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Paper 26
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

COALITION FOR AFFORDABLE DRUGS II LLC,
Petitioner,

v.

NPS PHARMACEUTICALS, INC.,
Patent Owner.

Cases IPR2015-01093
Patent 7,056,886 B2

Before LORA M. GREEN, JACQUELINE WRIGHT BONILLA, and SHERIDAN K. SNEDDEN, *Administrative Patent Judges.*

SNEDDEN, *Administrative Patent Judge*.

DECISION
Institution of *Inter Partes* Review
37 C.F.R. § 42.108

I. INTRODUCTION

Coalition for Affordable Drugs II, LLC ("Petitioner") filed a Petition to institute an *inter partes* review of claims 1–45 (Paper 1, "Pet.") of U.S. Patent No. 7,056,886 B2 (Ex. 1003, "the '886 patent"). NPS Pharmaceuticals, Inc., ("Patent Owner") filed a Patent Owner Preliminary Response. Paper 18 ("Prelim. Resp.").

Upon consideration of the above-mentioned Petition and Preliminary Response, we conclude that Petitioner has established that there is a reasonable likelihood that it will prevail with respect to at least one of the challenged claims. We institute an *inter partes* review as to claims 1–27, 31–40, and 44–45 of the '886 patent, but deny the Petition as to claims 28–30 and 41–43.

A. Related Proceedings

The parties inform us of no related litigation between them involving the '886 patent. Pet. 4; Paper 5. Concurrent with the filing of the present Petition, Petitioner also filed a different Petition requesting *inter partes* review of claims 46–52 and 61–75 of the '886 patent (IPR2015-00990). *Id.*

B. The '886 Patent (Ex. 1001)

The '886 patent discloses L-histidine stabilized drug formulations of glucagon-like peptide-2 ("GLP-2") and GLP-2 analogs. Ex. 1003, Abstract. The '886 patent disclosed that the GLP-2/GLP-2 analog formulations of the invention exhibit "superior stability following storage and/or exposure to elevated temperatures." *Id.* The formulations further comprise a phosphate

buffer, L-histidine (as a stabilizing amino acid), and mannitol or sucrose (as a bulking agent). *Id.* at 2:7–27.

The GLP-2 analogs may be agonists or antagonists. *Id.* at 4:19–31. "[A]ntagonists of GLP-2 analogs include any mutation or variation of the naturally occurring GLP-2 peptide which results in the inhibition of intestinotrophic activity of naturally occurring GLP-2 or GLP-2 analogs which exhibit agonist acitivity [sic]." *Id.* at 4:61–67. The GLP-2 analog known as "h[Gly2]GLP-2" is specifically disclosed. *Id.* at 5:21–32.

C. Illustrative Claims

Independent claim 1 is illustrative of the challenged claims, and is reproduced below:

> 1. A glucagon-like peptide 2 (GLP-2) formulation comprising:
> (a) a medically useful amount of a naturally occurring GLP-2 or an analog thereof;
> (b) a phosphate buffer in an amount sufficient to adjust the pH of the formulation to a physiologically tolerable level;
> (c) L-histidine; and
> (d) a bulking agent selected from the group consisting of mannitol and sucrose.

Ex. 1003, 12:9–18.

Claims 2–45 depend from claim 1, directly or indirectly.

D. Asserted Grounds of Unpatentability

Petitioner challenges claims 1–45 of the '886 patent on the following ground. Pet. 21–55.

Ground	References	Basis	Claims challenged
1	Drucker '379,[1] Kornfelt,[2] Osterberg[3]	§ 103(a)	1–27, 33–35, 38, 45
2	Drucker '379, Kornfelt, Osterberg, Munroe[4]	§ 103(a)	31, 32, 44
3	Drucker '379, Kornfelt, Osterberg, Holthuis[5]	§ 103(a)	28–30, 39–43
4	Drucker '547, [6] Kornfelt, Osterberg, Holthuis, Munroe	§ 103(a)	36–37

Petitioner relies also on the Declaration of Dr. Anthony Palmieri III, Ph.D., R.Ph., in support of the proposed grounds of unpatentability. Ex. 1001 ("Palmieri Declaration" or "Palmieri Decl.").

