

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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Florida Food Products

Petitioner

v.

Kerry Group Services Int'l Ltd.,

Patent Owner

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Case IPR2022-00006

Patent 11,071,304 B2

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**PATENT OWNER RESPONSE**

*37 C.F.R. § 42.120*

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**List of Patent Owner's Exhibits**

<b>Exhibit No.</b>	<b>Description</b>
<b>2001</b>	First Declaration of Dr. Andrew L. Milkowski
<b>2002</b>	<i>Curriculum Vitae</i> of Dr. Andrew L Milkowski
<b>2003</b>	Sindelar, J. J. et al., <i>Effects of varying levels of vegetable juice powder and incubation time on color, residual nitrate and nitrite, pigment, pH, and trained sensory attributes of ready-to-eat uncured ham</i> , 72 J. FOOD SCI. S388-395 (2007)
<b>2004</b>	Sindelar, J. J. et al., <i>Effects of vegetable juice powder concentration and storage time on some chemical and sensory quality attributes of uncured, emulsified cooked sausages</i> , J. FOOD SCI. S324-332 (2007)
<b>2005</b>	Ramarao et al., <i>Inactivation of Nitrate Reductase From Wheat and Rice Leaves</i> , 20 PHYTOCHEMISTRY, 1487, 1487-91 (1981)
<b>2006</b>	Kurihara, JP 2001-352935 (Translation provided by USPTO in the file history of the U.S. Patent No. 11,071,304 on December 20, 2016)
<b>2007</b>	Website printout: Florida Food Products, Product Solutions (Jan. 26, 2022), available at <a href="https://www.floridafood.com/product-solutions/">https://www.floridafood.com/product-solutions/</a> .
<b>2008</b>	Website printout: Florida Food Products, VegStable Natural Cure (Jan. 26, 2022), available at <a href="https://www.floridafood.com/products/vegstable-cure">https://www.floridafood.com/products/vegstable-cure</a>
<b>2009</b>	Chr. Hansen, <i>Production of fermented sausages with Chr. Hansen starter cultures</i> , Bactoform™ Meat Manual vol. I, pages 1-31 (Edition 2003)
<b>2010</b>	Bryan, N. S., Alexander, D. A., Coughlin, J. R., Milkowski, A. L., Boffetta, P., <i>Ingested nitrate and nitrite and stomach cancer risk: an updated review</i> , 50 FOOD AND CHEMICAL TOXICOLOGY, 3646-65 (2012)
<b>2011</b>	File History of U.S. Application No. 12/119,950 (now abandoned), the parent application of U.S. Patent No. 11,071,304
<b>2012</b>	<i>Ex parte Babcock</i> (Case No. 2011-011726, in Application Serial No. 10/636,834, decision issued May 9, 2012)
<b>2013</b>	Declaration of L. Roman Rachuba
<b>2014</b>	Second Declaration of Dr. Milkowski

<b>2015</b>	Transcription from the deposition of FFP's expert, Dr. Steven Baldwin held on June 21, 2022
<b>2016</b>	Dr. Noufoh Djeri, <i>Evaluation of Veg Stable™ 504 Celery Juice Powder for Use in Processed Meat and Poultry as a Nitrite Replacer</i> , UNIVERSITY OF FLORIDA, DISSERTATION (2010)
<b>2017</b>	<i>Dry and Semi-Dry Sausage</i> (e-book), MEAT PROCESSOR'S JOURNAL, SCIENCE, METHOD AND TRENDS, Vol. 2, (Handtmann and Meatingplace) (2015) at <a href="https://www.meatingplace.com/Ebook/MeatProcessorsJournalVol2">https://www.meatingplace.com/Ebook/MeatProcessorsJournalVol2</a> )
<b>2018</b>	Terns, Matthew J. et al., <i>Determining the impact of varying levels of cherry powder and starter culture on quality and sensory attributes of indirectly cured, emulsified cooked sausages</i> , 88 MEAT SCI. 311 (2011)
<b>2019</b>	Terns, Matthew J. et al., <i>Investigating the effect of incubation time and starter culture addition level on quality attributes of indirectly cured, emulsified cooked sausages</i> , 88 Meat Sci. 454 (2011)
<b>2020</b>	N. Djeri and S.K. Williams, <i>Celery Juice Powder Used as Nitrite Substitute in Sliced Vacuum-Packaged Turkey Bologna Stored at 4C for 10 Weeks under Retail Display Light</i> , J. of Food Quality 37 (2014)
<b>2021</b>	<i>Cocoa bean processing, Fermentation</i> , Britannica.com, at <a href="https://www.britannica.com/topic/cocoa-food/Fermentation">https://www.britannica.com/topic/cocoa-food/Fermentation</a>
<b>2022</b>	Second Declaration of L. Roman Rachuba

Pursuant to 37 C.F.R. § 42.120, Kerry Group Services Int'l Ltd. ("KGSI" or "Patent Owner") submits this Response to the Petition for *Inter Partes Review* (IPR) ("Petition") (*cited* "Pet., [page #]") of claims 1-5 of U.S. Patent No. 11,071,304 ("the '304 patent") (Ex.1001) filed by Florida Food Products ("FFP" or "Petitioner").

## **I. Introduction**

With the benefit of full consideration, the Board will appreciate that both of FFP's proposed grounds of rejection are deficient. The deficiencies are underscored by the testimony of FFP's expert, Dr. Baldwin, in his cross-examination, which confirmed that—on the critical issue of what a person of ordinary skill in the art ("POSA") would have understood at the time of KGSI's invention—none of the asserted prior art documents provided the requisite rationale to modify the primary prior art documents (Voorde for Ground I, and Fast for Ground II), let alone overcome the express teaching away found in each primary reference. Rather, FFP's rationales are rooted in the opinion testimony given by Dr. Baldwin. Dr. Baldwin's opinions, in turn, are not drawn from his expertise in meat science and curing, but in his attempt to quickly come up to speed in this art, guided heavily by hindsight. As such, Dr. Baldwin's opinions should be given little to no weight.



*In the case of Ground I*, FFP asserts that it would have been obvious in view of Hara to first heat Voorde's plant material *to kill germs*. Pet. at 33-36. This rationale is rooted on Dr. Baldwin's assertion that, "[t]o a POSITA, washing and heating, boiling, or steaming the vegetable would be as common as washing one's hands before cooking a meal—a matter of routine sanitization" (Ex.1002 ¶119); and also his assertion that, because Voorde sought to improve on Hara, "a POSITA would have retained the initial preparation steps of heating the vegetables as done throughout Hara" (Ex.1002 ¶121). In an effort to support his position, Dr. Baldwin testified that sterilization is what is "normally done" when "you're going to inoculate something with a -- with a microorganism." Ex.2015 (Baldwin deposition transcription), 112:9-113:20. Similarly, Dr. Baldwin testified that, "when people use microorganisms ... you generally start with a sterile medium." *Id.*, 116:14-21.

Dr. Baldwin's opinions are unscientific, incorrect, and fail to take into account key teachings of the references that are contrary to FFP's Ground I:

- A POSA would have understood that culturing a food product and growing a bacterial strain are two different processes, and would have been aware of many examples of food fermentations where a bacterial inoculum is added to non-sterilized media, such as *in situ* meat curing,

cheese making, bread making, and cocoa processing. Ex.2014

(Second Declaration of KGSI's expert, Dr. Milkowski) ¶¶66-71. Dr. Baldwin's failure to appreciate this distinction undercuts his simplistic rationale for modifying the Voorde process and demonstrates his lack of competency to opine as an expert on the issues raised in this proceeding.

- Hara does not disclose that the heating performed in its initial preparation steps *is for killing germs*. Instead, Hara used the initial heating for extracting plant juice to prepare its product. Furthermore, similar to Voorde, Hara discloses that its final product can be sterilized. Thus, a POSA concerned about killing germs would have understood that sterilizing Voorde's end product is consistent with the teachings of both Voorde and Hara and, if needed, could have looked to Hara for means for performing this sterilization. Ex.2014 ¶¶39-41.
- Voorde was fully aware of Hara's disclosures and, in context, purposely excluded Hara's initial heating step. When reviewing the reference as a whole, it is apparent that Voorde's improvement was the use of fresh plant material (such as fresh spinach), and a reliance on moderate heating to promote the conversion of plant-based nitrate

to nitrite, regardless of whether a starter culture is added to provide additional or supplementary organisms for affecting the conversion.

Ex.2014 ¶¶42-43.

- Voorde expressly warns against heating its plant material to temperatures over 80°C “in order not to excessively reduce the enzymatic and microbiological conversion processes necessary for the conversion of nitrate into nitrite” (Ex.1003, 8), and thus expressly teaches away from first heating its plant material by boiling or steaming. Including an initial step of boiling or heating would be fundamentally inconsistent with Voorde’s desire to use the natural enzymes and microbes of fresh plant material, as this would substantially kill the very same natural enzymes and microbes *required* by Voorde for affecting the conversion. Ex.2014 ¶¶43-48.
- Voorde does not disclose the use of starter culture as a substitute for the natural enzymes and microbes capable of affecting its conversion process. This is not simply a clear preference. Voorde used only the natural enzymes and microbes of fresh spinach in all of its Examples; never used a starter culture in its Examples; and the one sentence in Voorde mentioning the use of the optional starter cultures for the

conversion teaches the use of “additional organisms” (i.e., organisms that are added, extra, or supplementary to what is already present or available in the fresh plant material). Ex.2014 ¶49.

Accordingly, a POSA considering Voorde in view of Hara would have had no reason, based on these disclosures, to modify Voorde in the manner advocated by FFP; a modification requiring a substantial rewrite of Voorde to include a heating and cooling procedure not found in the prior art relied on by FFP, and then rely only on starter culture—a scenario a POSA would never have envisioned. Instead, FFP relies on the opinion testimony of Dr. Baldwin for the combination of references. However, Dr. Baldwin’s opinions not only fail to account for the actual, contextual teachings of Voorde and Hara noted above, which are inconsistent with FFP’s position, but also fail to provide a realistic perspective of a POSA in the relevant time period of 2007. Ex.2014 ¶¶50-74.

