

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

FLORIDA FOOD PRODUCTS, LLC,
Petitioner,

v.

KERRY GROUP SERVICES INT'L LTD.,¹
Patent Owner.

IPR2022-00006
Patent 11,071,304 B2

Before CHRISTOPHER L. CRUMBLEY, CHRISTOPHER M. KAISER,
and JULIA HEANEY, *Administrative Patent Judges*.

CRUMBLEY, *Administrative Patent Judge*.

DECISION
Granting Institution of *Inter Partes* Review
35 U.S.C. § 314

¹ The Petition as originally filed named Kerry Group and Kerry Luxembourg S.A.R.L. as Patent Owner. Paper 12. Patent Owner filed Updated Mandatory Notices disclosing that Kerry Group Services International Ltd. had acquired the entire right, title, and interest in the '304 patent. Paper 17. We have updated the case style accordingly.

I. INTRODUCTION

Florida Food Products, LLC (“FFP”) filed a Corrected Petition (Paper 12, “Pet.”) requesting the Board institute an *inter partes* review of claims 1–5 of U.S. Patent No. 11,071,304 B2 (Ex. 1001, “the ’304 patent”). Kerry Group Services International Ltd. (“KGSi”), the owner of the ’304 patent, filed a Preliminary Response to the Petition. Paper 17, “Prelim. Resp.” We subsequently granted authorization for FFP to file a limited Reply to the Preliminary Response (Paper 20, “Reply”), followed by a Sur-Reply from KGSi (Paper 23, “Sur-Reply”).

We have authority to determine whether to institute an *inter partes* review. *See* 35 U.S.C. § 314 (2018); 37 C.F.R. § 42.4(a) (2019). The standard for instituting an *inter partes* review is set forth in 35 U.S.C. § 314(a), which provides that an *inter partes* review may not be instituted “unless the Director determines . . . there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.”

Having considered the parties’ arguments and the evidence of record, we determine that, for the reasons discussed herein, FFP has established a reasonable likelihood that it would prevail with respect to at least one of the challenged claims. KGSi has not persuaded us that we should exercise our discretion under 35 U.S.C. § 325(d) to deny institution. We thus institute an *inter partes* review on all challenged claims on all asserted grounds. *See SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1354, 1359–60 (2018); *see also* Patent Trial and Appeal Board Consolidated Trial Practice Guide 64

(Nov. 2019)² (“TPG”) (“The Board will not institute on fewer than all claims or all challenges in a petition.”).

II. BACKGROUND

A. Related Matters

The parties have not indicated any related administrative or judicial proceedings involving the ’304 patent. Pet. 66–67; Paper 17. FFG notes that the Board previously decided an appeal (Appeal 2020-006388) involving the application that issued as the ’304 patent. Pet. 66–67.

B. The ’304 Patent (Ex. 1001)

The ’304 patent, entitled “Method and Composition for Preparing Cured Meat Products,” issued July 27, 2021, with claims 1–5. Ex. 1001, codes (54), (45), 12:30–61. The ’304 patent describes a curing agent comprising a plant-based nitrite, prepared using an organism capable of converting the naturally-occurring nitrates in a plant material into nitrites. *Id.* at (57). The patent also describes curing or preserving meat using this curing agent. *Id.*

According to the ’304 patent, methods of curing or preserving meat, including by treating the meat with nitrite, have been practiced for many years. *Id.* at 1:4–9. In one such method, nitrate-containing substances are applied to meat, and then bacteria or other organisms convert the nitrate to nitrite. *Id.* at 1:9–14. The ’304 patent discloses that the presence of nitrite gives the meat a distinct color and flavor, but existing methods presented several problems including the processing time required for the organisms to convert the nitrate to nitrite after contacting the curing agent to the meat. *Id.*

² Available at <https://www.uspto.gov/TrialPracticeGuideConsolidated>

at 1:15–24. The '304 patent proposes a solution in which the curing agent is prepared outside the meat curing process, so as to speed up the process and simplify the number of steps involved. *Id.* at 1:34–44.