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[1] Drucker et al., U.S. Patent No. 5,789,379, issued August 4, 1998. Ex. 1029 ("Drucker '379").

[2] Kornfelt et al., U.S. Patent No. 5,652,216, issued July 29, 1997. Ex. 1027 ("Kornfelt").

[3] Osterberg et al., *Physical state of L-histidine after freeze-drying and long-term storage*, 8 EP. J. OF PHARM. SCI. 301–308 (1999). Ex. 1030 ("Osterberg").

[4] Munroe et al., *Prototypic G-protein coupled receptor for the intestinotrophic factor glucagon-like peptide 2*, 96 PROC. NAT'L ACAD. SCI. 1569–1573 (1999). Ex. 1022 ("Munroe").

[5] Holthuis et al., U.S. Patent No. 5,496,801, issued March 5, 1996. Ex. 1005 ("Holthuis").

[6] Drucker et al., PCT Publication WO 98/03547, published January 29, 1998. Ex. 1028 ("Drucker '547").

II. ANALYSIS

A. Claim Interpretation

We interpret claims using the "broadest reasonable construction in light of the specification of the patent in which [they] appear[]." 37 C.F.R. § 42.100(b); *see also* Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48,766 (Aug. 14, 2012); *In re Cuozzo Speed Techs., LLC*, 793 F.3d 1268, 1278–79 (Fed. Cir. 2015) ("Congress implicitly approved the broadest reasonable interpretation standard in enacting the AIA," [7] and "the standard was properly adopted by PTO regulation."). Under the broadest reasonable construction standard, claim terms are given their ordinary and customary meaning, as would be understood by one of ordinary skill in the art at the time of the invention. *In re Translogic Tech., Inc*., 504 F.3d 1249, 1257 (Fed. Cir. 2007). "Absent claim language carrying a narrow meaning, the PTO should only limit the claim based on the specification . . . when [it] expressly disclaim[s] the broader definition." *In re Bigio*, 381 F.3d 1320, 1325 (Fed Cir. 2004). "Although an inventor is indeed free to define the specific terms used to describe his or her invention, this must be done with reasonable clarity, deliberateness, and precision." *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994).

We determine that no explicit construction of any specific claim term is necessary to determine whether to institute a trial in this case. *See, e.g.*, *Wellman, Inc. v. Eastman Chem. Co.*, 642 F.3d 1355, 1361 (Fed. Cir. 2011)

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[7] The Leahy-Smith America Invents Act, Pub. L. No. 112–29, 125 Stat. 284 (2011) ("AIA").

("[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)). At this stage of the proceeding, we have not made a final determination as to the construction of any claim term.

B. Principles of Law

An *inter partes* review may be instituted only if "the information presented in the [Petition and Preliminary Response] shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 314(a). To prevail in its challenges to the patentability of the claims, a petitioner must establish facts supporting its challenges by a preponderance of the evidence. 35 U.S.C. § 316(e); 37 C.F.R. § 42.1(d).

Obviousness is a question of law based on underlying determinations of fact. *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966); *Richardson-Vicks Inc. v. Upjohn, Co.*, 122 F.3d. 1476, 1479 (Fed. Cir. 1997). A patent may not be obtained if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains. 35 U.S.C. § 103(a). 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 skill in the art; and (4) objective evidence of nonobviousness, i.e., secondary considerations. *See Graham*, 383 U.S. at

17–18.

In *KSR Int'l Co. v. Teleflex Inc.*, the Supreme Court stated that an invention may be found obvious if trying a course of conduct would have been obvious to a person having ordinary skill:

> When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under § 103.

550 U.S. 398, 421 (2007). "*KSR* affirmed the logical inverse of this statement by stating that § 103 bars patentability unless 'the improvement is more than the predictable use of prior art elements according to their established functions.'" *In re Kubin*, 561 F.3d 1351, 1359 (Fed. Cir. 2009), citing *KSR*, 550 U.S. at 417.

