NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

T.F.H. PUBLICATIONS, INC.,	:	CIVIL ACTION NO. 11-3106 (MLC)
Plaintiff,	:	**MEMORANDUM OPINION**
v.	:	
3M COMPANY, et al.,	:	
Defendants.	:	

COOPER, District Judge

OUTLINE

PRELIMINARY STATEMENT

Plaintiff, T.F.H. Publications, Inc. ("Plaintiff") alleges infringement of two related patents directed to an edible dog chew. (Docket entry no. ("dkt.") 79, 2d Am. Compl.) The patents-in-suit are United States Patent No. 5,827,565 ("'565 patent") and United States Patent No. 6,126,978 ("'978 patent"). (Id., Exs. A & B.) Defendants, 3M Company ("3M") and Penford Products Co. ("Penford") (collectively, "Defendants") deny infringement and counterclaim for declaratory judgment of noninfringement and invalidity. (Dkt. 81, 82.)[1]

The Court filed an Order construing several patent terms soon after the claim construction hearing. (Dkt. 67.) This memorandum opinion addresses the two remaining

[1] The Second Amended Complaint, adding Penford as a defendant, was filed recently by leave of Court. (Dkt. 78, 79.) It refers to the two patents-in-suit as Exhibit A and Exhibit B attached (dkt. 79 at 3), but the exhibits were inadvertently omitted. Copies of the patents are attached as exhibits to the First Amended Complaint. (Dkt. 31, Exs. A & B.) We will cite the two patents simply by abbreviated patent numbers, rather than to a docket entry number.

patent terms in dispute: "a hardness-adjustable edible dog chew" and "a heat-expandable potato starch." (Dkt. 44, Joint Claim Construction & Prehearing Stmt., Ex. A, at 8-10, 16-18, 20-23.)

I. BACKGROUND

A. The '565 patent and '978 patent

The '565 patent and '978 patent are assigned to Plaintiff. The '565 patent, entitled "Process for Making an Edible Dog Chew," was issued to Glen S. Axelrod as inventor on October 27, 1998. The '978 patent, entitled "Edible Dog Chew," was issued to the same inventor as a continuation-in-part of the '565 patent on October 3, 2000. The '978 patent is subject to a terminal disclaimer linked to the '565 patent term. The specifications for the two patents are almost identical, with differences that we will discuss where pertinent.

The '565 patent, which is solely a method patent, has one independent claim and three dependent claims. Plaintiff has asserted infringement of claim 1 and claim 3 of that patent. (Dkt. 48 at 7.) Those claims read as follows:

> **1**. A method of producing a hardness-adjustable edible dog chew, comprising the steps of:
> extruding a mixture of a potato starch, water and calcium carbonate to form granules; and
> injection molding such mixture into the shape of the dog chew.
>
> **3**. The method of claim **1** further comprising the steps of adding to the mixture about 1-5% by weight natural vegetable additives and about 1-5% by weight of an attractant.

('565 patent, 4:1-16 (emphasis added).)

The ‘978 patent, which includes both method and product claims, has a total of sixteen claims, including seven independent claims. The asserted claims of the ‘978 patent are independent claims 4, 8, 14, and 16, and dependent claim 15. (Dkt. 48 at 7.)

Claim 4 is representative of the method claims of the ‘978 patent. It states:

> **4**. A method of producing a hardness-adjustable edible dog chew, comprising the steps in sequence of:
> extruding a mixture of a heat-expandable potato starch, water and calcium carbonate to form granules;
> adding a food coloring to such granules; and
> injection molding such ingredients into the shape of the dog chew.

(‘978 patent, 4:6-13 (emphasis added).)

Claim 16 is representative of the product claims of the ‘978 patent. It states:

> **16**. An improved edible dog chew comprising:
> an injection molded mixture of a heat-expandable potato starch, water, calcium carbonate and a breath sweetener.

(‘978 patent, 4:62-65 (emphasis added).)

B. Disputed Claim Terms

The term “hardness-adjustable dog chew” appears in the one independent claim of the ‘565 method patent (claim 1) and in each of the independent method claims of the ‘978 patent (claims 1, 4, 6, and 8). (‘565 patent, 4:1-7; ‘978 patent, 3:56-4:40.) This term does not appear in the asserted product claims of the ‘978 patent. (‘978 patent, 4:56-65.) The relevant text of each patent is quoted infra, nn. 20 and 25.

The term “a heat-expandable potato starch” does not appear in the ‘565 patent. Rather, the ‘565 patent claims “a potato starch.” (‘565 patent, 4:1-5.) Conversely, the term “a potato starch” does not appear in the ‘978 patent. Instead, the term “a heat-

expandable potato starch" appears in every independent claim of the '978 patent, both the method claims and the product claims (claims 1, 4, 6, 8, 10, 14, and 16.) ('978 patent, 3:56-4:65.)

Here we overlay the "Summary of the Invention" from the specifications for both patents. Language appearing in the '565 specification that was deleted from the '978 specification is shown in brackets. Changes or additions appearing in the '978 specification are in bold type:

> The present invention provides an edible dog chew that is completely digestible, nutritious, devoid of deleterious additives and of a modifiable texture or hardness that [is] **may be** quickly and easily tailorable by the owner to suit the need or preference of his particular dog. In addition, such edible dog chews have a long shelf life as compared to prior edible dog chews. The chews are biodegradable and extremely rugged so as to be able to withstand shocks resulting from shipping and handling. Upon removal from the chew's package, the chew can be caused to swell up to [6] **3** to 8 times its original volume, if desired, by subjecting it to microwave radiation. With this procedure, the chew's texture or hardness can be adjusted to any magnitude from its original high density extremely hard state to a low density expanded easily chewed state depending upon the amount of microwave exposure to which it is subjected. Accordingly, the chew can thereby be quickly and easily **adjusted**[2] to the texture preference of a wide variety of dogs from a strong large healthy dog to a small puppy with puppy teeth or an older dog with decayed molars.
>
> **The present invention also provides a dog chew having natural fruit flavor to increase a dog's appetite for such chew. Such fruit flavored dog chew may include natural food coloring to enhance the attractiveness of the dog chew to dog owners. The food coloring may correspond to the fruit flavor if desired.**

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[2] The word "adjusted" appears in the '978 patent specification, but is missing from the '565 specification. (Compare '565 patent, 2:1, with '978 patent, 2:4.) It is clear that the omission of the word "adjusted" in the '565 patent text at that location was a clerical error.

> **A dog chew of the present invention may also embody a breath sweetener for a dog such as mint, spearmint, peppermint or wintergreen and also include parsley.**
>
> Other features and advantages of the present invention will become apparent from the following detailed description taken into conjunction with the accompanying drawings which illustrate by way of example the principles of the invention.

('565 patent, 1:50-2:9; '978 patent, 1:54-2:22.)

It can be seen from reading this "Summary of the Invention" that it describes how a consumer could use the product in feeding the dog. However, none of that description appears in the claims of the patents-in-suit. Instead, the '565 patent describes a method for making the product, and the '978 patent elaborates on methods for making the product and also makes certain product ingredient claims. But how the product is supposed to be used and how it is supposed to perform is not in any of the claim language, except as referred to in the claim term "a hardness-adjustable edible dog chew," appearing in both patents. That is the focus of the parties' dispute about this claim term.

The opposing positions of the parties on construction of the term "a hardness-adjustable edible dog chew," in claim 1 of the '565 patent, are as follows:

> Plaintiff's Proposed Definition: "An edible dog chew possessing the capability of having its hardness adjusted, either in terms of becoming softer or harder." (Dkt. 44 at 8.)
>
> Defendants' Proposed Definition: "A dog chew that when microwaved will expand up to about 6 to 8 times the original volume with a commensurate reduction in hardness." (Id.)

The proposed definitions of the parties on construction of that same term, where it appears in the claims of the '978 patent, are identical except that Defendants substitute "3 to 8 times" in the latter definition. (Id. at 16.)[3]

The other disputed claim term is "a heat-expandable potato starch." As we have described above, this term is not in the '565 patent claims but only in the '978 patent claims. This disputed term in the '978 patent appears instead of the term "a potato starch," which was claimed in the '565 patent. It was introduced during prosecution of the '978 patent. See infra Sec. II.B.2.c.

We now similarly overlay the portion of the specifications for both patents addressing the potato starch ingredient. As above, language appearing in the '565 patent specification that was deleted from the '978 patent specification is shown in brackets. Changes or additions appearing in the '978 patent specification are in bold type:

> DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS
>
> The preferred form of edible dog chew of the present invention has as a basic ingredient, a **heat-expandable starch, such as a** potato starch product sold under the trademark PARAGON IM 1010 by AVEBE of Veendam, The Netherlands. The PARAGON product is sold in the form of thermoplastic granules**, beads or granules,** which are **manufactured by an extrusion process, and which are then** molded into a desired shape. The weight contents of such **extruded** pellets, **beads or granules** are about 70% potato starch, about 15% water (about 10% after the [pellets] **granules** are molded), about 5 to 10% calcium carbonate, and about 1 to 5% natural vegetable additives.

('565 patent, 2:19-30; '978 patent, 2:33-47.)

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[3] This reflects the corresponding change in the language of the specification for the '978 patent (quoted above). (Compare '565 patent, 1:50-2:9, with '978 patent, 1:54-2:22.) For claim construction purposes, the parties appear to regard that one numerical difference as immaterial. (Dkt. 48 at 8 n.1; dkt. 49 at 16.)

It is the meaning of the term "heat-expandable," when added to the term "a potato starch" in the '978 patent, that provides the focus of the parties' dispute about this claim limitation. The parties' opposing positions on construction of the term "a heat-expandable potato starch," in each claim where it appears in the '978 patent, are as follows:

> Plaintiff's Proposed Definition: "A potato starch that, when in presence of the other claimed ingredients, is capable of expansion upon being subjected to heat." (Dkt. 44 at 20.)
>
> Defendants' Proposed Definition: "Extruded granules that include potato starch, such that an injection molded chew formed from the granules will expand up to about 3 to 8 times the original volume when microwaved." (Id.)

We briefly describe, in the next Section, the pertinent procedural history and the proceedings and submissions on the claim construction issues in the case.

C. Parties' Claim Construction Submissions

The procedural history of this action to date is summarized in the margin.[4]

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[4] Plaintiff's original complaint was against defendant 3M and alleged infringement of the '978 patent only. (Dkt. 1 at 2-4.) The Amended Complaint against the same defendant alleged infringement of the '565 patent and '978 patent. (Dkt. 31 at 2-6.) It was on that basis that the parties prepared and filed their claim construction submissions. We conducted the Markman hearing on August 7, 2013, when the parties presented oral argument based upon their written submissions. (Dkt. 69.) After that hearing, we entered an Order on August 12, 2013, construing most of the disputed claim terms, and reserving decision on the two claim terms that are the subject of this memorandum opinion. (Dkt. 67.) We also requested a complete copy of the prosecution history of the '978 patent and an explanation of apparent discrepancies in that history, based upon our review of the original submissions. Plaintiff provided that material as requested. (Dkt. 68.) The parties also filed some supplemental submissions addressing their disputed definitions of a person of ordinary skill. (Dkt. 72, 73, 74.)

Plaintiff later requested and received leave of court to file the Second Amended Complaint. (Dkt. 78.) That pleading named Penford as an additional defendant, alleging that it

Proceeding pursuant to the Local Patent Rules of this District, the parties filed opening and responsive claim construction briefs and supplemental letter briefs (dkt. 48, 49, 55, 56, 72, 73, 74); a Joint Claim Construction and Prehearing Statement (dkt. 44); and declarations of counsel, attaching numerous exhibits including the prosecution histories of the two patents-in-suit (dkt. 48-1 to 48-6, 51, 55-1, 68-1 to 68-3).

The named inventor of both the '565 patent and '978 patent, Glen S. Axelrod, submitted a declaration on behalf of Plaintiff. (Dkt. 55-3, 65.) He was deposed, and portions of his deposition are also in the record. (Dkt. 51, Ex. 20.)

Plaintiff presented declarations by its scientific expert, Dr. Yen-Ping Chin Hsieh. (Dkt. 55-2, 72 at 2-4.) We requested and received from counsel a copy of Dr. Hsieh's complete deposition (not docketed).

Defendants presented a declaration by their scientific expert, Dr. Mrinal Bhattacharya. (Dkt. 50, 50-1 to 50-4.) The complete deposition of Dr. Bhattacharya is also in the record. (Dkt. 55-1, Ex. C.)[5]

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is the manufacturer of the accused products, which are distributed and sold as part of 3M's product lines. (Dkt. 79 at 3-4.) It made no substantive changes to the claims, and both Defendants are represented by the same counsel. (Dkt. 81, 82.) Thus, the addition of Penford as a defendant did not affect the claim construction phase of the case.

[5] Plaintiff moved in limine to exclude the testimony of Dr. Bhattacharya on grounds of lack of qualifications and net opinion. (Dkt. 63-1, 63-2.) 3M opposed that motion, adding that "if any expert is unqualified, it is TFH's expert, Dr. Hsieh. 3M reserves its Daubert rights should the case proceed to a jury trial." (Dkt. 64 at 1 n.1.) We considered that motion on the papers, and denied it at the claim construction hearing. (Dkt. 66, 69 at 3.) The qualifications and testimony of each expert are discussed infra, Section II.B.

This Court received oral argument at the claim construction hearing. (Dkt. 69.) Our claim construction rulings, as set forth in this memorandum opinion and in the prior Order construing other claim terms (dkt. 67), are based upon careful review of the documentary evidence and consideration of the arguments presented.

II. DISCUSSION

A. Legal Standard

A court must engage in claim construction to define the meaning and scope of patent claims, as it is a matter of law exclusively for a court. Markman v. Westview Instruments, 52 F.3d 967, 976, 979 (Fed.Cir. 1995), aff'd, 517 U.S. 370 (1996). A claim term receives its ordinary and customary meaning, which is the meaning that a "person of ordinary skill in the art" would give the term on the effective filing date of the patent application. Phillips v. AWH Corp., 415 F.3d 1303, 1313 (Fed.Cir. 2005); see NTP, Inc. v. Research In Motion, 392 F.3d 1336, 1346 (Fed.Cir. 2004).[6] A person of ordinary skill in the art is deemed to have read the claim terms in the context of the written description and the prosecution history. Phillips, 415 F.3d at 1313. Ordinary meaning may be derived from a variety of sources, including the claim language, the written description, drawings, prosecution history, dictionaries, and treatises. NTP, 392 F.3d at 1346.

A court looks first to the intrinsic evidence when construing claims. The focus here is on the language of the claims, "for it is that language that the patentee chose to use

[6] The effective filing date of the '565 patent is October 25, 1996. The '978 patent is a continuation-in-part, subject to a terminal disclaimer, and claims the same priority date as the '565 patent.

to 'particularly point[] out and distinctly claim[] the subject matter which the patentee regards as his invention.'" Interactive Gift Express v. Compuserve, Inc., 256 F.3d 1323, 1331 (Fed.Cir. 2001) (quoting 35 U.S.C. § 112). The intrinsic record includes the claims, specification, and complete prosecution history; it is the most significant source for the legally operative meaning of disputed claim language. Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1583 (Fed.Cir. 1996).

A court considers the context in which a term is used within both the claim at issue and claims not at issue. Phillips, 415 F.3d at 1314. A term appearing in different claims should be given the same meaning unless it is clear from the specification and prosecution history that the term at issue has a different meaning from claim to claim. Fin Control Sys. Pty v. OAM, Inc., 265 F.3d 1311, 1318 (Fed.Cir. 2001). Differences between claims are also useful in determining the proper construction of a term. Phillips, 415 F.3d at 1314. A dependent claim adding a limitation raises a presumption that the same limitation is not present in the independent claim. Id. at 1315.

The patent specification is relevant to claim construction and is the best guide to the meaning of a disputed term. Honeywell Int'l v. ITT Indus., 452 F.3d 1312, 1318 (Fed.Cir. 2006). But it is improper to read a limitation from the specification into the claims. Teleflex, Inc. v. Ficosa N. Am. Corp., 299 F.3d 1313, 1326 (Fed.Cir. 2002). A court should "not import limitations from a preferred embodiment" described in the specification. Seachange Int'l v. C-COR Inc., 413 F.3d 1361, 1377 (Fed.Cir. 2005). On

the other hand, "broad and vague statement[s] cannot contradict the clear statements in the specification describing the invention more narrowly." Honeywell Int'l, 452 F.3d at 1319. The court must interpret claim terms in light of the specification, which is "highly relevant" to claim construction and usually dispositive. Phillips, 415 F.3d at 1315.

A patent's prosecution history consists of the record of proceedings before the United States Patent & Trademark Office ("USPTO") and the prior art cited during the patent's examination. Phillips, 415 F.3d at 1317. Prosecution history "can often inform the meaning of the claim language by demonstrating 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 would otherwise be." Id. Nevertheless, because the prosecution history reflects the ongoing negotiations between the inventor and the USPTO, it is often less clear and less useful than the specification. Id.

A court may also consider extrinsic evidence, including "expert and inventor testimony, dictionaries, and learned treatises". Id. Such evidence generally is less reliable than intrinsic sources, but in some situations, ordinary meaning of claim language may involve nothing more than application of generally accepted meanings of commonly understood words. Id. at 1314, 1318. In such situations, general purpose dictionaries may be helpful. Id. at 1314. However, "heavy reliance on the dictionary divorced from the intrinsic evidence risks transforming the meaning of the claim term to the artisan into the meaning of the term in the abstract, out of its particular context, which is the

specification." Id. at 1321. For example, courts may "rely on dictionary definitions when construing claim terms, so long as the dictionary definition does not contradict any definition found in or ascertained by a reading of the patent documents." Id. at 1322 (quoting Vitronics, 90 F.3d at 1584 n.6). "A construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct definition." Renishaw PLC v. Marposs Societa' per Azioni, 158 F.3d 1243, 1250 (Fed.Cir. 1998).

B. Application

The Court applies the foregoing rules of claim construction as we proceed through the next portions of this memorandum opinion. This discussion also addresses additional legal principles as appropriate.

1. Definition of person of ordinary skill in the art

a. Statement of the issues

"A court construing a patent claim seeks to accord a claim the meaning it would have to a person of ordinary skill in the art at the time of the invention." Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc., 381 F.3d 1111, 1116 (Fed.Cir. 2004) (citations omitted). This is a statutory standard:

> By statute, the patent must provide a written description of the invention that will enable one of ordinary skill in the art to make and use it. 35 U.S.C. § 112, para. 1. Section 112, para. 2, also requires the applicant for a patent to

> conclude the specification with claims "particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention."

Markman, 52 F.3d at 978 (emphasis added).[7]

We encounter the same "person having ordinary skill in the art," when we apply the obviousness standard under 35 U.S.C. § 103(a), which provides in pertinent part:

> A patent may not be obtained ... 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) (emphasis added). See generally Graham v. John Deere Co., 383 U.S. 1, 17 (1966).

The parties strongly disagree as to the level of skill needed to be one of ordinary skill in the art of the patents-in-suit. (Dkt. 72, 73, 74.)

Plaintiff's position, as expressed by its expert, Dr. Hsieh, is as follows:

> It is my opinion that a person of ordinary skill in the art of the Patents in Suit, as of the date of the filing of those patents, would be a person with either: (1) a B.S. in Food Science and a minimum of ten years industry experience in food processing with an emphasis on starch-based formulations and extrusion at a production-level scale; or (2) a Ph.D. in a Food Science-related field and a minimum of five years industry experience in food processing with an emphasis on starch-based formulations and extrusion at a production-level scale.

(Dkt. 72 at 2.)

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[7] Although paragraph 1 and paragraph 2 of 35 U.S.C. § 112 were amended by the America Invents Act as of September 16, 2012, the pre-amendment versions of those paragraphs apply here because the patents-at-issue issued — and this action was initially brought — before that date. See Alcon Research Ltd. v. Barr Labs., Nos 12-1340 & No. 12-1341, 2014 WL 1013076, at *1 n.1 (Fed.Cir. Mar. 18, 2014); Novozymes A/S v. DuPont Nutrition Bioscis. APS, 723 F.3d 1336, 1342 n.3 (Fed.Cir. 2013), cert. denied, 134 S.Ct. 1501 (2014); Ernie Ball, Inc. v. Earvana, LLC, 502 Fed.Appx. 971, 978 n.4 (Fed.Cir. 2013).

Defendants' position, as expressed by their expert, Dr. Bhattacharya, is:

> In my opinion, a person of ordinary skill in the art as of the filing date of the '565 and '978 patents would be a person with (1) a B.S. in Food Process Engineering who has taken an elective course in polymer processing or (2) a B.S. in Food Science with 1 year of industry experience (in cereal snack goods, microwavable food products, or pet foods) who has taken a short course on polymer processing.

(Dkt. 50 at 5.)

Looking at these competing proposed definitions, it is evident that the parties have an underlying disagreement on a topic rarely seen in at the claim construction stage of a patent case and usually addressed in the obviousness analysis. That topic is the determination of the relevant art of the patents-in-suit. See, e.g., Mintz v. Dietz & Watson, Inc., 679 F.3d 1372, 1375-79 (Fed.Cir. 2012); Orthopedic Equip. Co., Inc. v. United States, 702 F.2d 1005, 1008-12 (Fed.Cir. 1983).

The question of what is the relevant field of art pertaining to the patents-in-suit is a threshold question in determining who is the person of ordinary skill in the art, for purposes of making any claim construction. See 35 U.S.C. § 112, para. 1. The fact that most litigants do not dispute what is the relevant field of art at the claim construction stage does not obviate that requirement, which confronts us here.

