United States District Court,
S.D. New York.

MEDTECH PRODUCTS, INC,
Plaintiff.
v.
RANIR, LLC, and CVS Pharmacy, Inc,
Defendant.
Medtech Products, Inc,
Plaintiff.
v.
Dentek Oral Care, Inc,
Defendant.
Medtech Products, Inc,
Plaintiff.
v.
Power Products, Inc,
Defendant.

No. 07 CV 3302(KMK)(LMS)

Oct. 12, 2007.

REPORT & RECOMMENDATION

LISA MARGARET SMITH**, United States Chief Magistrate Judge.**

TO: THE HONORABLE KENNETH M. KARAS, UNITED STATES DISTRICT JUDGE

Plaintiff Medtech Products, Inc. ("Medtech") brings this consolidated action pursuant to 35 U.S.C. s. 271, 15 U.S.C. s.s. 1116-1118, 1125(a), 17 U.S.C. s. 101, et seq. , New York General Business Law s.s. 349(h) and 360-O, and New York common law against DenTek Oral Care, Inc. ("DenTek"), Kelly M. Kaplan ("Kaplan"), Ray Duane ("Duane"), C.D.S. Associates, Inc. ("CDS") and Power Products, Inc ("Power Products"). FN1 In its Second Amended Complaint ("Second Amended Complaint"), Plaintiff claims that Defendants DenTek, Kaplan, Duane, and CDS engaged in unfair competition, breach of contract, tortious interference with contractual relations, civil conspiracy, trade secret misappropriation, tortious interference with an advantageous business relationship, and patent, trademark, and copyright infringement.

FN1. On June 25, 2007, Medtech, Ranir, and CVS Pharmacy signed a voluntary stipulation of dismissal pursuant to Rule 41(a). *See* Docket entry 36. As of the date of this Report and Recommendation the case against Power Products, Inc. remains open.

This case was referred to me for all purposes on April 24, 2007. On July 13, 2007, Medtech and DenTek filed claim construction statements for the disputed claim ("Claim 17") of the patent at issue in Medtech's patent infringement claim, and on July 20, 2007, the parties filed responses to each other's construction statements. On September 5, 2007, a *Markman* hearing was held in the matter. The remaining defendants did not submit claim construction briefs and did not participate in the *Markman* hearing. The following Report and Recommendation addresses the five disputed phrases of Claim 17.

I. BACKGROUND

A. *Summary of Relevant Facts*

Medtech markets, distributes, and sells an over-the-counter ("OTC") dental device called The Doctor's (R) Nightguard ("the Nightguard") throughout the United States. Second Amended Complaint at para. 1. The device is designed to protect the teeth and jaw from the detrimental affects of grinding, or bruxing, and clenching teeth. *Id*. at para. 2. Although Medtech's predecessor in interest, Dental Concepts LLC ("Dental Concepts"), had been selling the Nightguard since 1997, Dental Concepts obtained U.S. Patent No. 6, 830, 051 ("the 051 Patent") entitled "Interocclusal Appliance," in 2004 to cover a new version of the Nightguard and its improved technology. *Id*. at para.para. 47, 58-59. In the specification of the 051 Patent, Dental Concepts explained that the patented device and technology sought to overcome problems with previous self-fitting devices such as improper fitting, premature appliance wear, and dissolution of the structural integrity of the device resulting from the shear forces generated by bruxing and clenching. DenTek's Exhibit A at Col. 1: 44-62. The device essentially consists of two components that are bonded together-a bottom layer, called a base, that is molded into the shape of a maxillary dentition and a top layer, called an impression preform, that is molded over the base. *Id*. at Col. 1: 65-68; 2: 1-25. According to the 051 Patent, the impression preform softens when placed in hot water so that the user may "self-fit" the device to his or her bite. *Id*. at Col. 2: 30-35. After the device cools, the impression preform hardens and the device becomes "a reusable resilient flexible encasement for the maxillary dentition...." *Id*. at Col. 2:31-32.

Medtech alleges that in mid-March 2007, DenTek brought an OTC dental device to the market called the DenTek Nightguard, which infringes on its 051 Patent. Second Amended Complaint at para.para. 6, 193. Specifically, Medtech alleges that DenTek's Nightgaurd has characteristics that infringe on Claim 17 of the 051 Patent. Medtech's Claim Construction Brief at page 3. Claim 17 states:

17. A method of fabricating an interocclusal appliance for alleviation of the adverse effects of bruxing or clenching events, the method comprising the steps of:

a) molding and [sic] appliance base from a resin having a Vicat softening temperature of at least 70 (deg.) C. and a Shore A hardness of at least 80; and

b) molding over the base an impression preform from a resin comprising an ethylene vinyl acetate copolymer having approximately 30% by weight vinyl acetate.