***In the case of Ground II***, FFP asserts that it would have obvious to modify Fast in order to make a plant-based nitrite curing agent for preserving meat, simply because an unrelated reference, Voorde, discloses a plant-based nitrite curing agent. However, FFP and Dr. Baldwin failed to take into account:

- Both experts agree that Fast is directed to completely eliminating both nitrate and nitrite from nitrate polluted water and vegetables. Ex.2014 ¶82; Ex.2015, 104:8-105:19.
- Fast discloses that nitrite is harmful and unacceptable in an end product (Ex.2014 ¶83), and Dr. Baldwin held this belief during his cross-examination (Ex.2015, 104:8-19).
- Fast merely references that cured meat is one source of harmful nitrite in human diets, and that *Staphylococcus carnosus* (*S. carnosus*) is a known organism for converting nitrate to nitrite. However, after these Background statements, Fast's entire inventive disclosure is directed to systems and methods of efficiently ***eliminating both nitrate and nitrite***, and never discloses any curing agent, let alone a plant-based nitrite curing agent. Indeed, Fast is substantially directed to genetically modified proteins in *S. carnosus* so that it can more efficiently eliminate the nitrate in the polluted water or vegetables. Ex.2014 ¶84.
- A solution containing no nitrite would be useless as a curing agent for preserving meat, and Fast contains no Example where plant material is fermented to increase the amount of nitrite. Rather, in its one single

carrot example (Ex.1019, 13:43-58), the experiment was specifically designed for eliminating both nitrate and nitrite, and that goal was accomplished, as also acknowledged by Dr. Baldwin during his cross-examination (Ex.2015, 121:19-122:8). Ex.2014 ¶85.

- In addition to intentionally ignoring that Fast is directed to a GMO (Ex.2002 (Declaration of FFP's expert, Dr. Baldwin) ¶72), perhaps because a meat scientist would have quickly discarded Fast for this reason (Ex.2001 (First Declaration of KGSI's expert, Dr. Milkowski) ¶140), modifying Fast to produce a solution rich in plant-based nitrite would undermine the entire goal of Fast's work and its teaching that nitrite is harmful and unacceptable. Ex.2014 ¶¶86, 99.

Accordingly, a POSA considering Fast in view of Voorde and Yamamoto would have had no reason, based on these disclosures, to modify Fast in the manner advocated by FFP. As such, FFP relies on the opinion testimony of Dr. Baldwin, but Dr. Baldwin's opinions fail to account for the teachings of Fast that are wholly inconsistent with FFP's position.

Hindsight can be an opioid in an obviousness analysis. It is imperative that one properly frame the analysis from the perspective of a POSA at the time of the invention. In this regard, the aid of an expert can be critical, as long as the expert

in fact has the credentials to opine and guide. This is particularly true where, as here, FFP's rationale for carrying out the modifications to the primary references, Voorde and Fast, are not found in the prior art relied on by FFP, but in the testimony of Dr. Baldwin. On this record, only KGSI's expert, Dr. Andrew L. Milkowski, has the requisite qualifications to properly assist the Board as the trier of fact.

**II. FFP's grounds of unpatentability are rooted in the opinions of Dr. Baldwin in an area of science for which Dr. Baldwin lacks the requisite competency**

Understanding the state of the art at the time of the invention is fundamental to a determination of patentability of claims 1-5 of KGSI's '304 patent. Each of FFP's grounds of unpatentability is premised on a combination of prior art documents. Given that FFP requires testimony from Dr. Baldwin to establish its rationale to modify the primary references because that rationale is not found in the documents themselves, the Board must consider whether that testimony is both reliable and helpful when making its determinations as to whether the modifications would have been obvious to a POSA at the time of KGSI's invention. In light of Dr. Baldwin's demonstrated lack of competency in the area of meat science and curing, when weighing the evidence, the Board should give little to no weight to his testimony on these issues. This is particularly true where

Dr. Baldwin opines on the critical issues of the understanding of a POSA and the rationale to modify the teachings of the primary references—rationales that contravene express teachings in the prior art relied on by FFP.<sup>1</sup>

***A. Dr. Baldwin has no technical basis and is incorrect to assert that meat science and curing was routine, simple, and predictable at the time of KGSi's invention***

Dr. Baldwin's Declaration testimony attempts to characterize the technology of the '304 patent as simplistic and predictable. Ex.1002 ¶¶103, 119 (*citing* ¶¶97-98); Ex.2014 ¶¶37-38; *see also* Ex.1002 ¶¶88-95. This is far from accurate. The evidence, including Dr. Baldwin's testimony on cross-examination, makes clear that meat science and curing is far from simplistic, and Dr. Baldwin lacks the expertise to competently opine in this area.<sup>2</sup> Dr. Baldwin's lack of competency is

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<sup>1</sup> In its Decision on institution (D.I.), the Board recognized that FFP relies on Dr. Baldwin at least to support its contentions (D.I., 10), the qualifications of a POSA (D.I., 7), its alleged motivation to combine Voorde with Hara (D.I., 11), and its assertion that Voorde's disclosure of sterilization would inactivate added organisms (D.I., 14).

<sup>2</sup> Dr. Baldwin acknowledges that the '304 patent relates to the science of meat curing. Ex.2015, 30:10-16.



also relevant here because the unpredictability of the chemical arts—and especially meat science—makes it particularly necessary to articulate a sound reason why a skilled artisan would modify a known composition in a particular manner to obtain a predictable outcome. *See, e.g., Eisai Co. Ltd. v. Dr. Reddy's Laboratories, Ltd.*, 533 F.3d 1353, 1359 (Fed. Cir. 2008).

Meat science is an applied science that incorporates from a number of other basic and applied sciences, in specific applications of taking tissues from animals and using them for food. Ex.2014 ¶6. As Dr. Milkowski explains, “[b]ecause meat science has long been recognized as a highly specialized area of applied science, there are various organizations, journals, trade publications, conferences and trade shows dedicated to this science and a POSA would be expected to have gained knowledge on the latest developments in meat science from these sources.” Ex.2014 ¶8. Absent such exposure, one would lack the knowledge to competently opine on the subject as an expert. *Id.*

Dr. Milkowski identifies several of the prominent organizations in meat science, one or more with which a POSA would have been associated. Ex.2014 ¶¶9-14 (*e.g.*, American Meat Science Association (AMSA), the foremost

association of meat science professionals). Dr. Milkowski has been associated with each of these organizations. *Id.*, *see also* Ex.2002 (*curriculum vitae*).

Dr. Milkowski also identifies examples of publications in the relevant literature of meat science, which a POSA would have been expected to read on a regular basis. Ex.2014 ¶15 (*e.g.*, MEAT SCIENCE is one of the most prominent). Dr. Milkowski not only reads these publications on a regular basis but is a co-author of several articles. *Id.*; *see also* Ex.2002.

Dr. Milkowski further identifies several seminars, conferences, and tradeshowes relating to meat science. Ex.2014 ¶16 (*e.g.*, the Reciprocal Meat Conference (“RMC”) is one of the most recognized annual conferences). Dr. Milkowski regular attends these meetings.

Dr. Milkowski has not only worked extensively in the field of meat science, but has also conducted research, taught in this field, and acted as a key contributor in the research of many masters and doctoral students. Ex.2002, 1-2; Ex.2014 ¶18. Dr. Milkowski has also been given several awards and has been named on several patents, all related to his work in meat science. Ex.2002, 2.

Throughout his career, Dr. Milkowski has developed professional relationships with other scientists in the field, including Dr. Joseph Sebranek and

Dr. Jeffrey (“Jeff”) Sindelar—two of the authors cited in Dr. Baldwin’s declaration. Ex.2014 ¶¶19-20.

In contrast to Dr. Milkowski’s expertise as well as the qualifications of a POSA, Dr. Baldwin is a synthetic organic chemist and, by his own admission, lacks the requisite knowledge and expertise in the areas of food and meat science. Ex.2015, 30:19-31:11, 32:7-33:9; 37:12-17.

Dr. Baldwin testified that all of the documents cited in his Declaration, including the prior art, were provided to him by FFP’s counsel. Ex.2015, 19:15-19, 23:15-18. Moreover, Dr. Baldwin confirmed that the specific prior art combinations set forth in Grounds I and II were provided to him by FFP’s counsel. Ex.2015, 24:7-11, 26:4-20.

In order to familiarize himself with the technology, Dr. Baldwin testified that he spent “an afternoon” coming up to speed on meat curing, because “it’s not an area I follow.” Ex.2015, 135:10-17, 28:18-21. In fact, Dr. Baldwin testified that his knowledge of meat curing and meat science has been predominantly derived from his activities since about June of 2021 (when he was first retained by

FFP's counsel), which he described as a "crash course" for this IPR. Ex.2015, 38:10-16.<sup>3</sup>

Dr. Baldwin testified that he has no experience in meat curing, has never analyzed the composition of a meat curing agent, nor conducted any research in this area. Ex.2015, 29:7-30:2, 34:8-11, 59:7-9; 132:8-133:1. Duke University, where Dr. Baldwin has taught since 1970 (Ex.1031, 2) has no food science degree or department. Ex.2015, 35:4-19. Accordingly, Dr. Baldwin has never taught a course, at any level, in food science and food chemistry or meat science, and has never supervised any dissertations in the area of food science or science or meat curing. Ex.2015, 37:19-38:9, 38:21-39:2, 42:11-13.

