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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

GENOME & COMPANY,
Petitioner,

v.

THE UNIVERSITY OF CHIGAGO,
Patent Owner.

Case No. PGR2019-00002
Patent 9,855,302 B2

Before SUSAN L. C. MITCHELL, JACQUELINE T. HARLOW, and JOHN E. SCHNEIDER, *Administrative Patent Judges*.

SCHNEIDER, *Administrative Patent Judge*.

DECISION
Institution of Post-Grant Review
35 U.S.C. § 324(a)

I. INTRODUCTION

A. Background

Genome & Company ("Petitioner") filed a Petition requesting post-grant review of claims 1–29 of U.S. Patent No. 9,855,302 B2 (Ex. 1001 "the '302 patent"). Paper 1, ("Pet."). The University of Chicago ("Patent Owner") filed a Preliminary Response. Paper 6 ("Prelim. Resp.").

We have authority to determine whether to institute post grant review under 35 U.S.C. § 324, which provides that a post grant review may not be instituted unless the information presented in the Petition, if unrebutted, "would demonstrate that it is more likely than not that at least 1 of the claims challenged in the petition is unpatentable." 35 U.S.C. § 324(a). On April 24, 2018, the Supreme Court held that a decision to institute may not institute review on fewer than all claims challenged in the petition. *SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1355–56 (2018). Also, in accordance with USPTO Guidance, "if the PTAB institutes a trial, the PTAB will institute on all challenges raised in the petition." *See Guidance on the Impact of SAS on AIA Trial Proceedings* (April 26, 2018) (available at https://www.uspto.gov/patents-application-process/patent-trial-and-appealboard/trials/guidance-impact-sas-aia-trial).

Having considered the arguments and the evidence presented, for the reasons described below, we determine that Petitioner has demonstrated that it is more likely than not that at least one of the claims challenged in the Petition is unpatentable. Accordingly, we institute a post-grant review of all claims and all grounds asserted in the Petition.

B. Additional Proceedings

Petitioner represents that there are no related matters. Pet. 3.

C. Eligibility for Post Grant Review

Post-grant review is available only for patents "described in section 3(n)(1)" of the Leahy-Smith America Invents Act ("AIA"), Pub L. No. 112-29, 125 Stat. 284 (2011). AIA § 6(f)(2)(A). Those are patents that issue from applications "that contain[] or contained at any time . . . a claim to a claimed invention that has an effective filing date in section 100(i) of title 35, United States Code, that is on or after" "the expiration of the 18-month period beginning on the date of the enactment of" the AIA. *See* AIA § 3(n)(1).

Because the AIA was enacted on September 16, 2011, post-grant review is available only for patents that, at one point, contained at least one claim with an effective filing date, as defined by 35 U.S.C. § 100(i), on or after March 16, 2013. The earliest filing date for the '302 patent is June 1, 2015, which is after the March 16, 2013 date. *See* Ex. 1001 [60].

The AIA also requires that the petition be filed within nine months of the issue date of the patent being challenged. 35 U.S.C. § 321(c). The '302 patent issued on January 2, 2018. Ex. 1001 [45]. The Petition has been accorded a filing date of October 2, 2018, within the nine-month window.

Based on the foregoing, we conclude that the '302 patent is eligible for post-grant review and that Petitioner has timely filed its petition.

D. The '302 Patent (Ex. 1001)

The '302 patent, titled "Treatment of Cancer by Manipulation of Commensal Microflora" issued on January 2, 2018, from U.S. Patent Application No. 15/170,284 filed on June 1, 2016. Ex. 1001, [54], [45], [21], [22]. . The '752 patent claims priority to U.S. Provisional Application No. 60/169,112 filed on June 1, 2015, and U.S. Provisional Application No. 60/248,741 filed on October 30, 2015. *Id.* at [60].

The ’302 patent teaches the treatment or prevention of cancer through the use of commensal microflora either alone or in combination with one or more co-treatments. Ex. 1001, Abstract.

The ’302 patent discloses that the co-treatment can be the administration of an immune checkpoint inhibitor (“CPI”).[1] Ex. 1001, col. 5, ll. 7–8. The CPI used in the practice of the invention disclosed in the ’302 patent can be a protein of a peptide, an antibody or fragment thereof, or an interfering nucleic acid molecule. *Id*. at col. 5, ll. 7–20

The ’302 patent discloses that one of the microflora that can be used in practice of the disclosed invention is bacteria of the genus *Bifidobacterium*. Ex. 1001, col. 3, ll. 10–29.

E. Illustrative Claims

Of the challenged claims, claims 1 is the sole independent claim and reads as follows:

> 1. A method of treating cancer in a human subject comprising co-administering to the subject an immune checkpoint inhibitor and a bacterial formulation comprising bacteria of the genus *Bifidobacterium.*

Ex. 1001, col. 41, ll. 61–64.

F. The Asserted Grounds of Unpatentability

[1]Immune checkpoint inhibitors are described as follows: “We have learned over the last decade that powerful immunologic effector cells may be blocked by inhibitory regulatory pathways controlled by specific molecules often called ‘immune checkpoints.’ These checkpoints serve to control or turn off the immune response when it is no longer needed to prevent tissue injury and autoimmunity.” Ex. 1016, Abstract. Drugs that inhibit these pathways are called checkpoint inhibitors and their use is seen as a potential new strategy for treating cancer. *Id.*

Petitioner contends that the challenged claims are unpatentable on the following grounds. Pet. 7.