The particular curing agent described in the '304 patent is substantially free of non-natural nitrate or nitrite, meaning there is no nitrate or nitrite artificially added to the plant material. *Id.* at 2:58–64. Preferably, the plant material is a plant derivative that contains at least about 50 ppm nitrate, such as celery. *Id.* at 2:14–19. The plant derivative can then be subjected to additional steps, including heat treatment or sterilization that reduces the naturally-occurring microbial load. *Id.* at 3:5–8. Organisms capable of converting nitrate to nitrite, such as preferably *S. carnosus*, are added to the plant material, after which fermentation is conducted at any suitable temperature. *Id.* at 3:15–52. Once a predetermined nitrite level is reached in the curing agent, the organisms can be inactivated using known methods such as pasteurization, after which the curing agent can be stored or used to cure meat. *Id.* at 4:38–49.

C. Challenged Claims

FFP challenges claims 1–5 of the '304 patent. Pet. 29. Claims 1 and 5 are independent; claim 1 is illustrative and reads as follows, with line breaks added for readability:

1. A process for preserving a meat or meat product comprising contacting the meat or meat product to be preserved with a curing agent comprising a plant-based nitrite and an added organism, the plant-based nitrite being derived from a plant material comprising at least about 50 ppm nitrate and the organism, wherein the plant material is heat treated prior to addition of the organism so as to have a reduced microbial load

relative to a naturally occurring microbial load of the plant material,

the organism inactivated, wherein the organism was capable of converting nitrate to nitrite before the inactivation, and

preserving the contacted meat or meat product.

Ex. 1001, 12:31–44. Claim 5 is similar to claim 1, but is directed to a cured meat product having been treated with a curing agent according to the process of claim 1. *Id.* at 12:52–61.

D. Asserted Grounds of Unpatentability

FFP contends that the challenged claims are unpatentable based on the following grounds, each asserted under 35 U.S.C. § 103(a):³

Claim(s) Challenged	References
1–5	Voorde, ⁴ Hara ⁵
1, 4, 5	Fast, ⁶ Voorde, Yamamoto ⁷

³ The Leahy-Smith America Invents Act (“AIA”) includes revisions to 35 U.S.C. §§ 102, 103 that became effective on Mar. 16, 2013. Pub. L. No. 112–29, §§ 3(b), 3(c), 3(n)(1), 125 Stat. 284, 287, 293 (2011). Because the ’304 patent claims priority to a provisional application filed June 11, 2007, we apply the pre-AIA version of § 103 to this Decision.

⁴ Belgian Patent Application Publication No. 1014557A6 to Van de Voorde et al., granted December 2, 2003. An English translation of Voorde was submitted as Exhibit 1003.

⁵ U.S. Patent No. 3,911,146 to Hara et al., issued October 7, 1975 (Ex. 1023).

⁶ European Patent Application Publication EP 0805205 A1 to Fast et al., published November 5, 1997 (Ex. 1019).

⁷ Japanese Unexamined Patent Application Publication No. 2001/352935 to Yamamoto, published December 25, 2001. An English translation of Yamamoto was submitted as Exhibit 1024.

Claim(s) Challenged	References
2	Fast, Voorde, Yamamoto, Stumpf ⁸
3	Fast, Voorde, Yamamoto, Kurihara ⁹

Pet. 29. FFP contends that Voorde, Fast, Yamamoto, and Kurihara are prior art to the '304 patent under 35 U.S.C. §§ 102(a) and (b), while Hara and Stumpf are prior art under §§ 102(a), (b), or (e). *Id.* at 30. At this stage of the proceeding, KGSI has not argued that any of the asserted references are not prior art to the '304 patent.

III. ANALYSIS

A. Principles of Law

A patent claim is unpatentable under 35 U.S.C. § 103 if the differences between the claimed subject matter 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. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of underlying factual determinations including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of ordinary skill in the art; and (4) when in evidence, objective indicia (also called secondary considerations) of non-obviousness, such as

⁸ U.S. Patent No. 4,806,373 to Stumpf et al., issued February 21, 1989 (Ex. 1025).

⁹ Japanese Unexamined Patent Application Publication No. 48-82054 to Kurihara et al., published November 2, 1973. An English translation of Kurihara was submitted as Exhibit 1018.

commercial success, long-felt but unsolved needs, and failure of others. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966). We analyze the asserted grounds of unpatentability based on obviousness in accordance with the above-stated principles.