This issue is not the same as asking what kind of experts may give competent testimony to assist the court in claim construction. See, e.g., Phillips, 415 F.3d at 1318 ("extrinsic evidence in the form of expert testimony can be useful to a court for a variety of purposes, such as to provide background on the technology at issue"). Accord

Markman, 52 F.3d at 980, 986. We can and do observe that both sides' experts here, Dr. Hsieh and Dr. Bhattacharya, respectively, have expertise in some aspects of the technology pertaining to these patents. See infra Sec. II.B.2. However, that is not the same as asking what is the full scope of the relevant field of technology, and how to define the person of ordinary skill in that art, for claim construction purposes. See 35 U.S.C. § 112, para. 1.

We will focus for a moment on the operative legal principles, and then continue the discussion to define the level of ordinary skill in this case. Much of the case law addresses the parallel search to define the "person having ordinary skill in the art" under the obviousness provision, 35 U.S.C. § 103, but we believe it is equally applicable in the claim construction context.

"The issue of obviousness is determined entirely with reference to a hypothetical 'person having ordinary skill in the art.' It is only that hypothetical person who is presumed to be aware of all the pertinent prior art." Standard Oil Co. v. Am. Cyanamid Co., 774 F.2d 448, 454 (Fed.Cir. 1985) (emphasis in original). "The descriptions in patents are not addressed to the public generally, to lawyers or to judges, but, as section 112 says, to those skilled in the art to which the invention pertains or with which it is most nearly connected." In re Nelson, 280 F.2d 172, 181 (C.C.P.A. 1960) (quoted with approval in Phillips, 415 F.3d at 1303).

"The claims in suit provide a convenient starting point for determining the relevant art." Orthopedic Equip. Co., 702 F.2d at 1008. But that is only a starting point, as the

Federal Circuit has demonstrated. In Orthopedic Equipment, for example, the court looked at these factors to decide what was the relevant art: (1) the type of skill required to understand the disclosure of the subject patent; (2) the type of art applied to the claims by the USPTO; and (3) the nature of the problem confronting the inventor. Id. at 1008-09. Similar factors guided the Federal Circuit in its appraisal of the relevant art in Mintz. See 679 F.3d at 1376 (rejecting district court finding that field of art relevant to patented casing structure for meat products was limited to casing structures; holding that familiarity or experience with encasing meat products should have been included in defining the level of ordinary skill in the art).

The United States Supreme Court, in its landmark KSR decision, has made clear that defining the relevant art, at least to evaluate obviousness, can require taking a somewhat broader view than just what the USPTO and the inventor thought might be relevant. "When a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one." KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 417 (2007).

Once the relevant field of art is determined, the next question is what type and level of skill would describe that hypothetical construct, the "person of ordinary skill." It is well settled that "[f]actors that may be considered in determining the level of ordinary skill in the art include: (1) the educational level of the inventor; (2) type of problems encountered in the art; (3) prior art solutions to those problems; (4) rapidity with which

innovations are made; (5) sophistication of the technology; and (6) educational level of active workers in the field. Not all such factors may be present in every case, and one or more of these or other factors may predominate in a particular case." Envtl. Designs, Ltd. v. Union Oil Co., 713 F.2d 693, 697 (Fed.Cir. 1983) (citations omitted); Mintz, 679 F.3d at 1376 (citations omitted). "A person of ordinary skill is also a person of ordinary creativity, not an automaton." KSR, 550 U.S. at 421.

b. Relevant field of art

The claims of the patents-in-suit provide the starting point for determining the relevant field of art. As we have seen, the '565 patent is entitled "Process for Making an Edible Dog Chew," and its later continuation-in-part relative, the '978 patent, is entitled "Edible Dog Chew," although the '978 patent actually includes both product and method claims. The method claims of both patents are similar in structure and in most claim terms. See supra Sec. I.A. For present discussion purposes, we will focus on claim 4 of the '978 patent as representative of the method claims of both patents:

> **4**. A method of producing a hardness-adjustable edible dog chew, comprising the steps in sequence of:
> extruding a mixture of a heat-expandable potato starch, water and calcium carbonate to form granules;
> adding a food coloring to such granules; and
> injection molding such ingredients into the shape of the dog chew.

('978 patent, 4:6-13.)

The product claims, appearing only in the '978 patent, may be seen from claim 16 as representative:

16. An improved edible dog chew comprising:
an injection molded mixture of a heat-expandable potato starch, water, calcium carbonate and a breath sweetener.

('978 patent, 4:62-65.)

Just looking at these claims on their face, we can see that the patented invention pertains to an edible dog chew comprised of certain ingredients that have been processed in one or more ways. The method claims all feature both extrusion and injection molding. The product claims expressly feature only injection molding. All of the independent '978 claims, both product and method claims, feature "a heat-expandable potato starch." ('978 patent, 3:56-4:65.) The corresponding claim 1 of the '565 patent features "a potato starch." ('565 patent, 4:1-16.) Next, we look at the description of the invention in the specification.

The Abstract of each patent reads as follows:

A process for making a heat expandable dog chew comprised of injection molding potato starch granules and an attractant is disclosed.

('565 patent, title page.)

A heat expandable dog chew comprised primarily of injection molded potato starch, calcium carbonate, to which is added a fruit flavoring, a food coloring or a breath sweetener.

('978 patent, title page.)

The Field of the Invention disclosure, identical in the specification of both patents, states:

The present invention relates to dog chews, and more particularly, pertains to a potato starch-based or other vegetable starch-based, completely digestible,

> nutritious dog chew, the texture or hardness of which can be easily heat modified to suit a particular dog.

('565 patent, 1:5-11; '978 patent, 1:8-14.)

This specification disclosure refers to "a potato starch-based or other vegetable starch-based" composition, although the actual claims are limited to potato starch. It also refers to the feature that "the texture or hardness of [the product] can be easily heat modified to suit a particular dog."

The "Detailed Description of Preferred Embodiments," in the specification for each patent, describes only one "preferred form" of starch, as we have quoted supra, Section 1.A:

> The preferred form of edible dog chew of the present invention has as a basic ingredient, a **heat-expandable starch, such as a** potato starch product sold under the trademark PARAGON IM 1010 by AVEBE of Veendam, The Netherlands. The PARAGON product is sold in the form of thermoplastic granules**, beads or granules,** which are **manufactured by an extrusion process, and which are then** molded into a desired shape.... The resultant mixture is molded under heat and pressure into a desired form, such as a dog bone. Molding can be accomplished in an injection molding machine....

('565 patent, 2:19-37; '978 patent, 2:33-54.)

Thus, according to at least a preferred form of the invention of both patents, there is a potato starch that has been processed by being combined with water and calcium carbonate and then extruded to form thermoplastic[8] granules, which granules are then injection molded into a desired shape.

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[8] "Thermoplastic," which appears in the specification but not in the claims, is commonly defined as "having the property of softening or fusing when heated and of hardening and becoming rigid again when cooled." Webster's Third New International Dictionary (1986).

The "Summary of the Invention" section of each patent specification describes the usefulness of the invention, as we have quoted supra, Section 1.A:

> The present invention provides an edible dog chew that is completely digestible, nutritious, devoid of deleterious additives and of a modifiable texture or hardness that [is] **may be** quickly and easily tailorable by the owner to suit the need or preference of his particular dog.... Upon removal from the chew's package, the chew can be caused to swell up to [6] **3** to 8 times its original volume, if desired, by subjecting it to microwave radiation. With this procedure, the chew's texture or hardness can be adjusted to any magnitude from its original high density extremely hard state to a low density expanded easily chewed state depending upon the amount of microwave exposure to which it is subjected. Accordingly, the chew can thereby be quickly and easily **adjusted** to the texture preference of a wide variety of dogs from a strong large healthy dog to a small puppy with puppy teeth or an older dog with decayed molars.

('565 patent, 1:50-2:4; '978 patent, 1:54-2:7.)

This portion of the specification, and others in the Detailed Description, all refer to modifying the hardness of the product by heating in a microwave oven. For example, this text is in the "Detailed Description of Preferred Embodiments" of both patents:

> In use, the chew is given to the dog in its initial hardness state. If the dog is unwilling or is unable to chew on it, the chew is microwaved for short time increments and re-offered to the dog until the chew reaches a state of expansion and degree of hardness preferred by the dog. Large, strong and healthy dogs would probably prefer the chew in its unmodified and hardest state, while very small, young or very old dogs would prefer the chew in its most expanded state.

('565 patent, 2:66-3:1-7; '978 patent, 3:34-42.)

These disclosures, in the claims and in the specifications of the '565 patent and '978 patent, identify at least the following technical matters that a person of ordinary skill

in the art would need to understand at some level: (1) vegetable starches, including potato starches, as selected and used in preparing processed food products; (2) extrusion processing of starches, water, and calcium carbonate to form granules; (3) injection molding of "thermoplastic granules" made by extruding mixtures of starch, calcium carbonate, and water; and (4) heating such a finished product by microwave or other heating methods to expand the product and thereby modify the hardness of the product. The question here is what field of "art" encompasses those topics?

The next factor we will consider in answering this question is "the type of art applied to the claims by the PTO." Orthopedic Equip. Co., 702 F.2d at 1008. This will be a brief review, not as extensive as one would undertake when answering questions of anticipation or obviousness. Here we are merely observing what fields of endeavor the USPTO thought most relevant to the '565 patent and '978 patent applications.

The '565 patent lists seventeen United States patents as prior art references. It also lists one publication, Potato Processing, by Talburt, et al. ("Talburt publication"). ('565 patent, title page.) The later-issued '978 patent lists most of those same patents and several others, totaling twenty United States patents and three foreign patents. ('978 patent, title page.)

There were different examiners on the two applications. Each examiner selected some of the patent references cited in the respective applications to discuss in the separate file histories of the two patents. In addition, the examiner on the '565 patent made

handwritten notations on the Talburt publication, and included a copy in the file history. (See dkt. 43-3 at 90, 95.) We will start with that publication because it is a basic scientific reference, and then briefly describe the examiner-selected patent references.

The Talburt publication consists of excerpts from two chapters in a textbook entitled Potato Processing, published in the U.S. in 1986. (Dkt. 48-3 at 80-95.) Those chapters are entitled "Potato Starch" (id. at 81-88) and "Potato Flour" (id. at 88-95). The chapter on potato starch describes a rather elaborate manufacturing process, separate and different from the much simpler process used to produce potato flour. (Id. at 82-85, 89-92.) In fact, the publication refers to two distinct industries: "the potato starch and potato flour industries." (Id. at 91, 88.)

Talburt distinguishes the composition of potato starch and potato flour. The text describes a typical finished, dry potato starch as composed of approximately 98% starch, .5% fibrous material, and small amounts of ash, nitrogen compounds and sugars. (Id. at 83.) On the other hand, it describes the average composition of dry potato flour as 77% carbohydrate, 10% protein, 4.5% ash, and small amounts of fat and crude fiber. (Id. at 93.) However, it points out that "[m]ost of the carbohydrate in cooked potato flour is starch, all of which is gelatinized and in rather soluble form." (Id. at 94.)

The then-current industrial uses of potato flour, as distinguished from potato starch, are also summarized in the 1986 Talburt publication. It states that "[p]otato flour has long been associated with the baking of bread." (Id. at 88.) It describes other uses of

potato flour as a thickener in a wide range of foods such as soups and frozen pie crusts and fillings, and in some snack foods, as described in the margin.[9]

Talburt pauses to describe various forms of potato starch, before listing its commercial uses. Talburt teaches about the chemical structure of potato starch, then refers to various "starch fractions, modifications and derivatives." (Id. at 85-86.) Thus, it explains that potato starch contains two chemical structures: "cellulose-like, straight chain ... amylose," and "branched ... amylopectin." (Id. at 85.) It states that "potato starch, like other principal commercial starches, contains 74 to 78 per cent amylopectin." (Id.) It describes that chemical engineers in the Netherlands developed a successful "fractionation process" that can separate those two forms into amylose or amylopectin potato starch. It also lists a myriad of potato starch modifications and derivatives, in text excerpted in the margin.[10]

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[9] The Talburt publication describes this additional known use of potato flour:

> Several commercially produced snack foods are made with potato flour as the base ingredient. In the process described by Shephard (1939) a combination of tapioca starch and potato flour is made into a dough, heated to gelatinize the starch, sliced and dried, after which it may be puffed into a crisp cellular product by immersion in hot vegetable oil.
>
> Rivoche has described a process (1957) for the use of potato flour in making a potato chip-like fried product. In this the potato flour is mixed with suitable gelling agent to form a stiff gel of relatively high water content which can be sliced and fried in a conventional manner.

(Dkt. 43-3 at 95.)

[10] Talburt describes some then-known potato starch materials as follows:

> Most of the potato starch is sold in the native, unmodified form. For many years, however, sizable tonnages have been converted annually into dextrins by

Many then-current uses of potato starch are described in the Talburt publication, in the making of paper, textiles, food, adhesives, and an array of "miscellaneous." (Id. at 86-87.) Talburt lists some potato starch uses in food:

> Much of the potato starch utilized in the food industry is used in bakers' specialty items, such as Swedish and German style breads, in crackers and in matzoth. It is also used as a thickener in soups and gravies. Potato starch has been pelleted successfully to make puddings similar to those ordinarily made from tapioca starch. Pregelatinized potato starch is used in considerable quantity in "instant" puddings, in which its properties are preferable to those of cereal starches....

(Id. at 87.)

We can glean several points from the Talburt basic scientific text of the relevant period: (1) industrial chemists recognized that "potato flour" and "potato starch" were two different manufactured potato materials; (2) much of the content of "potato flour" was carbohydrate, which was starch, but that was not the same as the manufactured product known as "potato starch"; (3) "potato starch" had two chemical forms: amylose and amylopectin, which might be together in the "potato starch" or could be separated into "potato starch fractions"; (4) "potato starch" could come in many forms, including "native, unmodified," or modified/converted into other forms or derivatives such as

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> roasting and into pregelatinized starch. A few plants convert part of their production into thin-boiling starches by acid treatments and to oxidized starch....
> ...
> Much research has been conducted on the production of starch esters, such as starch acetate, and on others, such as allyl starch and hydroxyethyl starch....

(Dkt. 43-3 at 85.)

dextrins, pregelatinized starch, thin-boiling starches, oxidized starch, and starch esters; (5) "potato starch" was used in many industries, including the food industry; and (6) "potato starch" had similarities to other commercial starches such as tapioca and cereal starches, including similar amylopectin content and comparable uses as ingredients in some foods.

Here is a brief description of the topics of each of the patent references selected by the USPTO examiners for discussion or citation in the file histories for the '565 patent and/or '978 patent.[11] All of these patents, except Koepff '100 and Stepto '564, are classified, inter alia, within Class 426 of the USPTO's U.S. Patent Classification Code ("USPC"). Class 426 is Food or Edible Material: Processes, Compositions and Products. See www.uspto.gov.

Food processing methods including extrusion and injection molding are described in most of these patent references. The parties in this action do not dispute that extrusion and/or injection molding are also expressly claimed in the patents-in-suit, and they have no claim construction dispute about what those methods entail. See supra Sec. I.A. (See also dkt. 67 at 2-3.) However, because their claim construction disputes involve those processing methods as part of the underlying technology of the patents-in-suit, we provide a description of chemical processing by extrusion and by injection molding infra, Section

[11] This survey of USPTO-cited prior art references refers to each patent by its inventor name and last three numbers, e.g., Ando '491. Citations to the patent file histories are to the docketed page number, e.g., dkt. 48-3 at 52. We have obtained copies of each of the cited U.S. patents from the USPTO public website, because most are not in the claim construction filings on the docket. These brief summaries omit column and line citations to the cited patents, but the patents are in the public domain.

II.B.2.a. Here we give a brief summary of the referenced patents. Bracketed words within quotes are added by us for clarity.

Ando '491 (Dkt. 43-3 at 52.) "Method for manufacturing biodegradable molded articles." The articles are such as food containers, packaging materials, etc. Examples of materials for making the articles include starches, such as those of corn, potato, tapioca, rice, sweet potato, wheat, etc., and starch derivatives such as .alpha.-starches or denatured starches. Manufacturing method is applying electroconductive heating to the raw materials for an amount of time effective to foam and expand those materials to form the molded article.

Axelrod '212 (Dkt. 68-1 at 38-39; dkt. 68-2 at 24-26.) Method patent entitled "Dog chew with modifiable texture." Main ingredients are casein and gelatin. Molding methods include extrusion or preferably injection molding. Dog owner heats the product (preferably by microwave) to effect expansion to the degree of hardness preferred by the dog.

Axelrod '720 (Dkt. 48-3 at 53, 66.) Product and method patent (continuation-in-part of Axelrod '212 patent), also entitled "Dog chew with modifiable texture." Main ingredients are casein (with or without a substituted portion of poultry meal) and gelatin. Molding methods and dog owner use are similar to Axelrod '212 patent.

Axelrod '771 (Dkt. 48-3 at 55.) "Animal chew toy containing animal meal." Abstract describes "[a] chew toy for pets which is made from a molded synthetic thermoplastic having animal meal dispersed in the plastic." Example describes injection molding of thermoplastic polyurethane beads and food particles to mix the materials and form the chew toy.

Kehoe '270 (Dkt. 68-1 at 38-39; dkt. 68-2 at 24-26, 29-30.) "Elastomer encased active ingredients." Field of the Invention states the patent "relates to the use of elastomer encased active ingredients in chewable articles of commerce for the purposes of providing a long term release of such active ingredients during the mastication of such articles of commerce." Active ingredients include colorants, medicaments, and flavoring agents such as sweeteners, mint and fruit. Preferred embodiments include a wide range of chewable products such as antacid tablets, chewing gum, chewing tobacco, taffy-type candy, teething devices for babies, dog biscuits and chewable rubber toys for canines and felines.

Koepff '100 (Dkt. 48-3 at 68.) "Gelatine granules as well as methods and apparatus for their manufacture." Product patent in USPC Class 106: Compositions:

Coating or Plastic. Abstract describes solid thermoplastic gelatine granules obtained by plasticizing conventional gelatin. Description of preferred embodiment lists as additives: plasticizers including modified or natural starch, crosslinking agents (hardeners) including dialdehyde starch, and fillers including calcium carbonate and carbohydrate (starch and/or sugar). Manufacturing of the granules is conducted in a screw extruder, applying heat, pressure and shear forces. The finished granules can be used to make molded articles, foams, films, etc. by extrusion, injection molding and thermoforming, "exactly as with conventional thermoplastics."

Miller '607 (Dkt. 48-3 at 53-54, 66.) "Simulated bone." Method patent. Abstract states, "[a] simulated bone of improved hardness and color is provided having as a structural matrix a white, unpuffed farinaceous mixture [including controlled percentages of fat and moisture] ... thereby imparting a shear value to the matrix which is greater than 250 pounds." Typical farinaceous materials listed include white corn, wheat flour, potato flour or flakes, and rice flour.[12] "The dough is shaped under process conditions, in which puffing of the farinaceous material is specifically avoided to impart the desired texture and hardness to the simulated bone." Processing methods include feeding the dough "into an extruder, with a rotating screw operated at a temperature of between about 170.degree. to 240.degree.F. wherein the dough is mixed and formed by passing through a restricted orifice into a shape resembling a bone."

Miller '665 (Dkt. 68-1 at 38-39; dkt. 68-2 at 24-26.) "Simulated bone." Product patent. (Based upon divisional application under the application for the Miller '607 patent.) Specification for this patent is virtually identical to the Miller '607 specification.

Scaglione '808 (Dkt. 48-3 at 53, 66; dkt. 68-1 at 38-39; dkt. 68-2 at 24-25, 29-30.) "Dietetic dog biscuits containing vegetable hulls." Product patent. Field of the Invention states, "[i]n particular, this invention relates to dietetic dog biscuits containing vegetable hulls which are used to selectively balance the nutritional composition of the biscuit and make the biscuit low in calories, low in total protein, high in essential amino acids, high in fiber, or a combination of these." Claim 2 includes "a low protein containing component in an amount sufficient to provide a brittle product, ... selected from the group consisting of corn flour, ... potato flour...." Detailed Description states,"The use of fibers and farinaceous flours, to form a biscuit dough generally results in a thin biscuit. Farinaceous flours can include corn flour, corn meal, oat flour, barley flour, potato flour and others." Also, "Calcium carbonate is added in the most preferred embodiments in addition to bone meal to provide adequate calcium for the animal." Described production methods are a suitable forming apparatus and convection baking.

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[12] The dictionary gives a contemporary definition of "farinaceous" as "containing or rich in starch." Webster's Third New International Dictionary (1986).

Scaglione '973 (Dkt. 48-3 at 55.) "Nutritionally-balanced canine biscuits containing an inorganic pyrophosphate." Product patent. (Numerous prior art patents cited; as discussed in Description section, prior art not limited to pet food products.) Abstract states, "The nutritionally-balanced dog biscuits containing at least one inorganic pyrophosphate salt are chewed and/or eaten by dogs, with the result that tartar accumulations on their teeth are reduced or prevented." Detailed Description states that "[a]ny suitable dough comprising at least one flour, meal, fat and water can be employed for the product.... The meal used in the doughs ...can comprise ... vegetable matter including ... tuberous materials such as potato meal, and the like." Also, "[i]n order to provide sufficient calcium to achieve nutritional balance, calcium carbonate and calcium chloride are included in the preferred ... formula." "The dog biscuits are formed in any conventional or suitable manner, such as, by extrusion, stamping, cutting or molding." "The dough pieces can be baked using any suitable or conventional equipment and conditions."