Ground	References	Basis	Claims Challenged
1		§ 112(a) Lack of Enablement	1–29
2	Korman[2], Singh,[3] and Dong[4]	§ 103(a)	1–9, 12–17, 19–25, 27, and 28
3	Korman, Singh, Dong, and van der Waaij[5]	§ 103(a)	10, 11, and 26
4	Korman, Singh, Dong, and Topalian[6]	§ 103(a)	18 and 29
5	Korman and Kohwi[7]	§ 103(a)	1–4, 7–9, 12–17, 19–25, 27, and 28
6	Korman, Kohwi, and Singh	§ 103(a)	5, 6, 23, and 24
7	Korman, Kohwi, and van der Waaij	§ 103(a)	10, 11, and 26
8	Korman, Kohwi, and Topalian	§ 103(a)	18 and 29

[2] Korman et al., US 2009/0217401 A1, published Aug. 27, 2009 ("Korman") Ex. 1003.
[3] Singh et al., *Bifidobacterium longum, a lactic acid-producing intestinal bacterium inhibits colon cancer and modulates intermediate biomarkers of cancer carcinogenesis,* 18 CARCINOGENESIS 833 (1997) ("Singh") Ex. 1004.
[4] Dong et al., *The role of intestinal bifidobacteria on immune system development in young rats,* 86 EARLY HUMAN DEVEL. 51 (2010) ("Dong") Ex. 1005.
[5] van der Waaij et al., *The influence of antibiotics on gut colonization,* 18 J. ANTIMICROBIAL CHEMOTHERAPY 155 (1986) ("van der Waaij") Ex. 1010.
[6] Topalian et al., *Survival, Durable Tumor Remission, and Long-Term Safety in Patients with Advanced Melanoma Receiving Nivolumab,* 32 J. CLINICAL ONCOL. 1020 (2014) ("Topalian") Ex. 1006.
[7] Kohwi et al., *Antitumor Effects of Bifidobacterium infantis in Mice,* 69 GANN. 613 (1978) ("Kohwi") Ex. 1007.

Ground	References	Basis	Claims Challenged
9	Korman, Mohania,[8] and Prakash[9]	§ 103(a)	1–9, 12–17, 19–25, 27, and 28
10	Korman, Mohania, Prakash, and van der Waaij	§ 103(a)	10, 11, and 26
11	Korman, Mohania, Prakash, and Topalian	§ 103(a)	18 and 29

Petitioner also relies on the Declaration of Jonathan Braun, M.D., Ph.D. (Ex. 1002).

II. ANALYSIS

A. Claim Construction

In a post-grant review filed before November 13, 2018, the Board interprets claim terms in an unexpired patent according to the broadest reasonable construction in light of the specification of the patent in which they appear. 37 C.F.R. § 100(b) (2018);[10] *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2142 (2016) (affirming applicability of broadest reasonable construction standard to trial proceeding before the USPTO.). Under that standard, and absent any special definitions, we generally give claim terms

[8] Mohania et al., *Modulation of expression of Programmed Death-1 by administration of probiotic Dahi in DMH-induced colorectal carcinogenesis in rats*, 84 ACTA BIOMED. 102 (2013) ("Mohania") Ex. 1008.
[9] Prakash et al., US 2010/028449 A1, published Feb. 4, 2010 ("Prakash") Ex. 1009.
[10] The Office recently changed the claim construction standard to be employed in a post-grant review for petitions filed on or after November 13, 2018. *See Changes to the Claim Construction Standard for Interpreting Claims in Trial Proceedings Before the Patent Trial and Appeal Board*, 83 Fed. Reg. 51,340 (October 11, 2018). However, based on the filing date of the Petition in this proceeding, the applicable claim construction standard remains as set forth in 37 C.F.R. § 42.100(b) (2016).

their ordinary and customary meaning, as would be understood by one of ordinary skill in the art at the time of the invention. *See In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). Any special definitions for claim terms must be set forth with reasonable clarity, deliberateness, and precision. *See In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994).

We determine that it is unnecessary to expressly construe any claim terms for purposes of this Decision. *See Wellman, Inc. v. Eastman Chem. Co.*, 642 F.3d 1355, 1361 (Fed. Cir. 2011) ("[C]laim terms need only be construed 'to the extent necessary to resolve the controversy.'") (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999)).

B. Level of Ordinary Skill in the Art.

The level of ordinary skill in the art is a factual determination that provides a primary guarantee of objectivity in an obviousness analysis. *Al-Site Corp. v. VSI Int'l Inc.*, 174 F.3d 1308, 1324 (Fed. Cir. 1999) (citing *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966); *Ryko Mfg. Co. v. Nu-Star, Inc.*, 950 F.2d 714, 718 (Fed. Cir. 1991)).

Dr. Braun, Petitioner's proffered expert, defines a person of ordinary skill in the art as having an advanced degree or its substantial equivalent in the biological sciences, including specifically in the fields of immunology, microbiology and the microbiome, and oncology, coupled with research experience in those fields. Ex. 1002 ¶ 40. At this stage of the proceeding, and without opposition from Patent Owner at this time, we determine that Petitioner's description of the level of ordinary skill in the art is supported by the current record. *Id*. For purposes of this Decision, therefore, we adopt Petitioner's description.

We also note that the applied prior art reflects the appropriate level of skill at the time of the claimed invention. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001).

C. Ground 1 – Enablement.

Petitioner asserts that claims 1–29 are unpatentable for failure to comply with the enablement requirement set forth in 35 U.S.C. §112(a).

"Section 112 requires that the patent specification enable those skilled in the art to make and use the full scope of the claimed invention without undue experimentation. . . . [*S*]*ee also In re Goodman*, 11 F.3d 1046, 1050 (Fed. Cir. 1993) ('[T]he specification must teach those of skill in the art how to make and how to use the invention as broadly as it is claimed.')." *Invitrogen Corp. v. Clontech Labs. Inc.*, 429 F.3d 1052, 1070–71 (Fed. Cir. 2005) (internal quotes omitted).

Some experimentation, even a considerable amount, is not "undue" if, e.g., it is merely routine, or if the specification provides a reasonable amount of guidance as to the direction in which the experimentation should proceed. *In re Wands*, 858 F.2d 731, 736–37 (Fed. Cir. 1988). "Factors to be considered in determining whether a disclosure would require undue experimentation . . . include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims." *Id.* at 737. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." *Id.*

1. Petitioner's Position

Petitioner contends that the specification of the '302 patent fails to adequately enable one skilled in the art to make and use the disclosed invention for the full scope of the claims. Pet. 36. Petitioner argues that when the *Wands* factors are properly considered, the factors lead to the conclusion that undue experimentation would be required to practice the full scope of the claims. *Id.*

a. The Nature of the Invention

Petitioner begins by addressing the nature of the invention. Petitioner points out that the invention is directed to treating cancer in a human subject by administering both a CPI and a bacterial formulation comprising *Bifidobacterium*. Pet. 36. Petitioner contends that the claims are not limited to a specific form of cancer nor to a specific species of *Bifidobacterium*. *Id.* Petitioner also points out that the broader claims do not specify the CPI to be used. *Id.*