The factual inquiries for an obviousness determination also include secondary considerations based on evaluation and crediting of objective evidence of nonobviousness. *Graham v. John Deere Co.*, 383 U.S. at 17 (1966). Notwithstanding what the teachings of the prior art would have suggested to one with ordinary skill in the art at the time of the invention, the totality of the evidence submitted, including objective evidence of nonobviousness, may lead to a conclusion that the claimed invention would not have been obvious to one with ordinary skill in the art. *In re Piasecki*, 745 F.2d 1468, 1471–72 (Fed. Cir. 1984).

Such a conclusion, however, requires the finding of a nexus to

establish that the evidence relied upon traces its basis to a novel element in the claim and not to something in the prior art. *Institut Pasteur & Universite Pierre et Marie Curie v. Focarino*, 738 F.3d 1337, 1347 (Fed. Cir. 2013). All types of objective evidence of nonobviousness must be shown to have a nexus. *In re GPAC Inc.*, 57 F.3d 1573, 1580 (Fed. Cir. 1995) (nexus generally); *In re Kao*, 639 F.3d 1057, 1069 (Fed. Cir. 2011) (unexpected results); *In re Huang*, 100 F.3d 135, 140 (Fed. Cir. 1996) (commercial success); *Rambus Inc. v. Rea*, 731 F.3d 1248, 1256 (Fed. Cir. 2013) (long-felt need).

Objective evidence of nonobviousness also must be reasonably commensurate in scope with the claim. *In re Kao*, 639 F.3d at 1068. This does not mean that the proffered evidence must reach every embodiment within the scope of the claim, so long as there is an "adequate basis to support the conclusion that other embodiments falling within the claim will behave in the same manner." *Id.*

We analyze the instituted grounds of unpatentability in accordance with the above-stated principles.

C. Asserted Grounds of Unpatentability

1. Scope and Content of the Prior Art

a. Summary of Drucker '379 (Ex. 1029)

Drucker '379 discloses pharmaceutical compositions comprising a therapeutically effective amount of a GLP-2 analog. Ex.1029, 3:23–27. The GLP-2 analogs have intestinotrophic activity. *Id.* at 2:20–23, 15:1–35. The analog h(Gly^2)GLP-2 is disclosed. *Id.* at 6:52–55.

Drucker ’379 discloses formulations for injection buffered to physiologically tolerable pH. *Id.* at 9:35–56. Phosphate buffered saline is disclosed as a suitable buffer. *Id.* at 13:8–33. The GLP-2 formulations may be provided in lyophilized form. *Id.* at 10:25–33.

Drucker ’379 further discloses that the glucagon gene “yields a tissue-determined variety of peptide products that are processed from the 160 residue proglucagon product,” which include glucagon, glicentin, and the two glucagon-like peptides, GLP-1 and GLP-2. *Id.* at 1:17–27.

b. Summary of Kornfelt (Ex. 1027)

Kornfelt discloses stabilized pharmaceutical compositions comprising glucagon and a stabilizing amount of a pharmaceutically acceptable ampholyte, such as histidine. Ex. 1027, 2:21–44. The histidine may be present in an amount from 0.01 to 50 micromoles per mg glucagon in order to obtain the desired stabilization. *Id.* at 2:20–53 and 2:65–67.

The pharmaceutical compositions may also include an “excipient, e.g. for facilitating the lyophilization and rapid and complete redissolution thereof when reconstituting the preparation before use.” *Id.* at 2:45–53. Such excipients include mannitol and sucrose. *Id.* The excipient may be present in an amount of from 10 to 600 micromoles per mg glucagon giving an optimum stabilization. *Id.* at 2:58–60.

c. Summary of Osterberg (Ex. 1030)

Osterberg discloses that “[p]rotein drugs are generally chemically and physically unstable in solution and freeze-drying is frequently used to

obtain an acceptable shelf life . . .” Ex.1030, 301. Osterberg further discloses that the “selection of buffer for a protein formulation is very important.” *Id*. at 303. In this context, Osterberg discloses that “[s]ugars and amino acids protect the protein by preferential exclusion during freezing and by glass formation and/ or by functioning as a water substitute in the dried state.” *Id*. Osterberg teaches that amino acids may act as both a stabilizer and buffer, and highlights L-histidine as one such “multifunctional protein stabilizer.” *Id*. at 301, 307.