Scaglione '870 (Dkt. 48-3 at 55.) "Canine biscuits containing an inorganic pyrophosphate." Process patent. (Based upon divisional application under the application for Scaglione's U.S. Patent No. 5,000,943, another product patent -- not to be confused with the simultaneously-applied-for Scaglione '973 product patent described above.) Specification for this patent is similar to specification for Scaglione '973, without mention of calcium carbonate.

Stepto '564 (Dkt. 48-3 at 68.) "Method of forming shaped articles made from pre-processed starch." Method patent in USPC Class 265: Plastic and Nonmetallic Article Shaping or Treating: Processes. Description of the invention states that it is known that natural starch, found in vegetable products and containing an amount of water, can be treated in an injection molding machine or extruder to form a melt, and that the resulting thermoplastic melt can then be further treated, by injection molding or extrusion or other known techniques, to obtain shaped articles. This melt-producing treatment yields "an essentially destructurized starch," defined by the expression "pre-processed starch." The invention of this patent is to separate into two steps (1) the process of forming the "pre-processed starch," and allowing it to be extruded and cooled to a solidified granulated product, and (2) the process of then subjecting the granules to being extruded or molded into the intended article. This two-step process, according to the patent, serves to improve the strength and shape of the finished article. The specification contains the following lengthy definition of the "starch" ingredient, as used in the claims of this patent:

> The term "starch" is to be understood as chemically essentially non-modified starch. As such it includes for example carbohydrates of natural, vegetable origin, composed mainly of amylose and/or amylopectin. It may be extracted

> from various plants, such as potatoes, rice, tapioca, corn, and cereals such as rye, oats and wheat. Preferred is potato starch and corn starch, especially potato starch. It further includes physically modified starch, such as gelatinized or cooked starch, starch with a modified acid value (pH), ... Further is included starch, e.g., potato starch, in which the types and concentrations of the cations associated with the phosphate groups of the starch have been modified to influence processing conditions e.g. temperature and pressure.

This ends our survey of the scientific literature and patent references cited and/or discussed by the USPTO examiners who reviewed the applications for the '565 and '978 patents-in-suit. In addition, the examiner for the '978 patent application referenced the AVEBE thermoplastic potato starch granules product, disclosed in the specification for both the '565 patent and the '978 patent, as a potato starch that expands upon heating that was already known in the art at the time the claimed invention was made. (Compare dkt. 68-2 at 24-25, with '565 patent 2:22-30, and '978 patent 2:36-47.)[13] These references, taken together, provide the broad outlines of "the type of art applied to the claims by the PTO." Orthopedic Equip., 702 F.2d at 1008.

Another factor to consider in determining the relevant field of art is "the nature of the problem confronting the inventor." Id. at 1009. The '565 and '978 patents-in-suit, invented by Glen S. Axelrod, are assigned to Plaintiff. Plaintiff states in its pleadings that "TFH manufactures, among other things, a variety of edible and inedible dog bones under its Nylabone® product line. In connection with these products, TFH is the owner and/or

[13] In the '978 patent prosecution file, that portion of the specification is found at page 5, lines 7-10, as cited by the examiner. (Dkt. 68-1 at 13; dkt. 68-2 at 24-25.)

assignee of numerous United States Patents." (Dkt. 79 at 2.) The named inventor, Glen S. Axelrod, states that he is the President of Plaintiff, and was employed by Plaintiff at the time of this invention.[14] His explanation of the invention process for the patents-in-suit was as follows:

> Plaintiff began incorporating potato starch into its dog chew products in approximately the mid 1990s. In 1996, I began experimenting with potato starch formulations to invent the processes and products described in the '565 and '978 patents.

(Dkt. 65 at 2.)

A comparison of the prior patent references in the patent prosecution files of the patents-in-suit shows that without question, the closest prior art references are the Axelrod '212 patent and Axelrod '720 patent issued in 1993, summarized above. Those prior patents are directed to an edible dog chew "with modifiable texture." In fact, much of the specification language and all of the drawings in those patents are found also in the patents-in-suit. (See, e.g., dkt. 51-1 at 2-6; '565 and '978 patents (passim).) Plaintiff has explained that the inventor of the Axelrod '212 patent and Axelrod '720 patent, Herbert R. Axelrod, is the uncle of the inventor of the patents-in-suit, Glen S. Axelrod. (See dkt. 69 at 16.) In fact, the Axelrod '212 patent and Axelrod '720 patent are associated with the Plaintiff and are discussed in the specifications of the patents-in-suit. ('565 patent, 1:39-49; '978 patent, 1:43-52.) From this history we may reasonably conclude that the "nature of the

[14] Glen S. Axelrod states in his declaration that he worked at Plaintiff from 1979 to 1981, then left to pursue other ventures including real estate, and returned to Plaintiff in 1996 where he has since been continuously employed. (Dkt. 65 at 1.)

problem confronting the inventor" of the patents-in-suit was a motivation for further marketplace product development of edible dog chews with modifiable texture.

The last factor we will examine to help determine the relevant field of art is "the type of skill required to understand the disclosure of the [asserted] patent." Orthopedic Equip., 702 F.2d at 1008. Of course, the inventor usually will be one of more than ordinary skill, but his or her area of skill is always relevant to this inquiry. It is a "well-settled understanding that inventors are typically persons skilled in the field of the invention and that patents are addressed to and intended to be read by others of skill in the pertinent art." Phillips, 415 F.3d at 1313. We will also look at the technical areas identified by each of the parties' expert witnesses, whether or not the expert professed to have knowledge in all those areas.

The inventor of the patents-in-suit, Glen S. Axelrod ("Mr. Axelrod"), states that he has a bachelor's degree in biological sciences, with extensive study in chemistry, and a master's degree in ichthyology,[15] with extensive study in zoology. (Dkt. 65 at 1.) The date of this invention, assumed to be the application date for the '565 patent, was in October, 1996. See supra n.6. The record indicates that at that time, Mr. Axelrod had at most three years of experience in the pet food and pet supplies industry. See supra n.14.

Plaintiff's technical expert, Dr. Hsieh, is currently the proprietor of a consulting company specializing in food product development and flavor formation. She has a

[15] "Ichthyology" is "a branch of zoology that deals with fishes." Webster's Third New International Dictionary (1986).

bachelor's degree and master's degree in food science, with a focus on food chemistry. She also has a Ph.D. in meat science, specializing in flavor chemistry. She worked in industry for Procter & Gamble for 27 years as a food scientist and formulator in the Food and Pet Food Divisions. In both her academic and industry career, she has had decades of experience with potato starch. While at Procter & Gamble, she worked extensively in the development of PRINGLES® potato snacks and other salted snacks. She is a "certified food scientist." (Dkt. 55-2 at 1-2.)

Dr. Hsieh offered her expert opinion on claim construction of the term "heat-expandable potato starch," which is a term that appears only in the '978 patent and not the '565 patent. (Id. at 2.) She considers herself to have expertise in the "formulation" or "composition" part of the '565 patent and '978 patent, as well as the extrusion step. She does not claim expertise in the injection molding step. (Hsieh Dep. at 11-12.) She did not offer an opinion on construction of the claim term "hardness-adjustable edible dog chew." (Id. at 145.)

Dr. Hsieh stated that she had no experience in the science of microwaving or otherwise heating an injection molded edible dog chew. (Id. at 85-91, 140.) However, she did have knowledge about how potato starch will expand when exposed to heat and moisture. (Dkt. 55-2 at 2-3.) She also has done extensive work in developing "half products" based on potato starch and other starches. "Half products," she said, "are products that are extruded under strict moisture controls, thus becoming very shelf stable

for packaging, distribution, and sale. The 'half product' is then taken by the consumer and either baked, fried, microwaved, or otherwise heated to expand and thus create the final product." (Dkt. 55-2 at 2.)

Defendants' technical expert, Dr. Bhattacharya, is a faculty member at the University of Minnesota in two departments: Biosystems and Agricultural Engineering; and Mechanical Engineering. He has a bachelor's degree in technology from the Indian Institute of Technology, and a master's degree and Ph.D. degree from the University of Nebraska. His M.S. degree is in agricultural engineering with an emphasis in food engineering, and his Ph.D. is in bioenvironmental engineering. He has more than 26 years of experience in biosystems and agricultural engineering. He has been involved in research and writing relating to extrusion processing throughout his career, including analysis of the transformation of starch and starch-based polymers using both extrusion and injection molding. He has numerous publications, including having co-authored a paper entitled "Extrudate expansion during extrusion cooking of foods." He has two U.S. patents based on his work in developing plastic parts using natural substances such as starch, blended with synthetic polymers, and subjected to extrusion processing and injection molding. (Dkt. 50 at 2-4.) He states that he has "researched cell growth during baking, which is similar to the expansion process the claimed dog chew of the patents-in-suit encounters when exposed to microwave heating." (Id. at 4.)

Dr. Bhattacharya provided background information about the technology of the patents-in-suit in five main areas: (1) potato starch and plant-based starches in general;

(2) extrusion as a widely-used food processing technique; (3) transformation of starch by extrusion; (4) injection molding as a widely-used, high-volume manufacturing process used in many industries including injection molding of extruded starch-based granules; and (5) microwave expansion of starch-based food products. (Id. at 5-15.) He stated, for example, that starch is a common carbohydrate that is a key ingredient in many cereal and snack goods, microwaveable food products, and pet foods made with extrusion processing; and that chemically, "starch is a polymer of anhydrous (i.e., without water) glucose." (Id. at 5.)[16]

Similar to the background information provided by Plaintiff's expert, Dr. Hsieh, the declaration of Dr. Bhattacharya explained that extruders can be used to produce "indirect-expanded snacks," also known as "shelf-stable intermediate pellet products" or "half-products." He stated that "[t]hese half-products can be later processed to create an expanded product or a final product that can be expanded." (Id. at 7.) His declaration included examples of prior U.S. patents in that area of processed food technology. (Id., Exs. 7 & 8.) See also U.S. Patent No. 5,080,914 (1992); U.S. Patent No. 4,409,250 (1983); and U.S. Patent No. 4,251,551 (1981).

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[16] A general definition of "polymer" is "a natural or synthetic chemical compound or mixture of compounds formed by polymerization and consisting essentially of repeating structural units." Webster's Third New International Dictionary (1986). "Polymerization" means "a chemical reaction in which two or more small molecules combine to form larger molecules that contain repeating structural units of the original molecules and that have the same percentage composition as the small molecules if the small ones were all of the same kind." Id.

Dr. Bhattacharya offered his expert opinion on claim construction of various claim terms in the patents-in-suit, including "hardness-adjustable edible dog chew" and "heat-expandable potato starch." (Dkt. 50 at 18-22, 26-28, 30-34.) Those opinions, along with the opposing views expressed by the inventor and Plaintiff's expert, Dr. Hsieh, are discussed infra, Section II.B.2.

Based upon all of this data, we conclude that the "field of art" familiar to the hypothetical person of ordinary skill relevant to the '565 and '978 patents-in-suit would be food engineering in general. More specifically, the relevant art would include the science pertaining to extrusion and injection molding of chemical compositions containing plant starches to prepare edible "half products" that can be heated by the consumer to create or modify the final product. See, e.g., Orthopedic Equip., 702 F.2d at 1009 ("[I]t would seem that one can come no closer to pinpointing the relevant art of the claims than by choosing the art of information processing systems hardware.").[17]

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[17] These subtopics were those identified, for example, in the following exchange during the deposition of Defendants' expert, Dr. Bhattacharya:

> Q Can you identify the parameters that you used when you conducted your prior art search?
>
> A .... You ... look at what is there, starch, processing, starch extrusion[.] You would look at ... potato starch, injection moldings, ... microwaving, so those would be terms that I would use.

(Dkt. 55-1, Ex. C, at 43.)

c. Level of ordinary skill in the art

Having defined the relevant field of art, we now look to such of the following factors as may be relevant to determine the level of ordinary skill at the time of this invention: (1) the educational level of the inventor; (2) type of problems encountered in the art; (3) prior art solutions to those problems; (4) rapidity with which innovations are made; (5) sophistication of the technology; and (6) educational level of active workers in the field. Envtl. Designs, Ltd. 713 F.2d at 697.

Factors (1) and (2) pertain to the inventor and to the "type of problems encountered in the art." Id. As we have seen, Mr. Glen S. Axelrod, the inventor, obtained a B.S. in biological sciences with extensive study of chemistry, and a master's degree in ichthyology with extensive study of zoology. See supra n.15 and accompanying text. At the time of this invention, he had approximately three years of experience at Plaintiff company, but had only returned to the company in 1996 (the year of the invention), after a 15-year hiatus in unrelated ventures. See supra n.14.

Mr. Axelrod was aware of the existing product line of Plaintiff company at that time, including its use of potato starch in its other dog chew products since the "mid-1990's." (Dkt. 65 at 1.) He was aware of the Herbert R. Axelrod '212 patent and '720 patent for "dog chew with modifiable texture," issued in 1993. See supra Sec. II.B.1.b. We have also concluded that the "nature of the problem" confronting him as a potential inventor was a motivation for further marketplace product development of edible dog

chews with modifiable texture. Id. However, the "nature of the problem" of designing an edible product to be given to dogs that could be modified as to texture by the consumer would necessarily draw upon the technology on what was known in general about food "half-products" that could be finished or modified by the consumer.

Factors (3) through (5) relate to prior art solutions to those problems and the rate and relative sophistication of technological advance. For this we can look to the range of prior art patents and technical literature described supra, Section II.B.1.b. Those certainly reflect what was known in scientific and industry circles (and it appears that there was quite a bit known) about creating processed food items using starches and other edible materials, and subjecting the materials to some or all of the processes of extrusion, injection molding, and microwaving or other sources of heat.

The only information we have about factor (6) -- educational level of active workers in the field, other than the inventor -- comes to us from the conflicting views expressed by the parties' experts, Dr. Hsieh and Dr. Bhattacharya.

Plaintiff's expert Dr. Hsieh, possessing B.S. and M.S. degrees in food science and a Ph.D. in meat science and more than 27 years of experience as a food scientist in industry, opined that the "person of ordinary skill" would have a B.S. in Food Science and at least 10 years of experience in "food processing with an emphasis on starch-based formulations and extrusion at a production-level scale." (Dkt. 72 at 2.) Alternatively, such person in Dr. Hsieh's view would have the same level of skill, based upon a Ph.D. in a Food Science-related field and at least five years of that same experience. (Id.)

Dr. Hsieh stated her basis for this opinion as follows:

> First, starch is a very complex and interactive material. In my thirty-plus years of experience between my post-doctorate work, time at P & G, and recent years of consulting, I have learned that it takes many years of experience to fully understand the interactions and intricacies of starch.
>
> ....
>
> In my experience, working in industry is essential to understanding the way starch interacts and behaves at a large, production-level scale. I have found that, in academia, most research is done at a purely theoretical level using smaller proportions of material. The nature of starch's interaction and behavior can change very dramatically when using large scale proportions in the production side of industry. Purely academic experience, which is usually overly theoretical and lacking in practical approach, is insufficient alone to understand and predict how starch will behave in such large, production-level quantities. Thus, in addition to the academic experience of attaining a relevant degree, it is my opinion that the relevant work experience needed to be one of ordinary skill in the art of [these] patents is food processing with an emphasis on starch-based formulations and extrusion at a production-level scale.

(Id. at 2-3.)

Defendants' expert, Dr. Bhattacharya, possesses an M.S. degree in agricultural engineering with emphasis in food engineering and a Ph.D. in bioenvironmental engineering, with more than 26 years of experience in biosystems and food engineering in research relating to starch-based polymers processed by extrusion and by injection molding. (Dkt. 50 at 2-4).[18] He opined that the "person of ordinary skill" would have either (1) a B.S. in Food Process Engineering, with an elective course in polymer processing, or (2) a B.S. in Food Science with 1 year of industry experience (in cereal

[18] Dr. Bhattacharya, when asked to describe some of these scientific specialties, explained that the names of the academic disciplines in the broad field of agricultural engineering have changed over time and continue to change. (Dkt. 55-1, Ex. C, at 69-70.)

snack goods, microwaveable food products, or pet foods), with a short course on polymer processing. (Id. at 5.)[19] When Dr. Bhattacharya was asked in deposition why he considered himself a person of (at least) ordinary skill in the art, he stated that although he had not actually practiced the patents-in-suit, "my expertise in the area of starch processing would enable me to practice these if I choose to." (Dkt. 55-1, Ex. C, at 96-97.)

Based upon all of these relevant factors and the evidence as summarized here, we observe that perhaps the parties' experts were looking to define someone who could analyze and explain the rather complex science underlying the patents-in-suit, whereas the actual inventor was of a more practical background. As we have seen, the inventor, Mr. Axelrod, had no degrees in food science or agricultural engineering, his B.S. and M.S. degrees falling generally within scientific knowledge of biology and chemistry. See supra n.15 and accompanying text. He had only about three years of experience in the pet food/pet products business, all of that in the Plaintiff company. See supra n.14. He was aware of the 1993 Axelrod '212 patent and '720 patent held by his uncle, which are

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[19] Neither expert provided insight on the difference between a degree in Food Science and a degree in Food Process Engineering. However Dr. Hsieh, when asked about Dr. Bhattacharya's definition of "person of ordinary skill" above, disagreed as follows:

> Having gone through many years of work, understanding how complex and interactive starch can be and how complex extrusion is, I don't think the way he specified the qualification -- especially when you're talking about food product. It's so much more complicated. Takes years of experience to really understand the interactions and the intricacies of all that is implied.

(Hsieh Dep. at 168-69.)

extremely close prior art. See supra Sec. II.B.1.a. He had only returned to work at the Plaintiff company in 1996 after a gap of 15 years in other ventures, yet the application date for the '565 patent was October 25, 1996. See supra n.6.

Mr. Axelrod himself described the inventive process leading to the patents-in-suit as follows:

> 4. TFH began incorporating potato starch into its dog chew products in approximately the mid 1990s.
>
> 5. In 1996, I began experimenting with potato starch formulations to invent the processes and products described in the '565 and '978 Patents.
>
> 6. At that time, I understood both from my previous experiences with potato starch and from my experimentation in inventing the '565 and '978 patents, that some potato starches or types of potato starches would expand when combined with water and/or other ingredients and exposed to heat while other potato starches or types of potato starches would not.
>
> 7. One, but not the only, potato starch product that I experimented with at that time and found to expand was the PARAGON IM 1010 extruded bead sold by AVEBE ..., described in the specifications of both ... Patents.
>
> 8. ....
>
> 9. In my experimentation, I found that many factors went into the rate or degree of expansion of the potato starch and the end product including: the type of potato starch, the brand of potato starch, the formulation, the manner of heating the product, the temperature, the duration, and other factors.

(Dkt. 65 at 2.)

The inventor, of course, is regarded as one of at least ordinary skill in the art pertaining to a given patent. Phillips, 415 F.3d at 1313 ("well-settled understanding that inventors are typically persons skilled in the field of the invention and ... patents are

addressed to and intended to be read by others of skill in the pertinent art"). Here, the inventor had an academic background in biology and chemistry although none specifically in food science or food engineering, and then he had specialized experience of approximately three years in the Plaintiff company that actually develops and manufactures consumer pet products. He had familiarity with the prior art Axelrod '212 patent and '720 patent, claiming an edible dog chew that would expand upon heating by the consumer. He had the capability and facilities to experiment with various compositions containing potato starches, and to process the compositions using heat extrusion, injection molding, and additional heating such as microwave heating.

Taking all of this evidence into consideration, we conclude that the "person of ordinary skill" in the art of the patents-in-suit, at the relevant date in 1996, would have had at least a B.S. in science, including biology and chemistry, and at least two years of experience in the research or development of processed food half-products, using vegetable starch compositions and food processing techniques including heat extrusion, injection molding, and microwaving or other forms of heating to create or modify the final products.

2. Construction of disputed claim terms

a. Technology of the patents

The parties do not dispute the basic technology underlying the patents-in-suit. Here we provide a brief description of that area of science, as provided by the parties and

their experts. This background is necessary for any claim construction of the patents. To provide a frame of reference, all the claims of the '565 patent are quoted in the margin.[20]

Defendants' expert, Dr. Bhattacharya, provided an undisputed primer on the technology of heat extrusion and injection molding of edible products containing vegetable starches including potato starch. We will simply excerpt and quote his summary of those topics.

First is the process of heat extrusion involving starch, described as follows:

> Extrusion is a widely-used food processing technique because it allows for mass production of a uniform product. Many extruded products have high starch content.... During the extrusion cooking process, the starch is

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[20] The claims of the '565 patent are as follows:

1. A method of producing a hardness-adjustable edible dog chew, comprising the steps of:
extruding a mixture of a potato starch, water and calcium carbonate to form granules; and
injection molding such mixture into the shape of the dog chew.

2. The method of claim **1** wherein the starch and water weight content of the granules is about 70% starch and the weight content of the water is about 15%, and the weight content of the water is reduced to about 10% during the injection molding step.

3. The method of claim **1** further comprising the steps of adding to the mixture about 1-5% by weight natural vegetable additives and about 1-5% by weight of an attractant.

4. The method of claim **1**, where the granules are injection molded at a pressure of about 1,000-2,500 PSI and at a temperature of about 250°-400°F.