Petitioner relies on the Declaration of Dr. Braun to support these contentions. *Id.* (citing Ex. 1002 ¶¶ 129–31). In the paragraphs cited in the Petition, Dr. Braun cites to earlier portions of the declaration where he discusses the teachings of the '302 patent. Ex. 1002 ¶ 131 (citing to ¶¶ 59–63). Dr. Braun discusses the examples in the '302 patent and explains how the teachings of the examples are very limited. Ex. 1002 ¶¶ 59–63.

b. Level of Ordinary Skill in the Art

Petitioner argues that the level is skill in the art is high, an assessment with which we agree on this record. Pet. 37; *see supra* Section II.B. Petitioner contends that the ordinarily skilled artisan would have a specialized knowledge of cancer, immunology, and microbiota. Petitioner contends that this specialized training is necessary as developing a cancer therapeutic is difficult, complicated, and highly unpredictable. *Id.*

In support of these contentions, Petitioner points to the Declaration of Dr. Braun. *Id.*; Ex. 1002 ¶¶ 132 and 133. In his Declaration, Dr. Braun cites to earlier paragraphs in his declaration where he discusses in detail the support for his opinion as to the level of skill required to develop a cancer therapeutic. *Id.* ¶ 133 (citing ¶¶ 93–109).

c. The Breadth of the Claims

Petitioner contends that the claims are very broad in that they cover "thousands of different combinations of cancers, immune checkpoint inhibitors and genera of *Bifidobacterium*." Pet. 38. Petitioner contends that the claims are directed to any type of cancer and that the specification of the '302 patent lists more than 165 types of cancer that can be treated. *Id.* Petitioner also contends that the broader claims do not specify the CPI that is to be used and that CPIs include a broad class of agents such as proteins, including antibodies and fragments thereof, and nucleic acids. *Id.*

In support of these contentions, Petitioner cites to the Declaration of Dr. Braun. *Id.* at 38–41 citing Ex. 1002 ¶¶ 136–146. In the cited paragraphs, Dr. Braun cites to an earlier discussion in his declaration where he describes in detail different types of cancer and explains how each is treated by different methods. Ex. 1002 ¶ 138 (citing ¶¶ 95–96). In this earlier discussion, Dr. Braun cites to additional references that support his opinions. *See, e.g.* Ex. 1002 ¶ 95 (citing to Kandoth[11]); Ex. 1021.

Dr. Braun also discusses the different types of CPIs and how they have been effective in treating a limited number of cancers and only for a limited subset of patients affected by those cancers. Ex. 1002 ¶¶ 100–103.

[11] Kandoth, et al., *Mutational landscape and significance across 12 major cancer types,* 502 NATURE 333 (2013) ("Kandoth") Ex. 1021.

In support of his opinions, Dr. Braun cites to Pardoll,[12] which discusses CPIs and their use in treating cancer. *Id.*

d. Presence of Working Examples

Petitioner contends that the examples in the '302 patent are limited to two specific types of cancer, melanoma and bladder, and one CPI. Pet. 41. With respect to the *Bifidobacterium* used in the examples, Petitioner contends that the '302 patent only used mouse feces, which contains one species of *Bifidobacterium* and other gut bacteria and another composition comprising a mixture of four different species of *Bifidobacterium*. *Id.* at 41–42. Petitioner also notes that the data presented in the '302 patent are limited to mouse data and that no human data are presented. *Id.* at 42.

In support of these contentions, Petitioner relies on the Declaration of Dr. Braun. *Id.* As noted above, Dr. Braun discusses the limited nature of the experiments reported in the examples citing various passages in the '302 patent. Ex. 1002 ¶¶ 59–63 and 147–149.

e. Amount of Guidance in the Specification

Petitioner contends that the '302 patent provides no guidance as to which CPI to select to treat a specific cancer. Pet. 42. Petitioner contends that that only guidance in in the examples is limited to two types of cancer and one CPI. *Id.* Petitioner contends that given the scope of the claims and the unpredictable nature of the technology, the guidance given in the '302 patent is inadequate. *Id.* at 43.

Petitioner relies on the Declaration of Dr. Braun to support these contentions. *Id.* As discussed above, Dr. Braun discusses the examples

[12] D. Pardoll, *The blockade of immune checkpoints in cancer immunotherapy*, 12 NAT. REV. CANCER 252 (2012) ("Pardoll") Ex. 1026.

provided in the ’302 patent and the guidance given in the rest of the specification. Ex. 1002 ¶¶ 41–63, 150–151.

f. Predictability of the Art.

Petitioner contends that the art relating to the claimed invention is highly unpredictable. Pet. 43. Petitioner lists several different factors in support of this contention, including:

- Cancer is a term that embraces a variety of specific diseases with different etiologies, outcomes and therapies;
- There are a limited number of CPIs that have been shown to work for a limited number of cancers, and for only a limited subset of patients with those cancers;
- The properties of *Bifidobacterium* are species and sometimes strain specific; and
- Only certain species of *Bifidobacterium* have been shown to be effective against cancer.

Pet. 43.

Petitioner contends that cancer therapy is an unpredictable art. Pet. 44. Petition contends that cancers develop in different ways and can require different methods of treatment. *Id.*

In support of these contentions, Petitioner cites to the Declaration of Dr. Braun. *Id.* Dr. Braun provides a detailed analysis supporting his conclusion that the art of treating cancer is unpredictable. Ex. 1002 ¶¶ 93–109 and 152–155. In support of his conclusions, Dr. Braun cites to Kandoth and Kumar[13] for the proposition that there are a variety of different cancer

[13] Kumar et al., *Drug Target for Cancer Treatment: An Overview*, 5 MED. CHEM. 115 (2015) (“Kumar”) Ex. 1022.

types and different methods for treating cancers. Ex. 1002 ¶¶ 95–97. Dr. Braun cites to Pardoll to support his conclusions regarding the limited effectiveness of CPIs, and cites to DiMasi[14] for the proposition that development of a cancer therapy is difficult and complicated. *Id.* at ¶¶ 100–104.

g. Amount of Experimentation

Petitioner contends that it would require an undue amount of experimentation to practice the full scope of the claims of the '302 patent. Pet. 45. Petitioner argues that it would require more than 100,000 experiments to test all the disclosed CPIs with all the disclosed species of *Bifidobacterium* to test their effectiveness against the range of cancers recited in the '302 patent. *Id.* at 46. Petitioner contends that the number of experiments required is actually even greater as the patent does not give any specific guidance as to the routes of administration. Petitioner contends that the sheer volume or experiments required coupled with the limited guidance in the '302 patent compels the conclusion that undue experimentation is require to practice the full scope of the invention. *Id.* at 48.