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<sup>3</sup> In contrast, Dr. Milkowski has over 44 years of experience in food and meat science, including 30 years in industry as a scientist with Oscar Mayer specializing in meat products, and more than 14 years as an Adjunct Professor in the Meat Science & Animal Biologics Discovery Program of the Department of Animal and Dairy Sciences at the University of Wisconsin – Madison. Ex.2001 ¶¶1-7; Ex.2002.

Dr. Baldwin confirmed that he has never worked for, nor even visited, a company that processes meat, such as Smithfield, Hormel, or Oscar Mayer.

Ex.2015, 39:3-6; 59:10-17.

Given Dr. Baldwin's academic and professional background, it is no surprise that Dr. Baldwin has not identified that he is associated with any food or meat science organization, has not attended any relevant trade shows or conferences, has not published in the relevant literature, has not given a lecture devoted to meat curing, has not peer reviewed an article related to meat science, has not been an advisor on a dissertation related to meat science, is not familiar with the relevant food codes and regulations, and none of his prior 50 plus expert engagements related to meat curing. Ex.2015, 39:7-43:9, 58:20-60:20, 133:2-13.

It is also not surprising that Dr. Baldwin was not familiar with the authors of the articles given to him by FFP's counsel and to which Dr. Baldwin cites in his Declaration for the state of the art at the time of KGSI's invention (*e.g.*, Exs.1013, 1014 (Dr. Bacus), Ex.1006 (Dr. Sindelar), Ex.1008 (Dr. Sebranek), Ex.1009 (Drs. Sebranek and Bacus)). Ex.2015, 43:2-48:14.

Dr. Baldwin's testimony on redirect perhaps best sums up his failure to appreciate the complexity of meat science. When asked on redirect by FFP's counsel, "[h]ow long did it take you to come up to speed on meat curing, given

your Ph.D. in chemistry,” Dr. Baldwin answered: “I spent probably an afternoon doing a site-finder search and just reading the titles of papers” Ex.2015, 135:10-17. The fact that Dr. Baldwin believed an afternoon was sufficient to “come up to speed” on meat science in order to opine on the subject underscores his lack of appreciation for this science and cannot be reconciled with the balance of his testimony establishing his lack of knowledge and experience. Accordingly, Dr. Baldwin’s opinion testimony on the level of a POSA and whether a particular modification to any prior art process or product would or would not have been obvious to a POSA should not be credited.

***B. At the time of KGSI’s invention, meat scientists were investigating in situ curing, as evidenced by the articles FFP’s counsel provided to Dr. Baldwin for his education on meat science and curing and cited in his Declaration***

While KGSI’s invention is directed to an admittedly novel method of preserving meat or meat products with a plant-based nitrite curing agent, the state of the art at that time was still preoccupied with the development and uncertainties of *in situ* curing.<sup>4</sup> This is evidenced by the literature cited by Dr. Baldwin, which,

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<sup>4</sup> The concept of *in situ* curing involves directly combining meat with a nitrate-containing ingredient (*e.g.*, vegetables high in nitrate) and a reducing starter

as noted above, was provided to him by FFP's counsel for the purpose of educating him on meat science and curing. Ex.2015, 19:15-19, 23:15-18, 24:7-11, 26:4-20.

One such literature reference is the dissertation of Dr. Jeffrey J. Sindelar (Ex.1006), a Professor and Extension Meat Specialist in the Meat Science & Animal Biologics Discovery building at the University of Wisconsin's Department of Animal and Dairy Sciences.<sup>5</sup> The Sindelar dissertation published in 2006 and was cited thirteen times by Dr. Baldwin in his Declaration (Ex.1002). Dr. Sindelar's dissertation was an investigation into *in situ* curing (Ex.1006, 12), a process which Dr. Sindelar called at that time "unconventional" (Ex.1006, 11; *see also* Ex.1002 ¶95 (block-quoting this section of Dr. Sindelar from Ex.1006)).

Similarly, Dr. Baldwin cites fourteen times to a 2007 paper authored by Dr. Joseph Sebranek and Dr. James Bacus, entitled "Natural and Organic Cured Meat Products: Regulatory, Manufacturing, Marketing, Quality and Safety Issues"

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culture, followed by an incubation period to result in generated nitrite *in situ* available for curing reactions to take place. Ex.2014 ¶21-22.

<sup>5</sup> See [https://fri.wisc.edu/p\\_executive\\_committee\\_profile.php?id=jsindelar](https://fri.wisc.edu/p_executive_committee_profile.php?id=jsindelar). Dr. Milkowski is a colleague of Dr. Sindelar at the University of Wisconsin, where Dr. Milkowski is an adjunct professor. Ex.2014 ¶20.

(Ex.1009). As with Dr. Sindelar's dissertation, these meat scientists were investigating *in situ* curing.

Not surprisingly, Dr. Baldwin had not seen these publications contemporaneously, did not know the authors, and had never heard them speak. Ex.2015, 43:2-48:14 .

The scientific literature at the time of the '304 patent, contemporaneous with KGSI's invention, demonstrates that even the field of *in situ* curing was in need of further scientific research by persons of ordinary skill in the art as well as experts in the field. However, Dr. Baldwin admitted that he had no understanding of the concept of *in situ* curing until after he was retained by FFP for this proceeding (Ex.2015, 102:7-21), about fifteen years after the publication of the Sindelar dissertation.

***C. The 2010 dissertation of Dr. Djeri investigated FFP's own VegStable<sup>®</sup> product (a plant-based nitrate curing agent) and demonstrates that Dr. Baldwin's understanding of the state of the art was incomplete and incorrect***

Further scientific research published after the filing date of KGSI's invention also makes clear that the science of plant-based nitrite curing agents was



not well settled and predictable, but instead was in need of investigation.<sup>6</sup> In fact, Dr. Bacus, who Dr. Baldwin cites, was involved in advising a doctoral candidate in this area of research. In this regard, Dr. Baldwin confirmed during his cross-examination that doctoral research is for “brand-new science” and the “investigation of something that’s unknown.” Ex.2015, 51:6-15.

One example of such further scientific research is a doctoral dissertation by Dr. Noufoh Djeri (Ex.2016). The 2010 Djeri dissertation was an investigation of FFP’s own plant-based nitrite curing agent, VegStable™ 504 (a celery juice powder containing pre-generated nitrite (“CJPPN”)). Ex.2016, 11. The Djeri dissertation was not among the literature given to Dr. Baldwin by FFP for his “crash course” education in meat science and curing, and thus not considered by Dr. Baldwin. *See* Ex.2015, 17:8-19:19. As explained below, the Djeri dissertation further demonstrates Dr. Baldwin’s lack of competency in meat science and curing

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<sup>6</sup> When asked directly about whether there is unpredictability in meat science, Dr. Baldwin admitted during cross-examination “people don’t know exactly everything that’s present in the – you know, with the microorganisms and with the enzymes, et cetera, so there’s -- yeah. There’s some -- probably some unpredictability.” Ex.2015, 101:5-102:5.

and his failure to appreciate the understanding of a POSA at the time of KGSI's invention.

Dr. Baldwin in his Declaration oversimplifies the state of the art by implying that a plant-based nitrite curing agent was considered equivalent to *in situ* curing using plant material and starter culture at the time of KGSI's invention. For example, Dr. Baldwin states "[w]hether nitrite reduction occurs beforehand or *in situ* varies with recipes and tradition, but **the underlying chemical principles are the same.**" Ex.1002 ¶103 (emphasis added); *see also id.* ¶¶88-95. However, the Djeri dissertation investigated this very question, showing the uncertainty of the relevant science at the time of KGSI's invention. The fact that this was, to use Dr. Baldwin's words, "brand-new science" was not appreciated by Dr. Baldwin. Indeed, contrary to Dr. Baldwin's position, Dr. Djeri stated in 2010—three years after the '304 patent's filing—that "[m]eat processors are now provided with an **innovative** vegetable juice powder containing pre-generated nitrite (natural source)." Ex.2016, 56 (emphasis added).

At the time of her investigations, Dr. Djeri was well aware of *in situ* curing and cites to the same experts (namely, Drs. Sindelar, Sebranek, and Bacus) cited by

Dr. Baldwin.<sup>2</sup> Armed with this understanding, Dr. Djeri's dissertation work was directed, for example, to determining whether there were differences between products cured with commercially available sodium nitrite and products cured with VegStable™ 504 (a plant-based nitrite curing agent). Ex.2016, 16 (investigating whether there are "differences between products cured with commercially available sodium nitrite (modern cure) and uncured products with the intention of replacing sodium nitrite, using celery juice powder containing pre-generated nitrite").

What is also noteworthy about Dr. Djeri's dissertation is that she thanks FFP for providing its VegStable™ 504 product for her investigations. Ex.2016, 4. Certainly, Dr. Djeri was not investigating an area for her doctoral dissertation that was known to the meat curing scientific community, including FFP. Rather, as Dr. Baldwin testified, this would have been considered by experts at the time to be "brand-new science" and the "investigation of something that's unknown." *See, e.g.,* Ex.2015, 51:6-15.

Also relevant, Dr. Bacus was one of the three members of Dr. Djeri's dissertation committee. Ex.2016, 4. Dr. Bacus is an author of three different

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<sup>2</sup> Compare, e.g., Ex.2016, 15, 20, 23, 37, 40, 47, 54, 55 with Ex.1002 ¶4.

publications that were provided to Dr. Baldwin for his education on meat science and curing (Exhibits 1008, 1013, and 1014 include Dr. Bacus as an author and were cited eighteen times in total by Dr. Baldwin).

FFP and its counsel should have been aware of Dr. Djeri's dissertation at the time of retaining Dr. Baldwin. Given that Dr. Djeri's investigation is inconsistent with Dr. Baldwin's testimony and thus also FFP's proposed grounds of invalidity, it should have been provided to Dr. Baldwin and to the USPTO. *See, e.g.*, 37 C.F.R. § 42.51(b)(1)(iii) (requiring a party to serve information inconsistent with information advanced by the party).

