiraldi in support of this statement, either in the body of his report or in the claim chart at Exhibit 3. Nor does Dr. Gaffar explain the significance of Examples 2-5 of Schiraldi, or provide any explanation of why those Examples demonstrate how Schiraldi inherently discloses the HOM Limitations. Plaintiff's expert, Dr. Harald Heymann, reviewed Dr. Gaffar's Expert Report and agrees that Dr. Gaffar has provided no evidence supporting his conclusion with respect to the HOM limitations. (Doc. 89 at ¶¶ 36-37).

With respect to the '017 patent, Dr. Gaffar provides the following argument regarding the HOM Limitations:

> 143. With respect to Claim 1, the only additional limitation that is not already explained above with respect to Claim 1 of the '453 Patent is the particular flexural stiffness limitation. This limitation, too, is met by Schiraldi. The outer protective layer described in Schiraldi consists of a polymer mixture of, e.g., hydroxypropyl cellulose, ethyl cellulose and polyethylene. The bioadhesive film can be fabricated to a final product of flexible tapes. The thickness of the protective layer is 0.025.
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> 144. The flexural stiffness is not measured in Schiraldi. However, it is a material property that is a function of a combination of strip thickness, width and material modulus of elasticity and would necessarily be present in a thin film, like the backing layer of Schiraldi film even prior to being wet. In view of its compliant and flexibility characteristics, the thickness of 0.025-0.25 mm, and the material for the protective layer of hydroxypropyl cellulose, ethylcellulose, polyethylene etc., the protective layer would inherently have a flexural stiffness less than 50 g/cm (as supported by the Koch reference) for cellulose films and the fact that polyethylene is one of

the materials used for the strip of material in the '017 Patent.

(Doc. 92-9 at 133-34). Once again, Dr. Gaffar fails to establish that Schiraldi discloses the HOM Limitations, or that the specific flexural requirements of the HOM Limitations are necessarily present in the Schiraldi film. For example, Dr. Gaffar notes that flexural stiffness is a function of a combination of strip thickness, width and material modulus of elasticity. However, Dr. Gaffar notes that the Schiraldi film may be one of many different materials. Dr. Gaffar even finishes his list of materials with an "*etc*." (*Id*.) As Dr. Heymann explains, because the Schiraldi film is not limited to any particular material, it is not possible for Schiraldi to necessarily disclose any specific flexural stiffness. (Doc. 89 at ¶ 38). Indeed, in order to show that Schiraldi necessarily discloses the HOM Limitations, Dr. Gaffar must show that every possible "polymer mixture" that could be used as the Schiraldi protective layer would meet the flexural stiffness requirements of the HOM Limitations, and he has not done so.

Dr. Gaffar also makes vague reference to the "Koch reference[,]" but he provides no explanation as to how this reference is applicable or as to what it discloses. (Doc. 92-9 at 133-34). Nor does he explain how the materials described in Koch are the same as those described in Schiraldi. In his Rebuttal Expert Report on Validity, Dr. Gaffar attempted to bolster his argument by including new arguments related to the Morton reference:

> Morton tested a variety of films including polyethylene, polypropylene and regenerated cellulose films with varying thickness. The stiffness (SH) of films as measured via Handle-O-Meter in Morton is about 0.2 to 6.2 g/cm for polymeric films of that thickness. For regenerated cellulosic films, the stiffness is between about 5.5 and about 6.8 g/cm, And for polyethylene

> films, it is between about 0.06 to about 0.9 g/cm. Thus, all of the polymeric films are tested in Morton, and each has sufficient thickness. Within the range of 10 to 200 micron, all have a Handle-O-Meter flexural stiffness that falls within the range of the claims.

(*Id.* at 231). Dr. Gaffar's additional arguments fall well short of clear and convincing evidence. First, Dr. Gaffar's Rebuttal Report provides no further explanation as to how or why the Koch reference is applicable, or as to what it discloses. Second, the new discussion of the Morton reference does not cure the deficiencies in Dr. Gaffar's arguments. For example, Dr. Gaffar states that "Morton tested a variety of films including polyethylene, polypropylene and regenerated cellulose films." (*Id.* at 135). But Dr. Gaffar has not provided any explanation as to how or why those films are the same as the Schiraldi film; nor has he established that the Schiraldi film must necessarily be one of those materials described in Morton.

Moreover, Dr. Gaffar appears to link the Handle-O-Meter measurements in Morton to the Schiraldi film based on the thickness of the films tested in Morton. But even assuming that the Morton reference describes a material that is necessarily the same as Schiraldi – which it does not – Morton does not disclose the thickness of the films that were actually tested. (Doc. 89 at ¶¶ 38, 44) (confirming that Morton does not disclose the thickness of the films tested). Dr. Gaffar's reference to "the range of 10 to 200 micron" relates only to Morton's discussion describing the general characteristics of Handle-O-Meter testing. It does not specify the particular thicknesses of the films that were actually tested, and which resulted in the Handle-O-Meter measurements that Dr. Gaffar relies on. As such, Dr. Gaffar has failed to establish that the tested Morton films

are necessarily of the same thickness as the Schiraldi film. Therefore, none of the Handle-O-Meter measurements reported in Koch or Morton can be attributed to Schiraldi.

Accordingly, based on the foregoing, Schiraldi does not necessarily disclose a strip that has "a flexural stiffness of less than about 50 grams/centimeter as measured on a Handle-O-Meter per ASTM test method D2923-95" or a strip that has "a substantially constant flexural stiffness of less than about 5 grams/centimeter as measured on a Handle-O-Meter per ASTM test method D2923-95." (Doc. 89 at ¶ 40).

2. Saffir

With respect to the '453 patent, Dr. Gaffar again provides a single sentence regarding Saffir's alleged disclosure of the HOM Limitations: "The flexural stiffness requirements of claim 2 are also met by the 'Scotch tape' strip of Saffir." (Doc. 92-9 at 121).

Dr. Gaffar has provided no evidence supporting his conclusion with respect to the '453 patent and has not shown that the reference necessarily meets the claimed limitation. First, the material of Saffir is not Scotch tape, as Dr. Gaffar contends. (*Id.* at 135). It merely "physically resembles" Scotch tape. (*Id.*) Therefore, even if Scotch tape inherently possessed the flexural stiffness requirements of the HOM Limitations, at best Dr. Gaffar has established that the Saffir film "physically resembles" such a tape, not that it necessarily is Scotch tape. (Doc. 89 at ¶ 43) (noting that "Dr. Gaffar notes only that the Saffir film 'physically resembles' Scotch tape, not that it is Scotch tape"). This is fatal to Dr. Gaffar's position. Moreover, Dr. Gaffar has not established that the Scotch tape that

Saffir mentions does in fact possess the flexural stiffness requirements of the HOM Limitations. For example, as Dr. Heymann explains, Dr. Gaffar provides no discussion of the specific physical properties of "Scotch tape." (*Id*. at ¶ 45). Nor does he explain what the properties of a Scotch tape product in 1958 (when the Saffir patent issued) might have been or how those properties might differ from a Scotch tape product in 1997, when Plaintiff filed its patent applications leading to the Patents-In-Suit. (*Id*.) Further, Dr. Gaffar does not provide any citations to Saffir in support of this statement, either in the body of his report or in the claim chart at Exhibit 12. (*Id*.)

With respect to the '017 patent, Dr. Gaffar provides the following argument regarding the HOM Limitations:

> 151. The flexural stiffness of the backing is not measured in Saffir, however the limitation is inherently met by Saffir because this flexural stiffness is necessarily present in the backing of Saffir. In particular, Saffir describes that the tape physically resembles what is commonly called "Scotch tape" and the backing layer is a thin, transparent, non-fibrous cellulosic material, such as "regenerated cellulose."
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> 152. Koch provides a flexural stiffness of "regenerated cellulose" as less than 50 g/cm as measured on a Handle-O-Meter. Morton provides a flexural stiffness of "regenerated cellulose" as less than 50 g/cm as measured on a Handle-O-Meter. In view of the above, and further view of the thickness of Cellophane film, i.e., 0.88-1.75 mil as evidenced by Kellgren, the Saffir backing necessarily has a flexural stiffness less than 50 g/cm as measured on the standard recited in this claim.

(Doc. 92-2 at 135). Once again, Dr. Gaffar has failed to establish that Saffir discloses the HOM Limitations, or that the Saffir film necessarily has the specific flexural requirements of the HOM Limitations. First, as explained above, Saffir discloses that the film merely physically resembles Scotch tape, not that it is Scotch tape. Therefore, even

if Koch, Kellgren and Morton establish that Scotch tape would necessarily have the flexural stiffness requirements of the HOM Limitations, at best Dr. Gaffar has shown that the Saffir film "physically resembles" such a tape. (Doc. 89 at ¶ 43) ("even assuming that Scotch tape is Cellophane film, it does not follow that Saffir discloses the use of Cellophane film" (internal citations omitted)). This alone is fatal to Dr. Gaffar's position that Saffir inherently discloses the HOM Limitations. Moreover, as Dr. Heymann explains, Dr. Gaffar does not discuss the specific physical properties of "Scotch tape," or what the properties of a Scotch tape product in 1958 might have been or how those properties might differ from a Scotch tape product in 1997. (*Id*. at ¶ 45).

Dr. Gaffar goes on to note with respect to the '017 patent that the Saffir backing layer is made of "regenerated cellulose," and he relies on three references – Koch, Morton and Kellgren[3] – to allegedly establish that this limitation is inherently disclosed by Saffir. (Doc. 92-9 at 135). Although Dr. Gaffar does not explicitly say so, it appears that he is equating "regenerated cellulose" with "Cellophane" in an attempt to rely on Kellgren as disclosing a thickness for the "regenerated cellulose" films that were tested in Koch and Morton. But this argument falls apart immediately, because Saffir states only that its backing layer is made of a gelatinized cellulosic material such as regenerated cellulose, not that is must be regenerated cellulose. In fact, Saffir explicitly states that its backing layer can be made of materials that are not regenerated cellulose: "However,

[3] Koch (U.S. Patent No. 3,899,453) is a patent that issued in 1975 that relates to a cellulosic film having increased stiffness for use in push-feed machinery and/or snack packages. Kellgren (U.S. Patent No. 2,444,830) is a patent that issued in 1948 that relates to pressure-sensitive adhesive sheets for use as packaging tape, repair tape, electrical tape, etc. Morton is an article published in 1965 relating to the flexural stiffness of certain polymeric films. (*See* Doc. 92-9 at 311-28).

backings can be utilized comprised of materials other than gelatinized cellulosic materials…." (*Id.* at 298). Therefore, even if Koch, Morton and Kellgren establish that a regenerated cellulose of the thickness described in Saffir possesses the flexural stiffness requirements of the HOM Limitations, Saffir states only that it may be made of such a material, not that it must be. Even further, Dr. Gaffar has provided no evidence that all "regenerated cellulose" films are Cellophane films. Moreover, even if one were to assume (1) that regenerated cellulose necessarily refers to Cellophane, (2) that Saffir does disclose the mandatory use of Cellophane film, and (3) that the Cellophane film of Saffir has a thickness in the range described in Kellgren, Dr. Gaffar still has not established that Koch and Morton necessarily disclose that the Cellophane film has the required flexural stiffness. (Doc. 89 at ¶ 44). Neither Koch nor Morton discloses the thickness of the regenerated cellulose films that were actually tested therein, nor do they ever identify them as "Cellophane." (*Id*.)

Accordingly, based on the foregoing, Saffir does not necessarily disclose a strip that has "a flexural stiffness of less than about 50 grams/centimeter as measured on a Handle-O-Meter per ASTM test method D2923-95" or a strip that has "a substantially constant flexural stiffness of less than about 5 grams/centimeter as measured on a Handle-O-Meter per ASTM test method D2923-95." (*Id.* at ¶ 46).

3. Shapiro

With respect to the '453 patent, Dr. Gaffar again provides a single, conclusory sentence with respect to Shapiro's alleged disclosure of the HOM Limitations: "The thin flexible film of Shapiro in view of its compliant and flexibility characteristics inherently

meets the flexural stiffness characteristic of this claim." (Doc. 92-9 at 187). Dr. Gaffar also provides a citation to 2:61-3:9 of Shapiro. (*Id*.)

Dr. Gaffar has provided no evidence supporting his conclusion with respect to the '453 patent and has not shown that the reference necessarily meets the claimed limitation. Aside from a vague, unexplained citation to 2:61-3:9 of Shapiro, Dr. Gaffar does not provide any citations to Shapiro in support of this statement, either in the body of his report or in the claim chart at Exhibit 3. Further, Dr. Gaffar does not explain the significance of the portion of Shapiro that he cites, nor provide any explanation of why that portion of Shapiro demonstrates how Shapiro inherently discloses the HOM Limitations. (Doc. 89 at ¶ 49). Indeed, 2:61-3:9 of Shapiro says nothing about the flexural stiffness of the Shapiro shield, nor does it say anything about Handle-O-Meter measurements. (*Id*.)

With respect to the '017 patent, Dr. Gaffar provides the following argument regarding the HOM Limitations:

> Shapiro does not measure the flexural stiffness of the thin, flat disposable film. However, the film is made of polyethylene, the same material as the strip of material in the '017 patent, and the thickness of the film is 0.0245 mm, at minimum, and thus Shapiro film would necessarily have a flexural stiffness less than 50 g/cm when it is measured by the claimed standard.

(Doc. 92-9 at 214). Once again, Dr. Gaffar has failed to establish that Shapiro discloses the HOM Limitations, nor that the specific flexural requirements of the HOM Limitations are necessarily present in the Shapiro shield. For example, Dr. Gaffar's statement that the Shapiro shield "is made of polyethylene" is wrong; Shapiro states only that the shield is made of a polymer, such as polyethylene. (*Id.* at 309). There are many different types

of polyethylene. (Doc. 88-1 at 29). Therefore, while the Shapiro shield may be made of "polyethylene," it may also be made of other polymers. Dr. Gaffar also provides only a minimum thickness of Shapiro. (Doc. 92-9 at 214). Shapiro, however, provides no upper limit on the thickness of its shield. Therefore, while the Shapiro shield may be as thin as Dr. Gaffar suggests, it may also be thicker, and potentially much thicker. Dr. Gaffar has not shown that the Shapiro shield would necessarily be of the material or thickness he alleges.