Petitioner supports these contentions with the Declaration of Dr. Braun. *Id.* citing Ex. 1002 ¶¶ 156–165. Dr. Braun bases his opinion that undue experimentation would be required on his analysis of the '302 patent. Ex. 1002 ¶¶ 156–165.

2. Patent Owner's position

Patent Owner contends that Petitioner has not sufficiently established, for purposes of institution, that the challenged claims are non-enabled.

[14] DiMasi and Grabowski, *Economic of New Oncology Drug Development,* 25 J. CLINICAL ONCOL. 209 (2007) ("DiMasi") Ex. 1027.

Prelim. Resp. 2. According to Patent Owner, Petitioner's non-enablement argument "is deficient because it concludes, based solely on the quantity, that the allegedly required testing would have been undue." *Id.* at 3. Patent Owner contends that Petitioner has offered no other evidence to support the conclusion that the undue experimentation would be required. *Id.* Patent Owner also contends that even if a large number of experiments were required, that alone is not enough; Petitioner must also show that the experiments are not of a routine nature. *Id.* at 3–6. Patent Owner contends that Petitioner has not made such a showing. *Id.*

3. Discussion

We have considered the arguments advanced by the parties and conclude that, for purposes of this Decision, Petitioner has established that it is more likely than not that it will prevail in establishing that the claims are not enabled. Petitioner's *Wands* analysis establishes that the claims challenged under ground 1 are extremely broad in that they do not limit the type of cancer treated nor do they specify the genera of Bifidobacterium that can be used. Ex. 1002 ¶ 130. The broader claims are not limited as to the nature of the CPI that can be used. *Id.* The evidence of record shows that different cancers respond to different treatments differently. Ex. 1002 ¶ 96; Ex. 1022, 115–123. The record also shows that CPIs are numerous and varied. Ex. 1002 ¶¶ 100–103. There is evidence of record that developing a cancer treatment is difficult and complicated. Ex. 1002 ¶ 104; Ex. 1027, 206.

The working examples are markedly limited. The examples only address two types of cancer using only one CPI and 4 species of *Bifidobacterium*. Ex. 1001, col. 36, l. 56–col. 37, l. 10. In addition, the Specification gives no guidance as to how to select CPIs and

Bifidobacterium that will work in the claimed method without resorting to trial and error. Instead the Specification lists 36 different species of *Bifidobacterium*, *id.* at col. 3, ll. 10–29, and gives a broad definition of a CPI, *id.* at col. 5, ll. 8–11. Based on the record before us, we find that each of the *Wands* factors recited above weighs in favor of Petitioner's contention that the claims are not enabled for the full scope of the claims.

Patent Owner contends that Petitioner's *Wands* analysis is deficient in that it only relies on the quantity of experiments that are needed and does not address whether those experiments would have been routine or whether the Specification provides a reasonable amount of guidance. Prelim. Resp. 2–4. We are unpersuaded by Patent Owner's argument. As discussed above, Petitioner has demonstrated that the amount of guidance in the Specification is minimal. Pet. 42–43. In addition, Dr. Braun's conclusion that extensive and undue experimentation would be required in based not only on the number of experiments involved (which purportedly could exceed 100,000) but on additional factors such as the unpredictability of cancer treatments and the unpredictable nature of CPIs. Ex. 1002 ¶ 166. On the record before us, it appears that the Specification does not enable the full scope of the claims. Considering all of the *Wands* factors, we find that Petitioner is likely to prevail in showing the unpatentability of at least one claim of the '302 patent.

D. Grounds 2–4 Obviousness based on Combinations Including Korman, Singh, and Dong

Petitioner contends that claims 1–9, 12–17, 19–25, 27, and 28 would have been rendered obvious by the teachings of Korman combined with Singh and Dong. Pet. 50–57. Petitioner also alleges that claims 10, 11, and 26 are rendered obvious by the teachings of Korman, Singh, Dong and van

der Waaij. Pet. 57–58. Petitioner contends that claims 18 and 29 are rendered obvious over Korman, Singh, Dong and Topalian. Pet. 58–59. As discussed more fully below, on the record before us we find that Petitioner has not demonstrated that it more likely than not that at least one claim would have been obvious over the references in these grounds asserted by Petitioner.

Patent Owner addresses these three grounds together, and contends that one skilled in the art would not have been motivated to combine the teachings of Korman, Singh, and Dong. Prelim Resp. 6–12. Patent Owner contends that one skilled in the art would not have been motivated to combine the teachings of the references as the art teaches that the CPI of Korman is immunostimulatory and the *Bifidobacterium* of Singh and Dong are immunosuppressive. Prelim. Resp. 6.[15] Patent Owner contends that "combining an immunosuppressive *Bifidobacterium* with an immunostimulatory checkpoint inhibitor would have been antithetical to one of ordinary skill." *Id.* Patent Owner points out that the Examiner found a similar argument persuasive in allowing the present claims over similar prior art. *Id.*

We will address these three grounds together. The question of obviousness is resolved on the basis of underlying factual determinations

[15] Patent Owner asserts that during prosecution, it overcame an obviousness rejection by arguing that the *Bifidobacterium* species taught by that art is immunosuppressive "and that combining an immunosuppressive *Bifidobacterium* with an immunostimulatory checkpoint inhibitor would have been antithetical to one of ordinary skill." Prelim. Resp. 6. Petitioner does not appear to dispute Patent Owner's contention that an ordinarily skilled artisan would have avoided co-administration of an immunosuppressive *Bifidobacterium* species with an immunostimulatory CPI. *See* Pet. 2, note 1, 13–16.

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 skill in the art, and (4) where in evidence, so-called secondary considerations. *Graham*, 383 U.S. at 17–18. 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, the claim is unpatentable under 35 U.S.C. § 103(a). *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007).

An invention

> composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art. Although common sense directs one to look with care at a patent application that claims as innovation the combination of two known devices according to their established functions, it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does.

KSR, 550 U.S. at 418.