DenTek's Exhibit A at Col. 12: 47-56. According to Medtech, testing of Dentek's Nightguard revealed that its device "has an appliance base molded from a resin having a Vicat softening temperature of 87 (deg.) C (/5 (deg.) C), and a Shore A hardness of 87.4 (/2.3), with an impression preform molded over the base, the impression preform comprising an ethylene vinyl acetate copolymer having 34.3% by weight vinyl acetate." Medtech's Claim Construction Brief at 3. DenTek maintains that its device does not infringe on the 051 Patent. DenTek's Answer at para.para. 50-55.

II. DISCUSSION

A. *Standard of Review for Claim Construction*

"It has long been understood that a patent must describe the exact scope of an invention and its manufacture to 'secure to [the patentee] all to which he [or she] is entitled [and] to appraise the public of what is still open to them.' " Markman v. Westview Instruments, 517 U.S. 370, 373 (1996) (quoting McClain v. Ortmayer, 141 U.S. 419, 424 (1891)). These two objectives are achieved through the two distinct elements of a patent document-the specification and the claims. *Id*. Pursuant to 35 U.S.C. s. 112,

[t]he specification shall include a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his [or her] invention.

35 U.S.C. s. 112. Furthermore, 35 U.S.C. s. 112, paragraph 2, states that "[t]he specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his [or her] invention." *Id*.

"Victory in an infringement suit requires a finding that the patent claim 'covers the alleged infringer's product or process,' which in turn necessitates a determination of 'what the words in the claim mean.' " Markman, 517 U.S. at 374. Such a determination is a question of law for the judge, not a question of fact for the jury. Id. at 388-391. Although "there is no magic formula or catechism for conducting claim construction ... [and] the sequence of steps used by the judge in consulting various sources is not important[,] ... the court [is required] to attach the appropriate weight to be assigned to those sources in light of the statutes and policies that inform patent law." Phillips v. AWH Corp., 415 F.3d 1303, 1324 (Fed.Cir.2005). Under the statutes and policies that inform patent law, intrinsic evidence, which includes the language of the disputed claims themselves, other claims, the specification, and the prosecution history, must be given the most weight. *See* id. at 1313. Indeed, the claims of the patent are " 'of primary importance [ ] in the effort to ascertain precisely what it is that is patented.' " Id. at 1312 (quoting Merrill v. Yeomans, 94 U.S. 568, 540 (1876)). In considering the language of the claims, the words of the claims should be given their ordinary and customary meaning; in other words, they are to be given "the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application." Id. at 1313.

Additionally, because "the person of ordinary skill in the art is deemed to read the claim ... in the context of the entire patent ... [,]" the court should do likewise by considering the language of other claims, the specification, and the prosecution history. *Id*. The way a term is used in one claim can provide enlightenment as to its meaning in another claim and differences among claims can indicate differences in their meaning and scope. *Id*. at 1314. Additionally, the specification is " '[t]he best source for understanding a technical term....' " *Id*. at 1315 (quoting Multiform Desiccants v. Medzam Ltd., 133 F.3d 1473, 1478 (Fed.Cir.1998)). By statute, the specification provides a written description of the invention and can serve as a sort of dictionary in which the inventor either explicitly or impliedly defines the terms he or she has used. Id. at 1316. The specification may also include "an intentional disclaimer, or disavowal, or claim scope...." *Id*. The inventor's use of the specification as a dictionary or a source of disclaimers is dispositive of the construction of the claim. *Id*. Furthermore, the prosecution history, which "consists of the complete record of the proceedings before the [Patent Trademark Office] and includes the prior art cited during the

examination of the patent[,]" provides evidence of "how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it otherwise would be." *Id*. at 1317.

In addition to intrinsic evidence, the court may further consider extrinsic evidence consisting of expert testimony, inventor testimony, learned treatises, and dictionaries, but such evidence is " 'less significant than the intrinsic record' " in determining the meaning of claim language. *Id*. (quoting C.R. Bard, Inc. v.. U.S. Surgical Corp., 388 F.3d 858, 862 (Fed.Cir.2004)). Expert testimony can assist the court by providing background on the technology at issue and an explanation of how an invention works and the technical aspects of the patent. Id. at 1318. However, because expert testimony is prepared for the purposes of litigation and can suffer from bias, the court should "discount any expert testimony 'that is clearly at odds with the claim construction mandated by the claims themselves, the written description, and the prosecution history....' " *Id*. (quoting Key Pharms. v. Hercon Labs. Corp., 161 F.3d 709, 716 (Fed.Cir.1998)). Additionally, "conclusory, unsupported assertions by experts as to the definition of a claim term are not useful to a court." *Id*. Likewise, although dictionaries and learned treatises can be useful in determining the ordinary meaning of the words of a claim, they were not written or edited to be used for interpreting the meaning of patents and thus " 'cannot overcome art-specific evidence of the meaning' of a claim term." Id. at 1322 (quoting Vanderlande Indus. Nederland BV v. I.T.C., 366 F.3d 1311, 1321 (Fed.Cir.2004)).