***D. It would be error to rely on Dr. Baldwin's opinion on the state of the art and what a POSA would have thought at the time of KGSI's invention***

As explained above, at the time of the filing of KGSI's '304 patent, the concept of *in situ* curing was considered "unconventional" by a POSA in the field of meat science and curing, and the science of plant-based nitrite curing agents was even less understood by the same people. The evidence shows that the area of technology is as much artisanship gained from years of practical experience in the field, as it is a science, and therefore is one of those arts that lacks clear predictability. Ex.2014 ¶6. Further, Dr. Baldwin's opinions regarding the state of

the art are neither supported by the scientific literature to which he cites nor supported by other notable publications that reflect the state of the art.

Dr. Baldwin is not “qualified as an expert by knowledge, skill, experience, training, or education [to] testify in the form of an opinion or otherwise.” FRE 702. Further, Dr. Baldwin lacks the “scientific, technical, or other specialized knowledge [to] help the trier of fact to understand the evidence or to determine a fact in issue;” his testimony is not “based on sufficient facts or data;” his testimony is not “the product of reliable principles and methods;” and thus he has not “reliably applied the principles and methods to the facts of the case.” FRE 702.

For at least the reasons explained above, it would be error for the Board to rely on Dr. Baldwin’s opinion on the state of the art and what a POSA would have thought at the time of KGSI’s invention, much less the alleged rationale for combining prior art references on which FFP relies as a lynchpin to its two proposed rejections. Stated differently, Dr. Baldwin is not qualified to fill in the numerous gaps between the applied prior art documents and KGSI’s invention.

In short, as discussed throughout this paper, Dr. Baldwin, lacking the expertise, relies on conclusory statements arrived at through hindsight and should be rejected as such. *See Puma N. Am., Inc. v. Nike, Inc.*, IPR2019-01042, Paper 10 at 20-21 (P.T.A.B. Oct. 31, 2019) (informative) (rejecting opinion testimony that

lacked sufficient evidentiary support), citing *ActiveVideo Networks, Inc. v. Verizon Commc'ns, Inc.*, 694 F.3d 1312, 1327 (Fed. Cir. 2012) (“[T]he expert’s testimony on obviousness was essentially a conclusory statement that a person of ordinary skill in the art would have known, based on the ‘modular’ nature of the claimed components, how to combine any of a number of references to achieve the claimed inventions. This is not sufficient and is fraught with hindsight bias.”); *Cephalon, Inc. v. Watson Pharms., Inc.*, 707 F.3d 1330, 1338 (Fed. Cir. 2013) (expert’s ipse dixit statements entitled little weight); *TechSearch, L.L.C. v. Intel Corp.*, 286 F.3d 1360, 1372 (Fed. Cir. 2002) (finding that expert declarations that were “conclusory” and “devoid of facts” upon which the expert declarants’ conclusions were based were insufficient to create a genuine issue of fact and avoid summary judgment); *Telemac Cellular Corp. v. Topp Telecom, Inc.*, 247 F.3d 1316, 1329 (Fed. Cir. 2001) (holding that conclusory statements are not evidence).

**III. With respect to Ground I, FFP’s rationale to “kill germs” does not support its proposed modification to Voorde, and goes against Voorde’s express teaching away**

Claims 1-5 of the ’304 patent would not have been obvious over the teachings of Voorde in view of Hara, for at least the following reasons and the reasons set forth in KGSI’s Preliminary Response (“POPR”).<sup>8</sup>

***A. FFP’s Ground I requires a substantial rewriting of Voorde, for which Dr. Baldwin provides no credible technical basis***

With respect Ground I, FFP proposes a significant modification of Voorde’s process for preserving the color of animal tissue. Recognizing that Voorde at least fails to disclose a curing agent containing plant-based nitrite obtained by heat treating plant material to reduce its microbial load prior to adding an organism for converting nitrate to nitrite, FFP turns to rewriting Voorde with the benefit of

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<sup>8</sup> KGSI’s Preliminary Response (“POPR”) at Section VI. Section VI.A.1 of POPR explained that FFP failed to perform a product-to-product analysis and thus failed to take into account, for example, the unique composition obtained by the process step(s) of preparing a plant-based nitrite curing agent from plant material. *See also* EX.2001 ¶¶128-29, 173, note 23. For preservation purposes, KGSI maintains its POPR positions on those issues.

hindsight. However, the “[d]etermination of obviousness cannot be based on the hindsight combination of components selectively culled from the prior art to fit the parameters of the patented invention.” *ATD Corp. v. Lydall, Inc.*, 159 F.3d 534, 546 (Fed. Cir. 1998); *see also In re Fine*, 837 F.2d 1071, 1075 (Fed. Cir. 1988); *In re Gorman*, 983 F.2d 982, 987 (Fed. Cir. 1991).

Specifically, as Dr. Baldwin acknowledged, Voorde does not teach starting with a sterile medium. Ex.2015, 117:2-5. On the contrary, Voorde teaches moderately heating fresh plant material up to an “optimal” temperature in the range of 50°C-60°C so as to promote and stimulate the conversion of the plant nitrite to nitrite, and warns against using temperatures “higher than 80°C, and more preferably not higher 70°C, in order not to excessively reduce the enzymatic and microbiological conversion processes necessary for the conversion of nitrate into nitrite.” Ex.1003, 8; *see also* Ex.2015, 93:6-94:16 (*e.g.*, “we want to heat it to accelerate the formation of nitrate (*sic*), but we don’t want to kill off”); 99:12-14. Further, as explained in Section III.C below, a POSA would have understood that this heating process would be the same even in the case where the optional starter culture is added to supplement the natural enzymes and microbes affecting the conversion. Ex.2014 at 46, 49; Ex.2015, 88:18-90:8.



In rewriting Voorde, FFP proposes a fundamentally different heating and cooling procedure, requiring (1) heating Voorde's fresh plant material to 100°C by boiling or steaming to kill germs (which in turn would substantially kill the natural enzymes and microbes of the plant material used by Voorde); (2) allowing the heat-treated plant material to cool to 50°C-60°C; and (3) adding starter culture to the plant material cooled to 50°C-60°C. *See* Ex.1002 ¶124. This rewrite is illustrated below:

Finely chop fresh spinach leaves → heat the minced spinach to 100°C by boiling or steaming to kill germs (thereby substantially killing the natural enzymes and microbes) → allow the spinach to cool to 50°C-60°C → optionally add starter culture to the spinach cooled to 50°C-60°C → ~~heat the minced spinach to a temperature of 52°C mixture over a time period of three hours →~~ use (or optionally after sterilization store) the plant-based nitrite

*Compare* Ex.1002 ¶124 *with* Ex.1003, 7-10.

The significant modifications required by FFP's Ground I are not taught by the actual disclosures of Voorde or Hara, and in fact are counter to Voorde's teaching. Rather, FFP relies on the opinions of Dr. Baldwin's testimony, using the claims of KGSI's '304 patent as a roadmap.

Dr. Baldwin's testimony is not based on his expertise or first-hand knowledge but on a simplistic and unscientific statement that "washing and

heating, boiling, or steaming the vegetable would be as common as washing one's hands before cooking a meal—a matter of routine sanitization.” Ex.1002 ¶119 (citing ¶¶97-98). In paragraph 97 of his Declaration, Dr. Baldwin references several documents and notes that he has “seen frozen vegetables sold at grocery stores, such as Wal-Mart, Publix, Kroger, Food Lion, or Target that are often blanched before freezing.” Ex.1002 ¶97. However, neither the documents discussed by Dr. Baldwin nor his trips to the grocery store support his opinion that a POSA in 2007 would have found it obvious to first heat *Voorde*'s plant material to kill germs, in the context of forming a curing agent for meat curing as in the claims of the '304 patent. Other than Hara, none of the referenced documents in paragraph 97 of Dr. Baldwin's Declaration are relied on for Ground I. Moreover, Dr. Baldwin fails to explain how the different types of heating disclosed in each document, accounting for the specific purpose such heating was used, would have made it obvious to modify *Voorde*'s process. Ex.2014 ¶55-62.

Further, when Dr. Baldwin was asked on cross-examination for a basis for heating the plant material by boiling or steaming to kill germs prior to adding starter culture, Dr. Baldwin did not point to the disclosure of *Voorde* or Hara, or to any other document cited in his Declaration testimony. Ex.2015, 111:7-118:22. When pressed on this issue, he could only state, and without evidentiary support,

that sterilization is what is “normally done” when “you’re going to inoculate something with a -- with a microorganism.” Ex.2015, 112:9-113:20 (“that’s just the way -- I can’t cite to a particular reference, but that’s just the way I’ve seen it in the past”); 116:14-21 (“I don’t necessarily mean that I’ve been involved in or seen seminars on, you know, vegetable -- you know, nitrites/nitrates in vegetables or anything like that. But when people use microorganisms, and they do in -- you know, in chemistry for that matter, you generally start with a sterile medium”).

Dr. Baldwin’s opinion on what “normally done” is fundamentally incorrect. A POSA would have understood that culturing a food product and growing a bacterial strain are two different processes, and would have been aware of many examples of food fermentations where a bacterial inoculum is added to non-sterilized media, such as *in situ* meat curing, cheese making, bread making, and cocoa processing. Ex.2014 ¶¶63-71. Dr. Baldwin’s failure to appreciate this distinction undercuts his simplistic rationale for modifying the Voorde process and demonstrates his lack of competency to opine as an expert on the issues raised in this proceeding.

Dr. Baldwin’s failure to appreciate what was “normally done” when using a starter culture is not surprising, given his lack expertise in this technology. In fact, Dr. Baldwin was not even aware of *in situ* curing prior to being retained by FFP’s

counsel for this proceeding (section II.B above), and he conceded never having performed this type of culturing (*e.g.*, Ex.2015, 114-8:11).