Further, even assuming that Shapiro discloses a shield that is necessarily made of the same polyethylene as is disclosed in Plaintiff's patents, and is necessarily of the thickness that Dr. Gaffar alleges, Dr. Heymann points out that Dr. Gaffar has provided no explanation as to how or why this shield would necessarily have a flexural stiffness less than about 50 g/cm as measured on a Handle-O-Meter. (Doc. 89 at ¶ 50). Dr. Gaffar simply states that the Shapiro shield is made of polyethylene (which it is not, necessarily) and that the thickness of the shield is 0.0245 mm (which is only a minimum), and then comes to the unexplained and unsupported conclusion that the "Shapiro film would necessarily have a flexural stiffness less than 50 g/cm when it is measured by the claimed standard." (Doc. 92-9 at 214).

Accordingly, based on the foregoing, Shapiro does not necessarily disclose a strip that has "a flexural stiffness of less than about 50 grams/centimeter as measured on a Handle-O-Meter per ASTM test method D2923-95" nor a strip that has "a substantially constant flexural stiffness of less than about 5 grams/centimeter as measured on a Handle-O-Meter per ASTM test method D2923-95." (Doc. 89 at ¶ 51).

4. The PTAB

As further evidence that Defendants cannot meet their burden of showing that claims 1-3 and 7 of the ’017 patent and claims 2-3, 6-9, 11 and 18 of the ’453 patent are invalid, the PTAB recently rejected the same inherency arguments, with respect to the same references, under a lower standard of proof. On July 12 and July 15, 2013, Clio filed petitions for *inter partes* review with the USPTO challenging the validity of each of the Patents-in-Suit. (Doc. 88-1 at 30). In two of those proceedings, Clio, relying on the testimony of Dr. Gaffar, argued that the same three references – Schiraldi, Saffir, and Shapiro – inherently disclose the HOM Limitations of the ’017 and ’453 patents. (*Id.*) Dr. Gaffar made the same inherency arguments there that he makes here, relying on Koch, Kellgren and Morton as allegedly establishing that Schiraldi, Saffir, and Shapiro inherently disclose the HOM Limitations. (*Id.*)

In this litigation, Defendants bear the burden of establishing invalidity by clear and convincing evidence. (*Id.*) In order to show that the challenged claims are invalid in the IPR proceeding, however, Clio must only meet a preponderance of the evidence standard. 35 U.S.C. § 316(e). Further, for the PTAB to institute proceedings in the first place, Clio needed only to show a reasonable likelihood that it would ultimately succeed under the lower “preponderance of the evidence” burden. 35 U.S.C. § 314(a). Nevertheless, under this “reasonable likelihood” standard, which is significantly lower than the “clear and convincing” burden in this litigation, the PTAB found that Clio’s and

Dr. Gaffar's inherency arguments were insufficient.[4]

For example, before the PTAB, Clio attempted to establish that Saffir inherently discloses the HOM Limitations of the '017 patent and relied on Koch, Kellgren and Morton to try to show that the "Scotch tape" of Saffir is the same as Cellophane, that Kellgren describes the thickness of Cellophane, and that Koch and Morton provide Handle-O-Meter measurements of thin regenerated cellulose films. The PTAB rejected these attenuated arguments for multiple reasons:

> Clio's evidence does not persuade us that Saffir's regenerated cellulose film backing necessarily has a flexural stiffness less than about 50 g/cm as measured on a Handle-O-Meter per ASTM test method D2923-95. Saffir describes the film as merely *physically resembling* "Scotch tape." If we accept, for the sake of argument, that "Scotch tape" is Cellophane tape, it does not follow that Saffir discloses the use of Cellophane tape; at most, it discloses the use of something that resembles Cellophane tape. But even if we accept, further, that Saffir does disclose the use of Cellophane tape, and that the Cellophane tape has a thickness in the range specified in Kellgren, it does not follow from Koch and Morton that Cellophane tape necessarily has the claimed flexural stiffness. Neither Koch nor Morton discloses the thickness of the regenerated cellulose films they tested, nor do they identify them by the term "Cellophane." Instead, they each report the weight per unit area of the regenerated cellulose films in grams per square meter (g/m2). Clio does not explain how the weight per unit area of a sheet of regenerated cellulose is indicative of the sheet's thickness. Although Koch and Morton may support a contention that *some* regenerated cellulose sheets have a flexural stiffness of less than 50 g/cm, they do not establish that those regenerated cellulose sheets having the thickness of Cellophane tape (as evidenced by Kellgren) possess the claimed flexural stiffness.

[4] Opinions from administrative agencies may be properly considered as evidence under Fed. R. Evid. 803(8) if the findings are trustworthy and probative of the issues. *See, e.g., United States v. Paducah Towing Co.*, 692 F.2d 412, 420-21 (6th Cir. 1982). This Court takes judicial notice of the fact of the PTAB's decision rejecting Clio's petition for IPR of the claims containing HOM Limitations. *Standard Havens Prods., Inc. v. Gencor Indus.*, 897 F.2d 511, 514 n.3 (Fed. Cir. 1990) ("Although we do not rely on it, we take judicial notice of the 'adjudicative fact' of the January 8, 1990, first office action on reexamination, rejecting the Hawkins claims").

(Doc. 92-9 at 342-43) (emphasis in original).

Similarly, Clio relied on the Koch reference in attempting to establish that Schiraldi inherently discloses the HOM Limitations of the ’017 patent. The PTAB rejected this argument for similar reasons:

> P&G argues that Clio has not established that Schiraldi’s cellulosic film or polyethylene film necessarily has the claimed flexural stiffness. Prelim. Resp. 45-46. We agree with P&G, for reasons similar to those explained, above, with regard to the challenges based on Saffir. Clio has not explained how either Koch or Morton discloses the thickness of the materials tested in those references. Morton’s Fig. 8, like Fig. 7 discussed above, identifies the films tested by weight per unit area, not by thickness. Clio has not established that any of the films tested in Koch or Morton have Schiraldi’s thickness. For this reason, Clio has not established that Schiraldi’s hydroxypropyl cellulose and polyethylene films necessarily possess the claimed flexural stiffness.

(*Id.* at 345).

Finally, with respect to Shapiro, Clio provided the same unsupported conclusory argument that the Shapiro film would satisfy the flexural stiffness requirements of the HOM Limitations of the ’017 patent. The PTAB rejected this argument as well:

> Clio cites no evidence to support its assertion that Shapiro’s film would have the required flexural stiffness. The evidence Clio puts forward elsewhere regarding flexural stiffness of polyethylene sheets is unpersuasive because it does not establish that polyethylene sheets of the thickness Shapiro describes have the flexural stiffness required by the claims.

(*Id.* at 348). Ultimately, the PTAB declined to institute proceedings for any of the claims of the ’017 patent that include the HOM Limitations.

Before the Board, Clio also made all of the same arguments regarding Saffir, Schiraldi and Shapiro with respect to the ’453 patent. While the Board did not specifically address Clio’s arguments regarding Schiraldi and Shapiro with respect to the

’453 patent, as those grounds were denied as redundant, the Board rejected Clio’s arguments regarding Saffir for all of the same reasons stated above. (*Id.* at 366-67). The PTAB also declined to institute proceedings for any of the claims of the ’453 patent that include the HOM Limitations.

The PTAB rejected Clio’s inherency arguments, under a lower standard of proof, not once, but twice. On January 23, 2014, Clio requested rehearing of the PTAB’s institution decisions in IPR2013-00438 and IPR2013- 00448. (Doc. 88-1 at 33). Clio directed its requests for rehearing almost exclusively to the PTAB’s rejection of the HOM Limitation inherency arguments. (*Id*.) In both instances, the PTAB rejected Clio’s requests, confirming its ruling that Clio had failed to show a reasonable likelihood that it could prove, by a preponderance of the evidence, that Schiraldi, Saffir and/or Shapiro inherently disclose the HOM Limitations. (Doc. 92-9 at 372-82).

Accordingly, based on the foregoing, Plaintiffs have demonstrated their entitlement to partial summary judgment that the ’453 Patent, Claims 2-3, 6-9, 11, and 18, and the ’017 Patent, Claims 1-3 and 7, are not invalid.

B. Defendants’ Motion for Summary Judgment of Invalidity

1. The ’453 Patent

Defendants allege that claims 1-3, 6-9, 11, 18, and 21 of the ’453 Patent are invalid. (Doc. 90 at 14-35). Defendants bear the burden of proving invalidity by clear and convincing evidence.

a. Schiraldi

Defendants argue that Schiraldi anticipates claims 1-3 and 6-7 of the ’453 Patent.

i. Claim 1

"Tooth Whitening Substance"

Independent claim 1 of the '453 Patent requires a "tooth whitening substance." (Doc. 92-1 at 14). The Court defined "tooth whitening substance" to mean "one or more materials that separately or collectively provide a bleaching active and adhesive attachment to the teeth[.]" (Doc. 71 at 8-10). The Patent Examiner expressly considered Schiraldi during prosecution of the '453 Patent. (Doc. 98 at 29-35). Plaintiff successfully distinguished Schiraldi, as well as numerous other references, on various grounds, and the Examiner allowed the '453 Patent to issue thereafter. (*Id.* at 40-45).

Dr. Gaffar notes that Plaintiff distinguished Schiraldi on three bases during prosecution of the '453 Patent. (Doc. No. 90-10 at 5). First, Plaintiff correctly argued that Schiraldi does not disclose a tooth whitening substance as required by the claims. (Doc. 98 at 40-45). After Plaintiff distinguished Schiraldi, the Examiner issued the '453 Patent without further examination or amendment. The issuance of the patent is clear evidence that the Examiner was persuaded by Plaintiff's argument. Moreover, Schiraldi simply does not disclose a "tooth whitening substance." (Doc. 93-2 at ¶ 42). Schiraldi discloses a device intended to be used for mucosal (*i.e.*, soft tissue, not teeth) applications. (*Id*. at ¶ 44). The entire patent is directed to mucosal applications, aside from one single mention of treatment of a tooth. (Doc. 92-9 at 302). While Schiraldi does disclose the delivery of medicaments, including antibacterials, to mucosal surfaces, it does not mention a peroxide anywhere.

Further, the use of a peroxide as an antibacterial is different from its use as a tooth whitener, and even if a particular antibacterial may be used as a tooth whitener, Schiraldi provides no disclosure of doing so. Nor does Schiraldi include any suggestion to a person of skill in the art ("POSA") that it could be done. (Doc. 93-2 at ¶ 44). A POSA at the time of the filing of the '453 Patent would not have understood the disclosure of an oral antiseptic to be the same as disclosure of a tooth whitening substance. (*Id.*)

Schiraldi does not specifically disclose any material that could be used for tooth whitening. Nor does it mention tooth whitening at all. Accordingly, Schiraldi does not disclose a tooth whitening substance, and Plaintiff properly distinguished Schiraldi during the examination of the '453 Patent.

"Flexible Strip of Material"

Second, Dr. Gaffar correctly states that Plaintiff further distinguished Schiraldi by explaining that "Schiraldi discloses that the film must be hydrated to be flexible which does not meet the flexibility as required in part (a) of the independent claims." (Doc. 90-10 at 5). Part (a) of claim 1 of the '453 Patent states as follows: "[A] strip of flexible material having a sufficient flexibility to form a curved shape on a plurality of teeth, said strip of material being readily conformable to tooth surfaces and to interstitial tooth spaces without permanent deformation when said delivery system is placed thereagainst[.]" (Doc. 92-1 at 14). With respect to this distinction, Dr. Gaffar repeats his assertion that he does not "find any evidence in the file history that this particular argument had any effect on the Examiner." (Doc. 90-10 at 12). But, once again, after Plaintiff distinguished Schiraldi, the Examiner issued the '453 Patent without further

examination or amendment. (Doc. 98 at 40-45). This is clear evidence that the Examiner was persuaded by this argument as well.

Finally, as discussed above, Schiraldi does not disclose a strip that meets the flexibility requirements of part (a) of independent claim 1.

"Substantially Transparent"

Third, Dr. Gaffar states that Plaintiff further distinguished Schiraldi during prosecution by noting that Schiraldi does not teach or suggest a delivery system that is substantially transparent and is almost unnoticeable when worn. Plaintiff amended the claims during prosecution to add these two limitations. Dr. Gaffar states that he disagrees with this characterization of Schiraldi, but he offers no evidence to support his opinion. (Doc. 90-10 at 12). Defendants do not provide any citations to where Schiraldi allegedly discloses this limitation. Rather, Defendants merely provide conclusory statements, with no citation: "Substantially transparent thin films were well known at the time of the patent filing. The thin film described by Schiraldi necessarily includes substantially transparent films." (Doc. 90 at 17; Doc. 90-6 at 2). This unsupported, conclusory assertion is not clear and convincing evidence sufficient to show that Schiraldi discloses the "substantially transparent" limitation of claim 1 of the '453 Patent. Dr. Gaffar concedes that Schiraldi does not disclose a substantially transparent film when he points to Saffir, instead of Schiraldi, as allegedly demonstrating a substantially transparent film. (Doc. 90-10 at ¶ 24 n.20).

With respect to the "almost unnoticeable when worn" limitation, Dr. Gaffar explains that the film of Schiraldi "is so thin and flexible so as to be unobtrusive and

'hardly noticeable' to the patient after placement." (*Id*. at ¶ 22). Defendants make the exact same argument in their motion. (Doc. 90 at 17). However, the Court defined "almost unnoticeable when worn" to mean "not readily apparent to others when worn." (Doc. 71 at 13).