Osterberg discloses that:

> Freeze drying of L-histidine from solutions having a pH in the range 4-8 showed that L-histidine has a rather low tendency to crystallize during freeze drying.

Id. at 305.

Osterberg further discloses that:

> Another important observation was that the addition of sucrose abolished the crystallization of L-histidine. The reduced tendency for crystallization of L-histidine is very important in the formulation design. . . .

Id. at 304.

d. Summary of Munroe (Ex. 1022)

Munroe discloses an assay for the screening and identification GLP-2 analogs that uses a cell line that expresses the GLP-2 receptor. Ex. 1022, 1570–71, 1573, Table 2.

e. Summary of Holthuis (Ex. 1005)

Holthuis relates to freeze-dried “preparations containing parathyroid

hormone that has been stabilized with an excipient and buffering agent." Ex. 1005, Abstract, 6:6–58. "Preferred preparations incorporate human PTH(1–84), mannitol as excipient and citrate as buffering agent, and are incorporated in vials as a freeze-dried powder for reconstitution to treat osteoporosis." *Id.* at Abstract. Holthuis discloses that the reconstituted PTH preparations according to the invention are stable. Specifically, Holthuis discloses as follows:

> SDS-PAGE analysis of the reconstituted PTH preparations, performed in the conventional manner, similarly revealed no significant decrease of purity during storage at either pH, temperature and storage temperatures examined, as shown in FIG. 2. Some decrease in purity was revealed by RP-HPLC analysis of the reconstituted formulation, but only at the higher 37° C. storage temperature (0.7% decrease in purity per month of storage), with 4° C. storage showing no significant purity decrease by reversed phase-HPLC analysis. The stability of the intact PTH was also revealed by immunoassay (Allegro) to be constant throughout the storage period at all concentrations, pHs and temperatures evaluated.

Id. at 7:6–18.

f. Summary of Drucker '547 (Ex. 1028)

Drucker '547 discloses GLP-2 antagonists that are structural analogs of the intestinotrophic GLP-2 peptides. Ex.1028, Abstract, 3:29–4:4. The GLP-2 antagonists have been mutated so that at least one amino acid is substituted with an amino acid which does not naturally occur at that position in the reference GLP-2. *Id.* at 2:25–36. For example, amino acid positions of human GLP-2 at Asp^{15}, Phe^{22}, Thr^{29}, Thr^{32}, and Asp^{33} may be

substituted with an amino acid which does not naturally occur at that position. *Id.* In another example, position Ala^2 is substituted with any one of Leu, Cys, Glu, Arg, Trp, and PO_3–Tyr. *Id.*

2. Grounds 1, 2, and 4: Obviousness of Claims 1–27, 31–38, and 44–45 over the Combination of Drucker '379, Kornfelt, Osterberg, Munroe, and Drucker '547

a. Petitioner's Contentions

In Ground 1, Petitioner contends that claims 1–27, 33–35, 38, and 45 would have been obvious over the combination of Drucker '379, Kornfelt, and Osterberg. Pet. 22–42. Petitioner contends that Drucker '379 discloses a pharmaceutical composition comprising a therapeutically effective amount of a GLP-2 analog meeting the requirement of claim 1 for "a medically useful amount of a naturally occurring GLP-2 or an analog thereof." *Id.* at 28–29 (citing Ex. 1029, 3:23–27, 11:22–26, 13:8–33; Ex.1001 ¶¶ 49–51). Drucker '379 specifically discloses the h(Gly2)GLP-2 analog. *Id.* at 25 (citing Ex. 1029, 6:52–55; Ex. 1001 ¶ 67).

Petitioner further relies on Drucker '379 for the use of phosphate buffered saline to buffer the formulation at a physiologically tolerable pH, thus meeting element (b) of claim 1. *Id.* at 28–29 (citing Ex. 1029, 13:8–33).