Despite Dr. Baldwin's lack of understanding on what a POSA would have "normally done," FFP's Ground I relies on Dr. Baldwin's opinion alone to support its rationale for modifying Voorde's process—that is, it would have been routine to first heat Voorde's starting plant material to kill germs when adding a starter culture. Admittedly no such teaching is found in Voorde, thereby requiring a substantial rewriting of Voorde's process in a way Voorde tells you not to do—textbook hindsight.

Dr. Baldwin's forced interpretation of Voorde also necessitates a very different *heating and cooling* procedure than what is taught by Voorde. On the one hand, Voorde teaches moderately heating the fresh plant material up to an optimal temperature for promoting the conversion process. On the other hand, in an attempt to match the language of the '304 patent, Dr. Baldwin proposes first heating the fresh plant material by heating or boiling to a temperature well beyond what is taught by Voorde, followed by allowing the heated plant material to *cool* to Voorde's optimal temperature range of 50°C-60°C. *See* Ex.1002 ¶124, Ex.1003, 7-10. Neither this heating nor this cooling finds support in Voorde, but comes only from Dr. Baldwin—textbook hindsight.

***B. Sterilizing Voorde's end product, if this optional step were selected by a POSA, would be consistent with the teachings of both Voorde and Hara***

Among the references discussed in paragraph 97, Dr. Baldwin cites to the heating step that Hara used in its Examples for the purpose of extracting liquid from plant material (i.e., boiling, steaming, etc. at 100°C). Ex.2001 ¶¶68-69; Ex.2015, 75:7-76:5. It is this heating step in Hara for making its plant juice that FFP explicitly relies on to modify Voorde's process—not for extracting juice as taught by Hara—but for FFP's asserted rationale of killing germs.

What FFP's position on obviousness fails to take into account is that, if a POSA starting with Voorde wanted to “kill germs” according to FFP, the teachings of both Voorde and Hara explicitly provide a step of sterilizing ***at the end, after making their products***. Specifically, Voorde teaches as another optional step “the nitrite-containing product that has been produced can first be stored for a certain period of time ... after sterilization.” Ex.1003, 8. Likewise, Hara teaches as another optional step that “[u]nless the water-soluble plant ingredients are to be used immediately after their preparation, it is preferred to sterilize the material.” Ex.1023, 1:59-2:4. In other words, a step of sterilizing the end product (which a POSA would understand would kill germs) is expressly compatible with both Voorde at Hara.

As such, a POSA concerned with “killing germs” would have followed the path for a sterilization process actually taught by these two references, but on the end products, and only then based on selections. This would be consistent with both Voorde and Hara, and a POSA could have looked to Hara for its disclosure on how one can sterilize the end product, as the end sterilization step of Hara is a process step not improved upon by Voorde. Indeed, while Voorde simply states that the end product can be “sterilized” (Ex.1003, 8), without explaining steps for sterilizing its end product, Hara explains such sterilization of the end product in more detail.<sup>2</sup> This also would be consistent with FFP’s position that a POSA

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<sup>2</sup> Hara teaches that the sterilization of its end product can be affected by exposing its plant juice end product to a temperature of about 90°C for 10 minutes (Ex.1023, 1:59-2:4). Moreover, in its Example 6, Hara exemplifies the sterilization of its end product as follows: (1) cabbage was sliced, pressed, boiled for 30 minutes, and the solids removed to obtain a plant juice; (2) the plant juice obtained from the cabbage was mixed with the same adjuvants used in Example 5; and (3) Hara’s end product (a mixture of the plant juice and adjuvant) was sealed in a bottle “and *heated until sterile.*” Ex.1023, 6:13-28 (emphasis added).

would look to Hara “for background steps not improved upon in Voorde.” Pet.,  
43.

In its Decision on Institution, the Board stated:

the heating of Hara [to kill germs] is at a different point in the curing process than Voorde’s heating. Specifically, *Hara discloses heating prior to storage of the plant-derived solution, to sterilize it*, whereas Voorde’s heating step is during treatment, to encourage the nitrate conversion process. We do not understand combining these two heating steps into one process to be incompatible.

Decision on Institution (“D.I.”), 13 (emphasis added).

What the Board may have misapprehended is that, as explained above, Voorde already discloses a corresponding sterilization step on its end product. Therefore, a POSA looking to adopt Hara’s heating for sterilization would do so consistent with both disclosures, *i.e.*, on the end product. In fact, FFP’s proposed ground of unpatentability looks to Hara “for background steps *not improved upon in Voorde*, such as heating the vegetables, concentrating curing solutions, and

processing the curing solutions to make it last for months.”<sup>10</sup> Pet., 43 (emphasis added) (citing Ex.1002 ¶¶162-163). Because Voorde states that its end product can be “sterilized,” without explaining how, this is the type of step a POSA could have looked to Hara as background teaching not inconsistent with Voorde’s disclosure. But FFP ignores the corresponding teaching in Hara with respect to sterilization, and instead proposes modifying Voorde at the exact point where Voorde improves upon Hara. As such, FFP’s modification of Voorde is contrary to its stated “motivation to combine.” Pet., 43.

FFP’s only apparent basis for departing from the teachings of Voorde and Hara is FFP’s reliance on Dr. Baldwin’s simplistic assertion that such a modification would have been as routine as washing hands before eating. Again, it would be error for the Board to rely on Dr. Baldwin for this type of rewriting of the prior art, as Dr. Baldwin lacks the requisite competency to opine on such issues.

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<sup>10</sup> FFP characterizes its obviousness ground as a “combination” of Voorde and Hara (*see, e.g.*, Pet., 43). As explained throughout this paper, FFP is clearly advocating a *modification* of Voorde’s process.



***C. Voorde's improvement over Hara includes the use of fresh plant material, and FFP's modification to first boil or steam Voorde's plant material to "kill germs" is contrary to Voorde's express teachings not to do so***

Aside from the fact that both Voorde and Hara expressly teach sterilization *only* at the end, and given FFP's position that one would look to Hara "for background steps not improved upon in Voorde," a POSA would not have thought to modify Voorde in a manner that is inconsistent with Voorde's teaching. Namely, a POSA would not have found it obvious to heat Voorde's fresh plant material to a high temperature, such as 100°C, to kill germs. This is for at least the reasons discussed below.

***1. Hara's first heating, explicitly relied on by FFP, is for making a plant juice, not killing germs***

As explained in Section III.B above, FFP cites to the first heating in Hara's Examples to support their argument that heating to kill germs was routine and conventional. Specifically, FFP and Dr. Baldwin point to Hara's processing steps for preparing its plant juice ("water-soluble ingredients of vegetal matter") (*i.e.*, "heating, boiling, or steaming" to kill germs (*e.g.*, "100°C for 30 minutes") (Pet., 33-35)). However, as explained above, the first heating used in Hara's Examples was only for making juice, not for killing germs. Ex.2014 ¶39.

2. Voorde had a full understanding of Hara's full disclosure

Voorde had an understanding of Hara's full disclosure, and Voorde looked to provide a better process for preserving the red color of meat. Indeed, Voorde repeatedly cites to Hara as follows.

Voorde first discusses Hara's invention generally, stating that Hara "discloses a method for preserving the color of animal tissue" using "plant juice" "separated by extraction or pressing from plant material," which should be "used immediately after its preparation ... or sterilized and stored." Voorde then explains that Hara did not correlate the low amount of nitrite optionally present in the plant material with color retention. Ex.1003, paragraph bridging 2-3.

Voorde next explains the drawbacks of Hara. Ex.1003, 3, first-full-paragraph. Dr. Milkowski previously explained these drawbacks. Ex.2001, ¶73.

Voorde then explains that Hara's plant juice was prepared from celery juice and added to meat with a starter culture of nitrite-forming bacteria, but no homogenous color was obtained. Ex.1003, 3, second-full-paragraph.

Voorde next explains that, contrary to Hara, by first converting a part of the nitrate of plant material into nitrite before contacting the meat, an immediate effect on the coloration of meat can be obtained. Ex.1003, 4, second-full-paragraph.

Finally, Voorde then explains that, contrary to Hara, Voorde's process does introduce a significant amount of nitrate into the meat. Ex.1003, 5, first-full-paragraph.

3. Voorde's preparation of the starting plant material uses the same mechanical steps as Hara, and does not mention heating

Voorde's disclosure includes a section on preparing its plant material for use in its process. Specifically, Voorde discusses plant material preparation including comminuting, grinding, and chopping the plant material, and also mentions pressing and centrifuging. Ex.1003, 6. These are all of the same mechanical steps used by Hara for preparing its plant juice. Ex.1023, 2:5 ("chopped, shredded, or otherwise comminuted"); 3:11 ("centrifuging"); 5:48-49 ("press"). Notably, Voorde does not teach the use of heating to prepare its plant material for use in its process, as also acknowledged by Dr. Baldwin (Ex.2015, 86:10-88:12).