B. Level of Ordinary Skill in the Art

FFP contends that a person of ordinary skill in the art at the time of the invention would have had:

a master's or doctorate degree in food science, biology, chemistry, or a similar field; or a bachelor's degree in food science, biology, chemistry, or a similar field along with at least 2-3 years of experience in food preservatives generally or more specifically 2-3 years of experience in the chemistry associated with food preservation and nitrates/nitrites [and] would have known that the USDA regulated nitrites for curing meat and would have been able to find these USDA regulations affecting meat products.

Pet. 23–34 (citing Ex. 1002 ¶ 48).

KGSI's recitation of the level of ordinary skill in the art is nearly identical. Prelim. Resp. 13–14 (citing Ex. 2001 ¶¶ 43–44 (Milkowski Declaration)). To the extent the parties' formulations of the level of skill differ, the differences do not appear to be material to any dispute between the parties or any issue of patentability that we must resolve in order to determine whether to institute trial. We determine that, on the current record, the level of ordinary skill the parties propose is consistent with the challenged patent and the asserted art, and adopt that level for purposes of this Decision.

C. Claim Construction

FFP addresses the construction of only one claim phrase, but also submits that the construction of that phrase does not affect our decision

whether to institute. Pet. 24. Specifically, FFP asks us to adopt a construction that “clarifies that the nitrite results from the added organism reducing the plant nitrate.” *Id.* at 25. KGSI does not address this construction (Prelim. Resp. 13), and we agree with FFP that adoption of the construction has no effect on our decision whether to institute. Thus, we need not adopt it. *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017); *Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999) (“[O]nly those terms need be construed that are in controversy, and only to the extent necessary to resolve the controversy.”).

KGSI, for its part, argues that the claims should be given their plain and ordinary meaning (Prelim. Resp. 13), which we understand to mean that no claim term of the ’304 patent requires express instruction. But KGSI also points out that claim 1 is a method claim that contains a “nested” product-by-process element. *Id.* Specifically, KGSI argues that the method of claim 1 involves the use of a “curing agent” that is defined by the process of making it: it contains a plant-based nitrite “derived from a plant material comprising at least about 50 ppm nitrate and the organism, wherein the plant material is heat treated prior to addition of the organism.” *Id.*

FFP contends that, because of certain arguments made by the applicant during prosecution, “the ‘curing agent’ of challenged claim 1 should not be construed to include a nested product-by-process limitation because Patent Owner’s own statements show that it was never intended to be construed that way.” Reply 3.

The law of product-by-process claims “developed in response to the need to enable an applicant to claim an otherwise patentable product that

resists definition by other than the process by which it is made.” *In re Thorpe*, 777 F.2d 695, 697 (Fed. Cir. 1985). But “[t]he patentability of a product does not depend on its method of production.” *Id.* (citing *In re Pilkington*, 411 F.2d 1345, 1348 (CCPA 1969)). Thus, while the scope of a product-by-process claim for infringement purposes is limited by the process, when determining patentability the claim is considered only in view of the resulting product. *See Amgen Inc. v. F. Hoffman-La Roche Ltd.*, 580 F.3d 1340, 1370 n.14 (Fed. Cir. 2009) (“a patent is invalid if a product made by the process recited in a product-by-process claim is anticipated by or obvious from prior art products, even if those prior art products are made by different processes”). Only if the process of manufacture results in “structural and functional differences” in the product can the process distinguish the claim over the prior art. *Id.* at 1370; *see Greenliant Sys., Inc. v. Xicor LLC*, 692 F.3d 1261, 1268 (Fed. Cir. 2012). Analysis of a product-by-process element “nested” within a method claim does not differ from the analysis of a product-by-process claim itself. *Biogen MA Inc. v. EMD Serono, Inc.*, 976 F.3d 1326, 1334 (Fed. Cir. 2020) (“The nesting of the product-by-process limitation within a method of treatment claim does not change the proper construction of the product-by-process limitation itself.”).