Schiraldi does not disclose whether the film is noticeable to a person other than the patient. Specifically, Dr. Gaffar previously opined during claim construction that the claim limitation "almost unnoticeable when worn" relates to whether the strip is noticeable by another person, as opposed to the wearer: "The concept of 'noticeability' as used in the Patents in Suit, has reference to 'observability' of the strip by a person other than the wearer. Contrast this with prior art references in which 'noticeability' was about whether the appliance was comfortable to the wearer." (Doc. 98 at 159). Dr. Gaffar previously admitted during claim construction that the portion of Schiraldi he now cites in his Declaration as disclosing the "almost unnoticeable when worn" limitation relates to whether the strip is noticeable by the wearer, as opposed to another person:

> The prior art references are concerned with whether the wearer is irritated by the appliance or strip – whether the strip is physically noticeable by the wearer because it is uncomfortable or bulky. For example, Schiraldi notes that "the films are so thin that when placed in the mouth after they become wet they soon become unobtrusive, and hardly noticeable by most patients." Schiraldi does not specifically address how the films are perceived by others.

(*Id.* at 160).

Finally, Dr. Gaffar previously conceded that Schiraldi does not disclose this limitation, and not only admitted that Plaintiff properly distinguished Schiraldi on this basis, but also noted the utility of Plaintiff's distinction:

> As shown above, Schiraldi does clearly discuss whether the system is noticeable to the patient (i.e., the wearer). The alternative, then, is that P&G was arguing that Schiraldi does not teach or suggest that the delivery system is unnoticeable to others. In fact, Schiraldi does not seem to address this issue at all. And, as stated by P&G, the new limitation was intended to convey that the strip is intended to appear similar to the wearer's teeth. The utility of this would be so that the strip would not be noticed by others while worn – a feature that would possibly save the user from embarrassment.

(*Id.* at 161).

Dr. Gaffar asserts that "the idea of a 'substantially transparent and almost unnoticeable' delivery system is inherent in the disclosure of Schiraldi, if not described outright." (Doc. 90-10 at 8). To establish that a limitation is inherently disclosed in a reference, Defendants must put forth evidence to make clear that the missing descriptive matter is necessarily present in the thing described in the reference. *Transclean*, 290 F.3d at 1373. The possibility or probability that a certain thing may result from a given set of circumstances is not sufficient to establish inherency. *Mentor*, 244 F.3d at 1376. Defendants have not provided evidence sufficient to go forward on the claim of the inherency of the "substantially transparent" or "almost unnoticeable when worn" limitations.

Neither Defendants nor Dr. Gaffar have provided any evidence to establish that either of these limitations is necessarily present in Schiraldi. Dr. Gaffar states, with no evidence in support, that "it was very common to find such films in a 'substantially transparent' form." (Doc. 90-10 at ¶ 24). Even assuming this statement to be true, it does not establish whether Schiraldi inherently discloses a delivery system that is substantially unnoticeable when worn. A probability or possibility that Schiraldi's film

may be transparent is not enough to establish inherency. *Mentor*, 244 F.3d at 1376. Further, Dr. Gaffar has previously admitted that Schiraldi does not disclose the "almost unnoticeable when worn" limitation, either expressly or inherently. (Doc. 98 at 159).

"Without Permanent Deformation"

Finally, the Court defined the "without permanent deformation" limitation of '453 claim 1 to mean "without permanently conforming to the shape of the teeth[.]" (Doc. 71 at 6). Dr. Gaffar contends that "this two layer film is different than the prior putty-like substances that permanently deformed to the shape of the wearer's teeth. Thus, the film described in Schiraldi did not exhibit 'permanent deformation' as that term has been construed by this Court." (Doc. 90-10 at ¶ 23). Defendants make a similar, unsupported, argument:

> Schiraldi describes his system as using a thin film strip that "has very little or no mouthfeel" and which adheres to the tissue and teeth so as to be unobtrusive. Thus, in contrast to the prior art putty and trays, Schiraldi was thin and flexible and took the shape of the teeth without permanently conforming to the shape of the teeth.

(Doc. 90 at 17).

Neither Defendants nor Dr. Gaffar provides any explanation of these statements, nor do they provide any citations to the Schiraldi patent, nor to any other evidence. And Defendants do not provide any explanation as to what relevance the "mouthfeel" of Schiraldi's film has to whether or not it exhibits permanent deformation. Schiraldi does not disclose a strip that is readily conformable to tooth surfaces and to interstitial tooth spaces without permanently conforming to the shape of the teeth. (Doc. 93-2 at ¶ 64).

Schiraldi does not disclose (1) a "tooth whitening substance," (2) a system that is "substantially transparent," (3) a system that is "almost unnoticeable when worn," or (4) a strip that is "readily conformable to tooth surfaces and to interstitial tooth spaces without permanent deformation when said delivery system is placed there against[.]" Consequently Defendants have not presented evidence to meet their burden of showing that Schiraldi anticipates claim 1 of the '453 Patent.

ii. Claim 2

Claim 2 of the '453 Patent is dependent on claim 1 and requires that the strip of claim 1 "has a substantially constant flexural stiffness of less than about 5 grams/centimeter as measured on a Handle-O-Meter per ASTM test method D2923-95." (Doc. 92-1 at 14). As established above, Schiraldi does not disclose the Handle-O-Meter limitations of the '453 Patent.

iii. Claim 3

Claim 3 of the '453 Patent is dependent on claim 2 and requires that the strip of material be "comprised of materials which are compatible with one or more tooth whitening actives." (*Id.*) Dr. Gaffar provides only a single conclusory paragraph with respect to this claim. Dr. Gaffar states: "The Schiraldi disclosure is appropriate for use with a wide variety of medicaments and therapeutic compositions. Tooth whitening substances are included in this group." (Doc. 90-10 at 9). As established above, however, Schiraldi does not disclose a tooth whitening substance or active.

iv. Claim 6

Claim 6 is dependent on claim 3 and requires that the tooth whitening substance be a gel. (Doc. 92-1 at 14). The Court has construed the term gel to mean "a material ranging from near-liquid to near-solid that resists flow in the steady state[.]" (Doc. 71 at 18-20). Dr. Gaffar provides two arguments with respect to this claim.

Dr. Gaffar states, without any explanation, that "the bioadhesive layer of Schiraldi, adhering to wet mucosal surfaces as a gel, would suggest adhesive substances that are gels for use in oral care delivery devices." (Doc. 90-10 at ¶ 28). This statement does not make sense. Moreover, the portion of Schiraldi to which Dr. Gaffar refers says nothing about a gel. (Doc. 93-2 at ¶ 72). Dr. Gaffar also states that, in his opinion, the definition of "gel" adopted by the Court does nothing to clarify the meaning of the term, but he concludes that the definition is "extremely broad" and that it "must include the substance described by Schiraldi." (*Id.* at ¶ 28 and n.26). Dr. Gaffar provides no support or explanation for these conclusions, nor does he attempt to apply the Court's construction of the term "gel" to Schiraldi.

Defendants make the same unsupported and conclusory arguments in their Motion, they are wholly insufficient to establish that Schiraldi discloses a tooth whitening substance that is a gel. (Doc. 90 at 19). Schiraldi does not disclose a tooth whitening substance that is a gel as the Court has defined that term. (Doc. 93-2 at ¶ 74). Defendants have failed to carry their burden of evidencing anticipation.

v. Claim 7

Claim 7 is dependent on claim 6 and requires that the tooth whitening substance be a substantially uniform continuous coating on the strip of material. (Doc. 92-1 at 14). Dr. Gaffar provides a single sentence with respect to claim 7: "Claim 7 is also met by Schiraldi, in which the extruded layers are of the same width and layered one on the other." (Doc. 90-10 at ¶ 29). Neither Defendants nor Dr. Gaffar provide any explanation as to how Schiraldi discloses a tooth whitening substance that is a substantially uniform continuous coating.

First, as established, Schiraldi does not disclose a tooth whitening substance. Second, Defendants and Dr. Gaffar do not explain how "extruded layers [] of the same width and layered one on the other" necessarily discloses a substantially uniform continuous coating. Whether or not the layers of Schiraldi are of the same width and layered on each other does not mean that Schiraldi discloses a substantially uniform continuous coating. As an example, layers could be applied intermittently (as in a striped or dotted pattern) or irregularly across a consistent width, producing a non-uniform and non-continuous coating.

Defendants have not carried their burden of proving that Schiraldi anticipates Claim 7.

For all of the above reasons, Schiraldi does not anticipate claims 1-3 or 6-7 of the '453 Patent, and neither Defendants nor Dr. Gaffar have come forward with sufficient evidence to show that it does.

b. Saffir

Dr. Gaffar also opines that Saffir anticipates claims 1-3 of the ’453 Patent.

i. Claim 1

“Plurality of Adjacent Teeth”

Claim 1 of the ’453 Patent is directed to a delivery system for delivering a tooth whitening substance to “a plurality of adjacent teeth.” (Doc. 92-1 at 14). Every discussion and every figure of Saffir discloses application of a film to a single tooth or to an isolated portion of a single tooth. (Doc. 93-2 at ¶ 84). Saffir does not suggest to a POSA that the film could or should be used on a plurality of adjacent teeth. (*Id*.) Dr. Gaffar concedes that Saffir “does not explicitly address this use.” (Doc. 90-10 at ¶ 34). In support of his argument that Saffir inherently discloses a system for use on a plurality of adjacent teeth, Dr. Gaffar provides only a single, unsupported assertion: “[t]he nature of this material and the uses for which it is designed (i.e., treating stains on teeth) means that it inherently could be used on multiple adjacent teeth, even if Saffir does not explicitly address this use.” (*Id*.) While Defendants do not address this limitation in the body of their Motion, they similarly assert without explanation or evidence in their claim chart at Exhibit 21, that the system disclosed in Saffir is “capable of being used on multiple adjacent teeth.” (Doc. 90-6 at 6).

First, by asserting that Saffir “could be” used on multiple adjacent teeth, or is “capable” of doing so, Defendants concede that Saffir does not anticipate the asserted claims. Defendants’ assertion that Saffir is merely “capable” of being extended to a plurality of adjacent teeth falls well short of the requirement that the claimed feature is

"necessarily" present in the reference for inherent anticipation. *Transclean*, 290 F.3d at 1373. Second, Dr. Gaffar provides no explanation or citation to evidence to support his conclusion. This deficiency is also fatal to his argument. Third, Dr. Gaffar has mischaracterized the use for which Saffir was designed. Saffir was specifically designed for spot treatments of specific portions of a tooth, or for a single tooth. (Doc. 93-2 at ¶ 87). While Saffir does mention in one place that it could be used for spot-treating a stain on a portion of a single tooth, a POSA would recognize and understand that Saffir was not designed for the type of broader-scale tooth whitening that is disclosed and claimed in the Patents-in-Suit. (*Id.*)

In contrast, Saffir actually discloses several reasons why one of ordinary skill in the art would not extend it to a plurality of adjacent teeth. (*Id.*) Saffir teaches away from a patch being placed across multiple teeth and coming in contact with the adjoining soft tissue, because a stated object of Saffir is "limiting medication to only a given spot or area so that the danger of a strong drug's spreading where it is not needed and can cause irritation, is eliminated." (Doc. 92-9 at 298). Saffir further states: "This device contemplates sealing the medicament against the tooth by means of a thin sheath of cellulosic film or the like, one surface of which has been coated with a medicated adhesive." (*Id.*) A POSA reading Saffir would recognize that applying the single-tooth product of Saffir to a plurality of adjacent teeth would severely compromise Saffir's stated goal of sealing a medicament against a tooth. (Doc. 93-2 at ¶ 88). A POSA would not be motivated to modify the Saffir single-tooth system as Defendants and Dr. Gaffar contend.

"Readily Conformable"

Further, independent claim 1 of the '453 Patent requires a strip of flexible material that is "readily conformable to tooth surfaces and to interstitial tooth spaces[.]" (Doc. 92-1 at 14). Saffir does not disclose a strip that is conformable to the interstitial tooth spaces, as required by claim 1 of the '453 Patent. Saffir makes no mention of a strip that conforms to the gaps between the teeth. (Doc. 93-2 at ¶ 89). This is not surprising, because Saffir is directed to the treatment of a single tooth or of a specific area of a single tooth. (*Id*.) While Dr. Gaffar relies on the figures of the patent to argue that the Saffir film is conformable to the surfaces of the teeth, neither Defendants' Motion nor Dr. Gaffar's Declaration addresses the interstitial tooth spaces at all. This fact alone is fatal to Defendants' position that Saffir anticipates claims 1-3 of the '453 Patent.

"Without Permanent Deformation"

Independent claim 1 of the '453 Patent also requires that the strip of material is readily conformable to tooth surfaces and to interstitial tooth spaces "without permanent deformation when said delivery system is placed thereagainst[.]" (Doc. 92-1 at 14). The Court has construed "without permanent deformation" to mean "without permanently conforming to the shape of the teeth[.]" (Doc. 71 at 6-8).

The only support that Dr. Gaffar provides for his position that Saffir discloses this limitation is that the Saffir film allegedly can be easily removed, and that "[t]his easy removal coupled with the common sense knowledge of the physical properties of 'Scotch tape'-type products shows that the Saffir device after application does not become permanently deformed to the shape of the teeth." (Doc. No. 90-10 at 11-12). Dr. Gaffar

provides no explanation or evidence to support this statement. Dr. Gaffar does not explain what the "common sense knowledge" of the physical properties of "Scotch tape-type products" includes. Nor does he explain what the properties of a Scotch tape of 1958 might have been or how those properties might differ from a Scotch tape product in 1997. (Doc. 93-2 at ¶ 93). Nor does he explain what constitutes a "Scotch tape-type" product. (*Id.*) Dr. Gaffar's unsupported conclusory statements are insufficient by clear and convincing evidence to establish that Saffir discloses this limitation.