4. Voorde teaches heating up to a moderate temperature that is optimal for promoting the conversion reaction, and warns against heating to higher temperatures

Voorde expressly teaches heating at moderate temperatures to promote and stimulate the conversion reaction, and unequivocally warns against heating above 80°C. Ex.1003, 7-8. Indeed, Voorde makes clear that the primary purpose of its

heating is to promote faster conversion of nitrate to nitrite, not to negatively affect or terminate the conversion process:

Preferably, the conversion of nitrate into nitrite is **promoted** by carrying it out at least partially at a temperature higher than 20°C. In this way **less time is required for the necessary conversion** than if this conversion were, for example, carried out exclusively at a temperature between 5 and 20°C. The conversion of nitrate into nitrite is preferably **further stimulated** by heating to a temperature higher than 40°C, and more preferably to a temperature higher than 50°C. Heating to a temperature higher than 50°C, for example to 52°C, is further preferred because at these temperatures undesired micro-organisms are killed and the material is thus (partially) sterilized. In particular, the plant juice and/or the aqueous extraction liquid, preferably containing the vegetable material, can be heated to such temperatures, after which the heating can then be stopped when the desired temperature is reached and the whole can slowly

cool down to room temperature. Preferably, the heating is not higher than 80°C, and more preferably not higher than 70°C, in order not to excessively reduce the enzymatic and microbiological conversion processes necessary for the conversion of nitrate into nitrite. Preferably, heating is carried out to a temperature of between 50 and 60°C, such that on the one hand sufficient sterilization is obtained and, on the other hand, the nitrate is converted into nitrite in a sufficiently short time, in particular within a period of 24 hours.

Ex.1019, 7-8 (emphasis added).

Dr. Baldwin acknowledged that the temperature of 52°C used in Voorde's Example 1 "seems to be optimal for this particular enzymatic process of converting nitrate to nitrite." Ex.2015, 99:12-14; *see also* Ex.2015, 75:18-76:5 (acknowledging Voorde's express teaching not to heat the vegetable materials above the preferred range); 91:21-92:6 (acknowledging that there is no disclosure in Voorde where all of the inherent enzymes and microbes are killed off by a high-heating step before starter culture is added, or at any time).

5. Voorde teaches the optional starter culture is additional (*i.e.*, extra or supplementary) to the natural enzymes and microbes, and not a substitute

Voorde's single sentence on the use of starter cultures in its conversion process is sufficiently clear—the starter culture is additional, extra, or supplemental to what is already provided by the natural enzymes and/or microbes of the plant material. Voorde never discloses substituting starter culture for the natural enzymes and microbes present in fresh plant material. Rather, a plain reading of Voorde's disclosure confirms that the optional starter culture is “additional” (*i.e.*, extra or supplementary)<sup>11</sup> to what is already present or available in the fresh plant material for affecting the conversion.

Dr. Baldwin also acknowledged that the starter culture is not a substitute for the natural enzymes and microbes during his cross-examination. When asked to review Voorde's hearing for promoting the conversion reaction (*i.e.*, Ex.1003, paragraph bridging 7-8), Dr. Baldwin stated “there may also have been additional microorganisms added, like starter cultures, *along with the natural -- you know,*

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<sup>11</sup> The Oxford Languages dictionary defines “additional” when used as an adjective means “added, extra, or supplementary to what is already present or available.” The Meriam-Webster dictionary defines “additional” as “more than is usual or expected.”

*you have the inherent materials from the vegetable matter.”* Ex.2015, 90:1-17

(emphasis added). Dr. Baldwin further acknowledged that, when the optional starter culture is added, “there would be *nitrite being formed from plant-based enzymes and nitrites being formed from starter culture* microorganism.”

Ex.2015, 93:3-5 (emphasis added). Likewise, Dr. Baldwin agreed that the language in the second translation of Voorde provided by FFP (Ex.1004) teaches that the starter culture is not a substitute for the natural enzymes and microbes.

Ex.2015, 117:6-16; *see also* Ex.2015, 88:18-90:8 (acknowledging that Voorde’s disclosure about optionally adding starter culture would not be understood to be to the “exclusion” of the microbes and enzymes naturally present in the plant); 91:21-92:6 (agreeing there is no disclosure in Voorde where all of the inherent enzymes and microbes are killed off by a high-heating step before starter culture is added, or at any time); 117:2-118:22 (agreeing that Voorde neither discloses starting with a sterile medium nor discloses discarding the natural enzymes and microbes).

In other words, when asked to review the teachings of Voorde, Dr. Baldwin confirmed that Voorde’s starter culture, if used, is in addition to (*i.e.*, extra or supplementary) the natural enzymes and microorganism of the plant material.

6. All of Voorde's Examples used "fresh" plant material

In Voorde's Examples, and consistent with its disclosure on preparing the plant material for use, Voorde used *fresh* spinach, which was then finely chopped and subjected to moderate heating up to 52°C. Ex.1003, 9-10 ("Fresh spinach (with stems) were finely chopped ... water was added ... and the whole was heated to 52°C"). Again, Dr. Baldwin acknowledged that there is no reference in Voorde's Example 1 to initial heating of the plant material to 100°C. Ex.2015, 98:1-11.

7. Voorde, when properly read as a whole, purposely excluded Hara's initial heating step, which confirms the teaching away

Given all of these disclosures, a POSA would have understood that *Voorde purposely excluded Hara's initial heating step*. Ex.2014 ¶46; Ex.2015, 85:13-88:12. In other words, fully aware of Hara's teaching, Voorde's improvement included the use of fresh plant material and a reliance on moderate heating to promote the conversion of plant-based nitrate to nitrite using the natural enzymes and microbes, regardless of whether a starter culture is added. *Id.* Voorde's careful consideration of Hara shows that Voorde's omission of any initial heating step from Hara was not accidental, but intentional, which confirms that Voorde teaches away from FFP's proposed Ground I. *See, e.g., In re Enhanced Security Research, LLC*, 739 F.3d 1347, 1355 (Fed. Cir. 2014) (it is improper to "stitch



together an obviousness finding from discrete portions of prior art references without considering the references as a whole.”); *In re Wesslau*, 353 F.2d 238 (CCPA 1965) (“It is impermissible within the framework of section 103 to pick and choose from any one reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art.”).

Also, fully aware of Hara’s first heating for making plant juice, Voorde does not teach such first heating for any reason, let alone at a high temperature suitable for killing germs. This would be contrary to a plain reading of Voorde, as acknowledged by Dr. Baldwin on cross-examination. Therefore, if a POSA wanted to kill germs, he or she would have looked to Voorde’s teaching of a sterilization step of the end product, as explained in Section III.B above.

Of course, the obvious question remains, if killing germs was as common and routine as FFP argues, regardless of the specific application, why did Voorde neither teach this step nor use this step in its Examples? The answer is that Voorde’s invention relies on the use of the natural enzymes and microbes in fresh plant material and moderate heating to affect the conversion reaction, and such would be consistent with known processes of culturing food. Ex.2014 ¶¶66-72.

Consistent with this teaching, Voorde provided for an optional sterilization process on its end product.

References that teach away, as is the case here, cannot serve to create a *prima facie* case of obviousness. As explained in *Spectralytics Inc. v. Cordis Corp.*, 649 F.3d 1336, 1343 (Fed. Cir. 2011), “‘teaching away’ does not require that the prior art foresaw the specific invention that was later made, and warned against taking that path.” The court stated: “A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference or would be led in a direction divergent from the path that was taken by the applicant.” *Id.* Here, FFP and Dr. Baldwin ignored that Voorde explicitly discouraged a POSA from using temperatures greater than 70°C so as to not excessively reduce the natural enzymes and microbes Voorde requires for its conversion. Ex.2001 ¶¶76, 114.

8. The teachings of Voorde and Hara are incompatible with respect to FFP’s proposed modification, as Voorde teaches more than a mere preference for natural enzymes and microbes

While the Board acknowledged Voorde’s warning not to excessively heat the plant material, it stated that, on the preliminary record, it did not “believe the two disclosures to be incompatible or that application of Hara would render Voorde’s process inoperable.” D.I., 12. However, as explained above, Voorde

teaches that the natural enzymes and microbes of the plant material are used for converting the nitrate to nitrite. *See* III.C.1-**Error! Reference source not found.** above. Given their role in Voorde's invention, a POSA would not have found it obvious to eliminate them. *In re Ratti*, 270 F.2d 810, 813 (CCPA 1959) (holding the suggested combination of references improper under 35 U.S.C. § 103 because it "would require a substantial reconstruction and redesign of the elements shown in [a prior art reference] as well as a change in the basic principles under which [that reference's] construction was designed to operate").

Again, a POSA desiring to "kill germs" would have followed the teachings of Voorde and Hara and included their optional step of sterilizing the end product, which would have been compatible with their teachings. *See* III.B above. As such, to the extent an operable process results from FFP's proposed modification, that process is KGSI's invention arrived at through hindsight.

The Board also stated:

We do not understand Voorde's disclosure to ***exclude processes*** in which the nitrite-generating microbes are added via starter culture, rather than naturally occurring in the plant material. Voorde ***does not express any preference*** for naturally-occurring microbes, or suggest

that results are superior to processes in which a starter culture is added.

D.I., 13 (emphasis added).

The Board's preliminary interpretation of Voorde suggests that Voorde is neutral with respect to the use of natural enzymes and microbes as opposed to starter cultures. That is not a fair reading of Voorde, as it places too great a weight on Voorde's one sentence reference to starter culture and ignores the plain meaning of "additional." As explained in Section III.C.5 above, Voorde does not teach that the added starter culture is a substitute; rather, it optionally can be used in addition. In fact, when Voorde is read as a whole as explained in Section III.C above, a POSA would have read this sentence in context with Voorde's disclosure, with the understanding that Voorde expresses more than a preference for the natural enzymes and microbes. Moreover, the Board does not account for the fact that sterilizing the media is not what is "normally done" when culturing food.

Ex.2014 ¶¶66-71; *see also* Section III.A above.

In addition, Voorde does not provide detail on the use of the optional starter culture. However, that silence does not open the door to rewrite its process and ignore its actual teachings. Rather, a POSA would have read the starter culture sentence consistent with its plain meaning, in context with Voorde's larger

disclosure, and with the general understanding of a POSA. Thus, based on a fair reading, Voorde teaches adding the starter culture with the fresh plant material and moderately heating the whole to affect the conversion.