The formulation of Drucker '379 does not include L-histidine, as required by claim 1. For this claim element, Petitioner relies on the teachings of Kornfelt and Osterberg. Petitioner contends that Kornfelt teaches L-histidine as a stabilizing amino acid useful in the formulation of

protein drugs across a broad range of pH levels (pH 1–7). Pet. 22 (citing Ex.1027, 3:9–11; Ex. 1001 ¶ 101). Petitioner further contends that Kornfelt discloses an amount of L-histidine per mg of peptide (i.e., glucagon) that is within the range specified by the claims. *Id.* at 24 (citing Ex. 1027, 2:65–67; Ex. 1001 ¶ 63.); *see* Ex. 1003, claim 16 ("about 0.5 to about 1% L-histidine"). Additionally, Petitioner contends that Osterberg further supports a finding that L-histidine was well known as a buffer and a stabilizing agent useful in lyophilized pharmaceutical formulations of peptides. Pet. 22 (citing Ex.1030, 305, 307; Ex. 1001 ¶¶ 55–58, 101).

With regard to the use of mannitol or sucrose as a bulking agent, Petitioner contends that "sucrose and mannitol were both well known as conventional bulking agents or excipients in the art of pharmaceutical formulations prior to the effective filing date of the '886 patent as described in Osterberg and Kornfelt." Pet. 17 (citing Ex. 1027, 2:43–57; Ex. 1030, 301; Ex. 1001 ¶¶ 37, 65).

In Ground 2, Petitioner further relies on Munroe to meet the elements of dependent claims 31, 32, and 44. Pet. 27–28, 40–42. Petitioner contends that Munroe discloses an assay for the screening and identification GLP-2 analogs. *Id.* at 27, 40 (citing Ex. 1022, 1570–73 and Table 2; Ex.1001 ¶¶ 76–77).

In Ground 4, Petitioner further relies on Drucker '574 to meet the elements of dependent claims 36 and 37. Pet. 15, 46–48. Petitioner contends that Drucker '574 discloses a GLP-2 formulation containing the specific GLP-2 antagonists specified in claim 36 and 37. Pet. 46–47 (citing

Ex.1028, 2:7–37; Ex, 1001 ¶ 88).

In support of its assertion that the challenged claims would have been obvious, Petitioner sets forth the foregoing teachings of Drucker '379, Kornfelt, Osterberg, Munroe, and Drucker '574 and provides a detailed claim chart explaining how each claim limitation is disclosed in the combination of references. Pet. 22–42, 46–48. Petitioner contends that one would have had a reason to combine the teachings of Drucker '379, Munroe, and Drucker '547, disclosing buffered GLP-2 analog formulations, with Osterburg and Kornfelt, because Osterburg and Kornfelt disclose the use of L-histidine in combination with an excipient such as mannitol or sucrose in protein formulations for the purposes of protein stabilization. *Id.* at 49–52. In particular, Petitioner contends that because all the elements of the invention are described in the combined references, and because the prior art provides guidance for preparing storage stable lyophilized formulations for peptide formulations, "[t]he claimed GLP-2 formulation is nothing more than a combination of known ingredients for a predictable result of stability as confirmed by routine testing." *Id.* at 48–49 (citing *Pfizer, Inc. v. Apotex, Inc*., 480 F.3d 1348 (Fed. Cir. 2007); Ex.1001 ¶ 91); *see also, id.* at 50 ("[O]ne of ordinary skill in the art would certainly recognize that the same storage stable formulation can be applied to molecules structurally similar to glucagon like GLP-2."). Petitioner also argues that one of ordinary skill in the art would have had a reasonable expectation of success in "formulating GLP-2 in combination with L-histidine and sucrose or mannitol to create a lyophilized storage stable formulation in view of the combination of

references cited in this petition for IPR." *Id.* at 52–55.

b. Patent Owner's Contentions and Analysis

(1) Petition Fails to Articulate Sufficient Motivation to Combine the References or Establish a Reasonable Expectation of Success