Saffir does not disclose a system for delivering a tooth whitening substance to a "plurality of adjacent teeth" or a strip that is "readily conformable to tooth surfaces and to interstitial tooth spaces without permanent deformation when said delivery system is placed thereagainst," and thus Defendans have failed to carry their burden of evidencing that it anticipates claim 1 of the '453 Patent.

iii. Claim 2

Claim 2 of the '453 Patent is dependent on claim 1 and requires that the strip of claim 1 "has a substantially constant flexural stiffness of less than about 5 grams/centimeter as measured on a Handle-O-Meter per ASTM test method D2923-95." (Doc. 92-1 at 14). As established above, Saffir does not disclose the Handle-O-Meter limitations of the '453 Patent.

iv. Claim 3

Claim 3 is dependent on claim 2 and requires that the strip of material be "comprised of materials which are compatible with one or more tooth whitening actives." (*Id.*). Once again, Dr. Gaffar provides only a single conclusory sentence with respect to

this claim. Dr. Gaffar states: "[w]ith respect to Claim 3, Saffir specifically recites that the strips are capable of being used with tooth whitening or bleaching actives." (Doc. 90-10 at ¶ 38).

Although Saffir discloses that various bleaching agents can be used in small quantities for treating stained spots on teeth, the only "bleaching agent" that Saffir discloses is potassium chlorate. (Doc. No. 90-3 at 11). Dr. Heymann, a practicing dentist for more than 35 years, has never seen or heard of potassium chlorate being used for whitening teeth. (Doc. 93-2 at ¶ 99). Accordingly, Saffir does not disclose a strip that is compatible with one or more tooth whitening actives and Defendants have not met their burden of proving that it anticipates claim 3.

For all of the above reasons, neither Defendants nor Dr. Gaffar have presented sufficient evidence to go forward on the allegation that Saffir anticipates claims 1-3 of the '453 Patent.

c. Schiraldi/Gaglio

Defendants argue that it would have been obvious to combine Schiraldi and Gaglio, and that this combination would render obvious claims 1-3, 6-9, and 11 of the '453 Patent. Dr. Gaffar offers a blanket statement as purported support for the alleged motivation to combine Schiraldi with Gaglio:

> To the extent that any of the elements of the asserted claims of the '453 Patent are not found in Schiraldi, those elements are supplied by other publications which were available to a person of ordinary skill in the art. A person of ordinary skill in the art would have been motivated to combine these references with the Schiraldi patent because each of the references deals with methods and products for delivery of medicaments, tooth

> whitening substances, and other compositions to the surface of the teeth. One such prior art reference is Gaglio.

(Doc. 90-10 at ¶ 40). Even assuming that Schiraldi and Gaglio are in the same or related fields, Dr. Gaffar's bald assertion is not sufficient to establish the necessary motivation to combine the references. *KSR*, 550 U.S. at 418. As Dr. Heymann explains, a POSA would not have been motivated to combine Schiraldi and Gaglio because there is nothing in the disclosure of Schiraldi, which is directed to the treatment of oral mucosa, that would have motivated a POSA to modify the Schiraldi device for the purpose of whitening a plurality of teeth. (Doc. 93-2 at ¶ 108).

The Court has already established above. the claim limitations that Schiraldi does not disclose.

i. Claim 1

"Flexible Strip of Material"

Although it is unclear, Defendants appear to rely on Gaglio as disclosing the flexibility limitations of part (a) of claim 1. Defendants and Dr. Gaffar rely on Figure 6 of Gaglio to state that "[t]he delivery system device of Gaglio possesses sufficient flexibility to form the curved shape of its Figure 6[.]" (Doc. 90 at 24; Doc. 90-10 at ¶ 43). This assertion is insufficient to carry Defendants' burden of proof.

"Readily Conformable"

Even if Figure 6 were sufficient to show a device that has sufficient flexibility to form a curved shape on a plurality of adjacent teeth, it does not disclose a film that is readily conformable to tooth surfaces and to interstitial tooth spaces. (Doc. 93-2 at ¶

111). Aside from a single conclusory statement in their Motion, Defendants do not provide any explanation as to how or where Gaglio discloses these limitations.

Figures 6-8 of Gaglio depict a device that does not conform to the entire tooth surface or to the interstitial tooth spaces. (Doc. No. 90-4 at 4). The device of Figure 6 forms a hemispherical shape, contacting only the outermost surfaces of the teeth. (*Id*.) Figures 7-8 show that the device does not conform to the gaps between the teeth and the gums. (*Id*.) This can be contrasted with Figures 5-8 of the '453 Patent, which show a strip that conforms to the interstitial tooth spaces as well as the space between the tooth and the gums. (Doc. 92-1 at 7). SJA0003.

"Without Permanent Deformation"

Although it is unclear, it appears that Defendants also rely on Gaglio as disclosing the "without permanent deformation" limitation. The Court has construed "without permanent deformation" to mean "without permanently conforming to the shape of the teeth[]." (Doc. 71 at 6-8). Dr. Gaffar does not reference this limitation in his declaration. However, in Exhibit 22, Defendants state with respect to Gaglio that "[t]he thin film strip is not permanently deformed." (Doc. 90-6 at 2). Defendants do not provide any explanation for this statement, do not apply the Court's claim construction to the reference, and do not provide any citations to the Gaglio patent. Gaglio does not disclose a strip that is "readily conformable to tooth surfaces and to interstitial tooth spaces without permanent deformation when said delivery system is placed there against[.]" (Doc. 92-1 at 14).

"Tooth Whitening Substance"

Defendants also argue, without support, that "[t]he extrusion-resistant whitening agent of Gaglio would readily be substituted for the anticaries or anesthetic agent of Schiraldi[.]" (Doc. 90 at 23). First, Defendants' reliance on Gaglio to fill a gap in Schiraldi confirms that Schiraldi does not disclose a tooth whitening substance. Second, Defendants provide no explanation for this conclusion, and do not explain why either of these references would motivate a POSA to combine the teachings of Gaglio and Schiraldi. Defendants also appear to rely on Gaglio as disclosing a tooth whitening substance that provides adhesive attachment between the device and the tooth. (*Id.* at 24) ("Gaglio also teaches that substances (including time-release substances) are carried by adhesive means of holding the material against a surface for an extended period of time"). (*Id.* at 32). Defendants do not provide any citations to the Gaglio patent or cite any other evidence to support this statement.

Gaglio does not teach a tooth whitening substance that provides adhesive attachment between the device and the tooth. (Doc. 93-2 at ¶ 116). Rather, Gaglio states that "the gel-filled pockets 38 can be attached to an adhesive covered backing 46 which can then [be] used to hold the gel-filled pocket 38 over a site of interest for a particular purpose." (Doc. 90-4 at 12). The Gaglio device is attached to the teeth by a separate adhesive backing, not by any tooth whitening substance. Further, as Dr. Heymann explains, a POSA would not have been motivated to combine Schiraldi and Gaglio because there is nothing in the disclosure of Schiraldi, which is directed to the treatment

of oral mucosa, that would have motivated a POSA to modify the Schiraldi device for the purpose of whitening a plurality of teeth. (Doc. 93-2 at ¶ 117).

The combination of Schiraldi and Gaglio does not render claim 1 of the '453 Patent obvious, and Defendants have failed to meet their burden of proffering sufficient evidence to try the allegation that this claim is invalid.

ii. Claim 2

Claim 2 of the '453 Patent is dependent on claim 1 and requires that the strip of claim 1 "has a substantially constant flexural stiffness of less than about 5 grams/centimeter as measured on a Handle-O-Meter per ASTM test method D2923-95." (Doc. 92-1 at 14). Defendants do not assert that Gaglio discloses the limitations of claim 2. (Doc. 90 at 24). As established above, Saffir does not disclose the Handle-O-Meter limitations of the '453 Patent.

iii. Claim 3

Claim 3 is dependent on claim 2 and requires that the strip of material be "comprised of materials which are compatible with one or more tooth whitening actives." (Doc. 92-1 at 14). Dr. Gaffar provides only a single conclusory paragraph with respect to this claim. Dr. Gaffar states: "Claim 3 also is obvious based on Gaglio's teaching of using the pad to apply a tooth whitening active." (Doc. 90-10 at ¶ 48). Neither Defendants nor Dr. Gaffar cites any evidence to support this conclusion. They also do not explain how or why a POSA would have been motivated to combine Schiraldi with Gaglio with respect to claim 3. Additionally, even if one assumes that Gaglio discloses a device that is compatible with one or more tooth whitening actives, a POSA would not

have been motivated to combine Schiraldi and Gaglio because there is nothing in the disclosure of Schiraldi, which is directed to the treatment of oral mucosa, that would have motivated a POSA to modify the Schiraldi device for the purpose of whitening a plurality of teeth. (Doc. 93-2 at ¶ 122). Accordingly, the combination of Schiraldi and Gaglio does not render claim 3 obvious, and Defendants have failed to meet their burden of proffering sufficient evidence to try the allegation that this claim is invalid.

iv. Claim 6

Claim 6 is dependent on claim 3 and requires that the tooth whitening substance be a gel. (Doc. 92-1 at 14). The Court has construed the term gel to mean "a material ranging from near-liquid to near-solid that resists flow in the steady state[.]" (Doc. 71 at 18-20). Neither Defendants nor Dr. Gaffar explain how or why a POSA would have been motivated to combine Schiraldi with Gaglio with respect to claim 6. Further, even assuming that Gaglio discloses a tooth whitening substance that is a gel, a POSA would not have been motivated to combine Schiraldi and Gaglio because there is nothing in the disclosure of Schiraldi, which is directed to the treatment of oral mucosa, that would have motivated a POSA to modify the Schiraldi device for the purpose of whitening a plurality of teeth. (Doc. 93-2 at ¶ 123). Accordingly, the combination of Schiraldi and Gaglio does not render claim 6 obvious, and Defendants have failed to meet their burden of proffering sufficient evidence to try the allegation that this claim is invalid.

v. Claim 7

Claim 7 is dependent on claim 6 and requires that the tooth whitening substance be a substantially uniform continuous coating on the strip of material. (Doc. 92-1 at 14).

Dr. Gaffar provides a single sentence with respect to claim 7: "For the same reason, Gaglio's teaching of the gel applied along the entirety of the backing material renders Claim 7 obvious." (Doc. 90-10 at ¶ 50). Dr. Gaffar relies on the following passage from Gaglio: "the dispensing material 32 can be carried by the entirety of the backing material 30 and the gel 10 saturated into the dispensing material 32." (Doc. 90-4 at 11). Defendants make a similar argument in their Motion. (Doc. 90 at 25).

First, as explained above, Schiraldi does not disclose a tooth whitening substance. A POSA would not have been motivated to use the material of Gaglio in the Schiraldi device because there is nothing in the disclosure of Schiraldi, which is directed to the treatment of oral mucosa, that would have motivated a POSA to modify the Schiraldi device for the purpose of whitening a plurality of teeth. (Doc. 93-2 at ¶ 125). Second, Defendants and Dr. Gaffar do not explain how this passage discloses a substantially uniform continuous coating. In fact, this passage says nothing about a coating, let alone whether it is uniform. (*Id*.) Accordingly, the combination of Schiraldi and Gaglio does not render claim 7 obvious, and Defendants have failed to meet their burden of proffering sufficient evidence to try the allegation that this claim is invalid.

vi. Claim 8

Claim 8 is dependent on claim 6 and requires that the tooth whitening active in the tooth whitening substance is selected from the group consisting of peroxides, metal chlorites, perborates, percarbonates, peroxyacids, and combination thereof. (Doc. 92-1 at 14). (Doc. 92-1 at 14). Even if one assumes that Gaglio discloses a peroxide-based tooth whitening active, Schiraldi does not disclose a tooth whitening substance, and a POSA

would not have been motivated to use the material of Gaglio in the Schiraldi device, because there is nothing in the disclosure of Schiraldi, which is directed to the treatment of oral mucosa, that would have motivated a POSA to modify the Schiraldi device for the purpose of whitening a plurality of teeth. (Doc. 93-2 at ¶ 126). Accordingly, the combination of Schiraldi and Gaglio does not render claim 8 obvious, and Defendants have failed to meet their burden of proffering sufficient evidence to try the allegation that this claim is invalid.

vii. Claim 9

Claim 9 is dependent on claim 8 and requires that the strip with the tooth whitening substance thereon – in other words, both components of the delivery system – have an overall thickness less than about 1 mm. (Doc. 92-1 at 14). Dr. Gaffar asserts only that: "Claim 9 is obvious in light of Gaglio's teaching that the material is as thin as 1/32" or 0.79 mm." (Doc. 90-10 at ¶ 52). Defendants make the same argument. (Doc. 90 at 25).

Defendants ignore any teaching about the Gaglio device. Defendants rely on the disclosure of the minimum thickness of only one part of the Gaglio device, the backing material. (Doc. 93-2 at ¶ 128). As Dr. Gaffar recognizes, however, the Gaglio device is comprised of two layers. (Doc. No. 90-10 at ¶ 42). The Gaglio device also has a dispensing material, which the patent explains has a minimum thickness of 1/16" (approximately 1.59 mm). (Doc. No. 90-4 at 11). Therefore, the overall thickness of the Gaglio device is a minimum of 2.38 mm, which is more than double the 1 mm limitation of claim 9. Accordingly, Gaglio does not disclose the limitation of claim 9.

In contrast to the body of their Motion, Defendants add in their claim chart at Exhibit 22, without citation to any evidence, that the "[b]ioadhesive layers disclosed in Schiraldi can be very thin, with a total thickness of less than about 1mm." (Doc. 90-6 at 12). Not only is there no proof of the thickness of the Schiraldi device, it is not clear whether Defendants are relying on Schiraldi or Gaglio as disclosing the limitation of claim 9. Further, to the Defendants are relying on a combination of both references, a POSA would not have been motivated to use the material of Gaglio in the Schiraldi device, because there is nothing in the disclosure of Schiraldi, which is directed to the treatment of oral mucosa, that would have motivated a POSA to modify the Schiraldi device for the purpose of whitening a plurality of teeth. (Doc. 93-2 at ¶ 129). The combination of Schiraldi and Gaglio does not render claim 9 obvious, and Defendants have failed to meet their burden of proffering sufficient evidence to try the allegation that this claim is invalid.

viii. Claim 11

Claim 11 is dependent on claim 9 and requires that the strip of material with the tooth whitening substance is removable from the tooth surface without the use of an instrument, a chemical solvent, or undue friction. (Doc. 92-1 at 14). Dr. Gaffar again offers a single conclusory statement: "Claim 11 is obvious in light of Gaglio's teaching that the applicator can be easily discarded." (Doc. 90-10 at ¶ 53). Defendants argue that "Gaglio teaches that the applicator can be easily discarded 'upon arriving at work' which implies removability without the use of an instrument, a chemical solvent, or undue friction." (Doc. 90 at 25).