***D. FFP's substantial rewrite of Voorde is textbook hindsight***

FFP's Ground I requires several modifications and selections:

- a. *select* from Hara an initial high heating *for the purpose of killing germs*, although no such teaching is found in Hara;
- b. boiling or steaming Voorde's plant material to *heat the plant material to a temperature of at least 100°C*, despite Voorde's warning not to heat past 80°C;
- c. allow the heated plant material to *cool down to Voorde's optimal temperature* for promoting the reaction, although no such cooling procedure is described;
- d. *select* the addition of the *optional starter culture*, which was not done in any Example of Voorde and therefore was not preferred; and
- e. for obtaining inactivated organism in the product, *select an optional sterilization* on the end product, which was also not done in any Example of Voorde and therefore not preferred, or another modification based on Hara.

Ex.2014 ¶73.

For all of the reasons discussed in Sections III.A-III.C above, a POSA would not have found it obvious to rewrite Voorde in this manner. The fact that counsel selected not only the prior art but the precise proposed grounds of rejection (Ex.2015, 19:15-19, 23:15-18, 24:7-11, 26:4-20), confirms the use of hindsight. Not being a POSA, counsel in rote fashion parses the claims it challenges, then uses the claims as the blueprint to reconstruct the prior art *ex post facto*. In contrast, an expert looking at the prior art from the viewpoint of a POSA in 2007, would consider whether the prior art in fact naturally suggests the claimed subject matter.

In short, FFP is taking the ingenuity of the inventors of the '304 patent and, without any record basis other than the testimony of Dr. Baldwin, attributing that knowledge as the motivation to make the inventions at issue—textbook hindsight.

***E. The heating to reduce the microbial load imparts structural changes affecting the qualitative characteristics of the curing agent defined in the claims of the '304 patent***

FFP also failed to address that variations inherent in the biological processes for producing a plant-derived nitrite curing agent, in addition to selecting the plant material and organism, result in qualitative differences in the curing agent, and which, when applied to meat, affect taste, smell, texture, and color. Ex.2001

¶¶127-131. In this regard, Voorde intentionally employs moderate heating to promote a conversion process affected by the natural enzymes and microbes in fresh plant material. This results, for example, in the accumulation of varying microbial generated byproducts, all of which a POSA would appreciate impact qualitative characteristics. *Id.* In other words, following the teachings of Voorde results in ***a product different in composition*** from the plant-based nitrite curing agent in the claims of the '304 patent. Ex.2014 ¶¶103.

The plant-based nitrite curing agent in the claims of the '304 patent is derived from plant material heat treated to have a reduced microbial load prior to adding the organism for converting nitrate to nitrite. This process step provides a curing agent that gives meat products consistently unique and predictable flavor, smell, and/or color characteristics, all of which are expected by consumers and meat processors. Ex.2001 ¶¶127-131, 181; Ex.2014 ¶¶102-104.

These variations are not addressed by FFP or Dr. Baldwin, an omission that is inconsistent with the marketing material on FFP's website, which touts similar features of its VegStable® product. Ex.2008 (*e.g.*, "With low-color impact, low turbidity and zero off notes in application, our GMO-free products are of consistently high, trusted quality from field to fork"); Ex.2001 ¶¶41-42, 130.

***F. FFP failed to present a case of prima facie obviousness for the cured meat product of claim 5***

For claim 5, FFP's primary argument is that "[c]laim 5 recites a meat product created by the process of claim 1 and is therefore obvious for the same reasons." Pet., 41. For each limitation of claim 5 (except the preamble), FFP only refers back to its arguments for claim 1. *See* Pet., 41-43. Thus, FFP's primary argument fails to make a *prima facie* case of obviousness for at least the reasons in Section III.A-III.E above.

In addition, FFP failed to compare a cured meat product of Voorde to the cured meat product of claim 5. Because FFP never compared the composition, or any properties of a cured meat in Voorde versus a claim 5 cured meat, there is a failure of proof and no case of *prima facie* obviousness is presented for claim 5. This is important because a POSA would readily appreciate that compositional distinctions in a curing agent, when applied to meat, result in cured meat that is also compositionally and qualitatively distinctive. Ex.2001 ¶¶122-131, 181; *see also* Section III.E above.

When discussing the "cured meat or meat product" recitation in the preamble of claim 5, FFP asserts that "variation of steps makes no difference" when comparing (i) meat treated with a curing agent including a pre-generated plant-based nitrite *with* (ii) meat cured *in situ* with plant material and starter



culture, because a plant-based nitrite is utilized in both processes. *See* Pet.,42 (*citing* Ex.1002 ¶103). However, this statement not only ignores the qualitative differences due to the various biological conversion processes (Ex.2001 ¶¶130, 181; *see also* Section III.E above) but also ignores the uncertainty in this art at time of KGSI's invention (Sections II.B and II.C above). Indeed, as explained in Section II.C above, the Djeri dissertation (published in 2010, three years after the filing date of the '304 patent) investigated questions of this nature.

Further, in paragraph 103 of Dr. Baldwin's Declaration, Dr. Baldwin states "[w]hether nitrite reduction occurs beforehand or *in situ* varies with recipes and tradition, but the underlying chemical principles are the same." This statement is misleading. While synthetic nitrite, nitrite derived from plant material *in situ*, and pre-generated plant-based nitrite function to cure meat, the specific composition of the curing agent, and manner in which it was made, clearly affect curing and thus the quality of the cured meat. Ex.2001 ¶131. Dr. Baldwin's failure to address or appreciate this point renders his analysis incorrect and unreliable. Again, the Djeri dissertation investigated questions of this nature, demonstrating Dr. Baldwin's failure to appreciate the state of the art in 2007. *See* II.C above; *see also* Ex.2016, 99 ("After analysis, the composition of the CJPPN was found to contain crude protein, fibers, carbohydrates and minerals, in addition to the nitrite.").

FFP's failure is inexcusable, given that its own marketing materials, which it did not cite, are inconsistent with its positions on claim 5. Ex.2008; Ex.2001 ¶¶42, 43, 129, note 24.

**IV. FFP's Ground II lacks merit at least because a POSA starting from Fast would not have found it obvious to make a curing agent containing plant-based nitrite for preserving meat**

Claims 1-5 of the '304 patent would not have been obvious over the teachings of Fast in view of Voorde and Yamamoto.

In its proposed Ground II, FFP relies on Fast as a primary reference for allegedly teaching "how to make a plant-based nitrite curing solution." Pet., 55. FFP further relies on Voorde as allegedly teaching the application of "these types of plant-based nitrite curing solutions to meat to cure the meat." *Id.* Thus, FFP concludes that a POSA would have found it obvious "to make Fast's curing agent and use it for a suitable, well-known purpose (curing meat as taught by Voorde) to enjoy the predictable benefits of curing and preserving meat." *Id.* FFP also relies on Yamamoto as allegedly rendering obvious a further modification of Fast by inactivating Fast's organisms prior to completing the elimination of nitrite, which would have frustrated Fast's entire goal of completely eliminating both nitrate and nitrite.

The Board in its Decision on Institution the Board acknowledged that KGSI's position (*e.g.*, Fast teaches away from increasing the amount of nitrite in a plant-based material, because it discloses the harmful effects of such compounds and suggests the complete elimination of them) raises credible doubts regarding FFP's articulated reason to combine the prior art." D.I., 17-18. For the following reasons, and for the reasons set forth in Section VII of POPR, the Board should not adopt FFP's proposed Ground II of unpatentability.

***A. Fast is not instructive on a curing agent for preserving meat***

A POSA looking for a method of preserving meat would not have found Fast to be instructive at all. Fast is specifically directed to the total elimination of nitrate and nitrite from polluted water and vegetables. Ex.2001 ¶¶89, 94. The reasons provided by Fast are as follows.

As acknowledged by the Board, Fast explains that "severe health problems can arise from the transformation to nitrite in the human body during digestion." Ex.1019, 17-18; *see* D.I., 18. Therefore, Fast explains that "research on the reduction of nitrate (and nitrite) in vegetables is pursued." Ex.1019, 18. Further, Fast expressly warns that "[f]or the reduction of nitrate in vegetables, nitrite as end product is not acceptable since nitrite is more toxic than nitrate." Ex.1019, 5:34-36. During his cross-examination, when asked about drawbacks to using chemical

nitrite to cure meat today, Dr. Baldwin stated that “The drawback is that it’s -- I mean, chemical nitrite is a -- is -- you know, has toxicity and people -- you know, the expectation is that your food is going to be safe rather than contain compounds that are -- you know, that can hurt you.” Ex.2015, 108:8-14.

In its background section, Fast discloses the use of chemical nitrite to cure meats, and references the use of *S. carnosus* starter cultures for making meats. Fast’s reference to chemical nitrite is simply to identify a source of nitrite in human consumption. Ex.1019, 2:9-27. Fast’s reference to *S. carnosus* was to identify an organism capable of reducing nitrate to nitrite, which Fast later explains will also reduce and thereby eliminate the accumulated nitrite. Ex.2014 ¶¶84, 89-93.

Recognizing that *S. carnosus* was slow to reduce nitrite, Fast’s stated invention is to genetically modify the *S. carnosus* to more efficiently reduce both nitrate and nitrite. Ex.1019, 2:29-34. Thus, in view of Fast’s disclosure, a POSA would not have found Fast relevant to making a plant-based nitrite curing agent for preserving meat. Rather, a POSA would have quickly discarded Fast. Ex.2001 ¶ 140; Ex.2014 ¶¶86, 99. To a POSA interested in curing meat at the time of KGSI’s invention, Fast’s background section merely stated what was already known in the art—the use of chemical nitrite. If one were interested in traditional

meat product manufacturing (*e.g.*, making sausage), Fast teaches what was already known in the art—the addition of *S. carnosus* to meat. Ex.2001 ¶146. A POSA starting from Fast would not have found it obvious, and would not have had a reason, to go to the trouble of making a plant-based curing agent from nitrate polluted vegetables, rather than using chemical nitrite.<sup>12</sup> Ex.2014 ¶¶75-76.