Our preliminary construction at this stage of the proceeding is that claim 1 does contain a nested product-by-process limitation, which defines the claimed curing agent as containing a plant-based nitrite derived using a particular process involving heat treatment prior to introduction of the nitrite-producing organism. We are not persuaded on the current record, however, that this process imparts any structural or functional differences to the recited curing agent product, as opposed to curing agents produced by

other means. KGSI contends that “the variations inherent in the biological processes for producing plant-derived nitrite, in addition to selecting the plant material and organism, result in qualitative differences in the curing agent that, when applied to meat, affect taste, smell, texture, and color, while also impacting the safety of the product.” Prelim. Resp. 23 (citing Ex. 2001 ¶¶ 127–131). But Dr. Milkowski does not provide any evidence of these “qualitative differences” beyond citations to FFP’s marketing materials. Ex. 2001 ¶ 129 n.23. On this preliminary record, therefore, we construe the product-by-process element of claim 1 to not be limited by the process steps recited.¹⁰

Nevertheless, we also note that FFP provides, in its Petition, analysis regarding the process limitations of claims 1 and 5. And below, we include these steps in our evaluation of the Petition. For that reason, even if the process steps of the product-by-process limitations do carry patentable weight, our ultimate determination regarding institution of trial would not change.

D. Obviousness Over Voorde and Hara

FFP contends that claims 1–5 are unpatentable under 35 U.S.C. § 103(a), as their subject matter would have been obvious over the combined disclosures of Voorde and Hara. Pet. 30–43. FFP relies on the testimony of Steven W. Baldwin, Ph.D. (Ex. 1002) to support its contentions. *Id.*

Voorde discloses a method of heat treating meat products to reduce discoloration, comprising treating the meat with a solution containing nitrite.

¹⁰ This reasoning also applies to the interpretation of claim 5, which the parties agree is a product-by-process claim in its entirety. (Pet. 41; Prelim. Resp. 13).

Ex. 1003, 1. Voorde uses a vegetable material containing nitrate as a starting material, and then converts the nitrate into nitrite. *Id.* at 3. Multiple methods of conversion are disclosed, including “allowing the natural enzymatic and/or microbiological conversion processes to run their course” or, optionally, “additional micro-organisms or . . . so-called starter cultures can be added for this purpose.” *Id.* at 5–6. Conversion to nitrite is further stimulated by heating, preferably to a temperature higher than 50 °C, because “at these temperatures undesired micro-organisms are killed and the materials is thus (partially) sterilized.” *Id.* at 6. Voorde warns against heating higher than 80 °C, however, to avoid excessively reducing the enzymatic and microbiological conversion processes. *Id.* at 7.

Voorde, in its background section, also discusses Hara as disclosing “a method for preserving the color of animal tissue during heat treatment in which no chemical nitrite and/or nitrate is used.” *Id.* at 1–2. Voorde notes that Hara calls for sterilizing the liquid phase containing the water-soluble plant ingredients immediately after its preparation. *Id.* at 2. Hara states that “[e]xposure to a temperature of about 90 °C . . . for about 30 minutes, is effective.” Ex. 1023, 1:59–64.

FFP contends that a person of ordinary skill in the art would have had reason to combine these disclosures of Voorde and Hara, especially in view of Voorde’s express citation to Hara. Pet. 43. FFP also notes that both references relate to plant-based curing solutions for preserving meat. *Id.* As such, a person of ordinary skill “would have looked 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.” *Id.* (citing Ex. 1002 ¶¶ 162–163).