1. Korman

Korman relates to the use of human monoclonal antibodies to treat cancer. Ex. 1003 Abstract. Korman teaches the use of anti-PD-1 antibodies and anti-CTLA-4 antibodies to treat cancer. *Id.* Korman teaches that the antibodies act as CPIs as they bind to the respective proteins thereby enhancing the immune response to cancer cells. Ex. 1003 ¶¶ 498 and 501. Korman teaches that the antibodies can be effective against colorectal cancer cells and SA1/N fibrosarcoma cells. *Id.*

2. Singh

Singh reports a study to determine the effectiveness of *Bifidobacterium longum* to treat cancer. Ex. 1004, 1 Abstract. Singh teaches that oral administration of *Bifidobacterium longum* exerts strong antitumor activity. *Id.* Singh teaches that daily oral administration of lyophilized cultures of *B. longum* resulted in "significant suppression of colon cancer incidence, tumor multiplicity and reduced tumor volume." *Id.*

3. Dong

Dong reports a study on the effect of intestinal bifidobacteria on the development of immunity during development. Ex. 1005 Abstract. Dong teaches that administration of bifidobacteria "promoted dendritic cell maturation in Peyer's Patches, up-regulated IL-12, IL-10, interferon-γ mRNA and the interferon-γ/IL-4 ratio in intestinal mucosa, increased interferon-γ gene expression in cultured PBMCs, and raised immunoglobulin-M secretion in cultured PBMCs." *Id.* Dong teaches intestinal bifidobacteria can affect "the development of both gut and systemic immunity in early life." *Id.*

4. Analysis

Petitioner contends that Korman teaches a method for treating cancer in humans by administering CPIs such as anti-PD-1 and anti-CTLA-4 antibodies that bind to their respective immune checkpoint proteins. Pet. 50. In support of this position, Dr. Braun testifies that "Korman '401 showed that that intraperitoneal injection of anti PD-1 and anti CTLA-4 antibodies both alone and in combination reduced tumor growth in MC38 colorectal cancer cells and SA1/N fibrosarcoma cells." Ex. 1002 ¶ 168.

Petitioner contends that Singh teaches that oral administration of *Bifidobacterium longum* exerts strong antitumor activity. Pet. 50. In support of this position, Petitioner's expert testifies that "Singh showed that

daily oral administration of "[l]yophilized cultures of *B. longum* … equivalent to 4 x 1010 live cells/g diet" (*Id* at p. 2, 2nd col.) resulted in 'significant suppression of colon tumor incidence, tumor multiplicity, and reduced tumor volume.'" Ex. 1002 ¶ 169 (quoting Ex. 1004 Abstract).

Petitioner contends that Dong teaches that *Bifidobacterium longum* is immunostimulatory. Pet. 50. In support of this position, Dr. Braun testifies that "Dong showed that *Bifidobacterium longum* induced maturation in dendritic cells characterized by increased expression of CD86, IL-12, and IFN-γ, and that such induced maturation of dendritic cells would favor a T-helper cell response of the body in a Th1 type." Ex. 1002 ¶ 170.

Petitioner contends that it would have been obvious to one skilled in the art to combine the teachings of Korman and Singh to treat cancer in a human subject. Pet. 51. Petitioner contends that on skilled in the art would have been motivated to combine the teachings of the references as the CPIs of Korman and the *Bifidobacterium* of Singh are both shown to be effective in treating colon cancer and are both immunostimulatory. *Id.*

Patent Owner responds that one skilled in the art would not have been motivated used the bifidobacteria of Singh with the CPIs of Korman as the *Bifidobacterium* used in Singh is immunosuppressive and not immunostimulatory. Prelim. Resp. 7. Patent Owner contends that one skilled in the art would not use an immunosuppressive agent in combination with an immunostimulatory agent, and, therefore, would not have combined Singh's purportedly *immunosuppressive* bifidobacterium with Korman's *immunostimulatory* CPIs. *Id.*

In support of this contention Patent Owner points to the teaching in Singh that the administration of *Bifidobacterium longum* upregulated the production of IL-10, which is described in the art as anti-inflammatory.

Prelim. Resp. 7, citing Ex. 1005, 7. Patent Owner contends that one skilled in the art would not have considered *Bifidobacterium longum* to be immunostimulatory as Dong teaches that the bacteria has both an anti-inflammatory and proinflammatory effect. Prelim. Resp. 7–8. Patent Owner also contends that the conclusions in Dong are tentative and would not lead one skilled in the art to conclude that the *Bifidobacterium* used in Dong were immunostimulatory. *Id.*

On the limited record before us it appears unlikely that Petitioner will prevail in showing obviousness as to any claim on grounds 2–4, as the parties appear to agree that an ordinarily skilled artisan would have avoided co-administration of immunostimulatory and immunosuppressive agents. The limited evidence before us, however, teaches that the *Bifidobacterium longum* used in Singh exhibits an immunosuppressive effect, and CPIs exhibit an immunostimulatory effect. Ex. 1005, 7.

We have considered the additional references cited by Petitioner, van der Waaij and Topalian, and do not find any teachings in either reference that addresses the issue of whether the species of *Bifidobacterium* used in Singh and Dong are immunosuppressive or immunostimulatory.

E. Grounds 5–8: Obviousness based on Combinations Including Korman and Kohwi

Petitioner contends that claims 1–4, 7–9, 12–17, 19–25, 27, and 28 are rendered obvious by the teachings of Korman combined with Kohwi. Pet. 59–67. Petitioner also alleges that claims 5, 6, 23, and 24 are rendered obvious by the teachings of Korman, Kohwi and Singh. Pet. 67–68. Petitioner contends that claims 10, 11, and 26 are rendered obvious over Korman, Kohwi and van der Waaij. Pet. 68. Petitioner contends that claims

18 and 29 are rendered obvious over Korman, Kohwi, and Topalian. Pet. 68–69. As discussed more fully below, we find that, on the record before us. Petitioner has demonstrated that it is more likely that not that at least one of the challenged claims would have been obvious over the references advanced in these grounds.

Patent Owner addresses these four grounds and their corresponding claims together, contending that one skilled in the art would not have been motivated to combine the teachings of Korman and Kohwi. Prelim Resp. 12–14. Patent Owner contends that the *Bifidobacterium* in Kohwi are immunosuppressive and that one skilled in the art would not combine an immunosuppressive bacteria with an immunostimulatory CPI.

We shall consider these grounds together.