('565 patent, 4:1-16.) The claims of the continuation-in-part '978 patent are more numerous. All asserted claims of the '978 patent are quoted infra, note 25.

destructured (or gelatinized) and undergoes molecular degradation (e.g. reduction in molecular weight) under the combined action of heat, moisture, and shear force.

.... An extruder is a machine consisting of a large, rotating screw (or alternatively two screws) tightly fitting within a stationary barrel, at the end of which is a die.[21] The extruder's rotating screw conveys the material toward the die, through which it then passes and exits to the atmosphere.

.... Ingredients enter through the hopper into the feed section of the extruder. Heat is applied in the feed section ... as the material is conveyed to the transition or compression section of the extruder. The compression section is characterized by a tapered screw with decreasing screw flight in the direction of the discharge. Because of the heat from the barrel walls and dissipation (in the form of heat) of mechanical energy imparted by the screw shaft, the material transforms from a powder into a viscose, doughy, molten mass. That melt, in turn, enters the final metering section ... which delivers the melt to the die. The die determines the size and shape of the extrudate. The extrudate is then cut to the desired length by blades at the output of the extruder.

.... Extrusion converts starch from a granular and partly crystalline material to a homogeneous starch-water melt. Extrusion applies heat and shear to the starch in the presence of water, leading to the gelatinization and molecular degradation of starch. In the presence of heat, shear, and water, the starch granules rupture, collapse, and fragment; the crystalline regions of the starch melt into amorphous forms; the starch granules irreversibly dissolve and disappear into a homogenous starch-water melt.... The heat and shear forces break down the intermolecular bonds (between and amongst the amylose and amylopectin components) of starch molecules; the heat and shear forces also break down the intramolecular bonds (within the amylopectin components) of starch molecules. The hydrogen bonding sites within the starch ... can now absorb water. This conversion of starch to a homogenous starch-water melt, allows for subsequent expansion of starch-based products. ...[W]hether the

---

[21] A schematic illustration of a heat extrusion apparatus is included in Dr. Bhattacharya's declaration. (Dkt. 50 at 8.) The die portion of the drawing corresponds to the following dictionary definition of the noun "die." "A perforated block through which plastic material is forced to make it assume a desired shape." Webster's Third New International Dictionary (1986).

> starch-based products expand (and the degree of any expansion) depends on the processing conditions and the composition of materials used.

(Dkt. 50 at 7-9.)[22]

Next to be described is the process of injection molding:

> Injection molding is a widely-used, high-volume manufacturing process used in many industries ... to create products of a desired shape. With injection molding, [material] (typically in the form of granules or pellets) ... is fed into a heated barrel, melted, and homogenized, and forced by a screw-type plunger into a mold cavity where it cools and hardens to the configuration of the cavity.
>
> .... [In] the injection molding process[, t]he extruded granules or pellets are fed into a hopper and then conveyed by the screw flights, with accumulating pressure, through a heated cylinder. Based on the combination of viscous heat (caused by the mechanical working of the screw on the material as it is conveyed down the cylinder) and heat conduction from the cylinder, the granules/pellets are converted to a molten state. When there are sufficient amounts of molten material, the screw retracts and injects the material, under high pressure, through a small nozzle into a mold. The pressurized material is held in the mold until it solidifies and then is ejected.

(Id. at 11-12.)

Comparing the above two processes and their effect on the starch component, Dr. Bhattacharya confirmed that "similar principles of flow, heat, and pressure play key roles in the extrusion and injection molding processes." (Id. at 12.) It is noteworthy, however, that the extrusion step produces an "extrudate" that can be cut into lengths forming granules/pellets. Then the injection molding step re-melts and further processes those

---

[22] We understand that in this case, when any document or witness refers to the "extrusion" process, what is meant is the heat extrusion process as generally described above. There is also a process known as "cold extrusion," but it is not relevant to the patents-in-suit. (See dkt. 55-1, Ex. C, at 114-16.)

extruded granules/pellets and injects the material into the shape created by the mold, such as in this case a dog chew shape. See '565 patent claims, quoted supra n.20. Thus, as explained by Dr. Bhattacharya, "injection molding of extruded starch-based granules can lead to further transformation of the starch material (e.g., further molecular degradation)," during the injection molding step of the process. (Dkt. 50 at 12.)

As we have seen and will discuss below, the parties have a sharp claim construction dispute about whether the invention of the patents-in-suit is limited to microwave heating of the claimed edible dog chew. See infra Secs. II.B.2.b. and c. They do not disagree, however, about the basic science describing what happens when a starch-based food product produced by heat extrusion and injection molding is subjected to microwave heat, which is the preferred embodiment described in both the '565 patent and '978 patent specifications. Defendants' expert, Dr. Bhattacharya, provided this background information on that topic:

> The patents-in-suit teach potato starch-based products (i.e., dog chews) that expand after application of microwave heat. As elaborated below, it is the moisture incorporated into the starch during processing that is the driving force behind expansion of these products, not the raw material of potato starch, in and of itself.... Indeed, studies have shown that a completely dehydrated starch-based product will not expand when microwaved.... Thus, in order for the claimed potato starch-based dog chew to expand upon exposure to microwave heat, the raw potato starch must be transformed or modified by processing (e.g., extrusion and injection molding) into a starch matrix with trapped water that will subsequently expand upon microwaving....
>
> It is worth noting that entrapped bubbles in the starch-based food product also play a role in expansion. During the process of extrusion, bubbles are formed (i.e., a process known as nucleation) within the starch-based extrudate....

> Microwave radiation applies a rapidly changing electromagnetic field. Upon exposure to microwave radiation, the water molecules in the starch-based product start to oscillate. Since water is a dipole with one positively-charged end and one negatively-charged end, the alternating electromagnetic field causes the water in the material to rotate. Heat is generated by collisions between the oscillating water particles and adjacent molecules. As a result, the water in the microwaved product is heated and converted to superheated steam. At the same time, bubbles introduced into the starch-based product will grow due to nucleation and increased temperature.... Heat also softens the starch matrix such that it is able to deform. The vapor pressure of the heated steam and the growing bubbles cause the starch matrix to stretch and expand. Upon the cessation of microwave heating, the matrix cools and the final structure is formed. In sum, the heated steam pressure (generated by water) is the driving force behind the microwave expansion of the starch-based products. The patents recognize as much, teaching that '[t]he expansion of the moisture within the chew causes the chew to expand.'"

(Dkt. 50 at 12-14 (emphasis added; citations omitted); see also dkt. 51-1 at 64, 69-70, 121 (agreeing that according to both patents, the moisture in the chew is necessary for the chew to expand upon application of heat).)[23]

Dr. Hsieh, Plaintiff's expert, did not profess to have scientific expertise about the injection molding or the microwaving aspects of the patents-in-suit. (Hsieh Dep. at 82-88, 104.) Her stated expertise was in the areas of potato starch in general, and extrusion processing of starches. (Id. at 11-17, 113-16.) She did agree, however, that the expansion of the moisture, and not just the potato starch alone, within the edible dog

[23] Some of Dr. Bhattacharya's scientific references were dated after the critical date, but he explained in his deposition that the basic scientific principles were known in the field in 1996, and were reflected in prior art patents. (See dkt. 50, Exs. 7-18; dkt. 55-1, Ex. C, at 113-14, 123-24, 232-34, 247-49.) The Court is satisfied with his explanation that these scientific principles were known to those of ordinary skill in the art as of October, 1996, when the application for the '565 patent was filed.

chew of the '565 patent and '978 patent, would cause the chew to expand. (Id. at 92-105.) Specifically, she agreed that the expansion of the moisture within the edible dog chew causes the chew to expand. (Id. at 93.)[24]

b. Claim term: "a hardness-adjustable edible dog chew"

The '565 patent, as we have stated, has one independent claim and three dependent claims, all quoted in the margin supra, note 20. Plaintiff asserts infringement of claim 1 and claim 3 of the '565 patent. The '978 patent has seven independent claims and a total of sixteen claims. Plaintiff asserts infringement of claims 4, 8, 14, 15, and 16 of the '978 patent. Those asserted claims of the '978 patent are quoted in the margin here.[25]

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[24] Dr. Hsieh testified that she assumed that adding calcium carbonate to the mixture would also play a role in causing the '565/'978 dog chew to expand when microwaved, because it is a "leavening agent." She had not, however, done any experiment to verify that assumption. (Hsieh Dep. at 98.) The parties do not emphasize the calcium carbonate in their claim construction submissions, so we simply note this point without relying upon it in this opinion.

[25] The asserted claims of the '978 patent are as follows:

4. A method of producing a hardness-adjustable edible dog chew, comprising the steps in sequence of:
extruding a mixture of a heat-expandable potato starch, water and calcium carbonate to form granules;
adding a food coloring to such granules; and
injection molding such ingredients into the shape of the dog chew.

....

8. A method of producing a hardness-adjustable edible dog chew, comprising the steps in sequence of:
extruding a mixture of a heat-expandable potato starch, water and calcium carbonate to form granules;
adding a breath sweetener to such granules; and
injection molding such ingredients into the shape of the dog chew.

...

The claim term "a hardness-adjustable edible dog chew" appears in claim 1 of the '565 method patent, and in all of the independent method claims of the '978 patent including asserted claims 4 and 8. ('565 patent, 4:2-7; '978 patent, 3:57-4:40.) Because the '978 patent derives from the same parent application as the '565 patent and this claim term is common to both patents, the term must be interpreted consistently across the two patents. NTP, 392 F.3d at 1345-46.

The opposing positions of the parties on construction of the term "a hardness-adjustable edible dog chew," in claim 1 of the '565 patent, are as follows:

> Plaintiff's Proposed Definition: "an edible dog chew possessing the capability of having its hardness adjusted, either in terms of becoming softer or harder." (Dkt. 44 at 8.)
>
> Defendants' Proposed Definition: "a dog chew that when microwaved will expand up to about 6 to 8 times the original volume with a commensurate reduction in hardness." (Id.)

---

14. An improved edible dog chew comprising:
an injection molded mixture of a heat-expandable potato starch, water, calcium carbonate and a food coloring.

15. An edible dog chew as set forth in claim **14**, which further includes a breath sweetener.

16. An improved edible dog chew comprising:
an injection molded mixture of a heat-expandable potato starch, water, calcium carbonate and a breath sweetener.

('978 patent, 4:6-65.)

The proposed definitions of the parties on construction of that same term, where it appears in the claims of the '978 patent, are identical except that Defendants substitute "3 to 8 times" in the latter definition, based on the range stated in the '978 specification. (Id. at 16.) We have noted that the parties appear to regard that numerical difference as immaterial for claim construction purposes. See supra n.3.

The intrinsic evidence bearing on this disputed claim term -- and on the other claim term construed in this opinion -- consists of the claims of the two patents, their specifications, and the patent prosecution history of each, including prior art cited during the patents' examination, all to be viewed from the perspective of the person of ordinary skill in the art. Phillips, 415 F.3d at 1313-18. The available extrinsic evidence includes the declarations, exhibits, and deposition testimony of the inventor and the expert witnesses, and written sources such as dictionaries and treatises if helpful. Id.

There are at least three fundamental points of difference between the parties' disputed interpretations of this claim term, "a hardness-adjustable edible dog chew." Those are whether, according to the invention of these patents: (1) the chew can be adjusted to become harder or softer, or only to become softer; (2) the means by which the chew's hardness can be adjusted is inherent in the term "hardness-adjustable," and if so whether that means is limited to microwave heat; and (3) whether the concept of expandability of the chew is included in this term, and if so whether a numerical volume of expandability (i.e., 3/6 to 8 times) is required.

On the first point, Plaintiff offers the ordinary dictionary definitions of "hardness" and "adjustable," the latter meaning "can be adjusted," in support of its position that the hardness of the '565/'978 dog chew can be adjustable to become either softer or harder. (Dkt. 48 at 7.) Defendants argue that to use a dictionary definition with no reference to the teachings of the patent would be error in this instance, where all of the intrinsic evidence points to the capability of the dog chew to be adjusted from an initial very hard state to softer states to suit the individual pet. (Dkt. 49 at 8-13.) On this point we agree with Defendants. We find that the teachings of these patents as a whole require that the dog chew of the invention be adjustable to become less hard, rather than potentially even harder than its initial state.

On the third point, Plaintiff argues that the concept of expandability of the chew is by no means necessary in order to construe what it means for the chew to be "hardness-adjustable." Plaintiff also contends that it would be improper to import from the specification any numerical criteria for how expandable the chew should be. (Dkt. 48 at 13.) Defendants point to the repeated explanations and illustrations in the specification, and statements in the prosecution files, about how the dog chew of the invention is capable of expanding and thereby having its hardness adjusted, and just what the numerical range of that expansion is described to be. (Dkt. 49 at 19-21.) We find that the patents clearly specify that the way that the dog chew becomes "hardness-adjustable" is that it can expand, thereby becoming less dense and less hard. That inherent quality of

expandability of the finished product is necessary according to the science underlying the patents, and is integral to the explanations of the invention in the patent specifications and prosecution files. Therefore, it must be included in construing the term "hardness-adjustable." We agree with Plaintiff, however, that it would be improper to impose a numerical range of expandability upon the construction of this term.

It is the second point that poses the closest question, in our view. Plaintiff argues that because there is no description in the claim language itself about how the "hardness" of the dog chew is to be "adjustable," then there should be no mention of that mechanism in the construction of this term. Plaintiff also vigorously disputes that the construction of this term should limit the scope of the invention to microwave heating of the product that results from the claimed methods. (Dkt. 48 at 8-10.) Defendants argue that the entire thrust of the claimed invention, as described in the specifications and in the prosecution files, is that the product of these method claims will be a dog chew that the owner can quickly and easily adjust to the hardness preference of the animal, and the only way that is described as being achievable is by the microwaving of the product. Defendants argue that such would also be consistent with the understanding of the ordinary artisan of the time, being familiar with other half-products that would expand exponentially when microwaved by the consumer. (Dkt. 49 at 9-14.) We have carefully studied this issue, based upon the entire intrinsic record and the extrinsic evidence presented by the parties. We conclude that this term should be construed to include the core concept of the

invention, namely that the "hardness-adjustable edible dog chew" produced by the asserted method claims is a chew designed to be microwaved and thereby its hardness can be adjusted conveniently to a softer texture, until acceptable to the individual pet.

Based upon these rulings, this Court construes the term "a hardness-adjustable edible dog chew," in claim 1 of the '565 patent and in claim 4 and claim 8 of the '978 patent, to mean "an edible dog chew possessing the capability of being adjusted by expanding and becoming softer when microwaved." Here is the factual basis for this ruling.

i. Comparison of specifications - both patents

The name of the '565 patent is "Process for Making an Edible Dog Chew." The name of the '978 patent is "Edible Dog Chew," but its claims include both process and product claims. The abstract of each patent is slightly different:

> '565 Abstract:
>
> A process for making a heat expandable dog chew comprised primarily of injection molding potato starch granules and an attractant is disclosed.
>
> '978 Abstract:
>
> A heat expandable dog chew comprised primarily of injection molded potato starch, calcium carbonate, to which is added a fruit flavoring, a food coloring or a breath sweetener.

We note that each abstract describes the dog chew as "heat expandable," whereas the claims use the term "hardness-adjustable." Thus, the abstracts place the expandability concept at the forefront of the description of the invention, as they should given the statements and illustrations in the rest of the specification.

The entire specifications of the two patents-in-suit, after the Abstract portion and up to the Claims portion, are substantially similar when overlaid together. Because they are not particularly lengthy and the parties argue from much of that text, we will set it forth in full here. Again, words appearing in the '565 specification that are deleted from the '978 text are shown in brackets, and new words appearing the in '978 text are in bold.

Here is an overlay quote of the body of the specifications of both patents:

> 1. Field of the Invention
>
> The present invention relates to dog chews, and more particularly, pertains to a potato starch-based or other vegetable starch-based**,** completely digestible, nutritious dog chew, the texture or hardness of which [is] **can be** easily heat modified to suit a particular dog.
>
> 2. Brief Description of the Prior Art
>
> Most dogs enjoy chewing on things although preferences vary as to the hardness of the substances favored. Some dogs like to chew on very hard materials such as cow bones, wood, nylon, others prefer softer chews such as polyurethane or rubber**,** while still others favor freeze dried snacks. Some dogs, due to their age, may not be able to chew on the very hard substances. Young dogs have insufficiently developed teeth, while old dogs may have diseased gums or may have lost some of their teeth.
>
> Many indigestible objects are given to dogs as a chew and although the dogs may enjoy chewing thereon, the objects are often swallowed in whole or in part. Once swallowed, these objects or fragments thereof can have an adverse effect on the dogs digestion and can become impacted in the dog's intestinal tract with life-threatening consequences. By way of example, dog chews have been marketed which utilize an ethylene copolymer which can be fractured by the chewing action of a dog, and when ingested can block the dog's stomach passages.
>
> Other edible dog chews have been marketed which have a comparatively short shelf life and therefore must be replaced by retail outlets at frequent intervals. Yet other prior art dog chews are lacking in

structural integrity whereby they are susceptible to breakage during handling and shipping.

Applicant's assignee**,** T.F.H. Publication**s**, Inc.**,** has previously developed an edible dog chew that is wholly digestible, nutritious and having a texture or hardness which is individually adjustable by the application of heat to suit a wide variety of dog's preferences or needs. Such dog chews utilize a mixture containing primarily casein and are disclosed in Herbert R. Axelrod U.S. Pat. Nos. 5,200,212 and 5,240,720. Such dog chews, while constituting a major improvement over other prior art edible dog chews, do not provide all the advantages of the dog chew of the present invention.

SUMMARY OF THE INVENTION

The present invention provides an edible dog chew that is completely digestible, nutritious, devoid of deleterious additives and of a modifiable texture or hardness that [is] **may be** quickly and easily tailorable by the owner to suit the need or preference of his particular dog. In addition, such edible dog chews have a long shelf life as compared to prior edible dog chews. The chews are biodegradable and extremely rugged so as to be able to withstand shocks resulting from shipping and handling. Upon removal from the chew's package, the chew can be caused to swell up to [6] **3** to 8 times its original volume, if desired, by subjecting it to microwave radiation. With this procedure, the chew's texture or hardness can be adjusted to any magnitude from its original high density extremely hard state to a low density expanded easily chewed state depending upon the amount of microwave exposure to which it is subjected. Accordingly, the chew can thereby be quickly and easily **adjusted** to the texture preference of a wide variety of dogs from a strong large healthy dog to a small puppy with puppy teeth or an older dog with decayed molars.

The present invention also provides a dog chew having natural fruit flavor to increase a dog's appetite for such chew. Such fruit flavored dog chew may include natural food coloring to enhance the attractiveness of the dog chew to dog owners. The food coloring may correspond to the fruit flavor if desired.

A dog chew of the present invention may also embody a breath sweetener for a dog such as mint, spearmint, peppermint or wintergreen and also include parsley.

Other features and advantages of the present invention will be come apparent from the following detailed description taken into conjunction with the accompanying drawings which illustrate by way of example the principles of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 illustrates a preferred embodiment of an edible dog chew embodying the present invention in its unexpanded state[;]**,**

FIG. 2 illustrates the dog chew of FIG. 1 in its partially expanded state; and

FIG. 3 illustrates the dog chew of FIG. 1 in its fully expanded state.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

The preferred form of edible dog chew of the present invention has as a basic ingredient, a **heat-expandable starch, such as a** potato starch product sold under the trademark PARAGON IM 1010 by AVEBE of Veendam, The Netherlands. The PARAGON product is sold in the form of thermoplastic granules**, beads or granules,** which are **manufactured by an extrusion process, and which are then** molded into a desired shape. The weight contents of such **extruded** pellets, **beads or granules** are about 70% potato starch, about 15% water (about 10% after the [pellets] **granules** are molded), about 5 to 10% calcium carbonate, and about 1 to 5% natural vegetable additives. To [such mixture] **this granule pre-mixture** is added an attractant such as chicken powder, liver powder, ham, turkey, beef, and/or fish in the amount of 1 to 5% by weight. Natural vegetable additives [s]**S**uch as spinach or carrots may also be added. The resultant mixture **is** molded under heat and pressure into a desired form, such as a dog bone. Molding can be accomplished in an injection molding machine at temperatures between 250 to 400 degrees F and pressures of 1000 to 2500 PSI depending upon the injection molding machine utilized, the materials location within the molding machine, the type of additives, the particular mold, and the size of the bone being molded.

In accordance with the present invention, a fruit flavoring may be added to the granules of the mixture of potato starch, water and calcium carbonate, before Such mixture is molded to increase a dog's appetite for the finished dog chew. Natural fruit flavorings are

preferred. In addition, a bright food coloring may be added to such mixture to enhance the attractiveness of the dog chew to the dog owner. A natural food coloring is preferred, and the food coloring may correspond to the fruit flavor. The weight content of the fruit flavoring in such mixture may be 1 to 5%. Likewise, where a food coloring is added its weight content in such mixture may be 1-5%.

If desired, a breath sweetener may be added to the granule mixture before the molding step, e.g. mint, spearmint, peppermint or wintergreen and parsley. The weight content of such breath sweetener may be 1-3% spearmint, peppermint or wintergreen and 1-5% parsley.