KGSI contends that a person of ordinary skill would not have combined Voorde and Hara, because they are different technologies and “what works for Hara does not work for Voorde.” Prelim. Resp. 33. KGSI argues that Hara’s heat treatment step is not for sterilizing the plant solution to reduce microbes; instead, Hara discusses preventing decomposition by enzymes. *Id.* KGSI concedes, however, that Dr. Baldwin “correctly states that such sterilization . . . would inherently reduce the microbial load of the composition.” *Id.* at 34 n.6. But KGSI also argues that this would “destroy the natural enzymes and microbes Voorde relies on, fundamentally changing Voorde’s principle of operation.” *Id.* at 31. In KGSI’s view, “Voorde’s disclosure as a whole, including its Examples, requires a conversion process using the plant’s natural enzymes and microbes.” *Id.* at 26 (citing Ex. 2001 ¶¶ 102–108). KGSI focuses on the fact that Voorde discloses adding a starter culture of microbes as an optional step, and refers to them as “additional micro-organisms,” and argues that this “makes clear that the natural microbes remain in the material.” *Id.* (emphasis omitted). In addition, KGSI argues, Voorde “expressly warns against temperatures above 70°C” to avoid reducing the “enzymatic and microbiological conversion processes,” whereas Hara discloses heating to 90°C. *Id.* at 27. As such, KGSI contends that Voorde teaches away from a heat treatment step that would reduce microbial load. *Id.*

Upon review, we are persuaded that FFP has set forth a sufficient rationale why a person of ordinary skill in the art would have modified Voorde’s process to use Hara’s sterilization step. We do not, on this record, believe the two disclosures to be incompatible or that application of Hara would render Voorde’s process inoperable. While recognize that Voorde

warns against heating to 90°C as disclosed in Hara’s sterilization process, we note that the heating of Hara 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.

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. Nor are we persuaded that a person of ordinary skill in the art, having used Hara’s sterilization step, would have been unaware that the sterilization would have reduced the microbial load of the plant material and that addition of a starter culture—which Voorde expressly suggests—would be beneficial.

Turning to the disclosures of the two references as combined in the manner FFP proposes, we have evaluated the disclosures outlined in the Petition and conclude that they appear to disclose all elements of the challenged claims. For example, FFP reasonably sets forth how Voorde discloses contacting a meat product with a curing agent comprising a plant-based nitrite and an added organism. Pet. 31–32 (citing Ex. 1003, 3, 6–7). Furthermore, FFP shows that Voorde discloses deriving its nitrite from a plant material comprising at least 50 ppm nitrate, as Voorde’s Example 1 uses spinach containing 2826 ppm nitrate. *Id.* at 33 (citing Ex. 1003, 8–9). And FFP relies on Hara as disclosing heat treating the plant material to have

a reduced microbial load, and Voorde discloses addition of an organism through its starter culture. *Id.* at 33–35 (citing Ex. 1003, 6; Ex. 1023 3:3–6, 13–16). Finally, FFP observes that Voorde discloses sterilizing its nitrite-containing product for storage, which a person of ordinary skill in the art would have understood would have inactivated the added organism. *Id.* at 36 (citing Ex. 1003, 7; Ex. 1002 ¶ 127). Thus, even if the process steps of the nested product-by-process limitation of claim 1, and the process steps of product-by-process claim 5, are given patentable weight, the record before us is sufficient to indicate that the prior art discloses these steps.¹¹

¹¹ KGSI devotes a substantial portion of its brief to arguing that a product-by-process claim analysis requires a “product-to-product analysis.” Prelim. Resp. 16–25. Specifically, KGSI argues that the law requires identifying a single product in a single prior art reference, and using that “specific product in the prior art as the comparator” to the one produced by the process steps of the claim. *Id.* at 17–18. KGSI contends that FFP did not identify such a product in Voorde or Hara, and thus, the Petition is deficient. *Id.* at 17–25.

We disagree with KGSI’s legal analysis, which relies heavily on references to “a product of the prior art” in precedent such as *In re Thorpe*, 777 F.2d at 698. *Id.* at 17. Having reviewed the cases cited, we find no indication that the Federal Circuit intended to create a specific, higher standard for showing unpatentability of a product-by-process claim, which would require relying only on a specific product disclosed in a single prior art reference. In an obviousness ground of unpatentability, Petitioners are entitled to rely on the disclosures of multiple prior art references, if those disclosures would have been combined by a person of ordinary skill in the art. If such a combination would have resulted in a product, KGSI has not persuaded us that that product cannot then be compared against the result of a product-by-process claim. Indeed, such a product of a combination would be a “product of the prior art,” (*Thorpe*, 777 F.2d at 698) in the sense that “the prior art” includes multiple references.