***B. Fast and Voorde are not “similar references”***

Contrary to FFP’s repeated characterization, Fast and Voorde are not “similar references.” *See, e.g.*, Pet., 46-47, 55-56; Ex.1002 ¶220. This is explained below.

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<sup>12</sup> In its Decision on Institution, the Board stated: “[g]iven these disclosures, a person wishing to implement Voorde’s method of curing meat using a plant based curing agent could have looked to Fast’s disclosure and implemented an *S. carnosus* starter culture.” D.I., 18. The Board’s analysis here appears to misapprehend Ground II, by making Voorde the primary reference (*i.e.*, making Voorde the starting point for a POSA). While even this ordering of the references would not render obvious the ’304 patent claims, it requires a different analysis not set forth in the Petition, and therefore is not a ground in this trial.

**One reason** is that Fast never discloses a plant-based nitrite curing agent for preserving meat. Other than the reference to chemical nitrite in its background, Fast discloses no curing agent, let alone a plant-based nitrite curing agent. To be sure, in the only example using a plant material (*i.e.*, carrots), Fast used a combination of *S. carnosus* and *L. plantarum* (entrapped in carrageenan beads) to eliminate all nitrate and nitrite. Ex.2019, 13:45-51, 57-58; Ex.2015, 125:6-12. All of Fast's other examples were lab-made buffer solutions, often containing harsh chemicals unsuitable for consumption, used simply for testing reaction variables and *S. carnosus* mutants. Ex.2014 ¶97.

**A second reason** is that Fast considered both nitrate *and* nitrite to be unsafe. *See, e.g.*, Ex.1019, 2:17-19. Indeed, Fast disclosed that the existence of nitrite in the product "is not acceptable since nitrite is more toxic than nitrate." Ex.1019, 5:34-35. Thus, Fast's entire objective was to provide a method of making a nitrite free solution, which obviously could not be used to cure meat, as both experts agree. Ex.2014 ¶98; Ex.2015, 104:8-19, 105:3-19.

**A third reason** is that Fast is directed to a GMO type of *S. carnosus*. As explained by Dr. Milkowski, the use of GMO presents difficult regulatory concerns. Ex.2001 ¶140; Ex.2014 ¶99.

Accordingly, Fast and Voorde are far from “similar references,” and a POSA interested preserving meat would have quickly discarded Fast, and would never have thought to modify Fast’s process to make a plant-based nitrite solution for curing meat. Ex.2014 ¶100.

The facts of *In re Clay* are illustrative. In *Clay*, both the patented invention and the prior art reference related to the petroleum industry, and both taught using a gel. *In re Clay*, 966 F.2d 656, 658-59 (Fed. Cir. 1992). Nevertheless, as later summarized approvingly by the Federal Circuit in *Smith & Nephew, Inc. v. Hologic, Inc.*, the references in *Clay* “were not directed to the same field of endeavor because the two inventions were used in very different environments (one, the extraction of crude petroleum, and the other, the storage of refined liquid hydrocarbons).” *Smith & Nephew, Inc. v. Hologic, Inc.*, 721 F. App’x 943, 949 (Fed. Cir. 2018). Further, in *Clay*, the reference was not reasonably pertinent to the problem the inventor was trying to solve, because they explicitly were intended to solve different problems. *In re Clay*, 966 F.2d at 658-59.

The facts in the present case are even more compelling. Not only is Fast not in the field of meat curing, the problem it addresses—elimination of nitrite from polluted solutions—is far from that of the ’304 patent, *i.e.*, creation of plant-based nitrite curing agents. As such, Fast is not reasonably pertinent and would not

logically have commended itself to a POSA concerned with preserving meat, let alone with a plant-based nitrite curing agent.

***C. Meat science and curing are complex and unpredictable arts***

FFP's ground of rejection is premised on a false characterization of meat science, and meat curing in particular, as simplistic and "predictable." Pet., 55. For support, FFP cites to Dr. Baldwin. *Id.* However, as explained in Sections II.B and II.C above, at the time of KGSI's invention, both *in situ* curing and plant-based nitrite curing agents were in need of investigation and not settled areas of science.<sup>13</sup> *See also Eisai Co. Ltd.*, 533 F.3d at 1359 (noting the chemical arts are unpredictable, making potential solutions less likely to be genuinely predictable). Given this reality, and the fact that Fast is not about making a curing agent or preserving meat, a POSA *starting from Fast* and desiring the "predictable benefit[] of curing and preserving meat" (Pet., 55) would have found this reference

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<sup>13</sup> As noted in Section II.B above, Dr. Baldwin was not even aware of the concept of *in situ* meat curing until after he was retained by FFP's counsel for this proceeding, and thus he is not qualified to opine on this area of science, including how a POSA would have viewed Fast.



unhelpful. Rather, a POSA would have used chemical nitrite, which was straightforward and conventional.

***D. A POSA would not have considered modifying Fast by inactivating the very same organisms and systems Fast designed for eliminating both nitrate and nitrite***

FFP argues that a POSA would have looked to the sterilization techniques in Voorde and Yamamoto to inactivate Fast's organisms. Pet., 49-50. But even if that argument were given credence—and it should not—a POSA making such a modification to Fast's process would have done so, if at all, only after the nitrite reduction reaction had run its course, leaving a nitrite-free solution or vegetable juice. Ex.2001 ¶¶170-172.

In fact, Fast's only example using plant material (carrot juice) teaches away from inactivation for several reasons. First, in the carrot juice example, Fast ran the process to eliminate nitrite completely, and that goal was accomplished, as acknowledged by Dr. Baldwin. Ex.1019, 13:55-56; Ex.2014 ¶85; Ex.2015 121:19-122:8. Second, Fast used a combination of *S. carnosus* and *L. plantarum* as its organisms, because the *L. plantarum* is a more efficient nitrite reducer than *S. carnosus*. Ex.1019, 12:45-47; Ex.2001 ¶¶96, 133-34; Ex.2014 ¶¶78, 91. Third, Fast entrapped and immobilized the *S. carnosus* and *L. plantarum* in carrageenan gelbeads. Ex.1019, 13:45-49; Ex.2001 ¶172. This system allowed Fast to carry

out several fermentations “with the same gelbeads without any significant changes in the nitrate and nitrite reduction.” Ex.1019, 13:57-58; Ex.2001 ¶172; Ex.2014 ¶77. Accordingly, killing the organisms entrapped in the gelbeads by sterilization, prior to total elimination of nitrite, is contrary to Fast’s goal and its entire premise for using (and reusing) both the gelbeads and the combination of *S. carnosus* and *L. plantarum*. Thus, the modification proposed by FFP undermines Fast and would not have been obvious.

Again, as with Voorde, the fact that counsel selected not only the prior art but the precise proposed grounds of rejection (Ex.2015, 19:15-19, 23:15-18, 24:7-11, 26:4-20), confirms the use of hindsight. Not being a POSA, counsel in rote fashion parses the claims it challenges, then uses the claims as the blueprint to reconstruct the prior art *ex post facto*. In contrast, an expert looking at the prior art from the viewpoint of a POSA in 2007, would consider how the prior art might naturally suggest the claimed subject matter. The former approach, which occurred here, is classic improper hindsight.

***E. FFP failed to present a case of prima facie obviousness for the cured meat product of claim 5***

For claim 5, FFP’s primary argument is that “[c]laim 5 recites a meat product created by the process of claim 1 and is obvious for the same reasons.” Pet., 53. For each limitation of claim 5 (except the preamble), FFP only refers

back to its arguments for claim 1. *See* Pet., 54-55. Thus, FFP's primary argument fails to make a *prima facie* case of obviousness for at least the reasons in Sections IV.A-IV.D above.

In addition, Fast never discloses applying its solution (free of nitrate and nitrite) to meat. Instead, FFP alleges that Voorde, which has an entirely different goal from Fast, suggests the use of Fast's product for curing meat but provides no reasoned analysis to support this conclusion. Pet., 53-54. However, ignoring that Fast and Voorde are not similar and are in fact incompatible on a basic level, FFP never compared the composition, or any properties of a cured meat, in Fast (or Voorde) versus a claim 5 cured meat. This is a failure of proof, and thus no case of *prima facie* obviousness is presented for claim 5.

In addition, in its carrot juice example, Fast relied on gelbeads loaded with both *S. carnosus* and *L. plantarum*, as this was shown to efficiently and repeatedly eliminating nitrate and nitrite. The product (treated carrot juice) of each run of this Example was free of nitrite, and the beads were effective for reusing the microbes. Fast never discloses applying the nitrite-free carrot juice to meat, and even if one accepted that hypothetically, the meat would not be cured.

Accordingly, the plant-based nitrite curing agent of the claims of the '304 patent is compositionally distinct and nonobvious from any solution described by

Fast. Since the plant-based nitrite curing agent of the claims of the '304 patent is distinct from Fast, a POSA would readily appreciate that the meat treated in claim 5 would also be compositionally distinct. *See, e.g.*, Ex.2001 ¶¶126, 130, 180, 181.

## V. Conclusion

For the reasons set forth above, the Board should find that FFP has not carried its burden of showing with particularity that any of the challenged claims 1-5 of the '304 patent are unpatentable.

Respectfully submitted,

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**WORD COUNT CERTIFICATE OF COMPLIANCE**

Pursuant to 37 C.F.R. § 42.24(d), I certify that this PETITIONER'S REPLY complies with the type-volume limits of 37 C.F.R. § 42.24(c)(1) because it contains 12,697 words, based on the word-processing system used to prepare this reply, excluding the parts of this reply that are exempted by 37 C.F.R. § 42.24(a).

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**CERTIFICATE OF SERVICE**

The undersigned certifies that a copy of the attached **Patent Owner**

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