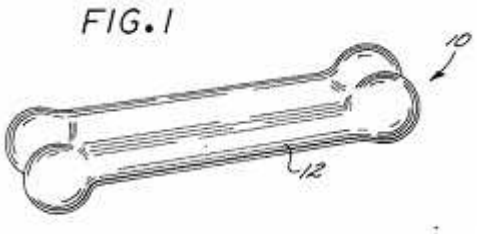
Upon removal from the package, the person feeding the dog can **if desired** modify the texture or hardness of the molded chew by heating, [preferably] in a microwave oven. The expansion of the moisture within the chew causes the chew to expand. Subjecting the chew to microwave radiation facilities the heating of areas deep within the chew at the same time the exterior heats up and expands. FIG. 1 illustrates the chew 10 prior to heating, in which state it has a substantially smooth exterior surface 12 and is of an extremely hard texture preferred by some dogs. A short exposure to microwave radiation initiates the expansion process. FIG. 2 illustrates the chew 10 in a partially expanded state evidenced by partially bubbled surface 14. In this state the chew 10 is of an intermediate hardness preferred by other dogs. FIG. 3 illustrates the chew 10 in a fully expanded state as may result from a 25 seconds to [1] **a 2** minute exposure in a standard household microwave oven, depending upon the size of the bone and the power setting of the oven. The entire chew 10 has a bubbled surface 14 and is easily chewable by most dogs. The chew in this state is ideal for small dogs with puppy teeth or old dogs who suffer from gum disease or may have lost teeth. Sufficient exposure to microwave radiation will cause the chew to expand up to about [6] **3** to 8 times its original volume with a commensurate reduction in hardness.

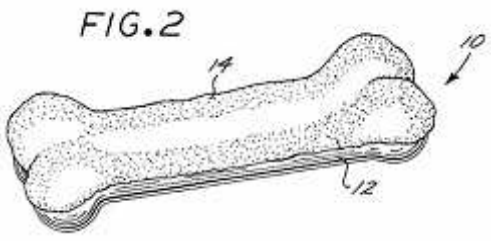
In use, the chew is given to the dog in its initial hardness state. If the dog is unwilling or is unable to chew on it, the chew is microwaved for short time increments and re-offered to the dog until the chew reaches a state of expansion and degree of hardness preferred by the dog. Large, strong and healthy dogs would probably prefer the chew in its unmodified and hardest state, while very small, young or very old dogs would prefer the chew in its most expanded state.

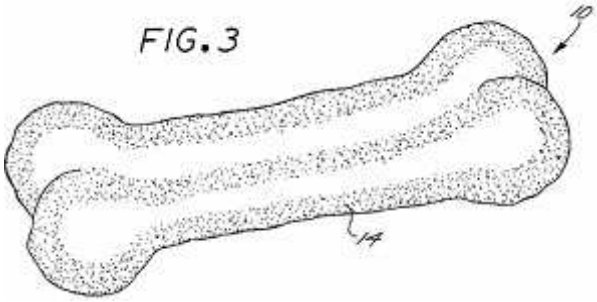
> It should be particularly noted that an edible dog chew made in accordance with the present invention does not dry out and fall apart after being packaged and accordingly can have a shelf life of several years without being packaged in a waterproof container. Additionally, the dog chew is extremely resistant to breakage during shipping and handling.
>
> While a particular form of the invention has been illustrated and described it will be apparent to those skilled in the art that various modifications can be made without departing from the spirit and scope of the invention. Accordingly, it is not intended that the invention be limited except as by the appended claims.

('565 patent, 1:1-3:20; '978 patent, 1:1-3:55.)

This text expressly teaches that the edible dog chew of the invention can have its hardness adjusted from its "unmodified and hardest state" to its "most expanded state," the latter state being "ideal for small dogs with puppy teeth or old dogs who suffer from gum disease or may have lost teeth." The text describes no adjustment of the hardness that is accomplished without having the dog chew expand. Nor does the text describe the dog chew's hardness as ever being adjusted from its "initial hardest state" to an even harder state (if such were even linguistically possible after starting at "hardest"). Thus, the adjustability of the hardness of the dog chew as described here is a progression from its hardest state to more expanded, less dense, and thus less hard states. The illustrations support these concepts, as reproduced here.







('565 patent, Fig. 1 - Fig. 3; '978 patent, Fig. 1 - Fig. 3.)[26]

We find that this basic intrinsic evidence, the specification itself, establishes that "hardness-adjustable," within the meaning of these two patents, connotes that the dog chew possesses the capability of becoming softer, not harder, and doing so by expanding. The prosecution history is not to the contrary, as summarized below. The only extrinsic evidence suggesting otherwise is testimony from the inventor and Plaintiff's expert, discussed infra, which we find not persuasive on these issues.

[26] These illustrations, shown as Fig. 1 - Fig. 3 in the patents-in-suit, also appear as Fig. 1 - Fig. 3 in the prior art patents Axelrod '212 and Axelrod '720. (See dkt. 51-1 at 3; dkt. 51-2 at 3.)

Turning now to the topic of the mechanism by which the dog chew of the present invention is to have its hardness adjusted, it is true that the specification takes pains to emphasize that microwaving is a preferred embodiment of applying "heat" to the product, which the consumer may practice "preferably" and "if desired." Nor does the Abstract use the word "microwave," rather it uses the word "heat." Also, the specification contains two entire paragraphs of standard "other features and advantages" and "various modifications can be made" language, indicating the intention of the applicant to claim as broadly as possible. However, we do not view those features of the specification to be dispositive of the questions whether the "heat" aspect of the invention is inherent in the claim term "hardness-adjustable edible dog chew," or whether this claim term indicates a broader range of "heat" sources for adjusting the hardness of the dog chew, in addition to microwave heat. Next we turn to the prosecution history of each patent.[27]

ii. Prosecution history - '565 patent

The application that ultimately led to both the '565 patent and the continuation-in-part '978 patent, filed on October 25, 1996, originally had nine product claims and no method claims. The name of the patent was Edible Dog Chew, and the Abstract

[27] We must consult the prosecution files of both patents-in-suit in order to construe each of the disputed claim terms addressed in this opinion: "a hardness-adjustable edible dog chew," and "a heat-expandable potato starch." This is necessary even though the latter term does not appear in the earlier '565 patent, having been substituted in the '978 patent for the term "a potato starch" in claim 1 of the '565 patent. When we make rulings on the construction of "a heat-expandable potato starch" in the following section of this opinion, it will be necessary to refer back to the summary of the two prosecution histories set forth here. See infra Sec. II.B.2.c.

described "A heat expandable dog chew comprised primarily of injection molded potato starch ...." When the '565 patent was eventually approved with only method claims, the name was changed to "**A Method of Making an** Edible Dog Chew," and the Abstract was amended to "**A process for making** a heat expandable dog chew comprised primarily of injection mold**ing** potato starch **granules** ...." (Dkt. 48-3 at 19, 28, 66 (emphasis added).) The specification of the '565 patent received no other changes during prosecution of that patent, except technical corrections. (Id. at 19-31.)

The original nine claims of the '565 application are quoted in the margin.[28]

---

[28] The nine claims in the original application for the '565 patent were:

1. A dog chew comprising injection molded potato starch and an attractant.

2. The dog chew of Claim 1 which further includes calcium carbonate.

3. The dog chew of Claim 1 which further includes vegetable attractants.

4. An injection molded dog chew comprising about 70% potato starch by weight, about 15% water by weight, about 5 to 10% calcium carbonate by weight, about 1 to 5% attractant by weight, and about 1 to 5% natural vegetable additives.

5. The dog chew of Claim 4, wherein the water content decreases to about 10% after injection molding.

6. The dog chew of Claim 4, wherein the injection molding takes place at about 1000 to 2500 PSI and a temperature of about 250 to 400 degrees F.

7. The dog chew of Claim 5, wherein the injection molding taken [sic: takes] place at about 1000 to 2500 PSI and a temperature of about 250 to 400 degrees F.

8. The dog chew of Claim 6, wherein the molding is in the form of a bone.

9. The dog chew of Claim 7, wherein the molding is in the form of a bone.

(Dkt. 48-3 at 26-27.)

The examiner rejected all nine claims, primarily on the basis of obviousness. That portion of the examiner's explanation stated as follows:[29]

> Claim 1 is rejected ... as obvious over Ando ['491] et al.
>
> Ando ['491] discloses a method of making biodegradable molded articles. While dog chews are not specifically mentioned[,] other edible articles are recited at col. 10, lines 5-13. Examples 11 and 12 include potato starch in the molded product. The claim appears to differ from Ando in the recitation "injection molded" and in the recitation "dog chew." It would be obvious ... to use the product of Ando as the product of the claim since dogs typically chew a variety of articles that are edible and inedible. It is appreciated that "injection molding" is not indicated [by Ando] but no unobvious difference is seen between the molded product of Ando and that of the claim since there [sic: they] are both molded.
>
> ....
>
> Claims 1-9 are rejected [as obvious] over Miller (607) in view of Axelrod (720) and Scaglione (808).
>
> Miller ['607] discloses a simulated bone that contains potato flour ... as a suggested farinaceous material. The ingredients are mixed and then convey[ed] into an extruder operated at a temperature of 230 F. The product contains a "marrow" filling that contains poultry and beef meal and these ingredients are seen to be attractants. Claim 1 appears to differ from the [Miller '607] reference in the recitation that the product is injection molded. Axelrod ['720] teaches that it is well known to use injection molding in the manufacture of dog chews. It would be obvious ... to use the injection molding of Axelrod in the product of Miller since such a recitation is seen to be the mere substitution of one molding method versus another. Claim 2 appears to differ from Miller in the recitation of the inclusion of calcium carbonate. Scaglione ['808] teaches that it is well known to use calcium carbonate in the formulation of a dog bone. It would be obvious ... to use the calcium carbonate of Scaglione in the dog biscuit of Miller in order to supplement the

---

[29] We have summarized the prior art patents cited by the '565 and '978 examiners supra, Section II.B.1.b. See supra n.11 and accompanying text. Several of those patents were issued to the same inventor, e.g., Axelrod '212 and Axelrod '720. For clarity in quoting the prosecution histories, we will insert in brackets the particular patent number being discussed by the examiner or applicant. We also insert bracketed clerical notations to facilitate comprehension of the text.

> product with a calcium source. It is appreciated that vegetable attractants are not indicated [in Scaglione '808,] but to include vegetable products in the product of Miller is seen to be within the determination of one of ordinary skill ... who desires to vary the flavor of the product. It is appreciated that the particular pressure used in the molding is not indicated [in Axelrod '720,] but this pressure is seen to be inherent to the injection molding process.

(Dkt. 48-3 at 52-54.)

The applicant, in response to that rejection, filed an amendment that cancelled the nine original claims and substituted the four new claims that were ultimately approved as claim 1 through claim 4 of the '565 patent. (Compare id. at 58-59, with '565 patent, 4:1-16.) To overcome the examiner's obviousness objections, the applicant argued:

> Claim 1 stands rejected ... relative to **Ando** ('491). It is ... submitted that while the Ando articles may very well be biodegradable, nothing in the reference suggests that the consistency of the articles produced by subjecting a slurry of potato starch to a electroconduction heating process to provide a "sheet-like" material, [would] have a hardness adjustable characteristic suitable for use as a dog chew. Specifically, applicant injection molds a slurry of potato starch and other edible ingredients to provide a dog chew which in its manufactured state has an initial extremely hard texture preferred by some dogs. The hardness of such chew can be reduced by microwave heating, to meet the preference of other dogs. The initial hard texture is obtained by compressing the slurry under pressures of 1,000 to 2,500 PSI. **Ando** on the other hand does not compress the slurry, as evidenced by Fig. 1 of the **Ando** patent. Referring thereto, it will be seen that upper mold 2 and lower mold 3 are maintained separated by hard plastic insulators 5, and accordingly could not compress the slurry dough 5. Moreover, as recited in **Ando** Claim 1, the resulting molded product is foamed and expanded during the electroconduction step. **Ando** therefor[e] teaches directly away from applicant's invention.
>
> Applicant's claims were additionally rejected ... as obvious over **Miller** ... ['607] in view of **Axelrod** ... ['720] and **Scaglione** ... ['808]. Applicant's new claims are believed to overcome the obviousness rejection of applicant's original claims.

Applicant's new claims recite a method of producing a variable-hardness edible dog chew by first extruding a mixture of a potato starch, water and calcium carbonate to form granules and thereafter injection molding such mixture into the shape of the dog chew. The variable-hardness recitation covers the characteristic of varying applicant's dog chew from an initially molded hard texture to textures of lesser hardness by microwaving the chew. The chews of **Miller** ['607] and **Scaglione** ['808] do not provide this feature. As noted by the Examiner, **Miller** discloses a simulated bone that contains potato flour. Applicant's dog chew is instead primarily composed of a **potato** starch. Dog chews made primarily from vegetable flours such as potato flour mainly contain protein. Feeding a dog a high protein diet tends to place an undesirable load on the dog's kidneys. On the other hand, a dog chew primarily utilizing a potato starch permits the dog to be fed a low protein diet. The Examiner also notes that with **Miller's** process, the farinaceous material is extruded rather than being injection molded. Applicant on the other hand, teaches extruding a mixture of a potato starch, water, and calcium carbonate [into] granules. These granules are thereafter injection molded into the shape of a dog chew. It is critical in applicant's process that the starch, water, and calcium carbonate mixture be extruded into granules, since unless this step is taken, it is not possible to satisfactorily injection mold the dog chew. Accordingly, **Miller** neither discloses nor suggests applicant's two step process of first extruding the mixture into granules and thereafter injection molding such granules into the shape of a dog chew.

While **Axelrod** ['720] teaches injection molding a mixture of poultry meal, casein, and gelatin to form a dog chew, **Axelrod** does not teach the initial step of extruding the mixture to be injection molded into granules. Moreover, **Axelrod** also teaches forming the dog chew of a proteinaceous ingredient rather than applicant's potato starch. Accordingly, **Axelrod** does not contain any suggestion for modifying **Miller's** process so as to synthesize applicant's claimed method.

The Examiner properly notes that **Scaglione** ['808] teaches the use of calcium carbonate in the formulation of a dog bone. **Scaglione**, however, teaches **baking** the dog biscuit dough to form a dog biscuit. Merely baking the dough material cannot possibly provide applicant's dog chew having a high initial hardness resulting from injection molding applicant's ingredients. Accordingly, the teaching of **Scaglione** when added to the teaching of **Miller** and **Axelrod** fails to even remotely suggest the applicant's claimed method.

(Dkt. 48-3 at 59-62 (emphasis in original).)

The amendment and arguments submitted by the applicant prevailed, after a telephone interview with the examiner. (Id. at 64.) In issuing the approval, the examiner gave this statement of reasons:

> Applicant[']s arguments concerning the combination of references is persuasive. The potato flour of Miller ['607] is not granulated or processed to granular form as set forth by applicant at page 4, lines 10-13.[30] The injection molding of Axelrod ['720] does not utilize potato starch as a starting material. The dog biscuit of Scaglione ['808] does not use the ingredients of the claims or the process of the claims. There is no suggestion in the prior art that one could use the process of the prior art to achieve the product of the claims. There is no indication in Stepto ['564] that the process leads to an edible product, is a dog chew or contains calcium carbonate.

(Id. at 66-67.)[31]

Reviewing this file history of the '565 patent, two main features are significant to the present claim construction issues. First, the original nine claims made no reference to the fact that the "potato starch" ingredient, along with the water and calcium carbonate, were subjected to extrusion before being injection molded. See supra n.28. In contrast, claim 1 -- the only independent claim of the amended application and approved '565 patent -- expressly set forth a first step of "extruding a mixture of a potato starch, water and calcium carbonate to form granules," prior to the injection molding step forming the dog chew. See supra n.20. The applicant's arguments to overcome obviousness followed the same theme: "Applicant's new claims recite a method of producing a variable-hardness

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[30] Here the examiner is referring to the portion of the specification describing the AVEBE thermoplastic granules. (Compare dkt. 48-3 at 22, with '565 patent, 2:22-30.)

[31] The prior art patent reference Stepto '564 was added by the examiner in a Notice of References Cited, filed with the Notice of Allowance of the '565 patent. (Dkt. 48-3 at 65-68.)

edible dog chew by first extruding a mixture of a potato starch, water and calcium carbonate to form granules and thereafter injection molding such mixture into the shape of the dog chew.... Applicant ... teaches extruding a mixture of a potato starch, water and calcium carbonate [into] granules. These granules are thereafter injection molded into the shape of a dog chew. **It is critical in applicant's process that the starch, water, and calcium carbonate be extruded into granules, since unless this step is taken, it is not possible to satisfactorily injection mold the dog chew**." (Dkt. 48-3 at 61-62 (emphasis added).)

It was this first extrusion step to form granules using starting ingredients including a potato starch and water, followed by the second -- injection molding -- step, that enabled the applicant to distinguish Miller '607 (potato flour; extrusion only), Axelrod '720 (no potato starch; injection molding only), Ando '491 (electroconduction to form molded articles would be insufficient to create extreme hardness), and Scaglione (baking to form dog biscuit would be insufficient to create high initial hardness). (Id. at 60-62.) The examiner found those arguments persuasive in allowing the '565 patent to issue. (Id. at 66-67.)

The other main feature of this '565 file history, as bearing upon our inquiry, is that throughout this amendment -- as in the specification itself -- the applicant emphasized that the desirability of the entire invention was that "[t]he **hardness** of such chew can be **reduced by microwave heating**, to meet the preference of other dogs." As the applicant firmly declared to the examiner, "**The variable-hardness recitation covers the**

characteristic of varying applicant's dog chew from an initially molded hard texture to textures of lesser hardness by microwaving the chew." (Id. at 60-61 (emphasis added).) Those were the words used by the applicant, describing the "variable-hardness recitation," to explain the "hardness-adjustable edible dog chew" to the USPTO in seeking patent approval.

iii. Prosecution history - '978 patent

The continuation-in-part application that led to issuance of the '978 patent, subject to a terminal disclaimer tied to the '565 patent term, contained sixteen original claims. Four of those were independent method claims and three were independent product claims; the rest were dependent claims. There are also sixteen claims in the '978 patent as issued, including both product and method claims, but they differ in order and in just one significant wording change from the original sixteen claims applied for. Rather than reproduce all sixteen originally proposed claims, we quote representative excerpts in the margin.[32]

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[32] The following are representative of the originally proposed claims of the '978 patent:

1. A method of producing a hardness-adjustable edible dog chew, comprising the steps of:
extruding a mixture of a potato starch, water and calcium carbonate to form granules;
adding a fruit flavoring to such granules; and
injection molding such ingredients into the shape of the dog chew.

....

10. An improved edible dog chew comprising:
an injection molded mixture of potato starch, water, calcium carbonate and a fruit flavoring.

(Dkt. 68-1 at 18-21.)

Basically, the '978 application aimed to add fruit flavoring, food coloring, and/or a breath sweetener to the "hardness-adjustable edible dog chew" of the approved '565 patent. It also sought to establish both method and product claims, whereas the '565 patent contained only method claims. The applicant succeeded in those basic objectives, as reflected in the '978 patent as issued. (Compare '565 patent, 4:1-16, quoted supra n.20, with dkt. 68-1 at 18-22 (original '978 proposed patent claims), and '978 patent claims as issued, 4:6-65, quoted in part supra n.25.) That success did not come without a struggle, however, as we will describe.

The examiner (a different examiner from the examiner on the '565 application) initially rejected the '978 application in an Office Action mailed on October 23, 1998 ("the 10-23-98 Office Action"). (Dkt. 68-1 at 37-44.) The primary ground for the rejection was obviousness, as it had been for the '565 application.[33] That portion of the examiner's explanation stated as follows:[34]

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[33] We observe, but do not comment upon, that the application for the '565 patent had been approved after a patent prosecution that had overcome rejection based on obviousness; yet when the '978 continuation-in-part application was prosecuted, virtually the same obviousness objections were raised by the USPTO. The applicant noted that fact in responding to the rejection of the '978 application. (See dkt. 68-2 at 50 n.1.) Yet the applicant proceeded to address the USPTO's renewed obviousness objections substantively, in order to win approval of the '978 application.

[34] Here we follow the same quotation protocol used in quoting the '565 prosecution history. See supra n.29 and accompanying text.

Claims 1-14 [sic: 1-16] are rejected [as obvious] ... over Miller ... ['665] and Axelrod ... ['212][35] in view of Scaglione ... ['808] and Kehoe ... ['270].

Miller ['665] teaches a simulated bone made from farinaceous material such as potato which contains starch.... The patent teaches that the composition is extruded, heated and molded to the shape of a bone as a dog chew. It does not show the breath sweetener, fruit flavoring or food coloring or injection molding.

Axelrod ['212] teaches a chew that is adjustable with regard to the hardness and texture, according to the needs of the animal it is intended for.... At col. 2, the patent shows molding or extrusion, and also injection molding to achieve this bone with its benefits. Attractants are taught in Axelrod..., which includes food coloring. Note the moisture content shown by Axelrod at col. 2. To combine Miller's patent teachings of starchy vegetable with Axelrod's teachings would have been obvious ... because of the benefits shown by Axelrod ..., both patents being drawn to a product that is formed by combining milled constituents, heated and extruded. To incorporate Axelrod's proteinaceous material to form a bone would have also been obvious ... because of the advantages shown therein, which enables the artisan to modify the hardness and texture of the bone while at the same time providing a nutritious, proteinaceous and digestible chew. To adjust amounts of ingredients would have been within the routine skill of the artisan.[36]

The patents to Miller ['665] and Axelrod ['212] do not show calcium carbonate in the bone. Scaglione et al ['808] teach calcium carbonate as a nutrient, in particular as a desirable nutrient, to provide the animal an adequate supply of calcium. For these benefits, it would have been obvious to incorporate calcium carbonate into the dog chew product.... To adjust conditions used during the injection molding based on the product being molded is within the skill of the artisan.