Defendants and Dr. Gaffar cite a portion of Gaglio as alleged support for their contentions: "after breakfast and brushing, a user can place an applicator pad 28 in the mouth on the teeth 12 during a commuting period and discard it upon arriving at work." (Doc. 90-4 at 11). First, Gaglio does not say, as Dr. Gaffar and Defendants contend, that the applicator can be "easily" discarded. Second, whether or not the applicator can be discarded discloses nothing about how the applicator is removed from the teeth. (Doc. 93-2 at ¶ 131). Defendants provide no explanation for their conclusion that the ability to discard the applicator upon arriving at work somehow "implies" that it is removed without the use of an instrument, a chemical solvent or undue friction. The Gaglio patent does not disclose whether removal of the applicator requires an instrument, a chemical solvent, or undue friction. Defendants do not allege that Schiraldi discloses the limitations of claim 11. The combination of Schiraldi and Gaglio does not render claim 11 obvious, and Defendants have failed to carry their burden of proof.

For all of the reasons above, a POSA would not have been motivated to combine Schiraldi and Gaglio; and even if one was so motivated, the combination of Schiraldi and Gaglio does not render obvious claims 1-3, 6-9, or 11 of the '453 Patent, and neither Defendants nor Dr. Gaffar has come forward with sufficient evidence to show that it does.

d. Schiraldi/Gaglio/Biegajski

Defendants argue that it would have been obvious to combine Schiraldi, Gaglio and Biegajski, and that this combination would render obvious claims 18 and 21 of the '453 Patent. (Doc. 90 at 25). Defendants do not explain why a POSA would have been

motivated to combine Biegajski with Schiraldi and Gaglio. Defendants appear to argue that there would be motivation to combine the references because all of the references are allegedly in the same or related fields. However, even assuming that Schiraldi, Gaglio, and Biegajski were in the same or related fields, this bald assertion is not sufficient to establish the necessary motivation to combine the references. *KSR*, 550 U.S. at 418.

i. Claim 18

Claim 18 is dependent on claim 3, and adds the requirement of a release liner. (Doc. 92-1 at 14). As explained above, the combination of Schiraldi and Gaglio does not render obvious claims 1-3. Defendants do not rely on Biegajski as disclosing any of the limitations of claims 1-3, but rather rely on it solely for its disclosure of a release liner. (Doc. 90 at 26). Accordingly, the addition of Biegajski does nothing to cure the deficiencies of the Schiraldi/Gaglio combination with respect to claims 1-3. Because claim 18 depends from claims 1-3, the combination of Schiraldi, Gaglio and Biegajski does not render obvious claim 18 of the ’453 Patent, and Defendants have failed to meet their burden of proffering sufficient evidence to try the allegation that this claim is invalid.

ii. Claim 21

Claim 21 is similar to claim 1 of the ’453 Patent. Claim 21 does not recite the “substantially transparent and is almost unnoticeable” limitation of claim 1, and includes the additional requirement of a release liner. (Doc. 92-1 at 15). Although not explicitly stated, it appears that for claim 21 other than the release liner limitation, Defendants rely solely on their argument that the combination of Schiraldi and Gaglio renders claim 1

obvious. (Doc. 90 at 27). The Court has already established that the combination of Schiraldi and Gaglio does not render claim 1 obvious. Defendants do not rely on Biegajski as disclosing any of the limitations of claim 1, but rather rely on it solely for its disclosure of a release liner. (Doc. 90 at 27). Accordingly, the addition of Biegajski does nothing to cure the deficiencies of the Schiraldi/Gaglio combination with respect to the remainder of claim 21, and thus does not render claim 21 of the '453 Patent obvious. Defendants have failed to prove otherwise.

For all of the reasons above, a POSA would not have been motivated to combine Schiraldi, Gaglio and Biegajski; and even if one was so motivated, the combination of Schiraldi, Gaglio, and Biegajski does not render obvious claims 18 or 21 of the '453 Patent, and neither Defendants nor Dr. Gaffar have come forward with sufficient evidence to go forward on the allegation that it does.

e. Saffir/Gaglio

Defendants argue that it would have been obvious to combine Saffir and Gaglio, and that this combination would render obvious claims 1-3, 6-9, and 11 of the '453 Patent. Defendants provide a blanket assertion regarding the motivation to combine Saffir with Gaglio:

> [T]o the extent that any elements are deemed to not be present in Saffir, those elements are found in Gaglio. A person of ordinary skill in the art would have been motivated to combine Saffir and Gaglio because both references deal with methods and products for delivery of medicaments, tooth whitening substances, and other compositions to the surface of the teeth.

(Doc. 90 at 27).

Even assuming that Saffir and Gaglio are in the same or related fields, this bald assertion is not sufficient to establish the necessary motivation to combine the references. *KSR*, 550 U.S. at 418. Moreover, a POSA would not have been motivated to combine Saffir and Gaglio, because there is nothing in the disclosure of Saffir, which is directed to the focal treatment of localized defects in a tooth or a portion of a tooth, that would have motivated a POSA to modify the Saffir device for the purpose of whitening a plurality of teeth. (Doc. 93-2 at ¶ 145). The combination of Saffir and Gaglio does not render obvious claims 1-3, 6-9, or 11 of the '453 Patent.

Additionally, the age of the Saffir reference is strong evidence that the challenged claims are not obvious based on the combination of Saffir and Gaglio. *See Leo Pharm. Prods., Ltd. v. Rea*, 726 F.3d 1346, 1355-57 (Fed. Cir. 2013). In *Leo Pharm*., the Federal Circuit explained why such a long gap between the cited prior art and the filing of the patent application at issue is strong evidence that the claimed invention would not have been obvious to try:

> The elapsed time between the prior art and the '013 patent's filing date evinces that the '013 patent's claimed invention was not obvious to try. Indeed this considerable time lapse suggests instead that the Board only traverses the obstacles to this inventive enterprise with a resort to hindsight. It took over a decade … for Dikstein's formulations to be tested for storage stability. And, until the advancement made by the inventors of the '013 patent, no one had proposed a new formulation that would be storage stable. The problem was not known, the possible approaches to solving the problem were not known or finite, and the solution was not predictable. Therefore, the claimed invention would not have been obvious to try to one of ordinary skill in the art. Indeed ordinary artisans would not have thought to try at all because they would not have recognized the problem.

726 F.3d at 1356-57.

Here, Saffir issued in 1958, nearly 40 years before Plaintiff filed its initial patent applications. Clio relies on Saffir as disclosing all of the elements of the asserted claims of the '453 Patent, except the application of the strip to a plurality of adjacent teeth. (Doc. 90 at 27-30). But the fact that the Saffir reference was available for forty years, and that during that time, no one attempted to apply the Saffir device across multiple teeth shows that it would not have been obvious to do so. It also provides strong evidence that the Defendants, more than a decade after the '453 Patent was filed and more than 50 years after the Saffir patent granted, are using hindsight to argue that the claims of the '453 Patent would have been obvious to try in light of Saffir and Gaglio. Such hindsight is not permissible. *KSR*, 550 U.S. at 421. Without hindsight, there is no reason to believe that a POSA would have looked to the Saffir reference alone, or in combination with any other references, to provide the claimed invention.

Defendants do not provide any further discussion or explanation of Saffir. (Doc. 90 at 27). Rather, Defendants focus only on what Gaglio allegedly discloses, and Plaintiff has shown that Saffir does not disclose many of the limitations claimed in the '453 Patent. For example, Saffir does not disclose a system for delivering a tooth whitening substance to a "plurality of adjacent teeth" or a strip that is "readily conformable to tooth surfaces and to interstitial tooth spaces without permanent deformation when said delivery system is placed thereagainst." (Doc. 92-1 at 14).

Additionally, it appears that Defendants make the exact same arguments with respect to Gaglio as they do in the portion of their Motion relating to the combination of Schiraldi and Gaglio. (Doc. 90 at 30). For all the same reasons that Gaglio fails to

render the ’453 Patent obvious in combination with other references, it fails in combination with Saffir as well.

For all of the reasons above, a POSA would not have been motivated to combine Saffir and Gaglio; and even if one was so motivated, the combination of Saffir and Gaglio does not render obvious claims 1-3, 6-9, or 11 of the ’453 Patent, and Defendants and Dr. Gaffar have failed to meet their burden of proffering sufficient evidence to try the allegation that these claims are invalid.

f. Saffir/Gaglio/Biegajski

Defendants argue that it would have been obvious to combine Saffir, Gaglio, and Biegajski, and that this combination renders obvious claims 18 and 21 of the ’453 Patent. (Doc. 90 at 25). Defendants do not explain why a POSA would have been motivated to combine Biegajski with Saffir and Gaglio. Defendants appear to argue that there would be motivation to combine the references because all of the references are in the same or related fields. However, even assuming that Saffir, Gaglio, and Biegajski were in the same or related fields, that reason alone, without more, is insufficient to establish the necessary motivation to combine the references. *KSR*, 550 U.S. at 418.

i. Claim 18

Claim 18 is dependent on claim 3, and adds the requirement of a release liner. (Doc. 92-1 at 14). As discussed above, the combination of Saffir and Gaglio does not render obvious claims 1-3. Defendants do not rely on Biegajski as disclosing any of the limitations of claims 1-3, but rather rely on it solely for its disclosure of a release liner. (Doc. 90 at 31). Accordingly, the addition of Biegajski does nothing to cure the

deficiencies of the Saffir/Gaglio combination with respect to claims 1-3. Because claim 18 depends from claims 1-3, the combination of Saffir, Gaglio and Biegajski does not render obvious claim 18 of the ’453 Patent, and Defendants have failed to meet their burden of proffering sufficient evidence to try the allegation that this claim is invalid.

ii. Claim 21

Claim 21 is similar to claim 1 of the ’453 Patent. Claim 21 does not recite the “substantially transparent and is almost unnoticeable” limitation of claim 1, and includes the additional requirement of a release liner. (Doc. 92-1 at 15). Although not explicitly stated, it appears that for claim 21, other than the release liner limitation, Defendants rely solely on their argument that the combination of Saffir and Gaglio renders claim 1 obvious. (Doc. 90 at 31). As established, the combination of Saffir and Gaglio does not render claim 1 obvious. Defendants do not rely on Biegajski as disclosing any of the limitations of claim 1, but rather rely on it solely for its disclosure of a release liner. (Doc. 90 at 31). Accordingly, the addition of Biegajski does nothing to cure the deficiencies of the Saffir/Gaglio combination with respect to the remainder of claim 21, and thus does not render claim 21 of the ’453 Patent obvious. Defendants have failed to meet their burden of proffering sufficient evidence to try the allegation that this claim is invalid.

For all of the reasons above, a POSA would not have been motivated to combine Saffir, Gaglio and Biegajski; and even if one was so motivated, the combination of Saffir, Gaglio and Biegajski does not render obvious claims 18 or 21 of the ’453 Patent, and

neither Defendants nor Dr. Gaffar have come forward with sufficient evidence to go forward to trial.

g. Fischer/Shapiro

Defendants argue that it would have been obvious to combine Fischer and Shapiro, and that this combination renders obvious claims 1-3, 6-9, 11, 18, and 21 of the '453 Patent. Neither Defendants nor Dr. Gaffar explains why a POSA would have been motivated to combine Fischer with Shapiro, and they provide no citations or explanation regarding any motivation to combine. Defendants have not articulated any "reasoning with some rational underpinning to support the legal conclusion of obviousness[.]" *KSR*, 550 U.S. at 418 (quoting *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006)). In any event, Shapiro is non- analogous art that cannot be combined with Fischer and, even it were analogous art, the two references are so fundamentally different, a POSA would not have been motivated to combine them. (Doc. 93-2 at ¶ 157).

In *In re Bigio*, the Federal Circuit set forth the tests for defining the scope of analogous art:

> Two separate tests define the scope of analogous prior art: (1) whether the art is from the same field of endeavor, regardless of the problem addressed and, (2) if the reference is not within the field of the inventor's endeavor, whether the reference still is reasonably pertinent to the particular problem with which the inventor is involved.

381 F.3d 1320, 1325 (Fed. Cir. 2004). As the court explained, it is necessary to apply "common sense" in deciding "in which fields a person of ordinary skill would reasonably be expected to look for a solution to the problem facing the inventor." *Id*. at 1326 (quoting *In re Oetiker*, 977 F.2d 1443, 1447 (Fed. Cir. 1992)).

With respect to the first test, the Patents-in-Suit are directed to the application of a delivery system for treating the teeth. The use described in Shapiro has nothing to do with the application or delivery of any substance to the teeth, but instead is used for keeping substances off the teeth. As such, Shapiro does not fall within the same field of endeavor as the Patents-in-Suit.

The second test for whether prior art is analogous focuses on the "particular problem" the invention attempts to solve. *See id*. at 1325. The PTAB has cautioned that "[p]recise definition of the problem is important in determining whether a reference is from a nonanalogous art." *See Ex parte Dussaud*, 7 U.S.P.Q. 2d 1818, 1819 (B.P.A.I. 1988). In that case, the PTAB explained that "defining the problem too broadly, as done here, may result in considering prior art as 'analogous' which is inconsistent with real world considerations." *See id*. (reversing examiner's rejection because cited art was not analogous). Precisely defining the problem helps ensure that the prior art considered is that which "logically would have commended itself to an inventor's attention in considering his problem." *See id*.; *In re Clay*, 966 F.2d 656, 659 (Fed. Cir. 1992). In addition, evaluating "the purposes of both the invention and the prior art [is] important in determining whether the reference is reasonably pertinent[.]" *Clay*, 966 F.2d at 659. If a prior art reference "is directed to a different purpose, the inventor would accordingly have had less motivation or occasion to consider it." *Id*.