Finally, it should be noted that " 'claims may not be construed with reference to the accused device.' " Wilson Sporting Goods Co. v. Hillerich & Bradsby Co., 442 F.3d 1322, 1330 (Fed.Cir.2006) (quoting Neomagic Corp. v. Trident Microsystems, Inc., 287 F.3d 1062, 1074 (Fed.Cir.2002); SRI Int'l v. Matsushita Elec. Corp. of Am., 775 F.2d 1107, 1118 (Fed.Cir.1985)). Thus, the comparison between the patented device and the allegedly infringing product may provide the parameters and scope of the infringement analysis, including the claim construction component, but is otherwise irrelevant to claim construction and should not be used to bias the claim construction. *Id*.

B. ***Analysis of the Disputed Claim***

In the course of their exchange of claim construction briefs, the parties stipulated to the meaning of the following phrases and terms in Claim 17: "molding and [sic] appliance base," "having a Vicat softening temperature," "of at least 70 (deg.) C," "a Shore A hardness," "of at least 80," "an ethylene vinyl acetate copolymer," "bruxing," and "clenching." Medtech's Reply Brief at pages 3-4. Specifically, the parties agreed that "molding and [sic] appliance base" means "the step of forming or shaping the bottom support or layer of the appliance by molding," that "having a Vicat softening temperature" means "a temperature at which a flat-needle penetrates a specimen of the resin to the depth of 1 mm under a specific load when the resin is heated," that "of at least 70 (deg.) C" means "a temperature of 70 (deg.) C or more," that "a Shore A hardness" means "a measurement of the extent of indentation by the action of a Shore A durometer," that "of at least 80" means "a Shore A hardness of 80 or more," that "an ethylene vinyl acetate copolymer" means "copolymers of vinyl acetate and ethylene," that "bruxing" means "grinding of the teeth," and that "clenching" means "clenching teeth tightly." *Id*. However, the parties dispute the meaning of the following five terms: "interocclusal appliance," "a resin," "molding over the base," "an impression preform," "having approximately 30% by weight vinyl acetate." *Id*. at 4.

After reading the briefs of the parties, reviewing the evidence submitted by each side, and listening to the parties' arguments and expert testimony at the *Markman* hearing, I conclude, and respectfully recommend that Your Honor should conclude, that the intrinsic evidence consisting of the claims and the specification

and the extrinsic evidence consisting of the dictionary references are sufficient to determine the meaning of the disputed terms and phrases in Claim 17. Neither of the experts presented by the parties were experts in the fabrication of dental appliances, which is what the Court deems to be the relevant art in question. Rather, the experts presented by the parties were chemical engineers qualified only to offer testimony about the materials used to fabricate the appliance-the resins. Although the experts provided the Court with background information on the materials science of resins and the types of resins commercially available, I deem the intrinsic evidence sufficient to construe the term "a resin," as addressed further *infra*. Additionally, I conclude, and respectfully recommend the Your Honor should conclude, that the prosecution history of the patent provides no insight into the construction of Claim 17. The examiner's reasons for allowance, which are included in the prosecution history, are limited to the structure of the device, and are therefore irrelevant to the construction of Claim 17, which is focused on the fabrication of the device. Thus, by reviewing only the claim itself, the other claims, the specification, and dictionary definitions, I have construed the following disputed claims.

1. Interocclusal Appliance

DenTek proposes that "interocclusal appliance" should be defined as "a device that prevents full occlusion of all teeth." DenTek's Reply at page 5. Although Medtech argues that the phrase "interocclusal appliance" is part of the preamble of the claim and therefore does not need to be defined, Medtech proposes that if the Court determines that a definition is necessary, the term should be defined as "an appliance that is used or fitted, in whole or in part, between the portions of the upper and lower teeth." Medtech's Brief at page 4. During the *Markman* hearing, the arguments of the parties established that the source of contention in the construction of this term is whether or not "interocclusal appliance" should be construed to mean a device that must cover, or encompass, all of the user's teeth; the parties do not dispute that the device is fitted or placed between the upper and lower teeth.