---

[35] The later rejection, mailed 7-19-99, contains the following added phrase at this location in the text: "and the prior art disclosure in the specification at page 5, lines 7-10". (Dkt. 68-2 at 24.) The cited portion of the specification is quoted infra, n.38.

[36] The handwritten word, "Furthermore," becomes an additional sentence at this point in the text in the later rejection mailed 7-19-99. See discussion of 7-19-99 Office Action, infra.

> Kehoe ['270] teaches the use of colorants and flavorants such as mint and fruit in chewable articles such as dog biscuits, and chews for canines.... It would have been obvious to add flavorings such as mint in the product by Miller and Axelrod because it is known in the art to use such for canine products and such flavorants are known breath fresheners and this would have been obvious....

(Dkt. 68-1 at 38-39.)

The applicant, in response to the rejection in the 10-23-98 Office Action, filed an amendment on April 27, 1999 ("4-27-99 Amendment"). That amendment inserted the words "heat-expandable" into the phrase "a potato starch" in every claim where that phrase appeared. Those were all of the independent method and product claims. (Dkt. 68-1 at 50-53.) Thus, for example, proposed method claim 1, as amended, now read: "... extruding a mixture of a heat-expandable potato starch, water and calcium carbonate to form granules." (Id. at 50 (emphasis in original).) Proposed product claim 10, as amended, now read: "An improved edible dog chew comprising: an injection molded mixture of a heat-expandable potato starch, water, calcium carbonate and a fruit flavoring." (Id. at 52 (emphasis in original).)[37]

The 4-27-99 Amendment was accompanied by the applicant's rather lengthy arguments directed to the obviousness issue. Those arguments may be excerpted fairly by quoting the following portions:

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[37] The only other feature of the 4-27-99 Amendment was to insert the phrase "in sequence" after the word "steps" in each of the proposed method claims, 1-4. (Dkt. 68-1 at 50-51.) This Court has construed that claim term in a previous Order. (Dkt. 67 at 4.)

Independent claims 1, 2, 3, 4, 10, 11, and 13 have been amended to better clarify that Applicant's novel invention includes a heat-expandable potato starch. Support can be found in the specification at page 5, lines 7-14.[38]

....

Applicant's invention as amended herein recites a novel heat-expandable starch-based dog chew. See Amended claims 1, 2, 3, 4, 10, 11, and 13. Applicant respectfully submits that none of the combined limitations recited in these claims are disclosed or suggested in the references relied upon by the Examiner.

For example, in the primary reference of Miller ['665] ..., the Examiner correctly notes that Miller teaches a simulated bone made from farinaceous material and some vegetable proteins. However, there is no disclosure or suggestion that Miller's formulation includes a heat-expandable starch.

Axelrod ['212] ... discloses a dog chew comprising the intermixing of between 60-95% casein with 5-40% gelatin.... Axelrod preferably forms his dog chew by injection molding this casein/gelatin mixture.... Again, however, there is no disclosure or suggestion of the use of a heat-expandable starch!

Scaglione ['808] ... discloses and claims a low calorie dog biscuit containing vegetable hulls. In addition, Scaglione teaches the use of certain additives. For example, Scaglione teaches addition of calcium carbonate AND bone meal.... In addition, Scaglione teaches the use of fat along with the

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[38] That precise portion of the '978 specification, as set forth in the '978 application and as contained in the '978 patent as issued, stated:

> The preferred form of edible dog chew of the present invention has as a basic ingredient, a **heat-expandable starch, such as a** potato starch product sold under the trademark PARAGON IM 1010 by AVEBE of Veendam, The Netherlands. The PARAGON product is sold in the form of thermoplastic granules**, beads or granules,** which are **manufactured by an extrusion process, and which are then** molded into a desired shape. The weight contents of such **extruded** pellets, **beads or granules** are about 70% potato starch, about 15% water (about 10% after the [pellets] **granules** are molded), about 5 to 10% calcium carbonate, and about 1 to 5% natural vegetable additives. To [such mixture] **this granule pre-mixture** is added an attractant ....

(Dkt. 68-1 at 13, lines 7-14 (emphasis added; bold and bracketed material indicates where '978 specification differed from the prior '565 specification).)

calcium carbonate and bone meal. But, again, there is no disclosure or suggestion of the use of a heat-expandable starch!

Kehoe [‘270] ... teaches preparation of elastomer-encased ingredients which can subsequently be incorporated into certain chewable articles of commerce such as chewing gum. Kehoe teaches preparation of such elastomer-encased materials by first dispersing an “active ingredient” in the matrix of the elastomer, cooling that mixture ..., and grinding the cooled mixture to “form particles of elastomer, with the active ingredient encased therein.” .... Yet, there is no disclosure or suggestion of the use of a heat-expandable starch.

....

Thus, no combination of art as advanced by the Examiner would achieve Applicant’s claimed invention, and the invention as amended herein, comprising a dog chew including a heat-expandable starch[,] cannot be said to be disclosed or suggested by the combination of references relied upon by the Examiner.

As the Examiner is well aware, the omission of an element with retention of the element[’]s function is an indicia of non-obviousness. MPEP 2144.04(II)(B). Thus, the invention as claimed herein is clearly non-obvious over Miller [‘665]. Furthermore, the teachings of Axelrod [‘212] do not make up for the deficiency of Miller, even assuming Axelrod is properly combinable.

....

Assuming, arguendo, one simply combines Miller’s starch/fat/meat meal, with Axelrod’s casein and gelatin, the resulting mixture would differ materially from Applicant’s novel invention. Applicant’s novel invention as claimed herein requires no fat, no meat meal, no casein, and no gelatin.

....

The teachings of Scaglione [‘808] and Kehoe [‘270] do not make up for the deficiencies of Miller [‘665] and Axelrod [‘212]....

As discussed above, Scaglione [‘808] teaches the use of fat in his dog biscuit. In addition, Scaglione also teaches addition of calcium carbonate AND bone meal. “Calcium carbonate is added in the most preferred embodiments **in addition to bone meal** to provide adequate calcium for the animal.” ....

....

In sharp contrast, however, Applicant's novel invention as claimed herein requires no fat. Moreover, Applicant requires no bone meal in his invention. Thus, Scaglione ['808] teaches one away from Applicant's novel invention by requiring the use of both tallow and bone meal.

Kehoe ['270] teaches preparation of compositions comprising an "active ingredient" encapsulated in an "elastomer." ... [T]he elastomers used by Kehoe include polyisobutylenes, polyethylene and styrene-butadiene....

... Applicant ... submits that Kehoe ['270] clearly teaches one away from Applicant's novel invention as claimed herein.... Moreover, Applicant's method does not first require dispersal of additives into such an elastomer prior to incorporating those additives into the starch-based dog chew.

... Applicant ... submits it would not have been obvious ... to selectively use only one component of Miller's starch/fat/meat meal composition, with only one component of Scaglione's calcium carbonate/bone meal/fat combination, with only one component of Kehoe's elastomer/additive composition, resulting in Applicant's novel invention....

....

With respect to the enclosed Supplemental Prior Art Statement,[39] German [patent issued to Müller, '861] ... discloses and claims a foodstuff for dogs, and a method to form same. Müller's foodstuff comprises two separate components, namely a "dry" component comprising 55-97% of the foodstuff, and a binding agent component comprising 3-45% of the foodstuff....

The "dry component" of Müller's foodstuff comprises primarily meat and a starch carrier.... The meat subcomponent of the dry component can comprise up to 97% of the total foodstuff.... This meat subcomponent comprises two different elements, namely: (I) 50-60% dried, fat-coated, or fired meat pieces; and (ii) 40-50% extruded croquettes comprising 50-60% meat meal and 40-50% starch....

The starch carrier subcomponent [of Müller] can comprise ... up to 97% of the total foodstuff.... This starch is defined as "native and/or modified starch." .... Müller's binder component primarily comprises gelatin.... This binder component is present from 3-45%....

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[39] These additional prior art patents were cited by the applicant in a supplemental Information Disclosure Statement filed with the 4-27-99 Amendment. (Dkt. 68-2 at 15.)

> Thus, the composition taught by Müller comprises meat and starch, and, therefore, differs significantly from the composition of Applicant's claimed invention, as amended herein, which requires no meat. And, unlike Applicant's claimed invention, Müller doesn't include a heat-expandable starch.
> ....
> Forrest ['440] ... teaches a molding apparatus and a method for producing a food product from a food mixture having a heat sensitive binding agent.... The heat sensitive binding agent taught by Forrest comprises starch.... Table 1 sets forth the "typical ingredients" taught by Forrest. These ingredients comprise primarily 44.35% meatmeal, and 43.56% starch in the form of wheatgm [sic: wheatgerm]....
>
> Thus, the food composition taught by Forrest ['440] includes a substantial meat meal component. Again, there is no disclosure or suggestion in Forrest of the use of a heat-expandable starch. And, Applicant's novel invention requires no meat meal. Therefore, the teachings of Forrest neither anticipate Applicant's claims, as amended herein, nor render those amended claims obvious.
> ....

(Dkt. 68-1 at 53-62 (emphasis in original).)

The amended application was rejected in an Office Action mailed on July 19, 1999 ("7-19-99 Office Action"). (Dkt. 68-2 at 23-25.) There, the examiner repeated all of his prior obviousness reasons and added one more prior art basis for that rejection, namely the AVEBE thermoplastic granules disclosed in the specification. (Id. at 24.) The examiner stated:

> Furthermore, since a potato starch that expands upon heating was already known in the art at the time the invention was made, according to the specification at page 5, lines 7-10, it would have been obvious to either substitute the protein or modify the Axelrod dog chew which also has an heat expandable element and this would have been obvious to one of ordinary skill in the art.

(Id. at 25 (referring to the portion of the '978 specification quoted supra, n.38).)

The examiner, in issuing the 7-19-99 Office Action, also replied to the applicant's arguments set forth above. The examiner said he found those arguments not persuasive, explaining as follows:

> Applicant has argued that his invention has no fat, no meat meal, no casein and no gelatin. He also states that Kehoe ['270] uses elastomers to encapsulate his active ingredient and so Kehoe is not an applicable reference and that Scaglione ['808] is also not an applicable reference because it teaches both bone meal and calcium carbonate. Further, he states that no reference teaches heat expandable starch. The specification states that heat expandable potato starch was readily available on the market under the Trade name PARAGON and to substitute one heat expandable element with another would have been prima facie obvious. ... [A]pplicant states that Scaglione teaches a bone meal and calcium carbonate combination, whereas his claims call for calcium carbonate alone. The [Scaglione] patentee does teach the combination, but only as a preferred embodiment, and he also teaches the addition of vitamins and minerals. Thus it would have been prima facie obvious to use calcium carbonate, the most common form of supplemental calcium known.... As for Kehoe, note that this reference was used only for its disclosure that it was known to use such flavorants for canine chews. The fact that Kehoe uses encapsulants does not take away from this fact. It would be within the realm of ordinary skill to modify Kehoe to exclude elastomers since this was used only for extending the flavorant release into the product by patentee.... The fact that applicant's claims exclude fat, casein, gelatin, [and] meat meal are all unpersuasive. The instant claim language does not exclude any prior art dog chew elements nor does the specification explicitly assert this either.

(Id. at 29-30.)

The applicant filed a technical amendment only, on January 18, 2000. No substantive changes were made to the claims or the specification. (Id. at 48.) That filing included an extensive "Remarks" section that again presented the applicant's arguments in favor of allowance. (Id. at 48-50; dkt. 68-3 at 1-5.) Most of those arguments reiterated and elaborated upon the points made in applicant's prior submission distinguishing the

prior art patents, set forth above. Finally, the applicant addressed the examiner's reference to the AVEBE product as prior art, stating:

> ... Applicant notes the Examiner's citation to page 5, l. 7-10 of the specification. It is disclosed therein that the heat-expandable starch selected by Applicant is sold by AVEBE.... Applicant notes that the fact that a preferred embodiment of the starch utilized in Applicant's claims is available from AVEBE does not teach or suggest any of the following as recited in pending claim 1: adding fruit flavoring to granules comprising potato starch, water and calcium carbonate and injection molding said potato starch, water, calcium carbonate and fruit flavoring into a hardness-adjustable edible dog chew. FN 2.
>
> > FN 2: ... Applicant notes that the identification of AVEBE as the preferred source of starch was also disclosed in the parent application, now U.S. Patent No. ... 565.
>
> Thus, no combination of art as advanced by the Examiner would achieve Applicant's claimed invention, comprising a method of producing a hardness-adjustable dog chew comprising the steps in sequence of extruding a mixture of heat-expandable potato starch and calcium carbonate to form granules, adding fruit flavoring to such granules, and injection molding into the shape of a dog chew.

(Dkt. 68-3 at 4 (emphasis in original).)

Those arguments by the applicant prevailed, and the USPTO granted the '978 patent application, by Notice of Allowability mailed on April 7, 2000. (Id. at 31.)[40]

Based on this patent prosecution history, it is clear that the words "heat-expandable" were inserted into the '978 specification when it was originally filed, see supra n.38, and then into the claim phrase "a potato starch" by amendment to overcome the initial rejection of the application. However, the actual potato starch product

[40] The applicant made some procedurally erroneous filings during prosecution of the '978 patent. Those errors were corrected by further filings, as explained by counsel. (Dkt. 68.) That series of events had no effect on the substantive prosecution history, summarized above.

described as part of the preferred embodiment in both the '565 and '978 specifications was the identical AVEBE product. Id. It is equally clear that the arguments of the applicant in support of allowance of the '978 patent relied heavily on the feature of a "heat-expandable starch" in the invention.[41]

None of the discussions between the applicant and the examiner in the '978 file history focus on the "hardness-adjustable edible dog chew" claim term per se. That term is, however, carried over from the '565 patent into each of the method claims of the '978 patent including asserted claims 4 and 8, and continued to be asserted by the applicant in arguing the '978 patent prosecution. Nothing in the '978 file history is inconsistent with the discussion in the '565 file history about the meaning of that term.

iv. Prior art

The closest prior art patents, as we have seen, are the Axelrod '212 patent and Axelrod '720 patent. (Dkt. 51-1 at 2-6; dkt. 51-2 at 2-5.) They are each named "Dog Chew With Modifiable Texture." The '720 patent is based on a continuation-in-part application from the '212 patent, and large portions of the specifications overlap. We have previously noted that much of that specification language is repeated verbatim in the specifications of the patents-in-suit, and that the illustrations in the two sets of patents are identical. See supra n.26 and accompanying text. The '212 patent is a method patent only; the '720 patent contains both product and method claims.

[41] Our claim construction of the term "a heat-expandable potato starch" in the '978 patent is set forth infra, Section II.B.2.c.

The term "hardness-adjustable edible dog chew" does not appear in the Axelrod '212/'720 patents, or in any prior art, according to the record in this case. On the other hand, the claims of the Axelrod '212/'720 patents do address the use of the dog chew by the consumer, which is a feature not found in the claims of the patents-in-suit. As we have said, the only claim term in the patents-in-suit that does address the use of the dog chew of those patents is the inventor-coined claim term, "a hardness-adjustable edible dog chew." We have located enough information in the specifications and prosecution files of the patents-in-suit to be able to construe that claim term, as set forth in this Section.

We do observe, in conducting a thorough analysis of the claim term "a hardness-adjustable edible dog chew" in the patents-in-suit, that the claims of the Axelrod '212/'720 patents use the term "heat" in the independent method claims, and only use the term "microwave" in dependent claims. (Dkt. 51-1 at 5; dkt. 51-2 at 5.) It may be argued that such usage indicates that the Axelrod '212/'720 patents are not limited to using microwave heat to expand the dog chew of those patents, even though the specifications for those patents only identify microwaving as the means of expansion and softening the chew; and that this could influence the view of an ordinary artisan in interpreting the term "a hardness-adjustable edible dog chew" in the patents-in-suit. We reject that notion for two reasons: First, we have not been informed that the claims of the Axelrod '212/'720 patents have been subjected to any litigation and claim construction. Second, the inventor of the patents-in-suit did not draft the claims of these patents so as to preserve any such

argument under the doctrine of claim differentiation, because no dependent or independent claims of the '565 patent and '978 patent address the manner of heating the "hardness-adjustable edible dog chew" by the consumer. Cf. Bancorp Servs., L.L.C. v. Sun Life Assur. Co., 687 F.3d 1266, 1274-75 (Fed.Cir. 2012) (doctrine of claim differentiation creates rebuttable presumption).

None of the other prior art patents cited or discussed by the applicant or the examiners in the prosecution files of the '565 patent and '978 patent present a product (or a method to produce a product) that can have its texture modified by the consumer. See supra n.11 and accompanying text. Thus, those patents provide no guidance on how to construe the claim term "a hardness-adjustable edible dog chew," as used in this case.

v. Extrinsic evidence

Inventor Testimony

The declaration submitted by the inventor, Glen S. Axelrod, did not discuss the claim term "a hardness-adjustable edible dog chew." (Dkt. 65 at 1-2.) Instead, that declaration focused on the term "a heat-expandable potato starch," which we discuss infra, Section II.B.2.c.

Mr. Axelrod's deposition testimony, however, did address the various issues involved in construing this term, "a hardness-adjustable edible dog chew." (Dkt. 51-1.) First, according to Mr. Axelrod, that term in the patents-in-suit is not limited to adjusting the hardness to become softer only. He took the position that it could mean adjusting to

be either softer or harder than its initial state, although he was not aware of any chew that expanded and became harder when practicing the invention. (Id. at 40, 90-91.) Second, he stated that in his view, the concept of expandability of the dog chew was not included in the term "hardness-adjustable," as taught by his patents. (Id. at 90, 129-30.) Finally, he seemed to agree that the term "hardness-adjustable" did refer to being capable of being adjusted by heating (id. at 97); but he disputed that his patents were limited to microwave heating. (Id. at 49-53, 93-95, 97.)

When asked what heating methods, in addition to microwave heating, he had tried when creating his invention, Mr. Axelrod stated that he had placed prototype chews in a hot room (approximately 110°-145° F). However, in all of those cases, the chews only expanded less than two times their original size. (Id. at 49-51, 94-95.) He also mentioned possibly using a toaster oven or regular oven, but his testimony did not reveal any results if he used that method. (Id. at 47, 93-95.)[42] He did not know whether his patented dog chew would expand and become softer if it were boiled, grilled, pan fried or deep fried, because he did not try those methods. (Id. at 93-95.)

We disagree with the inventor's stated views that the patents-in-suit encompass a "hardness-adjustable" dog chew that can become either softer or harder when practicing the invention, and that the concept of expandability is not linked to being "hardness-

[42] We have carefully examined the portions of Mr. Axelrod's deposition included in the record, submitted by Defendants. (Dkt. 51-1.) Plaintiff did not include that deposition or any excerpts of it in its claim construction filings.

adjustable" as taught by the patents. Both of those assertions are flatly contradicted by the specifications and file histories of both patents, as we have explained above.

We also find nothing in the inventor's testimony that credibly establishes a basis for reading this claim term to include other methods of heating the patented chew other than microwave heating. The inventor had no practical information to offer on this subject. More importantly, the intrinsic evidence is strongly to the contrary. No other method is disclosed or suggested, in any of the intrinsic evidence, that would heat the chew in such a manner as to get it to expand as depicted (whether 3-8 times or any significant amount), and thereby adjust the chew quickly and conveniently from its initial hardest state to progressively softer states, "until the chew reaches a state of expansion and degree of hardness preferred by the dog." ('565 patent, 3:2-3; '978 patent, 3:37-38.)

Plaintiff's expert - Dr. Hsieh

Dr. Hsieh, Plaintiff's expert, is well-experienced in the food science industry. Her declaration stated that she has done extensive work in developing "half products" based on potato starch and other starches. (Dkt. 55-2 at 2.) Her declaration and deposition testimony centered on construction of the other disputed claim term, "a heat-expandable potato starch." (Id. at 2-4; Hsieh Dep. (passim).) We discuss that claim term infra, Section II.B.2.c, where we summarize her testimony on that topic.

The claim construction declaration of Dr. Hsieh offered no opinion on the meaning of the term "hardness-adjustable edible dog chew," as she confirmed at her deposition.

(Dkt. 55-2; Hsieh Dep. at 134-35, 140, 145-47.) Nevertheless, when asked at deposition to comment on that term, she said that "hardness adjustable" could mean the "hardness could go either way," i.e., adjustable to become either harder or softer. But she reiterated that she had not done enough work on the particular type of product described in the patents-in-suit to say she had expertise to opine on that term. (Hsieh Dep. at 145-46; id. at 87-90, 107-09, 141-44, 150.) She did agree that based on the teachings of those patents, the claimed hardness-adjustable dog chew expands upon application of heat. (Id. at 148-49, 166.) However, she could only speculate on whether any method of heating the patented chew, other than microwave heating, could cause it to expand and soften as described in the patents. (Id. at 87, 90-91, 107-09, 144.)

We take Dr. Hsieh at her word when she stated that she had no expertise or opinion on what the patents-in-suit mean when they claim "a hardness-adjustable edible dog chew." Therefore, we place no weight on her various deposition comments about those underlying factual issues.