Here, the problem that the inventors of the Patents-in-Suit addressed was the application of substances to the teeth. Indeed, the Fischer device is precisely the sort of prior art device described in the specifications of the Patents-in-Suit, and is the type of

device that Plaintiff improved on with the present inventions. In contrast, the problem that Shapiro addressed was the prevention of substances touching the teeth. A POSA at the time of the invention concerned with application of substances to the teeth, who had no knowledge of the invention claimed in the Patents-in-Suit, would never have turned to Shapiro – a device designed for the exact opposite function – for guidance. *Id*. (*see also* Doc. 93-2 at ¶ 35). Nor is there any teaching or suggestion in Shapiro that the device could be used to apply substances to the teeth even in the unlikely event that the POSA were to find the reference.

Thus, under either of the Federal Circuit tests, Shapiro is non-analogous art. Because it is non-analogous art, Shapiro cannot be used as a basis in an alleged obviousness combination for any claims of the Patents-in-Suit.

2. The ’017 Patent

Defendants allege that claims 1-3 and 7 of the ’017 Patent are invalid. (Doc. 90 at 35- 49). Defendants bear the burden of proving invalidity by clear and convincing evidence.

a. Schiraldi

Defendants argue that Schiraldi anticipates claims 1-3 and 7 of the ’017 Patent. Defendants have attached as Exhibit 27 to their Motion a claim chart comparing claims 1-3 and 7 of the ’017 Patent with Schiraldi. (Doc. No. 90-7 at 1-5). Defendants’ claim chart contains mostly conclusory statements, and it does not contain any citations to the Schiraldi patent. While Dr. Gaffar’s Declaration contains citations to the Schiraldi patent, it often does not reference the specific claim language. (Doc. 90-10 at ¶¶ 92-100).

Additionally, Defendants appear to rely on their arguments relating to the ’453 Patent, even though the claims of the ’017 Patent and the ’453 Patent are different. Further, they do not cite any specific pages of their Motion to direct the Court’s or Plaintiff’s attention to the referenced arguments. The arguments do not necessarily correspond, and it is therefore difficult to determine exactly what arguments Defendants are actually making with respect to each of the claims.

i. Claim 1

The Patent Examiner expressly considered Schiraldi during prosecution of the ’017 Patent. Plaintiff successfully distinguished Schiraldi, as well as numerous other references, on various grounds, and the Examiner allowed the ’017 Patent to issue thereafter. (Doc. 98 at 22-27). Dr. Gaffar correctly notes that the file history of the ’017 Patent parallels that of the ’453 Patent. (Doc. 90-10 at ¶ 92). Dr. Gaffar states that “P&G made the exact same arguments regarding Schiraldi that appear in the ’453 File History” and then states that, “[f]or the same reasons discussed above with respect to the ’453 Patent, I find P&G’s arguments about Schiraldi in the ’017 Patent application unconvincing.” (*Id*. at ¶¶ 92-93). Because the claims of the ’017 Patent and the ’453 Patent are slightly different, Plaintiff’s arguments to the Examiner were slightly different.

“Flexible Strip of Material”

First, Dr. Gaffar correctly states that Plaintiff distinguished Schiraldi by explaining that “Schiraldi discloses that the film must be hydrated to be flexible which does not meet the flexibility as required in part (a) of the independent claims.” (Doc. 90-10 at ¶ 16). Part (a) of claim 1 of the ’017 Patent states as follows:

[A] strip of material having a flexural stiffness less than about 50 grams/centimeter as measured on a Handle-O-Meter per ASTM test method D2923-95, said strip of material being readily conformable without permanent deformation to a shape of a tooth and its adjoining soft tissue when said delivery system is placed thereagainst[.] (Doc. 92-1 at 21). With respect to this distinction, Dr. Gaffar states that he does not "find any evidence in the file history that this particular argument had any effect on the Examiner." (Doc. 90-10 at ¶ 19). Once again, after Plaintiff distinguished Schiraldi, the Examiner issued the '017 Patent without further examination or amendment. (Doc. 98 at 22-27). This is clear evidence that the Examiner was persuaded by this argument.

Further, as established above, Schiraldi does not disclose the Handle-O-Meter limitations of the '017 Patent.

"Substantially Unnoticeable When Worn"

Second, Dr. Gaffar states that Plaintiff further distinguished Schiraldi by noting that Schiraldi does not teach or suggest a delivery system that is substantially unnoticeable when worn. Plaintiff also amended the claims to add this limitation. Dr. Gaffar states that he disagrees with this characterization of Schiraldi. (Doc. 90-10 at ¶ 21). With respect to the "substantially unnoticeable when worn" limitation, Dr. Gaffar explains that the film of Schiraldi "is so thin and flexible so as to be unobtrusive and 'hardly noticeable' to the patient after placement." (*Id*. at ¶ 22). Defendants and Dr. Gaffar are not applying the correct claim construction. (Doc. 90 at 17). The Court construed "substantially unnoticeable when worn" to mean "not readily apparent to others when worn." (Doc. 71 at 13).

Schiraldi does not disclose whether the film is noticeable to a person other than the patient. Defendants concede this, and Dr. Gaffar agrees. Specifically, Dr. Gaffar opined during claim construction that the claim limitation "substantially unnoticeable when worn" relates to whether the strip is noticeable by another person, as opposed to the wearer: "The concept of 'noticeability' as used in the Patents in Suit has reference to 'observability' of the strip by a person other than the wearer. Contrast this with prior art references in which 'noticeability' was about whether the appliance was comfortable to the wearer." (Doc. 98 at 159). Dr. Gaffar admitted during claim construction that the portion of Schiraldi he now cites in his Declaration as disclosing the "substantially unnoticeable when worn" limitation relates to whether the strip is noticeable by the wearer, as opposed to another person:

> The prior art references are concerned with whether the wearer is irritated by the appliance or strip – whether the strip is physically noticeable by the wearer because it is uncomfortable or bulky. For example, Schiraldi notes that "the films are so thin that when placed in the mouth after they become wet they soon become unobtrusive, and hardly noticeable by most patients." Schiraldi does not specifically address how the films are perceived by others.

(*Id.* at 160).

Finally, Dr. Gaffar previously conceded that Schiraldi does not disclose this limitation, and not only admitted that Plaintiff properly distinguished Schiraldi on this basis, but also noted the utility of Plaintiff's distinction:

> As shown above, Schiraldi does clearly discuss whether the system is noticeable to the patient (i.e., the wearer). The alternative, then, is that P&G was arguing that Schiraldi does not teach or suggest that the delivery system is unnoticeable to others. In fact, Schiraldi does not seem to address this issue at all. And, as stated by P&G, the new limitation was intended to convey that the strip is intended to

> appear similar to the wearer's teeth. The utility of this would be so that the strip would not be noticed by others while worn – a feature that would possibly save the user from embarrassment.

(*Id.*) at ¶ 80).

Dr. Gaffar also states in his Declaration with respect to the '453 Patent that "the idea of a 'substantially transparent and almost unnoticeable' delivery system is inherent in the disclosure of Schiraldi, if not described outright." (Doc. 90-10 at ¶ 24). The Court assumes that Dr. Gaffar, and the Defendants, are making the same argument with respect to the "substantially unnoticeable when worn" limitation of the '017 Patent.

To establish that a limitation is inherently disclosed in a reference, the evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference. *Transclean*, 290 F.3d at 1370. The possibility or probability that a certain thing may result from a given set of circumstances is not sufficient to establish inherency. *Mentor*, 244 F.3d at 1376. Defendants have not come close to establishing the inherency of the "substantially unnoticeable when worn" limitation.

Neither Defendants nor Dr. Gaffar have provided any evidence to establish that this limitation is necessarily present in Schiraldi. Dr. Gaffar states with no evidence in support that "it was very common to find such films in a 'substantially transparent' form." (Doc. 90-10 at ¶ 24). Even assuming this to be true, it has nothing to do with whether Schiraldi inherently discloses a delivery system that is substantially unnoticeable when worn. A probability or possibility that Schiraldi's film may be transparent is not enough to establish inherency. *Mentor*, 244 F.3d at 1376. Further, Dr. Gaffar has

previously admitted that Schiraldi does not disclose the "substantially unnoticeable when worn" limitation, either expressly or inherently. (Doc. 98 at 159).

"Without Permanent Deformation"

Finally, with respect to the "permanent deformation" limitation of claim 1 of the '017 Patent, Dr. Gaffar provides the following statements: "Additionally, this two layer film is different than the prior putty-like substances that permanently deformed to the shape of the wearer's teeth. Thus, the film described in Schiraldi did not exhibit 'permanent deformation' as that term has been construed by this Court." (Doc. 90-10 at ¶ 23). Similarly, in their Motion, Defendants state "Schiraldi describes his system as using a thin film strip that 'has very little or no mouthfeel' and which adheres to the tissue and teeth so as to be unobtrusive. Thus, in contrast to the prior art putty and trays, Schiraldi was thin and flexible and took the shape of the teeth without permanently conforming to the shape of the teeth." (Doc. 90 at 17).

Neither Defendants nor Dr. Gaffar provide any explanation of these statements, nor do they provide any citations to the Schiraldi patent, or to anything else. Nor do Defendants provide any explanation as to what relevance the "mouthfeel" of Schiraldi's film has to whether or not it exhibits permanent deformation. Schiraldi does not disclose a strip that is readily conformable to tooth surfaces and to interstitial tooth spaces without permanently conforming to the shape of the teeth. (Doc. 92-3 at ¶ 213).

Schiraldi does not disclose a system that is "substantially unnoticeable when worn," or a strip that has "a flexural stiffness less than about 50 grams/centimeter as measured on a Handle- O-Meter per ASTM test method D2923-95," or that is "readily

conformable without permanent deformation to a shape of a tooth and its adjoining soft tissue when said delivery system is placed thereagainst[.]" (Doc. 92-1 at 21). Consequently, Schiraldi does not anticipate claim 1 of the '017 Patent.

ii. Claim 2

Claim 2 of the '017 Patent is dependent on claim 1 and requires that the oral care substance be a gel. (Doc. 92-1 at 21). The Court has construed the term gel to mean "a material ranging from near-liquid to near-solid that resists flow in the steady state[.]" (Doc. No. 71 at 18-20). Dr. Gaffar provides two arguments with respect to this claim.

Dr. Gaffar states, without any explanation, that "the bioadhesive layer of Schiraldi, adhering to wet mucosal surfaces as a gel, would suggest adhesive substances that are gels for use in oral care delivery devices." (Doc. 90-10 at ¶ 28). This statement does not make sense. Moreover, the portion of Schiraldi to which Dr. Gaffar refers says nothing about a gel. (Doc. 93-2 at ¶ 216). Dr. Gaffar also states that, in his opinion, the definition of "gel" adopted by the Court does nothing to clarify the meaning of the term, but he concludes that the definition is "extremely broad" and that it "must include the substance described by Schiraldi." (*Id.* at ¶ 28 and n.26). Dr. Gaffar provides no support or explanation for these conclusions, nor does he even try to apply the Court's construction of the term "gel" to Schiraldi.

Defendants make the same unsupported and conclusory arguments in their Motion, which are insufficient to establish that Schiraldi discloses an oral care substance that is a gel. (Doc. 90 at 40). Schiraldi does not disclose an oral care substance that is a

gel as the Court has defined that term. (Doc. 93-2 at ¶ 218). Schiraldi does not anticipate claim 2.

iii. Claim 3

Claim 3 is dependent on claim 1 and requires that the oral care substance be a substantially uniform continuous coating on the strip of material. (Doc. 92-1 at 21). Dr. Gaffar provides a single sentence with respect to claim 3: "Claim [3] is also met by Schiraldi, in which the extruded layers are of the same width and layered one on the other." (Doc. 90-10 at ¶ 29). Defendants make the same argument in their Motion. (Doc. 90 at 40).

Neither Defendants nor Dr. Gaffar provides any explanation as to how Schiraldi discloses an oral care substance that is a substantially uniform continuous coating. Defendants and Dr. Gaffar do not explain how "extruded layers [] of the same width and layered one on the other" necessarily discloses a substantially uniform continuous coating. Whether or not the layers of Schiraldi are of the same width and layered on each other does not mean that Schiraldi discloses a substantially uniform continuous coating. (Doc. 93-2 at ¶ 220). As an example, layers could be applied intermittently (as in a striped or dotted pattern) or irregularly across a consistent width, producing a non-uniform and non-continuous coating. Schiraldi does not disclose a system with an oral care substance that is a substantially uniform continuous coating on a strip of material. (Doc. 93-2 at ¶ 221). Schiraldi does not anticipate claim 3, and Defendants have failed to meet their burden of proffering sufficient evidence to try the allegation that this claim is invalid.

iv. Claim 7

Claim 7 is dependent on claim 1 and requires that the strip of material has a length sufficient to cover a plurality of adjacent teeth while conforming to the curvature of the wearer's mouth and gaps between said plurality of adjacent teeth. (Doc. 92-1 at 21). Defendants state that claim 7 "re-introduces the 'plurality of adjacent teeth' limitation that was present in Claim 1 of the '453 Patent." (Doc. 90 at 40). While claim 1 of the '453 Patent does include a limitation relating to a "plurality of adjacent teeth[,]" claim 7 of the '017 Patent contains other limitations as well, and Defendants and Dr. Gaffar do not address any of them. Schiraldi does not disclose anything about a film that has a sufficient flexibility to form a curved shape on a plurality of adjacent teeth. (Doc. 93-2 at ¶ 223). Nor does Schiraldi disclose a film that is readily conformable to gaps between the teeth. (*Id*.) Neither Defendants nor Dr. Gaffar provides any explanation as to how or where these limitations are disclosed.