1. Kohwi

Kohwi describes a study into the possible antitumor effects of *Bifidobacterium infantis* and *Bifidobacterium adolescentis* in mice. Ex. 1007, 1. Kohwi teaches "[t]wo strains of *Bifidobacterium* isolated from a human exhibited a remarkable antitumor effect to Meth-A sarcoma cells transplanted into BALB/c mice." Ex. 1007, 617. Kohwi suggests that this anti-tumor response may be due to involvement of a host-mediated immunological response to the tumor, at least to some extent, together with the nonspecific local reaction. *Id.* Kohwi goes on to teach "[t]aken together, destruction of part of tumor cells by the local reaction induced by the bacteria and following immunological stimulation with the tumor may account for the antitumor mechanism of the bacteria." *Id.*

2. Analysis

Petitioner contends that Korman teaches a method for treating cancer in humans by administering CPIs such as anti-PD-1 and anti-CTLA-4

antibodies that bind to their respective immune checkpoint proteins. Pet. 59–60. In support of this position, Dr. Braun testifies that "Korman '401 showed that that intraperitoneal injection of anti PD-1 and anti CTLA-4 antibodies both alone and in combination reduced tumor growth in MC38 colorectal cancer cells and SA1/N fibrosarcoma cells." Ex. 1002 ¶ 181.

Petitioner contends that Kohwi teaches that *Bifidobacterium infantis* and *Bifidobacterium adolescentis* exhibit a remarkable antitumor effect on Meth-A sarcoma cells. Pet. 60. Petitioner also contends that Kohwi teaches that the antitumor effect shown by the bacteria was due to the bacteria being immunostimulatory. *Id.* In support of this contention Dr. Braun cites to these teachings in Kohwi. Ex. 1002 ¶¶ 182–184 (citing Ex. 1007, Abstract, 617).

Petitioner contends that it would have been obvious to one of ordinary skill in the art to combine the CPIs of Korman with the *Bifidobacterium* of Kohwi to treat cancer. Pet. 61. Petitioner contends that one skilled in the art would have been motivated to co-administer the *Bifidobacterium* of Kohwi with the CPIs of Korman as both have been shown to be effective against cancers such as SA1/N fibrosarcoma cells and both are immunostimulatory. *Id.*

Patent Owner contends that one skilled in the art would not have been motivated to combine the *Bifidobacterium* of Kohwi with the CPIs of Korman. Prelim Resp. 12–14. Patent Owner contends that Petitioner has offered no credible evidence that the *Bifidobacterium infantis* and *Bifidobacterium adolescentis* used in Kohwi are immunostimulatory. Prelim Resp. 12–13. Patent Owner also contends that the references of record teach that *Bifidobacterium infantis* and *Bifidobacterium adolescentis* are immunosuppressive. Prelim. Resp. 13. In support of this contention, Patent

Owner cites to O'Mahony[16], which Patent Owner asserts teaches that *Bifidobacterium longum infantis* is immunosuppressive, and Ménard[17], which Patent Owner asserts teaches that *Bifidobacterium adolescentis* has no ability to stimulate the immune system. *Id.* (citing Ex. 1017 ¶ 136; Ex. 2004, 665). Patent Owner contends that one skilled in the art would not have used an immunostimulatory agent with an immunosuppressive agent.

Patent Owner also argues that Petitioner has offered no evidence that the Bifidobacterium in Kohwi is immunostimulatory other that the Declaration of Dr. Braun. Prelim Resp. 12–13. Patent Owner suggests this evidence is not credible as it is identical to the wording in the Petition and is unsupported. *Id.*

We have considered the positions of the parties and conclude that, for purpose of this Decision, Petitioner has demonstrated that it is more likely than not that the claims challenged under ground 5 are unpatentable over Korman combined with Kohwi. We find Dr. Braun's testimony is persuasive and supported by evidence of record. Although Patent Owner is correct that Dr. Braun's testimony mirrors the statements in the Petition, Dr. Braun also cites to the specific teachings the references to support his conclusions. For example, with respect to the teachings of Kohwi, Dr. Braun quotes the passage where Kohwi states that the *Bifidobacterium* used is immunostimulatory. Ex. 1002 ¶ 184 (quoting Ex. 1007, 617).

[16] O'Mahony et al., US 2012/0276143, published Nov. 1, 2012 ("O'Mahony") Ex. 1017.
[17] Ménard et al., *Gnotobiotic Mouse Immune Response Induced by Bifidobacterium sp. Strains isolated from Infants*, 74 APPL. ENVIRON. MICROBIOL. 660 (2008) ("Ménard") Ex. 2004.

With respect to O'Mahony's alleged teaching that *Bifidobacterium longum infantis* is immunosuppressive, Patent Owner's arguments are unpersuasive. Although the cited paragraph of O'Mahony suggests that *Bifidobacterium longum infantis* is immunosuppressive, elsewhere in the same reference, O'Mahony teaches that the immunostimulatory effect of *Bifidobacterium longum infantis* varies from strain to strain with some strains exhibiting an immunosuppressive effect and others expressing an immunostimulatory effect. Ex. 1017 ¶¶ 103–109. Thus O'Mahony does not support unequivocally Patent Owner's assertion that it teaches *Bifidobacterium longum infantis* is immunosuppressive. Moreover, O'Mahony does not address specifically the properties of *Bifidobacterium adolescentis*, the antitumor effect of which Petitioner relies as taught by Kohwi.

Patent Owner's argument with respect to Ménard is also unpersuasive. Ménard teaches that under certain conditions, *Bifidobacterium adolescentis* produces an immunostimulatory effect. Ex. 2004, 665. In addition, the portion of Ménard cited by Patent Owner states no stimulatory effect had been observed for *Bifidobacterium adolescentis*. Ex. 2004, 665. This lack of observed stimulatory effect is not the same as an affirmative teaching that the bacteria is immune suppressive as asserted by Patent Owner. In addition, the statement that no stimulatory effect had been observed does not contradict the observation in Kohwi that the bacteria does exhibit a stimulatory effect. *Compare* Ex. 1007, 617, *with* Ex. 2004, 665.

Based on the record before us, we find that Petitioner has demonstrated that it is more likely than not that the claims challenged under ground 5are unpatentable over Korman combined with Kohwi.

We also have reviewed Petitioner's contentions with respect to the teachings of Singh, van der Waaij and Topalian. Based on the evidence before us, we conclude that Petitioner has demonstrated that it is more likely than not that the claims challenged under grounds 6–8 unpatentable over Korman combined with Kohwi and Singh, van der Waaij or Topalian.