Regarding dependent claims 2–4, we have reviewed FFP’s assertions as to these claims and find that the Petition adequately sets forth how Voorde and Hara teach these additional limitations. For example, claim 2 requires that the curing agent is concentrated before it contacts the meat product. Ex. 1001, 12:45–46. FFP directs us to Hara’s Example 6, which discloses “evaporat[ing] to dryness” its preservative before storing the resulting powder for six months. Pet. 38 (citing Ex. 1023, 6:12–36). Claim 3 requires that the plant-based nitrite is present in the curing agent in an amount ranging from about 50 ppm to about 200 ppm. Ex. 1001, 12:47–49. FFP indicates Example 1 of Voorde, in which a second curing solution was produced having 110 ppm nitrite. Pet. 39 (citing Ex. 1003, 8–9). And with respect to claim 4, which requires that the curing agent is substantially free of non-natural nitrate and nitrite, FFP directs us to Voorde’s admonition to avoid curing agents having such non-natural nitrates and nitrites. Ex. 1001, 12:50–51; Pet. 40 (citing Ex. 1003, 14). We note that KGSI did not address these additional limitations of the dependent claims, or argue their patentability apart from the arguments made with respect to the independent claims.

For these reasons, we find that the Petition sufficiently sets forth reasons why a person of ordinary skill in the art would have combined Voorde and Hara, and how such a combination would have disclosed the elements of claims 1–5. As such, FFP has demonstrated a reasonable likelihood that at least one claim of the ’304 patent is unpatentable on this ground of unpatentability.

E. Obviousness Over Fast, Voorde, and Yamamoto

FFP also contends that the subject matter of claims 1, 4, and 5 would have been obvious over the combined disclosures of Fast, Voorde, and Yamamoto. Pet. 43–58.

Fast discloses “a method for reducing nitrates in water, vegetables, and other nitrate polluted materials.” Ex. 1019, 2:4–5. It also notes that while nitrate itself has little primary toxicity, health problems can arise from the transformation into nitrites during digestion; thus, “research on the reduction of nitrate (and nitrite) in vegetables is pursued.” *Id.* at 2:17–19. Fast discloses using “suitable starter cultures” for this reduction, and notes that “*Staphylococcus carnosus* is of great importance as a component of starter cultures used in meat product manufacturing” because it “efficiently reduces nitrate to nitrite.” *Id.* at 2:23–25. Additionally, *L. plantarum* is discussed as permitting “complete nitrate reduction.” *Id.* at 2:20–23. Fast’s invention is directed to a recombinant protein involved in nitrate and nitrite reduction in *S. carnosus*, and a method of treating a nitrate-polluted material to recovering “the nitrate and nitrite free material.” *Id.* at 2:34–35, 54–56.

Yamamoto discloses that “[f]ood products and food ingredients are known to include plant materials that have been processed by the action of microorganisms.” Ex. 1024 ¶ 2. After fermentation using these microorganisms, Yamamoto teaches that sterilization should be performed to inactivate the microorganisms and stop the fermentation process, to achieve a “plant material with stable qualities.” *Id.* ¶¶ 7, 24.

FFP contends that a person of ordinary skill in the art would have combined Fast and Voorde because both relate to converting nitrate in a vegetable material into nitrite for curing a meat product. Pet. 55–57.

Specifically, FFP argues that the skilled artisan would have made Fast's microbial, nitrate-reducing agent and used it for a suitable purpose, such as the meat curing process as disclosed in Voorde. *Id.* With respect to Yamamoto, FFP contends that its disclosure of sterilization would have been applied to the teachings of Fast because both references "teach using similar bacteria to inoculate with plant material." *Id.* at 58. Furthermore, FFP notes that the Board, during an *ex parte* appeal during prosecution, affirmed the combination of Fast with Yamamoto. *Id.* at 57 (citing Ex. 1005, 1679).