Patent Owner contends that the Petition does not adequately address the differences between glucagon and GLP-2 and, thus, "it would not be predictable that each could interact similarly or could be stabilized in formulation by L-histidine." Prelim. Resp. 22–28. For example, Patent Owner argues that glucagon (the peptide disclosed in Drucker '379) and GLP-2 "share almost no biochemical properties, are processed differently from proglucagon in different tissues, and perform entirely different functions." *Id.*

We note the differences between glucagon and GLP-2 identified by Patent Owner (*id.*), and also note the similarities between GLP-2 and other protein drugs identified by Petitioner (Pet. 15–16). At this stage of the case, however, we find that Petitioner has offered sufficient evidence to institute trial. The information relied upon in the Petition tends to suggest that L-histidine has a stabilizing effect on peptide drugs generally, indicating that properties of peptides affecting L-histidine association (and, therefore, peptide stabilization) are relevant in a manner distinct from properties of peptides affecting biological activity of the peptides. Ex. 1027; Ex. 1030; Ex. 1001, ¶¶ 37, 48, 55, 83, 93–97.

Patent Owner also argues that:

> Petitioner ignores that peptide stabilization is far from routine or predictable. There are many factors that can cause destabilization and degradation.

Prelim. Resp. 25 (citing Ex. 2039). As indicated above, at this stage of the case, we find Petitioner has shown sufficiently that a person of ordinary skill in the art would have had a reasonable expectation of success in formulating GLP-2 in combination with L-histidine and sucrose or mannitol to create a lyophilized storage stable formulation in view of the guidance set forth in the prior art. Ex. 1027; Ex. 1030; Ex. 1001, ¶¶ 37, 48, 55, 83, 93–97; *see In re O'Farrell*, 853 F.2d 894, 903 (Fed. Cir. 1988) (stating that a reasonable expectation of success does not require absolute predictability). We note that at this stage of the proceeding, we have not made a final determination as to the patentability of any one of claims 1–27, 31–40, and 44–45.

(2) Secondary Considerations

Patent Owner contends that secondary considerations support a finding of nonobviousness of the claims. Prelim. Resp. 28–29. Specifically, Patent Owner contends that GATTEX®, a commercial formulation of the claims, met a long felt need and is a commercial success.

At this stage of the proceeding, we are not persuaded for the reasons discussed below.

i. Long-Felt Need

Among the secondary considerations that must be considered is the existence of a long-felt but unsolved need. *Graham*, 383 U.S. at 17–18. Patent Owner, however, does not present sufficient evidence of long-felt

need, but instead relies on argument and conclusory contentions, which we find insufficient to indicate non-obviousness of the challenged claims. Prelim. Resp. 28–29; Ex. 1001, ¶ 92; Ex. 1024, 2.[8] For example, Patent Owner does not provide evidence sufficient to permit a determination as to whether the long-felt need was met by the discovery of GLP-2 analogs having the necessary activity (disclosed in the prior art), or the use of L-histidine and mannitol or sucrose in a stabilized GLP-2 analog formulation. As such, the record before us does not sufficiently indicate that the claimed subject matter itself satisfied a long-felt need. *See Texas Instruments v. U.S. Int'l Trade Comm'n*, 988 F.2d 1165, 1178 (Fed.Cir.1993) ("[L]ong-felt need is analyzed as of the date of an articulated identified problem and evidence of efforts to solve that problem."); *Iron Grip Barbell Co. v. USA Sports, Inc.*, 392 F.3d 1317, 1325 (Fed. Cir. 2004) ("Absent a showing of long-felt need or the failure of others, the mere passage of time without the claimed invention is not evidence of nonobviousness."); *accord In re Wright*, 569 F.2d 1124, 1127 (CCPA 1977).

ii. Commercial Success

A showing of nexus between commercial success and claimed subject matter involves establishing that novel elements in the claim, not prior art elements, account for the objective evidence put forward to show nonobviousness. *In re Kao*, 639 F.3d at 1068.

Patent Owner states that:

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[8] Cleland et al., *Formulation and Delivery of Proteins and Peptides*, AMERICAN CHEMICAL SOCIETY, Washington D.C., Chapter 1 (1994).

> The nexus between the sale of GATTEX® and the challenged claims is self-evident. Stabilization of the GLP-2 analog, which was difficult, allows GATTEX® to have a sufficient shelf life for commercialization.