F. Grounds 9–11–Obviousness Based on Combinations Including Korman, Mohania and Prakash

Petitioner contends that claims 1–9, 12–17, 19–25, 27, and 28 are rendered obvious by the teachings of Korman combined with Mohania and Prakash. Pet. 69–78. Petitioner also alleges that claims 10, 11, and 26 are rendered obvious by the teachings of Korman, Mohania, Prakash, and van der Waaij. Pet. 79. Petitioner contends that claims 18 and 29 are rendered obvious over Korman, Mohania, Prakash, and Topalian. Pet. 79–80. As discussed more fully below, we find that, on the record before us, Petitioner has demonstrated that it is more likely that not that at least one of the challenged claims would have been obvious over the references advanced in these grounds.

Patent Owner addresses these three grounds and their corresponding claims together, contending that one skilled in the art would not have been motivated to combine the teachings of Korman, Singh, and Dong. Prelim. Resp. 15–18.

We will address these three grounds together.

1. Mohania

Mohania reports a study of the effect of the probiotic Dahi as a chemoprotective agent for colorectal cancer. Ex. 1008, 102. Dahi is a fermented milk product comprising a mixture of bacteria including

Bifidobacterium bifidum. Ex. 1008, 103. Mohania teaches that oral administration of Dahi to rats reduced expression of PD-1 and that "Dahi can be used as an effective chemoprotective agent in the management of colorectal cancer." Ex. 1008 Abstract.

2. Prakash

Prakash is directed to an oral preparation comprising bacteria and fermented milk for treating gastrointestinal disorders. Ex. 1009 Abstract. Prakash teaches that various species of *Bifidobacterium* including *Bifidobacterium bifidum*, can be used to treat cancer including colorectal cancer. Ex. 1009 ¶¶ 25, 30, and 79.

3. Analysis

Petitioner contends that it would have been obvious to one of ordinary skill in the art to co-administer a CPI of Korman with the *Bifidobacterium bifidum* of Mohania to treat colon cancer. Pet. 70. Petitioner contends that a person of ordinary skill in the art would have been obvious to combine the CPIs of Korman and the *Bifidobacterium bifidum* of Mohania as both have been shown to be effective against colorectal cancer. *Id.* at 70–71. Petitioner also contends that one skilled in the art would have been motivated to combine the two agents as both the anti-PD-1 antibody of Korman and the *Bifidobacterium bifidum* of Mohania act to minimize the function of PD-1 and their effects are additive. *Id.* at 71.

Petitioner supports these contentions with the testimony of its expert, Dr. Braun, who testifies that the antiPD-1 antibody blocks the PD-1 receptor from being activated and *Bifidobacterium bifidum* downregulates the PD-1 receptor's expression making the effect of the two agents additive. Ex. 1002 ¶ 203.

Petitioner also cites to the prosecution history of the child application of the '302 patent, USSN 15/718,735 ("'735 Appln."). Pet. 72. During prosecution of the '735 Application, the Examiner responded to Patent Owner's argument that the probiotic of Mohania and the anti-PD-1 antibody of Korman acted through "mutually counter productive [sic] mechanisms" by finding that the compositions of Korman, Mohania and Prakash work to inhibit or decrease the function of PFD-1 and are not counter-productive. Ex. 1015, 68.

Patent Owner contends that Petitioner has not shown that the claims are unpatentable. Patent owner contends Petitioner has not established that the anticancer effect seen in Mohania is due to the presence of *Bifidobacterium bifidum*, as the probiotic comprises additional bacteria. Prelim. Resp. 15. Patent Owner also contends that Petitioner has not shown that there is an additive effect in the administration of *Bifidobacterium bifidum* as the reported effect can be attributed to reduction of activated T cells rather than downregulation of PD-1 expression in cells. Prelim. Resp. 16.

Patent Owner also contends that Mohania is at best equivocal as to whether *Bifidobacterium bifidum* is immunosuppressive or immunostimulatory. Prelim. Resp. 16–17. Patent Owner contends that Petitioner has failed to overcome Patent Owner's argument that one skilled in the art would not have combined an immunosuppressive agent with an immunostimulatory agent.

We have considered the arguments advanced by the parties as well as the evidence of record and conclude that, based on the record before us, that Petitioner has demonstrated that it is more likely than not that the claims

challenged under ground 9 are unpatentable over Korman combined with Mohania and Prakash.

Patent Owner's arguments to the contrary are unpersuasive. With respect to Patent Owner's contention that Petitioner has not demonstrated that the *Bifidobacterium* in the probiotic of Mohania was the anticancer agent, although we agree that the probiotic composition of Mohania contains other bacteria in addition to *Bifidobacterium*, the claims of the '302 patent do not preclude the presence of other bacteria. *See* Ex. 1001, col. 41, ll. 61–64 ("a bacterial formulation **comprising** bacteria of the genus *Bifidobacterium*") (emphasis added). Thus the claims themselves do not require the *Bifidobacterium* exhibit anticancer activity—only that they be present in the composition. Combining the probiotic of Mohania with the CPI of Korman would appear to meet the limitations of the claims. One skilled in the art would have been motivated to make this combination, as the probiotic of Mohania has an anticancer effect and sodoes the CPI of Korman. Moreover, Prakash teaches that *Bifidobacterium bifidum* exhibits an anticancer effect. Ex. 1009 ¶¶ 30, 69. The presence of additional bacteria does not negate the motivation to combine the CPI of Korman with the *Bifidobacterium*-containing composition of Mohania.

With respect to the additive effect of the CPI and *Bifidobacterium*, as discussed above, Dr. Braun does not merely state that the effect would be additive, but explains the basis of his opinion. Ex. 1002 ¶ 203. Dr. Braun explains:

> both the anti PD-1 antibody of Korman '401 and *Bifidobacterium bifidum* of Mohania act to minimize the function of the immune checkpoint protein, the PD-1 receptor. The anti-PD-1 antibody blocks the PD-1 receptor from being activated by its cognate ligand(s) PD-L1 and/or PD-L2. The

> *Bifidobacterium bifidum* downregulates the PD-1 receptor's expression, leaving less PD-1 receptor capable of activation. Thus, the anti-tumor activities of the *Bifidobacterium bifidum* and anti-PD1 antibody are additive. Indeed, Korman '401 acknowledges that decreasing the absolute activity of the PD-1 receptor results in lessening immune suppression.

Id.