DenTek argues that the intrinsic evidence supports the conclusion that the device must encompass all of the user's teeth because the device is described in the patent as shaped to match the user's teeth. DenTek's Brief at page 14. DenTek cites the description of the preferred embodiments, which states that "the appliance 10 includes a lower base 12 having a plan configuration in the general shape of a maxillary dental arch." *Id*. DenTek also cites Academic Press Dictionary of Science and Technology for the definition of "interocclusal"-"situated between the occlusal surfaces of opposing teeth"-and "occlusal surfaces"-"any of the incising and masticating surfaces of the upper and lower teeth." FN2 *Id*. at page 13. Medtech argues that there is no support in the patent for requiring that the device cover, or encompass, all of the user's teeth. Medtech's Brief at page 11. Medtech points out that the specification states that the device's purpose is to prevent loss of "tooth structure" not "all teeth structure." Medtech's Reply at page 6.

FN2. Although the dictionary cited by DenTek defines "interocclusal" as "situated between the occlusal surfaces of opposing teeth," the dictionary does not define "occlusal surfaces," but instead defines "occlusion" as "any contact between the incising or masticating surfaces of the upper and lower teeth." DenTek's Exhibit B.

As an initial matter, I conclude, and respectfully recommend that Your Honor should conclude, that because the entire patent sets out to define the patented "interocclusal appliance" and every claim in the 051 patent includes in its preamble the same phrase-"the interocclusal appliance for the alleviation of the adverse effects of bruxing or clenching events ..." (*see generally* Cols. 11 and 12), the phrase "interocclusal

appliance" in Claim 17 need not be specifically construed. The meaning of "interocclusal appliance" is sufficiently defined by the words following the phrase-"for the alleviation of the adverse effects of bruxing or clenching events"-as well as the entire patent.

However, should Your Honor deem it necessary to define the term "interocclusal appliance," I conclude, and respectfully recommend that Your Honor should conclude, that the phrase should be construed as "a device that is placed between some or all of the occlusal surfaces of the teeth." Although DenTek argues that such a construction should also include a reference to the fact that all of the teeth are encased or covered by the appliance, the evidence does not support DenTek's construction. There is no reference in Claim 17, or in the entire patent for that matter, to a requirement that the device cover all of the teeth in order to achieve the purposes that the patented device sets out to achieve. Indeed, although the device is described in the specification as "having a plan configuration in the general shape of a maxillary dental arch" (Col.3:61-63), DenTek's expert admitted that the device might not cover all of the teeth of a person with a very large mouth and that the device could be trimmed to fit a person with a very small mouth. Additionally, DenTek's expert admitted that the device does not have a back wall that would prohibit teeth from "hanging out the back." Accordingly, I conclude, and respectfully recommend that Your Honor should conclude, that there is no support either in the intrinsic evidence or in the extrinsic evidence for inserting the limitation that the device must cover all of the user's teeth into the construction of the term "interocclusal appliance" in Claim 17.

2. A Resin

The term "resin" is used twice in Claim 17-once to describe the fabrication of the base and once to describe the fabrication of the impression preform. DenTek's Exhibit A at Col. 12: 47-56. The parties do not dispute that the term should be interpreted consistently. DenTek's Brief at page 16; Medtech's Brief at pages 14, 18. DenTek proposes that "a resin" should be defined as "a synthetic organic compound consisting of a noncrystalline solid or viscous liquid substance." DenTek's Brief at page 16. In its initial brief, Medtech offered the following compromise definition: "any number of organic or synthetic solid or semi-solid substances or compounds, which may include thermoplastic or thermosetting materials." Medtech's Brief at page 15. DenTek was prepared to accept Medtech's compromise definition; however, Medtech offered a different definition in its reply brief. DenTek's Reply at page 5 n. 1. In its reply brief, Medtech asserts that "a resin" should be defined as "any of a number of natural or synthetic substances and compounds that are solid or semi-solid after molding and may be thermoplastic or thermosetting." Medtech's Reply at page 8. At the *Markman* hearing, the arguments of the parties established that the dispute between the parties with regard to the construction of "a resin" centers on whether or not the term should be limited by the words "natural," "organic," and/or "synthetic."

DenTek argues that the term "a resin" should be limited to synthetic organic compounds because the compounds described in the summary of the invention and the abstract as suitable for making the device are all synthetic organic compounds. DenTek's Brief at pages 16-17; *see also* DenTek Exhibit A at Abstract; Col. 2:36-41; Col. 5:13-19. Medtech argues that DenTek's construction improperly limits the definition of "a resin" as it is used in Claim 17 and asserts that such limitations are inconsistent with the ordinary meaning of "a resin" and with the intrinsic record. Medtech's Brief at page 13. Specifically, Medtech points out that no specific type of resin is identified as required in the patent and that although the resins listed in the abstract and the specification are synthetic organic compounds, the specification states that they are "merely exemplary and various other and alternate thermoplastic resins may be selected for use in accordance with the invention." *Id.; see also* Col. 10: 29-33. Additionally, Medtech asserts that the American Heritage College Dictionary definition of "resin" includes natural and synthetic compounds. *Id.* at

14 (citing Medtech's Exhibit I).