KGSI argues that a person of ordinary skill in the art would not have combined the references in the manner proposed. Prelim. Resp. 45–60. KGSI notes that "Fast's entire objective is a nitrate and nitrite free solution," and therefore it does not suggest using nitrite-containing products for curing meat. *Id.* at 45–46. Fast allegedly only "discloses in the Background that it was known to add chemical nitrite to meat," and KGSI argues that this addition of chemical nitrite is not relevant to a process for curing meat using plant-derived curing agents. *Id.* at 45, 47. According to KGSI, 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. *Id.* at 48–50. For example, the only plant-based example disclosed in Fast, KGSI argues, has no nitrite. *Id.* at 50 (citing Ex. 2001 ¶¶ 150–152). And KGSI also argues that, even if a person of ordinary skill in the art would have used Yamamoto's sterilization technique to stop the fermentation process of Fast, they would have done so only after the process had run its course and eliminated all nitrites. *Id.* at 52.

Upon reviewing the parties' arguments and the supporting evidence, KGSI raises credible doubts regarding FFP's articulated reason to combine

the prior art. On the one hand, we acknowledge Fast’s disclosure that nitrites are useful in curing meats, and we note that in at least one example, the addition of *S. carnosus* was said to “reduce[] nitrate completely but does not reduce accumulated nitrite.” Ex. 1019, 13:38. Given 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. At the same time, however, we recognize that Fast discloses “severe health problems” are associated with nitrites and expresses the goal of eliminating nitrates and nitrites from food products. And, as Dr. Milkowski testifies, the only plant-based example in Fast, a carrot juice example, likely had no nitrite content following fermentation. Ex. 2001 ¶¶ 105–152.

As we have already determined, in the preceding ground of unpatentability, that at least one claim of the ’304 patent is likely unpatentable, we will proceed to trial on all claims and grounds in the Petition. We need not resolve the dispute between the parties regarding the reason to combine in this ground at this stage of the proceeding. We invite the parties to further address during trial the disclosure of Fast, and whether a person of ordinary skill would have had a reason to combine its teachings with those of Voorde and Yamamoto.

F. Other Obviousness Grounds Involving Fast, Voorde, and Yamamoto

FFP contends that the subject matter of claim 2 would have been obvious over the combined disclosures of Fast, Voorde, Yamamoto, and Stumpf. Pet. 58–59. FFP contends in a separate ground of unpatentability that claim 3 would have been obvious over the combined disclosures of Fast, Voorde, Yamamoto, and Kurihara. *Id.* at 60–61. We have reviewed FFP’s

contentions as to these additional references and combinations, which KGSI does not directly contest beyond its arguments as to the combination of Fast, Voorde, and Yamamoto discussed above. Beyond the doubts expressed above regarding the reason to combine Fast with Voorde and Yamamoto, on this record we find that the Stumpf and Kurihara adequately support the disclosures FFP relies on them for.

G. Discretionary Denial Under 35 U.S.C. § 325(d)

KGSI argues that, regardless of our determination regarding a reasonable likelihood of success on the merits, we should deny institution of trial under 35 U.S.C. § 325(d) because the Petition merely raises grounds that are the same or substantially the same as the prior art considered during prosecution. Prelim. Resp. 63–68. Although KGSI concedes that a full translation of Voorde was not before the Office during prosecution, it contends that “Voorde’s technology is substantially identical to Kurihara, and Petitioner applies Voorde . . . in substantially the same manner as Kurihara was applied by the Office.” *Id.* at 64. In particular, KGSI argues that both references “require the endogenous enzymes and/or microbes of fresh plant material to make a solution containing plant-based nitrite outside of a meat curing process.” *Id.* KGSI acknowledges that Voorde discloses the use of an optional starter culture, which is not disclosed in Kurihara, but claims this is immaterial because Voorde “requires” natural microbes to be used. *Id.* at 64–65.

We have discretion to deny review when “the same or substantially the same prior art or arguments previously were presented to the Office.” 35 U.S.C. § 325(d). In that respect, section 325(d) provides that the Director may elect not to institute a proceeding if the challenge to the patent is based

on matters previously presented to the Office.¹² *Advanced Bionics, LLC v. Med-El Elektromedizinische Geräte GmbH*, IPR2019-01469, Paper 6 at 7 (PTAB Feb. 13, 2020) (precedential) (“*Advanced Bionics*”).