Defendants' expert - Dr. Bhattacharya

Dr. Bhattacharya, Defendants' expert, stated in his declaration that according to his knowledge of the scientific principles and his reading of the patents and all intrinsic evidence, "[b]oth the '565 and '978 patents disclose 'hardness-adjustable edible dog chews' that share the same fundamental feature -- the ability to expand and soften when exposed to microwave heat." (Dkt. 50 at 15.) He opined that in view of the disclosures

of those patents and their prosecution files, a person of ordinary skill in the art would understand the term "hardness-adjustable edible dog chew" to mean "a dog chew that when microwaved will expand up to about [3 or 6] to 8 times the original volume with a commensurate reduction in hardness." (Id. at 18, 26.)

Defendants' expert disagreed with Plaintiff's proposed construction as being in conflict with all of that intrinsic evidence, and so broad as to render the limitation meaningless. (Id. at 18-22, 26-28.) He emphasized that "the '565 patent does not disclose any other means by which to adjust the hardness of the claimed dog chew apart from microwave expansion, nor does it disclose any dog chew that can be made harder." (Id. at 21.) Also, he pointed out that in the '565 patent prosecution, the applicant overcame the examiner's obviousness objection by defining the meaning of the "variable-hardness recitation" to "cover[s] the characteristic of varying applicant's dog chew from an initially molded hard texture to textures of lesser hardness by microwaving the chew." (Id. at 21 (quoting dkt. 48-3 at 61).) He stated that the '978 specification was similar in all pertinent aspects, and that common claim term would be interpreted in tandem. (Id. at 26-28.)

Dr. Bhattacharya's deposition testimony was consistent with the reasoning stated in his declaration on these points. (Dkt. 55-1, Ex. C, at 124-25, 128-29, 130-34, 137-40, 151-57.) He also referred to the scientific literature and prior art patents cited in his declaration, generally showing the effects of microwaving starch-based half-products to make them expand in multiples of their original size. (Id. at 162-65.)

We find that Dr. Bhattacharya provided useful testimony on how an ordinary artisan would read the claim term "a hardness-adjustable edible dog chew" in the '565 patent and '978 patent, in light of the intrinsic evidence and the scientific background of the claimed invention. His testimony aligns with our own reading of the intrinsic evidence, as set forth above. We decline to import any specific numerical degree of expansion capability from the specification into the claim construction, but otherwise we are satisfied that his proposed claim construction is essentially correct.

vi. Claim construction

For the foregoing reasons, this Court interprets the claim term "a hardness-adjustable edible dog chew," in the '565 and '978 patents-in-suit, to mean "an edible dog chew possessing the capability of being adjusted by expanding and becoming softer when microwaved." See Renishaw PLC, 158 F.3d at 1250 ("A construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct definition.").

c. Claim term: "a heat-expandable potato starch"

The term "a heat-expandable potato starch" makes its debut in the '978 patent, where it appears in all seven of the independent claims, including asserted method claims 4 and 8 as well as asserted product claims 14 and 16. See supra n.25. In the '565 patent, the corresponding location in independent claim 1 simply claims "a potato starch." See supra n.20. As we have seen, the words "heat-expandable" were added to the claims of the '978 patent during prosecution of that patent. See supra nn. 37 & 38, and accompanying text.

For convenient reference, we repeat in the margin an overlay of the portion of the specification of each patent where the preferred embodiment of the potato starch ingredient is described.[43]

The opposing positions of the parties on construction of the term "a heat-expandable potato starch," in each claim where it appears in the '978 patent, are:

> Plaintiff's Proposed Definition: "a potato starch that, when in presence of the other claimed ingredients, is capable of expansion upon being subjected to heat." (Dkt. 44 at 20.)
>
> Defendants' Proposed Definition: "extruded granules that include potato starch, such that an injection molded chew formed from the granules will expand up to about 3 to 8 times the original volume when microwaved." (Id.)

The term "a heat-expandable potato starch" was coined by the inventor of the '978 patent, in the sense that neither party can point to any patents or literature using such an

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[43] The only portion of the specifications of the two patents directly addressing the potato starch ingredient is as follows:

> The preferred form of edible dog chew of the present invention has as a basic ingredient, a **heat-expandable starch, such as a** potato starch product sold under the trademark PARAGON IM 1010 by AVEBE of Veendam, The Netherlands. The PARAGON product is sold in the form of thermoplastic granules**, beads or granules,** which are **manufactured by an extrusion process, and which are then** molded into a desired shape. The weight contents of such **extruded** pellets, **beads or granules** are about 70% potato starch, about 15% water (about 10% after the [pellets] **granules** are molded), about 5 to 10% calcium carbonate, and about 1 to 5% natural vegetable additives.

('565 patent, 2:19-30; '978 patent, 2:33-47 (bold indicates new text in '978 specification; brackets indicate deleted text in '978 specification, in comparison with '565 specification).)

expression, before or after the issuance of this patent. Plaintiff offers ordinary dictionary definitions of the words "heat," "expand," and "expansible." Plaintiff also points to the portion of the '978 specification quoted here in the margin.[44] Plaintiff also relies upon the declarations and deposition testimony of the inventor, Mr. Axelrod, and its expert, Dr. Hsieh. (Dkt. 44 at 21.) Defendant relies on various portions of the '978 specification, as well as the '978 prosecution history and the declaration and testimony of its expert, Dr. Bhattacharya, and cited scientific literature. (Id. at 21-22.) We discuss those materials and the parties' arguments below.

We conclude, after exhaustive review of the evidence and the arguments of the parties, that the term "a heat-expandable potato starch," as used in the '978 patent, is hopelessly ambiguous and therefore no meaningful construction can be placed on it. Accordingly we find that the term "heat-expandable," when used as a purported adjective to modify "a potato starch," in the context of the asserted '978 patent claims, adds nothing to the claim term "a potato starch" standing alone.

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[44] Plaintiff relies on the following portion of the '978 specification in support of its proposed construction of the term "a heat-expandable potato starch":

> Upon removal from the package, the person feeding the dog can if desired modify the texture or hardness of the molded chew by heating, in a microwave oven. The expansion of the moisture within the chew causes the chew to expand. Subjecting the chew to microwave radiation facilitates the heating of areas deep within the chew at the same time the exterior heats up and expands.

(Dkt. 44 at 20-21 (quoting '978 patent, 3:9-15).)

The teaching of the '978 patent provides no guidance as to what "a heat-expandable potato starch" may be, as distinguished from any other kind of "potato starch." Further, we are unpersuaded that the hypothetical person of ordinary skill in the art at the time of the '978 patent would have been able to place any meaning on that term based on a reading of the patent and prosecution history, or the knowledge of the prior art and relevant scientific principles. We similarly reject Defendants' argument that "a heat-expandable potato starch," as claimed in the patent, is synonymous with an AVEBE-type "potato starch product," consisting of extruded thermoplastic granules containing potato starch, water, and calcium carbonate as described in the specification. Therefore, this Court construes "a heat-expandable potato starch" in the '978 patent to mean "a potato starch," a generic term just like the unspecified potato starch starting ingredient claimed in the '565 patent. The factual basis for this ruling is as follows.

i. Comparison of claim terms

We begin by comparing just the pertinent portions of the method claims of the '565 patent and the '978 patent, which are written in parallel form:

'565 patent, claim 1

> A method of producing a hardness-adjustable edible dog chew, comprising the steps of:
>
> > extruding a mixture of **a potato starch**, water and calcium carbonate to form granules; ....

('565 patent, 4:2-5 (emphasis added).)

‘978 patent, claim 1

> A method of producing a hardness-adjustable edible dog chew, comprising the steps ... of:
>
> > extruding a mixture of **a heat-expandable potato starch**, water and calcium carbonate to form granules; ....

(‘978 patent, 3:57-60 (emphasis added).)[45]

This claim language, in method claim 1 of both patents, describes a first step of forming granules by extrusion, after mixing three starting ingredients: water, calcium carbonate, and “a potato starch” (‘565 patent) or “a heat-expandable potato starch” (‘978 patent). We will call those three ingredients the Starting Ingredients.

According to claim 1 of both patents, extruding a mixture of the three Starting Ingredients results in granules. This is the first step of the claimed process, under both patents: you begin with the three Starting Ingredients; you mix those ingredients together; you subject those ingredients to extrusion processing; and the result is the formation of granules.

Defendants’ proposed construction of the term “a heat-expandable potato starch” is “extruded granules that include potato starch....” (Dkt. 44 at 20.) Indeed, in the prosecution history of the ‘978 patent, both the applicant and the examiner seem to refer to the “heat-expandable potato starch” as if it were the extruded granules. See discussion of ‘978 patent prosecution, infra.

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[45] The other independent method claims of the ‘978 patent – claims 4, 6, and 8 – are identical to claim 1 of that patent, as to the portion of claim language quoted here. (‘978 patent, 4:6-37.)

This construction cannot be correct based upon the literal words of the method claims of this patent, however. You simply cannot have the extruded granules be one of the three Starting Ingredients, because the extruded granules are the result of step one, not a Starting Ingredient of step one. In other words, under Defendants' construction, claim 1 of the '978 patent would read thus:

> A method of producing a hardness-adjustable edible dog chew, comprising the steps ... of:
>
> extruding a mixture of a heat-expandable potato starch [defined as "extruded granules that include potato starch"], water and calcium carbonate to form granules; ....

Such a construction would be literally absurd. The plain meaning of the claim does not support a construction of the claim terms "a heat-expandable potato starch" and "granules" as synonyms. See Ethicon Endo-Surgery, Inc. v. U.S. Surgical Corp., 93 F.3d 1572, 1579 (Fed.Cir. 1996) (discussing "pusher assembly" and "pusher bar", which both appeared in same claim, and stating that if "the terms 'pusher assembly' and 'pusher bar' described a single element, one would expect the claim to consistently refer to this element as either a 'pusher bar' or a 'pusher assembly,' but not both, especially not within the same clause", and thus "the plain meaning of the claim will not bear a reading that 'pusher assembly' and 'pusher bar' are synonyms").

Certainly, under claim 1 of both the '565 patent and '978 patent, the extruded granules that are the result of step one may be purchased if available, and they do not have to be made by the inventor or by the accused infringer. That is the teaching of the specifications, in describing the then commercially-available AVEBE thermoplastic

granules containing potato starch, water, and calcium carbonate. See supra n.43. But knowing that such granules can be made, either from scratch or by a commercial supplier, does not tell the ordinary artisan anything about the potato starch Starting Ingredient that is part of method step one of claims 1, 4, 6, and 8 of the '978 patent. As a matter of pure English syntax and basic claim construction principles, the term "a heat-expandable potato starch," as used in step one of each of those independent method claims of the '978 patent, must be a Starting Ingredient and cannot be the extruded granules.

The three independent product claims of the '978 patent add further confusion to construction of the claim term "a heat-expandable potato starch," rather than dispelling it. Significantly, the '565 patent contained no product claims, those having been introduced in the continuation-in-part application for the '978 patent.

Each of these '978 product claims, including those asserted in claim 14 and claim 16, share the following format:

> An improved edible dog chew comprising:
> an injection molded mixture of a heat-expandable potato starch, water, calcium carbonate and ....

('978 patent, 4: 47-65.) The last ingredient in these claims is either "a fruit flavoring" (claim 10), "a food coloring" (claim 14), or "a breath sweetener" (claim 14). (Id.) See supra n.25.

These product claims do contain the term "a heat-expandable potato starch," but omit any reference to whether that starch is a Starting Ingredient, or whether it is the extruded thermoplastic granules containing potato starch, water, and calcium carbonate.

In fact, these product claims do not include the term "hardness-adjustable edible dog chew," found in all of the independent method claims of both patents. Thus, in these '978 product claims, the entire weight of what the dog chew is supposed to be able to do, when the consumer uses it, is placed upon that term "a heat-expandable potato starch."

One may assume that in these claims that term refers to the extruded thermoplastic granules containing a potato starch, water, and calcium carbonate, as Defendants argue. But the claim term itself offers no guidance; indeed, there is no reference to extrusion at all in these product claims. Nevertheless, if we do assume that the term refers to the extruded granules, and we attempt to define "a heat-expandable potato starch" as those granules, then we run into a conflict with the use of that same term in the method claims of the same '978 patent. As we have explained above, that term as used in the method claims must refer to potato starch as a Starting Ingredient, rather than in the form of extruded granules containing potato starch, water, and calcium carbonate.

It is axiomatic that we cannot have the same claim term meaning Starting Ingredient in the '978 method claims, and meaning extruded thermoplastic granules in the '978 product claims. That is, however, the quandary set up by use of the same claim term in perhaps two senses within the same patent. It thus qualifies under the dictionary definition of "ambiguous." "Language ... is 'ambiguous' when it is reasonably capable of being understood in more than one sense." Black's Law Dictionary, 6th ed. (1990) (citation omitted).

ii. Review of specification

The '978 specification ambiguously glides over the distinction between potato starch as a Starting Ingredient, and the extruded AVEBE-type thermoplastic granules containing potato starch, when it states: "The preferred form ... of the ... invention has as a basic ingredient, a heat-expandable starch, such as a **potato starch product** sold ... by AVEBE.... The ... product is sold in the form of thermoplastic granules ..., which are manufactured by an extrusion process.... The weight contents of such extruded ... granules are **about 70% potato starch**, ..." ('978 patent, 2:36-44 (emphasis added).) Rather than supporting Defendants' proposed construction, "extruded granules that include potato starch," this portion of the '978 specification only serves to highlight the ambiguity of the claim term "a heat-expandable potato starch."

The similar language about the AVEBE-type thermoplastic granules in the '565 specification does not impact claim construction of that patent, because neither its specification nor its claim language use the term "heat-expandable potato starch" as a Starting Ingredient. See supra n.38 and accompanying text. The extruded thermoplastic granules containing "a potato starch," resulting from practicing step one of claim 1 of the '565 patent, can indeed be "a potato starch product" such as the AVEBE granules.

Plaintiff points to the portion of the specification describing how the "molded chew" can have its texture modified by heating, in a microwave oven, whereby "the expansion of the moisture within the chew causes the chew to expand." See supra n.44. That text tells how the injection molded chew is caused to expand upon heating, but it

says nothing about the "heat-expandable potato starch" ingredient contained in the chew. In fact, that portion of the specification does not even mention the word "starch," much less describe or define the claimed "heat-expandable potato starch." So that language in the specification, standing alone, would provide no clue to the ordinary artisan as to what the inventor meant by his unique phrase, "a heat-expandable potato starch."[46]

A patentee may certainly act as his own lexicographer, but he must assume the concomitant responsibility to define what he means by his claim terms. To act as a lexicographer, an applicant must define claim terms "with reasonable clarity, deliberateness, and precision." In re Paulsen, 30 F.3d 1475, 1480 (Fed.Cir. 1994); see, e.g., In re Pond, 466 Fed.Appx. 876, 879 (Fed.Cir. 2012) ("The specification ... does not contain an express definition of 'unitary, one-piece construction.' Therefore Pond did not act as a lexicographer and define the phrase 'unitary, one-piece construction.'") We conclude that the inventor of the '978 patent did not act as a lexicographer and define expressly and clearly what he meant when he coined the term "a heat-expandable potato starch," as used in all independent claims of that patent, and as ambiguously referred to in the specification.

iii. Review of prosecution history

The prosecution history of the '978 patent has its central focus on this claim term, but is fraught with ambiguity and lack of clarity. We do know that the phrase "a heat-

[46] We discuss the experts' testimony about these portions of the specification, and the underlying scientific principles in this Section, infra.

expandable starch" was inserted into the specification for the '978 patent when the '978 application was filed; and that the words "heat-expandable" were added to modify "a potato starch" in all the independent claims, in order to overcome an initial obviousness rejection of that application. (Dkt. 68-1 at 13, 50; dkt. 68-2 at 1-3.)[47]

The applicant constantly repeated, in his arguments after both obviousness rejections, that none of the prior art patents cited by the examiner disclosed use of a "heat-expandable starch." (See, e.g., dkt. 68-2 at 3-12, 49-50; dkt. 68-3 at 1-4.) However, no description or definition of that claim element was provided in any of the applicant's arguments or the examiner's explanations, beyond citing the portion of the specification referring to the "heat-expandable starch, such as a potato starch product sold ... by AVEBE." (Dkt. 68-2 at 25 (examiner); dkt. 68-3 at 4 (applicant).) Even the applicant's citation to a German prior art patent by Müller, claiming "native and/or modified starch," received no discussion by the applicant as to how that differed from the "heat-expandable potato starch" of the '978 claims. (Dkt. 68-2 at 10.) And, of course, none of the cited prior art patents contained this unique claim term invented by the applicant.

A thorough review of the '978 prosecution history, as it bears upon construction of the claim term "a heat-expandable potato starch," reveals nothing more than the contents of the claim term and the specification itself. Evidently, the applicant and the examiner regarded that term as synonymous with the extruded thermoplastic granules containing

[47] All pertinent portions of the '978 prosecution history are summarized and quoted supra, Section II.B.2.b.

potato starch, described in the specification. But as we have explained, such a construction is not consistent with the plain language of the method claims of the '978 patent. Therefore, this claim term remains insolubly ambiguous after study of the prosecution files.

iv. Extrinsic evidence

Inventor Testimony

Mr. Axelrod submitted a claim construction declaration addressing the term "a heat-expandable potato starch." That declaration language, however, suffers from the same ambiguity that plagues the claims and the specification of the '978 patent, which is to conflate the concept of potato starch as a Starting Ingredient, with the concept of a "potato starch product," consisting of an extruded thermoplastic granule containing potato starch, water, and calcium carbonate. Here we quote, and annotate, that text in the Axelrod declaration.

> ... I understood both from my previous experiences with potato starch and from my experimentation in inventing the '565 and '978 patents, that **some potato starches or types of potato starches** would expand when combined with water and/or other ingredients and exposed to heat while other potato starches or types of potato starches would not. [Referring to potato starch as a Starting Ingredient.]
>
> One, but not the only, **potato starch product** that I experimented with at that time and found to expand was the PARAGON IM 1010 extruded bead sold by AVEBE ..., described in the specifications of both ... patents.
>
> **The AVEBE product** is referenced in the ... patents as **a non-exclusive example of a heat-expandable potato starch**, and not as the sole and only potato starch one may use to practice the patents. [Referring to "extruded bead

sold by AVEBE," i.e., the extruded granules containing potato starch, water and calcium carbonate.]

In my experimentation, I found that many factors went into the rate or degree of expansion of the potato starch and the end product including: **the type of potato starch, the brand of potato starch**, the formulation, the manner of heating the product, the temperature, the duration, and other factors. [Unclear whether referring to potato starch as a Starting Ingredient, or extruded AVEBE-type granules containing potato starch, water, etc.; or both.]

(Dkt. 65 at 2 (paragraph numbering omitted; emphasis added).)

The deposition testimony of Mr. Axelrod was similarly unenlightening to define or distinguish the concepts of potato starch as a Starting Ingredient, or on the other hand as a "potato starch product," such as the AVEBE extruded granules. The relevant portions of his testimony in this record are as follows:

Q In your own words, what desirable performance attributes did the AVEBE product impart in the finished dog chew product?

A Okay, in the finished dog chew product? It was -- it was hardness adjustable, it expanded when it was heated. It was able to -- you know, when in the presence of obviously other -- water, when it was molded with water, calcium carbonate and the like the finished product expanded and it was hardness adjustable. It was consistent in its use.

....

Q Do you agree ... that the heat-expandable potato starch of the '978 patent is responsible for the chew expanding upon microwaving?

A Well, the heat expandability, um, it's not solely responsible for the chew expanding on microwaving, but if you don't have the heat-expandable potato starch it won't expand.

Q Is it fair to say that the heat-expandable potato starch is necessary for the chew of the '978 to expand up to about three to eight times the original volume when microwaved?

A It's part of the reason it expands. It's -- if you don't have heat-expandable potato starch and use a potato starch that doesn't expand, it won't.

(Dkt. 51-1 at 4-6.)

Q [Y]ou cannot identify any heat-expandable potato starch that is not an extruded product, right?

A I haven't been involved in the purchase of that material for a number of years now, so what's currently available on the market or not available on the market and as to which are heat expandable and which are not, at the moment I really can't say.

(Id. at 23.)

We view this testimony in light of Plaintiff's proposed construction of the '978 claim term "a heat-expandable potato starch," as "a potato starch that, when in presence of the other claimed ingredients, is capable of expansion upon being subjected to heat." (Dkt. 44 at 20.) Yet nothing in Mr. Axelrod's declaration or deposition tells us whether that proposed construction refers to potato starch as a Starting Ingredient, or refers to the AVEBE-style extruded granules containing potato starch, water, etc., found at the end of step one of the method claims.

Plaintiff's Expert - Dr. Hsieh

Dr. Hsieh's declaration and her deposition testimony only serve to intensify this claim construction dilemma. In fact, her declaration discussed "a heat-expandable potato starch" as if it were a Starting Ingredient in the '978 patent; yet at deposition she ultimately agreed with opposing counsel that the term must refer to the post-extrusion granules.

Here is the relevant portion of the declaration of Dr. Hsieh, where she appeared to be referring to the '978 potato starch claim element in the sense of being a Starting Ingredient:

> In my opinion, the term "heat-expandable potato starch" is clear and unambiguous in that it means **a potato starch, either native or modified, that is capable of expansion when combined with certain other materials and exposed to heat and moisture**.[48]
>
> In my experience, most potato starches are capable of expansion when exposed to heat if they also have been combined with moisture. In fact, there are many starches, both native and modified, that are marketed as being more or less inclined to expand. However, **there are some potato starches, particularly retrograded potato starch, and some forms of modified potato starch, that will not expand when exposed to heat, even if also combined with moisture**. These retrograded and modified potato starches are thus not heat-expandable potato starches.
>
> **Retrograded starches are a subset of a larger group of starches called "resistant starch."** Resistant starches generally inhibit expansion and are used in the industry as a form of dietary fibers or fillers for that very reason.
> ....
> ....When one works in product development, as I have done for nearly 30 years, one frequently is very specific when ordering starch in specifying types of starches needed and the properties those starches should possess.
> ....
> It would be evident to anyone experienced in the field that if one were to attempt to practice the '565 or '978 Patent with retrograded potato starch, the resultant product would not expand.