I conclude and respectfully recommend that Your Honor should conclude, that "a resin," as it is used in Claim 17, should be construed as "a thermoplastic solid or semi-solid substance." Although DenTek argues that "a resin" should be limited to "synthetic organic" substances, and both parties are willing to include the word "thermosetting" in the definition, I find that the word "thermoplastic" is the only appropriate limitation on the type of resin required to fabricate the device that is supported by the intrinsic record. As Medtech points out, there is no evidence in the patent that the selected resin must be organic, natural, and/or synthetic, and the synthetic resins that are named in the patent as suitable are also described as merely exemplary. DenTek's Exhibit A at Col. 10:29-33. Furthermore, several well known dictionaries include in their definitions of "resin" the words "organic," "natural," and "synthetic." *See* Heritage Illustrated Dictionary of the English Language 1106 (1979); Webster's II New Riverside University Dictionary 1000 (1994); Dictionary.com Unabridged, *available at* http:// www.dictionary.reference.com/browse/resin (last visited Sept. 20, 2007). Additionally, the word "thermosetting" is not mentioned anywhere in the patent. Thus, because the patent does not specify whether the resin must be organic, natural, and/or synthetic, and does not mention that the resins can be thermosetting resins as opposed to thermoplastic resins, I conclude and respectfully recommend that Your Honor should conclude, that the term "a resin" in Claim 17 should not be limited to organic, natural, and/or synthetic compounds or to thermosetting compounds.

The word "thermoplastic," however, is used either in place of or to modify the word "resin" numerous times throughout the patent and there is no indication anywhere in the patent that the invention can be created with something other than a thermoplastic resin.FN3 *See* DenTek's Exhibit A at Abstract, sentences 1 and 2; Col. 2:1, 26, 36-38; Col. 4:59-60, 64; Col. 4: 7, 10, 41; Col. 6:34; Col. 7: 20; Col. 8: 7; Col. 9:54; Col. 10: 30-31; Col. 11: 37-48. Furthermore, the references to a "thermoplastic" or a "thermoplastic resin" are consistent with the description of the "self-fitting" process described by the patent. Specifically, the patent explains that the impression preform must be heated in hot water so that it softens sufficiently to allow the user to bite down on the device and that, when cooled, the device will form a "reusable flexible encasement for the maxillary dentition." *Id*. at Col. 2: 32. Thus, by referring to the resin as a "thermoplastic" or a "thermoplastic resin" and by describing the self-fitting process, I conclude, and respectfully recommend that Your Honor should conclude, that the inventor impliedly defined the term "a resin," as it is used in Claim 17 and throughout the patent, as a thermoplastic material and that such a limitation is therefore appropriately incorporated into the construction of "a resin" in Claim 17.

FN3. The American Heritage Science Dictionary's defines "thermoplastic" as "of or relating to a compound that can be repeatedly made soft and hard through heating and cooling ...." and "thermosetting" as "[r]elating to a compound that softens when initially heated, but hardens permanently once it has cooled...." American Heritage Science Dictionary, Results for Resin, *available at* http:// www.dictionary.reference.com/browse/resin.

3. Molding Over the Base

DenTek asserts that "molding over the base" should be defined as "contacting a heated resin with the entire upper surface of the appliance base." DenTek Brief at page 19. Although Medtech initially asserted that the phrase should be construed as "a step of molding over the base," Medtech offered the following compromise definition: "the step of forming the impression preform of the appliance into a shape on top of the appliance base." Medtech Brief at page 17. The focus of the dispute between the parties with regard to "molding over

the base" is whether Claim 17 is intended to describe an impression preform that covers the entire surface of the base rather than just part of the base. Medtech Brief at page 17.

DenTek argues that the patent itself reveals the inventor's intention that the impression preform be molded over the entire surface of the base including the horizontal surfaces of the side walls. Specifically, DenTek points to the summary of the invention which states that the impression preform is "molded into the base between and above the side walls." DenTek's Brief at page 20. DenTek also points to the description of the preferred embodiments which states, "The upper surface of the base and the opposed inner surfaces of the side walls, all of which are bonded to the impression preform when the preform is molded over the base...." *Id*. at page 20. Additionally, DenTek points to the examiner's reasons for allowance which states that "the impression material has a pilot channel having a generally planar face and a pair of space [sic] peripheral walls ... [and] a footing having a height extending from the opposite face of the base to the face of the pilot channel, the height of the footing being at least twice the distance between the occlusal face of the base and the opposite face of the base." DenTek's Exhibit D at page 55. DenTek argues that the statement in the examiner's reasons supports its construction because the "pair of spaced peripheral walls is formed only because the impression preform material completely covers the base and is molded over the walls over the base." *Id*. at page 21.