Schiraldi does not disclose a film that has a length sufficient to cover a plurality of adjacent teeth while conforming to the curvature of the wearer's mouth and gaps between said plurality of adjacent teeth. (*Id*. at ¶ 224). Schiraldi does not anticipate claim 7.

b. Saffir

Defendants argue that Saffir anticipates claims 1-3 and 7 of the '017 Patent. Defendants have attached as Exhibit 28 to their Motion a claim chart comparing claims 1-3 and 7 of the '017 Patent with Saffir. (Doc. No. 90-7 at 6-10). However, Defendants' claim chart contains mostly conclusory statements, and contains only limited citations to the Saffir patent. While Dr. Gaffar's Declaration contains some citations to the Saffir

patent, it often does not reference the specific claim language. (Doc. No. 90-10 at ¶¶ 101-105). Further, Dr. Gaffar does not mention claim 3 in his declaration.

i. Claim 1

"Flexural Stiffness"

Claim 1 of the '017 Patent requires that a strip of material "having a flexural stiffness less than about 50 grams/centimeter as measured on a Handle-O-Meter per ASTM test method D2923-95." (Doc. 92-1 at 21). As previously established, Saffir does not disclose the Handle-O-Meter limitations of the '017 Patent.

"Conformable, Without Permanent Deformation"

Further, independent claim 1 of the '017 Patent requires a strip of flexible material that is "readily conformable without permanent deformation to a shape of a tooth and its adjoining soft tissue[.]" (Doc. 92-1 at 21). Saffir does not disclose a strip that is conformable to the shape of the tooth or its adjoining soft tissue, as required by claim 1 of the '017 Patent. (Doc. 93-2 at ¶ 234). Defendants do not reference these limitations in their Motion. In their claim chart at Exhibit 28, Defendants rely entirely on figures 1-3 and 5 of the Saffir patent to argue that the Saffir film is conformable to the surfaces of the teeth and the adjoining soft tissue. (Doc. No. 90-7 at 7-8). However, none of the figures of Saffir disclose a strip that is readily conformable to the shape of a tooth and its adjoining soft tissue. (Doc. 93-2 at ¶ 234). In fact, all of the figures of Saffir show only the crown and root of a tooth, and they do not show any soft tissue. (Doc. 92-9 at 297; Doc. 93-2 at ¶ 234).

Claim 1 of the ’017 Patent also requires that the strip of material is readily conformable “without permanent deformation to a shape of a tooth and its adjoining soft tissue[.]” (Doc. 92-1 at 21). The Court has construed “without permanent deformation” to mean “without permanently conforming to the shape of the teeth[.]” (Doc. 71 at 6-8). Defendants and Dr. Gaffar appear to rely on their arguments relating to the ’453 Patent for this limitation. The only additional support that Defendants provide for their position that Saffir discloses this limitation is a single conclusory statement in their claim chart: “The ‘scotch tape’ type of material used by Saffir does not exhibit permanent deformation.” (Doc. 90-7 at 7).

Defendants provide no explanation for this statement, and they provide no citation to Saffir. Further, Defendants do not explain what the physical properties of “scotch tape type” products might be. Nor do they explain what the properties of a Scotch tape of 1958 might have been or how those properties might differ from a Scotch tape product in 1997. (Doc. 93-2 at ¶ 237). Even further, Saffir notes only that the film “physically resembles” Scotch tape. (Doc. 92-9 at 298). As such, there is no way to know what kind of physical properties the Saffir film might have. (Doc. 93-2 at ¶ 237). This single, unsupported conclusory statement is insufficient to establish that Saffir discloses this limitation.

Saffir does not disclose a strip of material “having a flexural stiffness less than about 50 grams/centimeter as measured on a Handle-O-Meter per ASTM test method D2923-95” or a strip that is “readily conformable without permanent deformation to a

shape of a tooth and its adjoining soft tissue[.]" (Doc. 92-1 at 21). Saffir does not anticipate claim 1 of the '017 Patent, and Defendants have not evidenced otherwise.

ii. Claim 2

Claim 2 is dependent on claim 1 and requires that the oral care substance be a gel. (Doc. 92-1 at 21). The Court has construed the term gel to mean "a material ranging from near-liquid to near-solid that resists flow in the steady state[.]" (Doc. 71 at 18-20). Defendants provide a single conclusory argument with respect to this claim.

Defendants state, without any explanation, that "[t]he medicated adhesive of Saffir is normally tacky and pressure-sensitive so that it secures good adherence of itself and the backing film to surfaces upon which it is pressed in use. This describes a gel as construed by the court." (Doc. 90 at 42). Dr. Gaffar makes a similar argument. (Doc. 90-10 at ¶ 104). First, the portion of Saffir to which Dr. Gaffar refers says nothing about a gel. (Doc. 93-2 at ¶ 240). Second, while Defendants and Dr. Gaffar reference the Court's claim construction, they provide no support or explanation for their conclusion that "this describes a gel." Nor do they even try to apply the Court's construction of the term "gel" to Saffir.

Notably, Defendants do not allege that Saffir anticipates claim 6 of the '453 Patent, which also requires that the tooth whitening substance be a gel. Saffir does not disclose an oral care substance that is a gel. (Doc. 93-2 at ¶ 241). Saffir does not anticipate claim 2 of the '017 Patent.

iii. Claim 3

Claim 3 is dependent on claim 1 and requires that the oral care substance be a substantially uniform continuous coating on the strip of material. (Doc. 92-1 at 21). Defendants provide a single conclusory sentence with respect to claim 3: "Saffir teaches that the medicated adhesive is coated on the backing layer and it is [sic] substantially uniform continuous coating on the backing layer." (Doc. 90 at 43). Defendants do not provide any support, citation or explanation for their conclusion. Dr. Gaffar does not mention claim 3 in his Declaration. Defendants do not allege that Saffir anticipates claim 7 of the '453 Patent, which also requires that the tooth whitening substance be a substantially uniform continuous coating. Saffir does not anticipate claim 3 of the '017 Patent. (Doc. 93-2 at ¶ 242). Defendants have failed to meet their burden of proffering sufficient evidence to try the allegation that this claim is invalid.

iv. Claim 7

Claim 7 is dependent on claim 1 and requires that the strip of material has a length sufficient to cover "a plurality of adjacent teeth while conforming to the curvature of the wearer's mouth and gaps between said plurality of adjacent teeth." (Doc. 92-1 at 21). Saffir does not disclose a film that is applicable to a plurality of adjacent teeth. (Doc. 93-2 at ¶ 243). Every discussion and every figure of Saffir discloses application of a film to a single tooth or to an isolated portion of a single tooth. (*Id*.) Saffir does not suggest to a POSA that the film could or should be used on a plurality of adjacent teeth. (*Id*.) Dr. Gaffar concedes that Saffir "does not explicitly address this use." (Doc. 90-10 at ¶ 34).

This admission is fatal to Defendants' position that Saffir anticipates claim 7 of the '017 Patent.

Dr. Gaffar provides only a single argument: "the length of the Saffir tape is sufficient to wrap completely around a single tooth as shown in Fig. 5. Thus, it is necessarily long enough and flexible enough to cover multiple adjacent teeth." (Doc. 90-10 at ¶ 105). Defendants also state, relying only on Dr. Gaffar, that "[t]he nature of the Saffir device means that it is capable of being conformed to multiple adjacent teeth." (Doc. 90 at 43). The film shown in Figure 5 of Saffir does not even cover the entire length of the tooth from gumline to incisal (i.e., cutting) edge. (Doc. 92-9 at 297). Even if such a film were extended to multiple teeth, it would only treat a limited strip-shaped portion of each tooth. (Doc. 93-2 at ¶ 245). Moreover, Saffir makes no mention at all of a strip that conforms to the gaps between the teeth. (*Id*.) This is not surprising, because Saffir is directed to the treatment of a single tooth or of a specific area of a single tooth.

Further, Defendants and Dr. Gaffar are mischaracterizing the "nature" of the Saffir device. (*Id*. at ¶ 246). Saffir was specifically designed for spot treatments of specific portions of a tooth, or for a single tooth. (*Id*.) While Saffir does mention in one place that it could be used for spot-treating a stain on a portion of a single tooth, a POSA would recognize and understand that Saffir was not designed for the type of broader-scale tooth treatment disclosed and claimed in the Patents-in-Suit. (*Id*.)

In contrast, Saffir actually discloses several reasons why one of ordinary skill in the art would not extend it to a plurality of adjacent teeth. (*Id*. at ¶ 247). Saffir teaches away from a patch being placed across multiple teeth and coming in contact with the

adjoining soft tissue, because a stated object of Saffir is "limiting medication to only a given spot or area so that the danger of a strong drug's spreading where it is not needed and can cause irritation, is eliminated." (Doc. 92-9 at 298). Saffir further states: "This device contemplates sealing the medicament against the tooth by means of a thin sheath of cellulosic film or the like, one surface of which has been coated with a medicated adhesive." (*Id.*) A POSA reading Saffir would recognize that applying the single-tooth product of Saffir to a plurality of adjacent teeth would severely compromise Saffir's stated goal of sealing a medicament against a tooth. (Doc. 93-2 at ¶ 247). A POSA would not be motivated to modify the Saffir single-tooth system as Dr. Gaffar contends. (*Id.*) Saffir does not anticipate claim 7 of the '017 Patent.

For all of the above reasons, Saffir does not anticipate claims 1-3 or 7 of the '017 Patent, and neither Defendants nor Dr. Gaffar has come forward with sufficient evidence to try the allegation that it does.

c. Schiraldi/Gaglio

Defendants argue that it would be obvious to combine Schiraldi and Gaglio, and that this combination renders obvious claims 1 and 7 of the '017 Patent. Defendants have attached as Exhibit 29 to their Motion a claim chart comparing claims 1 and 7 of the '017 Patent with the combination of Schiraldi and Gaglio. (Doc. 90-7 at 11-15). Defendants' claim chart contains mostly conclusory statements, and contains only limited citations to the Schiraldi and Gaglio patents.

Defendants simply provide a blanket statement that to the extent any teachings of the claim limitations are missing from Schiraldi, they are obvious in light of Gaglio.

(Doc. 90 at 44). Defendants do not explain (1) which limitations of the claims that he believes Gaglio allegedly teaches or which limitations may be missing from Schiraldi, (2) how those references might be combined, or (3) why a POSA would have been motivated to make that combination.

Dr. Gaffar has provided the following blanket statement regarding the motivation to combine Schiraldi with Gaglio:

> To the extent that any of the elements of the asserted claims of the '017 Patent are not found in Schiraldi, those elements are supplied by other publications which were available to a person of ordinary skill in the art. A person of ordinary skill in the art would have been motivated to combine these references with the Schiraldi patent because each of the references deals with methods and products for delivery of medicaments, tooth whitening substances, and other compositions to the surface of the teeth. One such prior art reference is Gaglio.

(Doc. 90-10 at ¶¶ 106-107).

Even assuming that Schiraldi and Gaglio are in the same or related fields, this is not sufficient to establish the necessary motivation to combine the references. *KSR*, 550 U.S. at 418. Additionally, a POSA would not have been motivated to combine Schiraldi and Gaglio, because there is nothing in the disclosure of Schiraldi, which is directed to the treatment of oral mucosa, that would have motivated a POSA to modify the Schiraldi device for the purpose of whitening a plurality of teeth. (Doc. 93-2 at ¶ 258). The combination of Schiraldi and Gaglio does not render obvious claims 1 or 7 of the '017 Patent.

i. Claim 1

Dr. Gaffar does not rely on Gaglio as disclosing any of the elements of claim 1, and the Court has already established that Schiraldi does not anticipate claim 1.

ii. Claim 7

Claim 7 is dependent on claim 1 and requires that the strip of material "has a length sufficient to cover a plurality of adjacent teeth while conforming to the curvature of the wearer's mouth and gaps between said plurality of adjacent teeth." (Doc. 92-1 at 21). Defendants rely solely on Figures 6-8 of Gaglio as allegedly disclosing this limitation. (Doc. 90-4 at 4).

Even if these Figures are sufficient to show a device that has a length sufficient to cover a plurality of adjacent teeth, they do not disclose a film that is readily conformable to gaps between the plurality of adjacent teeth. Aside from a single conclusory statement in Exhibit 29, Defendants do not provide any explanation as to how or where Gaglio discloses this limitation. (Doc. 90-7 at 3). Indeed, Gaglio does not disclose this limitation. (Doc. 93-2 at ¶ 262).

Figures 6-8 of Gaglio all show a device that does not conform to the entire tooth surface or to the gaps between the teeth. (Doc. 90-4 at 4). The device of Figure 6 forms a hemispherical shape, contacting only the outermost surfaces of the teeth. (Doc. 93-2 at ¶ 263). Figures 7-8 show that the device does not conform to the gaps between the teeth and the gums. (*Id*.) This can be contrasted with Figures 6 and 8 of the '017 Patent, which show a strip that conforms to the gaps between the teeth. (*Id*.) The combination

of Schiraldi and Gaglio does not anticipate claim 7 of the ’017 Patent, and Defendants have not carried their burden to prove otherwise.

For all of the reasons above, a POSA would not have been motivated to combine Schiraldi and Gaglio; and even if one was so motivated, the combination of Schiraldi and Gaglio does not render obvious claims 1 or 7 of the ’017 Patent, and neither Defendants nor Dr. Gaffar has come forward with sufficient evidence to try the allegation that it does.

d. Saffir/Gaglio

Defendants argue that it would be obvious to combine Saffir and Gaglio, and that this combination renders obvious claims 1 and 7 of the ’017 Patent. Defendants have attached as Exhibit 30 to their Motion a claim chart comparing claims 1 and 7 of the ’017 Patent with the combination of Saffir and Gaglio. (Doc. 90-7 at 16-19). Defendants’ claim chart contains mostly conclusory statements, and contains only limited citations to the Saffir and Gaglio patents. (*Id*.) Further, Dr. Gaffar’s Declaration relating to this combination does not provide any citations to the Saffir or Gaglio patents, and does not mention claim 1. (Doc. 90-10 at ¶¶ 108-109).