(Dkt. 55-2 at 2-4 (paragraph numbering omitted; emphasis added).)

---

[48] Dr. Hsieh, Plaintiff's expert, thus offered an interpretation of the claim term "a heat-expandable potato starch" that is different from Plaintiff's own proposed construction of that term. Dr. Hsieh's version is quoted here. Plaintiff's version, quoted above in this section, is "a potato starch that, when in presence of the other claimed ingredients, is capable of expansion upon being subjected to heat." (Dkt. 44 at 20.) We will not attempt to reconcile those two versions, finding that neither of them would yield an appropriate claim construction of the term.

Here we quote a representative portion of the deposition testimony of Dr. Hsieh on the same topic. First, she was asked about the term "heat expandable potato starch" itself, and responded as follows:

> Q In the roughly 30 years that you have been involved in the food industry, has anyone used the term "heat expandable potato starch" with you? Have you heard that term ever? .... In your experience, has anyone used the term "heat expandable potato starch"?
>
> A I don't recall in terms of situations in which that term was used per se. But in terms of–
>
> Q Is it fair to say that you don't recall anyone in the industry ever using the term "heat expandable potato starch"?
>
> A It's used as a descriptor for a functionality, if you're looking for a specific functionality that would be a property.
>
> Q My question is, is it fair to say that you don't recall anyone in the food industry ever using the specific term "heat expandable potato starch"?
>
> A I'm saying is, that is a property of starch in which people would describe as a functionality; but it's not like a term as defined -- but it's definitely a functionality of certain potato starches that -- It's a term that, just like many any [sic] other types of starches that you're working with, in which you say, I want something that is going to deliver crispy, crunchy, in which you can use -- or soft and chewy or all these terms, and then these different starches would have those properties that delivers that.
>
> So it's a term -- starches is so complex, so you have to use different descriptors to prescribe certain type of functionality of starches. So heat expandable would be something that you may say I want to have those kind of starches with those property, just like I want crispy/crunchy starches.

(Hsieh Dep. at 15-17.)

Next, Dr. Hsieh was asked to distinguish among potato starches that would or would not be heat-expandable. Unfortunately, her testimony on this subject was nearly

unintelligible, even allowing for possible communication difficulties. On the other hand, in this line of questioning her answers indicated that she was thinking of the claim term "heat-expandable potato starch" as a Starting Ingredient, rather than as an extruded potato starch product incorporating water and calcium carbonate. She testified:

> Q [D]oes heat expandable potato starch include native starch?
>
> A Yes.
>
> Q Are there any native starches that are not heat expandable potato starch?
>
> A Yes.
>
> Q Which ones?
>
> A Modified starch -- certain modified starches. Certain enzyme-treated starches. Resistance [sic] -- well, the thing is, resistance starch are being treated. To modified starches, I would say, yes.
>
> Q Are there any native starches that are not heat expandable potato starch?
>
> A Yeah. I mean, native starches -- some native starches are not heat expandable.
>
> Q Which native starches are heat expandable potato starches?
>
> A Heat expandable starches tend to have higher amylopectin. And so, therefore, very high amylose pectins containing -- tend to not be heat expandable. Again, the expandability, it's a limited term in the sense of some may expand more and less than the others.
>
> ....
>
> Q How would one of skill in the art know which native starches are heat expandable potato starch?
>
> A For example, if you have high -- if your native starch is as is, meaning extracted from potato, then if you treat it certain ways -- again, it depends on the treatment eventually, whether it's expandable or not. Native starch, it may not be expandable if the condition is not correct.

And so then there are other factors. Like modified starches of potato that can be heat expandable. It depends on what have you done to the potato. So you would work with your supplier to find out which kind of a starch you're looking for and you get the functionality.

Q Is it your position that heat expandable potato starch is distinct from run-of-the-mill potato starch? .... I'm trying to understand in your mind what the distinction is between potato starch and heat expandable potato starch. Perhaps you can just elaborate what the relationship is between the two.

A Heat -- well, native starch -- in order to be heat expandable -- native starch can be heat expandable; however, it depends again on the process conditions to how you impact. And so all of those are important as to how expandable it is. So the process has a lot to [do] with it.

Q Is it fair to say that, if processed appropriately, any native starch can be a heat expandable potato starch?

A What do you mean by "processed" -- can you elaborate "processed" ....

Q Well, you ... mentioned earlier in your answer that it depends again on the process and conditions.

A Right.

Q So .... Is it your position that depending on the native starch being processed a particular way, right, it can expand? .... Is it fair to say that if processed under the appropriate conditions, any native starch can be a heat expandable potato starch?

A No, that's -- that's not true in the sense of if you have certain processes that could literally destroy the structure of the potato, then -- of the starch, then, therefore, it wouldn't be expandable. So it would be a process you have to be more specific to achieve.

And that's why you have modified starches, because some of them is not achievable. So in terms of expandability, it depends on the process that you need to deliver.

(Id. at 26-31.)

Q Is it your position that certain potato starches are inherently heat expandable?

A I'm a bit bothered [by] your term "inherently" because, as I said before, the characteristics of starches can be completely different, even with the same starch, if you did certain, you know, processes that could inhibit expansion; but if you have done it a certain way to the starch, then you can make it expandable.

Q Is what makes a heat expandable potato starch heat expandable something that is inherent to the potato starch as sold, or is it based on subsequent processing of that potato starch?

A Certain processes can impact in terms of the expandability; however, if your starting material has certain property, then you can overcome those process issues.

Q Can you elaborate. I'm sorry, I'm really confused by your answer. What are you trying to say?

A For example, if your starting material has certain functionalities that would overcome your processes issues, for example, it's more shear resistant, okay -- like an extruder, you have shear issues -- then therefore it would impact expansion. So in terms of those kind of properties, it's important to have the right starting material. So, in other words, you want to be very selective as to your starches.

(Id. at 41-44.)

Dr. Hsieh was specifically asked about the AVEBE product described in the specifications of the patents-in-suit, and whether that was a "heat-expandable potato starch," within the meaning of the '978 patent. Initially, she said no:

Q Do you understand that "heat expandable potato starch" is a term used in the '978 patent? Yes?

A Yes.

Q Is it your position that the AVEBE product described in the 978 patent is a heat expandable potato starch?

A That was -- that was -- as being best practice -- that was example, right, used as -- for the -- for the '978, right? It's not -- it's not a starch; right? AVEBE was described as a pellet.

Q It's an extruded granule; is that correct?

A Granule, yes. So it's not -- [sic].

....

Q Is the AVEBE product described in the '978 patent a heat expandable potato starch?

A They're not -- they're two components. They're not the same, no.

....

Q Is it fair to say that you have no understanding as to whether a heat expandable potato starch is used in the AVEBE product that is described in the '978 patent?

A **I would assume that the AVEBE would have the heat expandable starch starting material**; but in terms of specifically how it was made, I would say that it has -- I have no information on that. But **you would assume that it would be started with a potato starch** [sic].

(Id. at 50-52 (emphasis added).)

The most that Dr. Hsieh could explain as to the difference between a "heat-expandable potato starch," and any other kind of potato starch, is that most potato starches would be expandable if subjected to certain processing. However, she said, such processing would not be sufficient if it consisted only of adding water and heating it. Thus she testified:

Q Is there any potato starch ... that I could put in a pan, add sufficient amount of water and heat it so that it could then be called a heat expandable potato starch?

A You have -- you have to do -- again, it's not starch and expandability. You have to do certain processes to develop that.

Q So it's fair to say that a starch is only a heat expandable potato starch if it has been processed under the appropriate conditions?

A Yes. In other words, you can't just add water and heat it and it would be expandable. So you have to do certain processes to it.

Q And those processes would include, by way of example, extrusion?

A Correct.[49]

....

Q If -- two terms, "heat expandable potato starch" and "potato starch." Is a heat expandable potato starch a subset of potato starch?

A Oh, I see. Okay. Yeah.

Q Now, are the vast majority of potato starches heat expandable potato starches?

A I would say so; however, there are -- there are more amylose-containing potato starches that would be significantly less expandable than that is higher amylopectin.

So I would say yes because majority of potatoes contains [sic] amylopectin higher than amylose. But then there are high amylose -- high amylose potato starches. So, therefore, the expandability, it's not all the same.

Q Generally speaking, are potato starches heat expandable potato starches?

A I would say yes.

Q So it is the rare exception when there's a starch that is not a heat expandable potato starch; is that fair?

A I mean, you can have them –

Q But it's rare?

---

[49] Note that this one segment of testimony appears to negate both versions of claim construction offered by Plaintiff and by Dr. Hsieh of this disputed claim term. See supra n.48 and accompanying text. (See also Hsieh Dep. at 152 (same).)

A -- specifically, yes.

Q But it's rare?

....

A Yes.

(Id. at 55-58.)

Having testified in her deposition that most potato starches can be characterized as heat expandable potato starches, Dr. Hsieh was asked what, then, was the difference between "a potato starch," claimed in the '565 patent, and "a heat-expandable potato starch," claimed in the '978 patent. She could identify no difference at all, from her reading of the patents and specifications and her knowledge of the underlying science. Her testimony on this point was as follows:

Q Your testimony earlier today -- was that most potato starches can be characterized as heat expandable potato starches; correct?

A Correct.

Q So if that's the case, isn't it true then that most potato starches can be used to practice Claim 4 of the '978 patent?

A Correct.

....

Q Now, Claim 1 of the '565 patent only refers to potato starch, but it does not refer to heat expandable potato starch. Do you understand that?

A [Yes.]

Q So my question to you is, is it your position that any potato starch can be used to practice Claim 1 of the '565 patent?

A I would say not -- I mean, a potato starch defined here, you would say a majority of the potato starch[es] would be able to fit into that, yes.

....
Q Are there certain potato starches that can be used for the '565 patent, but cannot be used for the '978 patent?

A Again, I'm not -- I don't know what the -- the person who wrote these two -- I don't know what his intentions are in terms of the way it is written, why he put this particular one -- because when I'm reading the two patents, they look very similar or similar. Okay.

And the thing is that just looking at the dates of this patent and between these two patents, he may have thought about being more specific on the '978 than the '565. And, again, I'm not -- Mr. Axelrod as to specifically why he made those kind of differentiation.

Because the starting material is the same. They are -- but it can be that maybe some of these new starches coming through, he may have wanted to be more specific. So -- but in my opinion, these two are similar.

....
Q So in your opinion, the potato starch of the '565 patent is the same as the heat expandable potato starch of the '978 patent; correct?

A From -- I would say very similar, yes.[50]

....
Q Sitting here today, is it fair to say that you cannot identify any differences between the potato starch of the '565 patent and the heat expandable potato starch of the '978 patent?

A I don't -- again, I don't know the intention of the -- of the author; but in terms of looking at it, I would say they're really, you know, quite similar in terms of the two starches, yes.

Q So in terms of looking at both patents, the potato starch of the '565 patent and the heat expandable potato starch of the '978 patent is similar?

A Similar, yes.

Q If not the same?

---

[50] For example, later in her deposition Dr. Hsieh testified that in her view, just like the '978 "heat-expandable potato starch," the "potato starch" claimed in the '565 patent is not a retrograded starch. (Id. at 111.)

A Yeah, I can't say that. But I'm just saying, again, I don't know what the intention of the author of making that differentiation; but I would say just the starting material is the same and everything, I would say these two are similar, yes.

Q Is it fair to say that the starting material of the '565 and '978 patents are similar?

A Correct.

Q And, indeed, they may even be the same?

A I cannot make that kind of a guess, but -- because I don't know the intention of the author. I can only provide you evaluation.

(Id. at 69-74.)

Again at a later point in the deposition, Dr. Hsieh reiterated her view that the "potato starch" claimed in both of the patents-in-suit was a "starting material." She stated:

Q The potato starch used in the dog chew of the '565, '978 patents is not causing expansion; correct?

A The native starch you're talking about –

Q Yes.

A -- the starting material? No.

Q Instead, it is the processed potato starch, meaning the extruded starch granules, that is causing the dog chew of the '565, '978 patents to expand, correct?

A If it [is] processed a certain way, yes, right.

....

Q Again, it's not the potato starch itself, but it's the extruded granules that contain potato starch and water that is causing expansion of the dog chew when it is microwaved; is that correct?

A And also calcium carbonate.

Q Your answer is yes?

A I would assume, yes. I mean, again, what's written up.

....

Q Is it the extruded granules that contain processed potato starch and water that is causing the dog chew of the '565 and '978 patent to expand when microwaved?

A Yes.

(Id. at 99-103.)

Ultimately, Dr. Hsieh contradicted her earlier deposition testimony interpreting the term "a heat-expandable potato starch" as a potato starch "starting material." That occurred after more discussion of the process whereby the dog chew product would expand when microwaved. She ended her deposition by appearing to agree with opposing counsel that the term refers to the extruded granules. Here is that exchange:

Q When the hardness of the edible dog chew is being adjusted, is that due to changes in the potato starch itself or is it due to changes in the potato starch that has been processed?

A Definitely potato starch that has been processed. Because you don't have the potato starch anymore, not the native -- you have something that has been evolved, that has been physically and chemically changed or modified.

Q So the heat expandable potato starch of the '978 patent is a potato starch that has been transformed through processing such as by extrusion; correct?

A Correct.

....

Q Now, let's go back to heat expandable potato starch.... So **do you agree that heat expandable potato starch means extruded granules that include potato starch** such that a chew formed from those granules will expand upon application of heat?

A **Yes**.

(Id. at 139-40, 151 (emphasis added).)

This self-contradictory testimony from Plaintiff's expert, on the meaning of "a heat-expandable potato starch," vividly demonstrates the ambiguity of the term, as inserted into the '978 patent by the applicant during patent prosecution. Even Plaintiff's expert found it impossible to resist reading this claim term in two different senses: as a Starting Ingredient, and as the thermoplastic granules formed by heat extrusion of a potato starch, water, and calcium carbonate.

We have also considered the scientific opinion expressed by Dr. Hsieh that when viewed as a Starting Ingredient, the term "a heat-expandable potato starch" must refer to most starches but there are rare starches such as retrograded starches that would not expand, even if processed by extrusion and later microwaved. Dr. Hsieh testified at some length at her deposition on that topic. (Id. at 26-31, quoted supra.) As we have commented, however, that segment of her testimony was largely meaningless -- not because of communication difficulties, but because it was profoundly vague and inconsistent. The difficulty is further complicated by the fact that Dr. Hsieh could find no difference between the potato starch Starting Ingredient in the '978 patent, as compared with the '565 patent, although only the '978 patent claims "a heat-expandable potato starch." See supra n.48 and accompanying text. Or, as the applicant called it when arguing for issuance of that patent, "a heat-expandable starch!". (Dkt. 68-2 at 4.)

Dr. Hsieh's position that there are some potato starches that cannot expand even when processed may or may not be technically correct, but it does not aid us in claim

construction for two reasons. First, it bears no resemblance to the claim construction proposed by Plaintiff, as to which even Dr. Hsieh could not agree. See supra n.49. Second, and more importantly, the patent itself, along with its specification and prosecution history, gives no hint that such would be the distinction between "a potato starch," as claimed in the '565 patent, and "a heat-expandable potato starch," as claimed in the '978 patent. Indeed, even the identity of the potato starch Starting Ingredient, contained in the AVEBE potato starch product common to both patents, is a mystery not elucidated by those patents or the knowledge available to the ordinary artisan at the critical time. Accordingly, from this record we can draw no information with which to construe what "a heat-expandable potato starch" would be if viewed as a Starting Ingredient in the '978 patent.

Defendants' Expert - Dr. Bhattacharya

Dr. Bhattacharya stated in his declaration that "it is the moisture incorporated into the starch during processing that is the driving force behind expansion of these products, not the raw material of potato starch, in and of itself.... Thus, in order for the claimed potato starch-based dog chew to expand upon exposure to microwave heat, the raw potato starch must be transformed or modified by processing (e.g., extrusion and injection molding) into a starch matrix with trapped water that will subsequently expand upon microwaving." (Dkt. 50 at 12.) He further explained:

> Thus, unprocessed potato starch is not an inherently "heat-expandable" ingredient. (In fact, there is nothing especially "heat-expandable" about potato

> starch compared to any other starch ingredients.) It is only after potato starch is transformed in the presence of heat, shear, and the appropriate amount of water that it may be formed into a potato starch product that may, depending on the processing conditions implemented and the composition of materials used, expand upon microwaving.

(Id. at 15.)

Dr. Bhattacharya thus opined that no unprocessed potato starch is inherently "heat-expandable," whereas Dr. Hsieh opined that most unprocessed potato starches are "heat-expandable." We find their scientific testimony to be basically consistent with each other on this point, however. As Dr. Hsieh acknowledged, merely heating a potato starch in the presence of water would not render that starch "heat-expandable." See supra n.49 and accompanying text. Both experts agreed that potato starch as a Starting Ingredient must be processed with water under heat and shear forces such as by heat extrusion, in order to make a product that can later expand when microwaved. See this Section, supra. The only possible exception to this overview came from Dr. Hsieh's discussion of the "rare" instance of a potato starch such as retrograded starch that would never expand. However, we have found that exception to be irrelevant to claim construction of the '978 claim term "a heat-expandable potato starch," as explained above.

Based in part upon the scientific fact that "unprocessed potato starch is not an inherently 'heat-expandable' ingredient," Dr. Bhattacharya supported the claim construction offered by Defendants, that the term must refer to the "extruded granules that include potato starch ..." (Dkt. 50 at 30.) He derived further support for this conclusion

from reviewing all of the intrinsic evidence pertaining to both of the patents-in-suit. (Id. at 30-34.) He concluded that "A person of ordinary skill in the art ... would understand that what the '978 patent refers to as 'a heat-expandable potato starch' is essentially the potato starch-based extruded granules of the '565 patent." (Id. at 33.) However, in his deposition he candidly stated that the claim term itself is ambiguous:

> Q Do you think that the phrase "heat-expandable potato starch" is on its face ambiguous?
>
> A Yes, it is ambiguous.
>
> Q Why?
>
> A Because it does not ... just the phrase itself does not capture what is happening here. What is happening is you are taking -- by the inventor's definition, you are taking these, this potato starch, and then you are forming it in thermoplastic granules which are manufactured by an injection molding process [sic: meaning extrusion process]. And then they are further injection molded to the -- so why call it a heat-expandable starch?

(Dkt. 55-1, Ex. C, at 172-73.)

We can and do accept the scientific testimony of Dr. Bhattacharya without agreeing to his proposed claim construction, for the controlling reason we have explained earlier in this Section. That is because such a claim construction conflates the claim terms "a heat-expandable potato starch" and "granules," as contained in every method claim of the '978 patent. In fact, Dr. Bhattacharya got it exactly right in his deposition when he called the term ambiguous. The ambiguity of the patent and its specification as to whether the claimed "heat-expandable potato starch" is a Starting Ingredient, or is

extruded thermoplastic granules containing potato starch, is not overcome by the proposed construction of Defendants' expert, any more than it was overcome by the testimony of the inventor or of Plaintiff's expert.

v. Claim construction

For the foregoing reasons, this Court interprets the claim term "a heat-expandable potato starch," in the '978 patent, to mean simply "a potato starch." This ruling reflects our conclusion that the inclusion of the words "heat-expandable," to modify "a potato starch," in all method claims of the '978 patent during prosecution of that patent, added nothing to the meaning of the claims of that patent other than was meant by the term "a potato starch," as used in the sole independent method claim of the parent '565 patent. See Teva Pharms. USA v. Sandoz, Inc., 723 F.3d 1363, 1369 (Fed.Cir. 2013) (stating the term "average molecular weight," in contrast to the term "molecular weight," was meaningless and thus of no value), cert. granted, No. 13-854, 2014 WL 199529 (U.S. Mar. 31, 2014).

Accordingly, we interpret this claim term, "a heat-expandable potato starch," as used in the '978 patent, to refer to a potato starch as a Starting Ingredient, rather than as the potato starch-based extruded thermoplastic granules that are the result of practicing step one of the method claims of the '565 patent and the '978 patent.

The claim term "a heat-expandable potato starch," which also appears in the three independent product claims of the '978 patent, must be interpreted under the same claim

construction. According to this construction, those three product claims only claim "a potato starch," viewed as a Starting Ingredient, and not viewed as potato starch-based extruded granules.

III. CONCLUSION

The Court has set forth in this memorandum opinion its findings and conclusions on construction of the two remaining disputed claim terms in the patents-in-suit. For the reasons stated herein, the claim construction of those terms is as follows.

The claim term "a hardness-adjustable edible dog chew," in asserted claim 1 of the '565 patent and in asserted claims 4 and 8 of the '978 patent, is construed to mean "an edible dog chew possessing the capability of being adjusted by expanding and becoming softer when microwaved."

The claim term "a heat-expandable potato starch," in asserted claims 4, 8, 14, and 16 of the '978 patents, is construed to mean "a potato starch."

The Court will issue an appropriate order.

s/ Mary L. Cooper
MARY L. COOPER
United States District Judge

Dated: April 30, 2014