DenTek also argues that the stated purpose of the invention-to provide a strong bond between the impression preform and the base to improve the durability of the device-supports its construction. *Id*. at page 20. Specifically, DenTek argues that because the strength of the bond between the impression preform and the base increases when the surface area of the base covered by the impression preform increases, and the strength of the bond is emphasized throughout the patent, "molding over the base" should be read to mean that the impression preform is molded over the entire surface of the base, including the horizontal surfaces of the side walls, so that the strongest bond possible is achieved. *Id*. Finally, DenTek argues that the definitions provided in Webster's Third New International Dictionary of the English Language for "molding" and "over," as they are used in Claim 17, support its construction because "molding" is defined as "to fit the contours of" and "over" is defined as "so as to cover, conceal or affect the whole surface or expanse." DenTek's Brief at page 21; DenTek's Exhibit C.

Medtech argues that DenTek's definition of "molding over the base" imposes improper limitations on the phrase. Medtech's Brief at page 17. Medtech argues that there is no basis in the patent for including the requirement that the impression preform cover the entire surface of the base including the horizontal surfaces of the side walls. *Id.;* Medtech's Reply at page 9. Medtech also argues that the examiner's reasons for allowance provide no support for DenTek's construction because the reasons do not address whether the impression preform covers the entire surface of the base. Medtech's Reply at page 11. Furthermore, at the *Markman* hearing Medtech argued that DenTek has offered no evidence to support their argument that the entire surface must be covered by the impression preform in order to achieve the strong bond described in the patent. *Id*. at page 10.

After reviewing the evidence submitted by the parties, I conclude, and respectfully recommend that Your Honor should conclude, that the term "molding over the base" should be construed to mean "the step of injecting a thermoplastic resin, the characteristics of which are further defined in 17(b), into an occlusal mold cavity into which the base described in 17(a) has been placed so that the thermoplastic resin becomes an impression preform that covers the space between the side walls of the base, the inner surfaces of the side walls, and the space above and on top of the horizontal surfaces of the side walls of the base." Such a definition is supported by the intrinsic evidence. First, the parties have stipulated that "molding an appliance

base ..." in 17(a) describes "the step of" fabricating the base. Medtech's Reply at page 3. Accordingly, 17(b) describes the next "step" in the fabrication of the device. Second, the parties discussed the process of injection molding with the Court at the *Markman* hearing and the preferred embodiments describe using injection molding to mold the impression preform over the base. DenTek's Exhibit A at Cols. 6: 45-46; 7: 31-32; 8: 17; 9: 9, 52, 65. Accordingly, incorporating the process of injecting the impression preform resin into a mold that already contains the base into the definition of "molding over the base" is appropriate. Third, as discussed *supra,* the inventor impliedly defined "a resin" as a thermoplastic material, making the incorporation of the term "thermoplastic" also appropriate. Finally, the requirement that the impression preform cover the space between the side walls of the base, the inner surfaces of the side walls, as well as the space above and on top of the horizontal surfaces of the side walls of the base is supported by the intrinsic record. Specifically, the summary of the invention states that the impression preform is to be "[m]olded into the base between and above the side walls." *Id*. at Col. 2:3-4. Additionally, each of the figures depicting the impression preform and the base in the patent show an impression preform extending above and on top of the horizontal side walls of the base. *See id*. at Figures 1, 4, 5, and 7. Although the embodiments are meant to be exemplary, these illustrations, together with the description in the specification indicating that the impression preform is to extend "above the side walls" establishes that the inventor intended that the impression preform cover the entire base including the space above and on top of the horizontal side walls of the base.FN4

FN4. It should be noted, however, that I do not base my conclusion on DenTek's argument that in order to create the bond required by the patent, the entire surface of the base must be covered by the impression preform. The patent states that the "surface ... of the base over which the impression preform resin is molded may include a coating of a bonding agent or priming material or may be textured to augment the bond, all within the context of the present invention." DenTek's Exhibit A at Col 10: 45-50. The construction I have recommended to Your Honor does not limit the creation of the bond to simply "contacting a heated resin with the entire upper surface of the base," but instead leaves open the possibility that the unitary bond that is formed between the impression preform and the base may be achieved by any one or more of the following: heating the resin, coating the base with a bonding agent or priming material, or texturing the surface of the base, as envisioned by the inventor.