Patent Owner's argument with respect to the anticancer effect of the probiotic of Mohania being due to reduction of T-cells as opposed to downregulation of PD-1 expression is also unpersuasive. Mohania states "[f]eeding rats with probiotic Dahi or piroxicam treatment *decreased the expression of PD-1* in DMH-induced colorectal mucosa. Combined treatment with probiotic Dahi and piroxicam was significantly more effective in reducing the expression of PD-1." Ex. 1008 Abstract (emphasis added.) Mohania makes it clear that the anticancer effects are due to downregulation of PD-1, supporting Dr. Braun's conclusion that the effects of the CPI in Korman and the *Bifidobacterium* of Mohania are additive. Ex. 1002 ¶ 203; Ex. 1008, 106. With respect to Patent Owner's contention that Petitioner has failed to overcome Patent Owner's argument in prosecution that *Bifidobacterium* are immunosuppressive and would not be combined with an immunostimulatory agent such as a CPI, as discussed above, the record shows that the immunostimulatory or immunosuppressive trait of *Bifidobacterium* is species specific, and in some cases, strain specific. Patent Owner has provided no evidence that the species of *Bifidobacterium* are immunosuppressive. Petitioner has demonstrated that the CPI of Korman and the *Bifidobacterium* of Mohania and Prakash are effective in treating colorectal cancer and that the effects of the agents are additive. On the record before us, we find that Petitioner has established that

one skilled in the art would have been motivated to combine the teachings of Korman, Mohania and Prakash to produce a method meeting the limitations of at least one of the claims of the ’302 patent.

Based on the record before us, we find that Petitioner has demonstrated that it is more likely than not that at least 1 of the claims challenged under gound 9 unpatentable over Korman combined with Mohania and Prakash.

We also have reviewed Petitioner’s contentions with respect to the teachings of van der Waaij and Topalian. Based on the evidence before us, we conclude that Petitioner has demonstrated that it is more likely than not that at least 1 of the claims challenged under gounds 10 and 11 is unpatentable over Korman combined with Mohania and Prakash and either van der Waaij or Topalian.

G. 35 U.S.C. § 325(d)

Patent Owner urges that we should exercise our discretion under 35 U.S.C § 325(d) and deny the Petition on the grounds that the Examiner has already addressed the issues presented in the Petition. Patent Owner advances two arguments in support of this proposition. Prelim. Resp. 18. First, Patent Owner contends that the Examiner already considered the issue of enablement in during prosecution of the ’302 patent and that Petitioner has not offered any new evidence to show that the Examiner erred in determining that the claims are enabled. Prelim. Resp. 19–20. Second, Patent Owner contends that Petitioner has not presented any evidence that the *Bifidobacterium* species discussed in the references are immunostimulatory, and therefore, Petitioner did not overcome Patent Owner’s arguments in prosecution. Prelim. Resp. 21.

Patent Owner has not persuaded us that we should exercise our discretion and deny the Petition.

We have reviewed the prosecution of the '302 patent and have not found any discussion of the question of enablement. Thus, we are unable to determine what conclusions the Examiner made with respect to enablement, let alone what evidence the Examiner considered in deciding the issue. Patent Owner points to Topalian and Lopez[18] as references considered by the Examiner in deciding whether the claims are enabled. Prelim. Resp. 19. Other than the initialed list of reference considered, Patent Owner does not cite to anything in the prosecution history to show that the Examiner considered these references in conjunction with determining that the claims were enabled.

Moreover, contrary to Patent Owner's assertion that Petitioner has offered no evidence to support Petitioner's arguments regarding enablement other that verbatim testimony from its expert, as discussed above, Dr. Braun cites additional references to support his conclusions of non-enablement. For example, Dr. Braun cites Kandoth, Kumar, Pardoll, and DiMasi to support his conclusions regarding enablement. Ex. 1002 ¶¶ 95–105. We find that Petitioner has offered new evidence concerning the issue of enablement to warrant instituting post grant review to resolve that issue.

Patent Owner's argument regarding the immunostimulatory effect of *Bifidobacterium* is also unpersuasive. As discussed above, Petitioner has presented evidence that at least *Bifidobacterium adolescentis* is immunostimulatory and has advanced a credible argument why one skilled

[18] Lopez et al., *Distinct Bifidobacterium Strains derive different immune responses in vitro*, 138 INT'L J. FOOD MICROBIOL. 157 (2010) ("Lopez") Ex. 1038.

in the art would have combined an anti-PD-1 antibody, a CPI, with *Bifidobacterium bifidum*. Pet. 59-62. On the present record we do not find sufficient reason to exercise our discretion to deny institution of the Petition.

III. CONCLUSION

After considering the evidence and arguments presented in the Petition, we have determined that it is more likely than not that the Petitioner would prevail with respect to at least one of the claims challenged in the Petition. We therefore grant the Petition and institute trial as to all challenged claims on all grounds asserted.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that pursuant to 35 U.S.C. § 324(a), a post grant review is instituted on all challenges raised in the Petition (Pet. 7):

Ground	References	Basis	Claims Challenged
1		§ 112(a) Lack of Enablement	1–29
2	Korman, Singh, and Dong	§ 103(a)	1–9, 12–17, 19–25, 27, and 28
3	Korman, Singh, Dong, and van der Waaij	§ 103(a)	10, 11, and 26
4	Korman, Singh, Dong, and Topalian	§ 103(a)	18 and 29
5	Korman and Kohwi	§ 103(a)	1–4, 7–9, 12–17, 19–25, 27, and 28
6	Korman, Kohwi, and Singh	§ 103(a)	5, 6, 23, and 24
7	Korman, Kohwi, and van der Waaij	§ 103(a)	10, 11, and 26
8	Korman, Kohwi, and Topalian	§ 103(a)	18 and 19

Ground	References	Basis	Claims Challenged
9	Korman, Mohania, and Prakash[19]	§ 103(a)	1–9, 12–17, 19–25, 27, and 28
10	Korman, Mohania, Prakash, and van der Waaij	§ 103(a)	10, 11, and 26
11	Korman, Mohania, Prakash, and Topalian	§ 103(a)	18 and 29

and

FURTHER ORDERED that pursuant to 35 U.S.C. § 324(c) and 37 C.F.R. § 42.4, notice is hereby given of the institution of a trial commencing on the entry date of this Decision.

[19] Prakash et al., US 2010/028449 A1, published Feb. 4, 2010 ("Prakash") Ex. 1009.

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