Defendants apply their same general statement about motivation to combine to the proposed combination of Saffir and Gaglio, *i.e.*, that there would be motivation to combine the references, because the references are in the same or related fields. (Doc. 90 at 44-45). Even assuming that Saffir and Gaglio are in the same or related fields, this is not sufficient to establish the necessary motivation to combine the references. *KSR*, 550 U.S. at 418. Further, a POSA would not have been motivated to combine Saffir and Gaglio because there is nothing in the disclosure of Saffir which is directed to the focal

treatment of localized defects in a tooth or a portion of a tooth, that would have motivated a POSA to modify the Saffir device for the purpose of whitening a plurality of teeth. (Doc. 93-2 at ¶ 269). Finally, as explained above, the age of the Saffir reference is strong evidence that the challenged claims are not obvious based on the combination of Saffir and Gaglio. The combination of Saffir and Gaglio does not render obvious claims 1, 7-8 or 12 of the '017 Patent.

Although Defendants include claims 1 and 7 in their claim chart at Exhibit 30, a review of Defendants' Motion and chart reveals that Defendants appear to be relying on Gaglio only with respect to claim 7. (Doc. 90-7 at 16-19). The Court has already explained the claim limitations that Saffir does not disclose.

i. Claim 1

Defendants do not rely on Gaglio as disclosing any of the elements of claim 1, and the Court has already established that Saffir does not anticipate claim 1.

ii. Claim 7

Claim 7 is dependent on claim 1 and requires that the strip of material "has a length sufficient to cover a plurality of adjacent teeth while conforming to the curvature of the wearer's mouth and gaps between said plurality of adjacent teeth." (Doc. 92-1 at 21). Defendants rely solely on Figures 6-8 of Gaglio as allegedly disclosing this limitation. (Doc. 90-4 at 4). Even if these Figures are sufficient to show a device that has a length sufficient to cover a plurality of adjacent teeth, they do not disclose a film that is readily conformable to gaps between the plurality of adjacent teeth. Aside from a single conclusory statement in Exhibit 30, Defendants do not provide any explanation as

to how or where Gaglio discloses this limitation. (Doc. 90-7 at 18). Indeed, Gaglio does not disclose this limitation. (Doc. 93-2 at ¶ 273).

Figures 6-8 of Gaglio all show a device that does not conform to the entire tooth surface or to the gaps between the teeth. (Doc. 93-2 at ¶ 274). The device of Figure 6 forms a hemispherical shape, contacting only the outermost surfaces of the teeth. (*Id*.) Figures 7-8 show that the device does not conform to the gaps between the teeth and the gums. (*Id*.) This can be contrasted with Figures 6 and 8 of the ’017 Patent, which show a strip that conforms to the gaps between the teeth. (Doc. 92-1 at 17). The combination of Saffir and Gaglio does not render obvious claim 7 of the ’017 Patent.

For all of the reasons above, a POSA would not have been motivated to combine Saffir and Gaglio; and even if one was so motivated, the combination of Saffir and Gaglio does not render obvious claims 1 or 7 of the ’017 Patent, and neither Defendants nor Dr. Gaffar has come forward with sufficient evidence to try the allegation that it does.

e. Fischer/Shapiro

Defendants argue that it would be obvious to combine Fischer and Shapiro, and that this combination renders obvious claims 1-3 and 7 of the ’017 Patent. As established above, under either of the Federal Circuit tests, Shapiro is non-analogous art and thus cannot be used as a basis in an alleged obviousness combination for any claims of the Patents-in-Suit.

3. The ’199 Patent

i. Priority of the ’199 Patent

The ’199 Patent claims priority, through a series of continuations and continuations-in-part, to U.S. Patent Application No. 08/870,330 (“the ’330 application”), now U.S. Patent No. 5,879,691 (“the ’691 patent”), which was filed on June 6, 1997. (Doc. 98 at 5-11). Defendants argue that the ’199 Patent is entitled to a priority date no earlier than March 15, 1999. (Doc. 90 at 4-7).

“The test for sufficiency of support in a parent application is whether the disclosure of the application relied upon ‘reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter.’” *Martek Biosciences Corp. v. Nutrinova, Inc.*, 579 F.3d 1363, 1369 (Fed. Cir. 2009) (quoting *Ralston Purina Co. v. Far-Mar-Co, Inc*., 772 F.2d 1570, 1575 (Fed. Cir. 1985)). “In other words, ‘the earlier application need not describe the claimed subject matter in precisely the same terms as found in the claims at issue.’” *Id*. (quoting *Tech. Licensing Corp. v. Videotek, Inc*., 545 F.3d 1316, 1331 (Fed. Cir. 2008)).

Although Defendants assert that none of the challenged claims are supported by the ’330 application, Defendants’ argument relies entirely on their incorrect assertion that there is no written description support for “Step B” for the method claimed in independent claim 17 of the ’199 Patent: “b) folding a second portion of the strip of material and tooth bleaching composition about the incisal edges of the plurality of adjacent teeth[.]” (Doc. 92-1 at 35). Defendants argue that “the ‘folding’ limitation was first disclosed by the inventors no earlier than March 15, 1999.” (Doc. 90 at 7).

However, a priority claim may be supported by any part of the specification, including the drawings. *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1565 (Fed. Cir. 1991) ("under proper circumstances, drawings alone may provide a 'written description' of an invention as required by § 112"); *Cooper Cameron Corp. v. Kvaerner Oilfield Prods., Inc*., 291 F.3d 1317, 1322 (Fed. Cir. 2002) ("Drawings constitute an adequate description if they describe what is claimed and convey to those of skill in the art that the patentee actually invented what is claimed"). Claim 17 of the '199 Patent is fully supported by the specification of the '330 application, including the drawings. Figures 7 and 8 of the '330 application show a strip contacting the front, incisal edges, and back of a row of teeth. (Doc. 98 at 6).

Defendants' argument rests entirely on the fact that Plaintiff filed a continuation-in-part application that elaborated on the "folding" limitation first disclosed in the '330 application. However, whether or not an applicant provides a more detailed description of a limitation in a later-filed application is not the test for whether that limitation was sufficiently disclosed in the parent specification. All that is required is that the '330 application "reasonably conveys to the artisan that the inventor had possession" of the claimed invention. *Martek*, 579 F.3d at 1369 (citation omitted). A skilled artisan would reasonably understand that the specification and figures of the '330 application disclose the steps of claim 17, including Step B.

Moreover, the PTAB rejected the same argument Defendants make here in the *inter partes* review case, IPR2013-00450. There, the PTAB explained that the figures of the '330 application properly disclose all of the limitations of claim 17:

> Although the ’691 patent does not state expressly that the strip was applied to the front, folded over, and applied to the back, Clio does not identify any reasonable way in which a flat strip of material (see Ex. 1004, Figs. 1-3 for initial flat configuration) could arrive in the position illustrated by Figures 7 and 8, other than by applying it to the front or back of the teeth, folding it over the incisal edge, and applying it to the other of the front and back of the teeth. Although Clio points out, correctly, that an express discussion of applying to the front, folding over, and applying to the back was first added in the March 15, 1999 filing, Clio has not explained how Figures 7 and 8 in the ’691 patent fail to provide adequate description for the relevant steps of claim 17. *See Vas- Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1565 (Fed. Cir. 1991) (drawings may provide written description).

(Doc. 98 at 55). The PTAB concluded that it was “not persuaded of a reasonable likelihood that claim 17 is not entitled to the benefit of the ’691 patent.” (*Id.* at 56). Accordingly, each of the challenged claims of the ’199 Patent is entitled to a priority date of June 6, 1997.

ii. Invalidity

Defendants argue solely that it would have been obvious to combine either Suzuki, Fisher, and Shapiro, or solely Fisher and Shapiro, and that these combinations render obvious claims 17, 20, 23-26, and 28-30 of the ’199 Patent. As a preliminary matter, Suzuki is not prior art to the ’199 Patent, and the Board rejected Clio’s argument that claim 17 is not entitled to the benefit of the filing date of the ’691 patent. (Doc. 98 at 56). Even more to the point and as established above, under either of the Federal Circuit tests, Shapiro is non-analogous art and thus cannot be used as a basis in an alleged obviousness combination for any claims of the Patents-in-Suit.

2. Secondary Considerations of Non-Obviousness

The Federal Circuit has made clear that evidence of secondary considerations must be considered in determining whether a patent is obvious. *Apple Inc. v. Int'l Trade Comm'n*, 725 F.3d 1356, 1365 (Fed. Cir. 2013). Evidence of secondary considerations is significant when there is a nexus between the claimed invention and the secondary considerations. *Rambus Inc. v. Rea*, 731 F.3d 1248, 1256 (Fed. Cir. 2013). A nexus is presumed "where 'the marketed product embodies the claimed features, and is coextensive with them.'" *Muniauction, Inc. v. Thomson Corp*., 532 F.3d 1318, 1328 (Fed. Cir. 2008) (citation omitted).

Plaintiff has evidenced that a POSA would not have been motivated to combine any of the references that Defendants rely on, and that even if the references were combined, the combination would not result in the claimed invention. Secondary considerations, such as the commercial success and industry praise of Plaintiff's Crest Whitestrips® products and the long-felt need that Plaintiff met, further establish that the asserted claims of the Patents-in-Suit would not have been obvious to a POSA at the time of the invention.

a. Commercial Success

The commercial success of a product that embodies the invention may be considered as evidence that the claimed invention would not have been obvious to a POSA at the time of the invention. *Leo Pharm*., 726 F.3d at 1358. Plaintiff's Crest Whitestrips® products embody the claims of the '453 Patent. (Doc. 93-3; Doc. 93-2 at ¶¶ 356, 364-370). Plaintiff's Crest Whitestrips® products have achieved approximately

$3 billion in net sales since their launch in 2000. (Doc. 93-5 at ¶ 4). This level of sales is remarkably significant and constitutes a commercially successful product line. Indeed, Plaintiff's Crest Whitestrips® products created an entirely new market for over-the-counter, at-home tooth whitening. The commercial success of the Plaintiff's Crest Whitestrips® products is due to the claimed features of the Patents-in-Suit, such as being substantially unnoticeable when worn, being thin and flexible and readily conformable to the curvature of the teeth and the spaces between the teeth, and providing a substance that both delivers an active to the teeth and provides the adhesive attachment to the teeth. (Doc. 93-2 at ¶ 356).

b. Industry Praise

Industry praise for a product also may be considered as evidence that the claimed invention would not have been obvious to a POSA at the time of the invention. *Apple*, 725 F.3d at 1366. Plaintiff's Crest Whitestrips® products have received numerous awards as well as substantial industry accolades. (Doc. 92-7 at 104-32). Further, Plaintiff's Crest Whitestrips® was named one of the top ten products of the decade (2000-2010). (*Id.* at 127-32). Paul Sagel, who was the lead inventor of the '453 Patent, was awarded the SCI Gordon E. Moore Medal for his work relating to Plaintiff's Crest Whitestrips® products. (*Id.* at 133-34).

This industry praise given to the Plaintiff's Crest Whitestrips® products, which embody the claims of the Patents-in-Suit, is due to the claimed features of the Patents-in-Suit, such as being substantially unnoticeable when worn, being thin and flexible and readily conformable to the surfaces of the teeth and the spaces between the teeth, and

providing a substance that both delivers an active to the teeth and provides the adhesive attachment to the teeth. (Doc. 93-2 at ¶ 359).

c. Long-Felt But Unmet Need

The fact that the claimed invention filled a long-felt but unmet need for a product is also considered evidence that the claimed invention would not have been obvious to a POSA at the time of the invention. *Leo Pharm.*, 726 F.3d at 1359.

When Paul Sagel and his team invented Crest Whitestrips®, the predominant at-home tooth bleaching option was a pre-formed dental tray that a patient obtained from the dentist, filled with a tooth bleaching material and wore at home. This dental-tray method of tooth bleaching, however, had a number of undesirable characteristics. (Doc. 93-2 at ¶ 361). For example, it was comparatively expensive and time consuming, it required elastomeric impressions for tray fabrication, multiple trips to the dentist, and it could be uncomfortable. (*Id*.) Tray bleaching also required a substantial amount of tooth bleaching material, the volume of which was difficult to control, and often resulted in unwanted side effects (such as tooth sensitivity, tissue irritation, and occasional sore throat). (*Id*.) Despite significant undesirable characteristics, this method was the most prevalent tooth whitening option for more than a decade before Plaintiff launched its Crest Whitestrips® product. (*Id*.)

There is no question that before the invention of Crest Whitestrips®, there was a long-felt but unmet need for an inexpensive, at-home tooth whitening system that would be non-bulky, easily conformable to the wearer's teeth, and that could potentially be worn during normal daily activity without being readily apparent to others. (*Id*. at ¶ 362).

Plaintiff's Crest Whitestrips® products, which embody the claims of the Patents-in-Suit, met this long-felt but unmet industry need. (*Id*.) By embodying the features claimed in the Patents-in-Suit, Plaintiff's Crest Whitestrips® represented a significant improvement over traditional tooth whitening approaches, not only because they virtually eliminated many of the aforementioned problems of tray bleaching, but also because they worked well for their intended purpose and were widely accepted by consumers and dental practitioners alike.

As demonstrated above, Defendants have failed to meet their burden of proffering clear and convincing evidence, sufficient to try the issues whether any of claims 1-3, 6-9, 11, 18, and 21 of the '453 Patent, claims 1-3 and 7 of the '017 Patent, or claims 17, 20, 23-26, and 28-30 of the '199 Patent are invalid.

V. CONCLUSION

Accordingly, based on the foregoing, Plaintiff's Motion for Partial Summary Judgment of No Invalidity (Doc. 88) is hereby **GRANTED**, and Defendants' Motion for Summary Judgment of Invalidity (Doc. 90) is hereby **DENIED**.

IT IS SO ORDERED.

Date: 7/3/14

/s/ Timothy S. Black
Timothy S. Black
United States District Judge