4. An Impression Preform

DenTek initially proposed that "an impression preform" should be construed as "a hardened resin structure containing a channel with curving sides and a flat bottom, and a footing that extends from a horizontal upper surface of the base to the channel face." DenTek's Brief at page 22. However, during the *Markman* hearing, DenTek amended its construction to "a hardened but softenable resin structure containing a channel with curving sides and a flat bottom, and a footing that extends from a horizontal upper surface of the base to the channel face." Medtech asserts that "an impression preform" should be defined as "a formable material overlying the base." Medtech's Brief at page 17. Thus, the focus of the dispute between the parties is whether the phrase "an impression preform" as it is used in Claim 17 encompasses the structural description of the impression preform as it is stated in Claims 1 and 13.

DenTek argues that the intrinsic evidence supports construing the "impression preform" to include the structural description of the impression preform. DenTek's Brief at page 22. Specifically, DenTek cites the examiner's reasons for allowance located in the prosecution history which, as discussed at the *Markman* hearing, directly incorporates language contained in Claim 13. DenTek's Brief at page 22; DenTek's Exhibit

A at Col. 12:15-30. The examiner's reasons for allowance state that "[t]he prior art does not disclose or suggest in [sic] interocclusal appliance having a base that has a plan configuration of a dental arch and a generally planar occlusal face, impression material bonded to the base, the impression material has a pilot channel having a generally planar face and a pair of space [sic] peripheral walls, the impression material has a footing having a height extending from the opposite face of the base to the face of the pilot channel, the height of the footing being at least twice the distance between the occlusal face of the base and the opposite face of the base." DenTek's Exhibit D at page 55. Claims 1 and 13 of the patent include similar language. DenTek's Exhibit A at Col. 11: 3-18.

Medtech argues that DenTek's construction improperly imports limitations from Claims 1 and 13 into Claim 17. Medtech's Brief at page 18. Specifically, Medtech argues that Claim 17 is an independent claim because it does not reference any other claims in its text. *Id*. Medtech argues that as an independent claim, Claim 17 has a different scope than Claims 1 and 13. *Id*. Namely, Medtech argues that Claim 17 addresses the fabrication of the device, while Claims 1 and 13 address the structure of the device. *Id.;* Medtech's Reply at page 12.

I conclude and respectfully recommend that Your Honor should conclude, that the phrase "an impression preform" should be construed to mean "a thermoplastic resin which serves as an impression material consistent with the remainder of the requirements in Claim 17." This construction is consistent with the intrinsic evidence. As explained *supra,* the patent teaches that the impression preform is made out of a thermoplastic resin. Additionally, there is no indication that Claim 17 was meant to incorporate the structural description of the impression preform as it is stated in Claims 1 and 13, and there is no indication that Claim 17 was meant to be dependent on Claims 1 and 13. Indeed, unlike Claims 2, 4, 6, 7, 8, 9, 10, 11, 12, 14, 15 and 16, which incorporate Claims 1 or 13 by stating "as constructed in accordance with claim 1 [or 13] ...," Claim 17 does not mention any other claim. This difference between the claims is significant because "the presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim." Phillips, 415 F.3d at 1315. Accordingly, the fact that Claims 1 and 13 are referenced in other claims and are not referenced in Claim 17 gives rise to the presumption that the limitations-the structural descriptions-included in Claims 1 and 13 were not intended to be present in Claim 17. Thus, I conclude, and respectfully recommend that Your Honor should conclude, that there is no need to incorporate the impression preform's structural description into Claim 17, and I further conclude, and respectfully recommend that Your Honor should conclude, that the description further defining the impression preform by its chemical makeup in Claim 17(b) is sufficient to convey what the inventor intended to mean when it used the term "an impression preform" in Claim 17.

5. Having Approximately 30% by Weight Vinyl Acetate

DenTek asserts that "having approximately 30% by weight vinyl acetate" should be construed as "having at least 25.0% by weight vinyl acetate but not more than 33.0% by weight vinyl acetate." DenTek's Brief at page 24. DenTek argues that construing "approximately 30%" to mean a specific range prevents ambiguity that "runs contrary to the notice function of claims and would render the Claim invalid under the second paragraph of 35 U.S.C. s. 112." *Id*. at page 25. DenTek further argues that the range it has chosen-25-33%-is supported by the intrinsic evidence. *Id*. at page 24. Specifically, DenTek argues that the patent sets the floor vinyl acetate content at 25% by stating that "[s]uitable resins for employment as the impression preform include an ethylene vinyl acetate (EVA) copolymer available from the Du Pont under the trademark ELVAX(R) having a vinyl acetate content of at least 25%." DenTek's Reply at page 9; *see also* DenTek's Exhibit A at Col. 5: 13-16. DenTek also argues that the patent sets the ceiling for vinyl acetate content at

33% by stating that "[a] preferred EVA copolymer is ELVAX(R) 150 having a 33% vinyl acetate content by weight...." DenTek's Reply at pages 9-10; *see also* DenTek's Exhibit A at Col. 5: 16-19.FN5

FN5. DenTek also argued that the only available copolymers that satisfy the requirements of the patent are within the range that they propose. This argument is based, however, on extrinsic evidence and need not be addressed here.