In evaluating the exercise of discretion to deny institution under § 325(d), the Board applies a two-part framework: (1) first, we determine whether the same or substantially the same art previously was presented to the Office, or whether the same or substantially the same arguments previously were presented to the Office; and (2) if either condition of the first part of the framework is satisfied, we examine whether the petitioner has demonstrated that the Office erred in a manner material to the patentability of challenged claims. *Advanced Bionics*, 8.

In applying the two-part framework, we consider several non-exclusive factors, including:

- (a) the similarities and material differences between the asserted art and the prior art involved during examination;
- (b) the cumulative nature of the asserted art and the prior art evaluated during examination;
- (c) the extent to which the asserted art was evaluated during examination, including whether the prior art was the basis for rejection;
- (d) the extent of the overlap between the arguments made during examination and the manner in which petitioner relies on the prior art or patent owner distinguishes the prior art;
- (e) whether petitioner has pointed out sufficiently how the examiner erred in its evaluation of the asserted prior art; and
- (f) the extent to which additional evidence and facts presented in the petition warrant reconsideration of the prior art or arguments.

¹² By regulation, the Director has delegated the decision whether to institute trial to the Board. 37 C.F.R. § 42.4(a) (2020).

Becton, Dickinson & Co. v. B. Braun Melsungen AG, IPR2017-01586, Paper 8 at 17–18 (PTAB Dec. 15, 2017) (precedential as to Section III.C.5, first paragraph) (“*Becton, Dickinson*”).

Factors (a), (b), and (d) of the *Becton, Dickinson* factors relate to whether the art or arguments presented in the petition are the same or substantially the same as those previously presented to the Office. *Advanced Bionics*, 10. Factors (c), (e), and (f) “relate to whether the petitioner has demonstrated a material error by the Office” in its prior consideration of that art or arguments. *Id.* Only if the same or substantially the same art or arguments were previously presented to the Office do we then consider whether the petitioner has demonstrated a material error by the Office. *Id.* “At bottom, this framework reflects a commitment to defer to previous Office evaluations of the evidence of record unless material error is shown.” *Id.* at 9.

Upon evaluating the disclosures of the references, we do not believe KGSI’s argument survives the first step of the *Advanced Bionics* framework. Specifically, as KGSI concedes, Voorde discloses the use of an optional starter culture, which is a disclosure central to FFP’s grounds of unpatentability and a disclosure that Kurihara lacks. We disagree with KGSI that this distinction is “immaterial,” because as discussed above, we do not conclude on this record that Voorde *requires* the use of naturally-occurring microbes, as opposed to exclusively added organisms. Even if we agreed with such a characterization, however, the addition of optional starter cultures in Voorde distinguishes its disclosure from that of Kurihara. We conclude that the art raised in the Petition is not the same or substantially the same as that presented to the Office during prosecution; nor do we consider

the arguments for unpatentability to be substantially similar.¹³ As such, we decline to exercise our discretion under 35 U.S.C § 325(d) to deny institution of trial.

IV. CONCLUSION

After considering the evidence and arguments the presented in the Petition and the Preliminary Response, we determine that FFP has established a reasonable likelihood that it will prevail with respect to at least one of the challenged claims. We are not persuaded that we should exercise our discretion to deny institution of trial. Accordingly, we institute an *inter partes* review of all of the claims and all of the grounds presented in the Petition. *See SAS*, 138 S. Ct. at 1354, 1359–60; TPG 64.

At this stage of the proceeding, the Board has not made a final determination as to the patentability of any challenged claims or any underlying factual or legal issues. The final determination will be based on the record as developed during the *inter partes* review.

¹³ Because we find that the full translation of Voorde sufficiently differentiates the prior art in the Petition from the art previously presented to the Office, we need not consider KGSI's other arguments regarding the disclosures of Hara, Fast, or Yamamoto. *See Prelim. Resp.* 65–66.

V. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that, pursuant to 35 U.S.C. § 314(a), an *inter partes* review is hereby instituted as to claims 1–5 of the '304 patent on all grounds set forth in the Petition; and

FURTHER ORDERED that, pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4(b), *inter partes* review of the '304 patent shall commence on the entry date of this Decision, and notice is hereby given of the institution of a trial.

IPR2022-00006
Patent 11,071,304 B2

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