Medtech initially asserted that the phrase "having approximately 30% by weight vinyl acetate" should be defined as "the resin has approximately 30% by weight vinyl acetate," but subsequently offered the following compromise definition: "having about, roughly, or around 30% by weight vinyl acetate." Medtech's Brief at page 20. Medtech argues that there is no support in Claim 17 or the specification that would support DenTek's proposed range, that DenTek improperly relies on the preferred embodiments of the patent as support for the proposed range, and that no range needs to be read into the claim because the term "approximately" has been upheld by other courts as not too ambiguous. *Id*. at pages 20-21; Medtech's Reply at pages 14-15.

I conclude, and respectfully recommend that Your Honor should conclude, that "having approximately 30% by weight vinyl acetate" should be construed as Medtech suggests in its compromise definition-"having about, roughly, or around 30% by weight vinyl acetate." Although the preferred embodiments include the language cited by DenTek immediately preceding the examples of the invention (DenTek's Exhibit A at Col. 5: 13-18), such language does not support importing DenTek's range limitation, or any limitation, from the specification into Claim 17. Indeed, the language cited by DenTek states that suitable resins "include" a particular copolymer with a vinyl acetate content of at least 25%, not that suitable resins "must be" copolymers with vinyl acetate contents of at least 25%. *Id*. Furthermore, the patent suggests a copolymer with a vinyl acetate content of 33% only as "a preferred" copolymer, and does not indicate that a vinyl acetate content of 33% is the highest content that can be used to make the patented invention. *Id*.

Additionally, the specification explicitly disclaims using the examples to place limitations on the characteristics of the thermoplastic resins used to make the device by stating that "[i]t should be appreciated that the foregoing is merely exemplary and various other and alternate thermoplastic resins may be selected for use in accordance with the invention." DenTek's Exhibit A at Col. 10: 29-32. The specification goes on to state the necessary characteristics of the "selected" resins-that the resin must have a suitable softening temperature that will not create temperature discomfort or damage to oral tissue, that substantial deformation will not occur during fitting and prolonged usage, and that the resin is well-suited to withstand the high shear and compression forces generated during bruxing and clenching events. *Id*. at Col. 10: 32-40. Such language indicates that the reader may "select" from a variety of resins having the required characteristics, not that the reader must select a resin with a vinyl acetate content of at least 25% but not more than 33% with the required characteristics. Accordingly, I find no support in the intrinsic evidence for incorporating DenTek's range, or any other range, of vinyl acetate content into Claim 17.

Furthermore, I conclude, and respectfully recommend that Your Honor should conclude, that the phrase "approximately 30%," or Medtech's construction of "about, roughly or around 30%," are not so ambiguous as to be in violation of the requirements of s. 112. At the *Markman* hearing, DenTek's expert testified that ethylene vinyl acetate copolymers are commercially available from Dupont at percentages of 25, 28, 32, and 40 percent by weight vinyl acetate. DenTek's expert testified that in his opinion 25, 28, and 32 percent by weight vinyl acetate, as well as any other percentage between 32 and 35 percent, if made commercially

available, would that the phrase "approximately 30%," or Medtech's construction of "about, roughly or around 30%," are not so ambiguous as to be in violation of the requirements of s. 112. At the *Markman* hearing, DenTek's expert testified that ethylene vinyl acetate copolymers are commercially available from Dupont at percentages of 25, 28, 32, and 40 percent by weight vinyl acetate. DenTek's expert testified that in his opinion 25, 28, and 32 percent by weight vinyl acetate, as well as any other percentage between 32 and 35 percent, if made commercially available, would be "approximately 30%" by weight vinyl acetate. DenTek's expert also stated that 23 and 24 percent are numerically closer to 20 percent and therefore would not be "approximately 30%." Just as a person skilled in the art of resins is capable of determining from the commercially available resins which ones have vinyl acetate content numerically close to 30 percent and are therefore "approximately 30%" by weight vinyl acctate, so a jury is capable of determining from that set of numbers which of the numbers are approximately 30. Thus, I find, and respectfully recommend that Your Honor should find, that there is no reason to incorporate a specific defined range for vinyl acetate content in Claim 17.

III. CONCLUSION

For the foregoing reasons, I conclude, and respectfully recommend that Your Honor should conclude, that the disputed claim terms and phrases should be construed in the manner stated herein.

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