Prelim. Resp. 29 (citing Ex. 2039).

As discussed above, however, GLP-2 formulations buffered with phosphate buffered saline were known in the prior art. Pet. 28–29 (citing Ex. 1029, 13:8–33). We cannot tell from the record before us if the asserted commercial success was due to the sale of a buffered formulation comprising GLP-2 generally, as compared to a buffered GLP-2 formulation comprising L-histidine and mannitol or sucrose, as recited in the challenged claims. Thus, there is insufficient information on the current record to establish sufficient nexus between the commercial success of the product and any novel element recited in the claims.

(3) Priority of the '886 Patent

The '886 patent claims the priority of its parent GB Application No. 9930882, filed December 30, 1999. Ex. 1003, 1; Prelim. Resp. 30. Osterberg was published in August 1999. Ex. 1030; Pet. 19. According to Patent Owner, Petitioner fails to demonstrate that the '886 patent is not entitled to the benefit of its priority application, and therefore Petitioner fails to establish that Osterberg qualifies as prior art under § 102(b). Prelim. Resp. 29–31. Patent Owner argues that the Petition should be denied on this basis because each of Petitioner's grounds for unpatentability of the challenged claims relies on Osterberg. *Id.*

Osterberg was published prior to the asserted foreign priority date of December 30, 1999, for the ’886 patent, and is therefore available as prior art under 35 U.S.C. § 102(a). On the current record, the distinction between § 102(a) and § 102(b) does not impact materially our conclusion that there is a reasonable likelihood that Petitioner will prevail with respect to at least one of the challenged claims. We decline to deny the Petition on the basis that Osterberg is unavailable as prior art under § 102(b) when the record before us indicates it is available as prior art under § 102(a).

c. Conclusion

Based on the current record, we are persuaded that a person of ordinary skill in the art would have recognized the above-mentioned teachings, and would have had a reason to combine these prior art disclosures with a reasonable expectation of success in arriving at the claimed subject matter. The information set forth in the Petition is sufficient to establish that buffered pharmaceutical formulations of GLP-2 analogs were known and that Osterburg and Kornfelt suggests that the use of L-histidine in combination with an excipient such as mannitol or sucrose in protein formulations was a predictable variation within the technical grasp of a person of ordinary skill in the art done for the purposes of protein stabilization. *KSR*, 550 U.S. at 416 (“If a person of ordinary skill in the art can implement a predictable variation, and would see the benefit of doing so, § 103 likely bars its patentability.”). Accordingly, we conclude that Petitioner has established a reasonable likelihood of prevailing on its assertion that claims 1–27, 33–35, 38, and 45 are unpatentable as obvious

over the combination of Drucker ’379, Kornfelt, and Osterberg. Additionally, we conclude that Petitioner has established a reasonable likelihood of prevailing on its assertion that claims 31, 32, and 44 are unpatentable as obvious over the combination Drucker ’379, Kornfelt, Osterberg, and Munroe. Finally, we conclude that Petitioner has established a reasonable likelihood of prevailing on its assertion that claims 36 and 37 are unpatentable as obvious over the combination Drucker ’379, Kornfelt, Osterberg, and Drucker ’574.

3. Ground 3: Obviousness of Claims 28–30 and 39–43 over the Combination of Drucker ’379, Kornfelt, Osterberg, and Holthuis

Petitioner contends that dependent claims 28–30 and 39–43 would have been obvious over the combination of Drucker ’379, Kornfelt, Osterberg, and Holthuis. Pet. 42–46. Petitioner relies on Osterberg and Holthuis for the elements of those dependent claims. Pet. 42–46.

a. Claims 28–30 and 41–43

Claims 28–30 are directed to lyophilized GLP-2 formulations having less than about 5%, 4%, or 2% degradation. Ex. 1003, 13:33–42. Claims 41–43 are directed to a GLP-2 formulation of claim 1 that is stable at 4° C for up to 18 months, as evidenced by a degradation of less than 5%, 4%, or 2%. *Id.* at 14:14–22.

Petitioner contends that “Holthuis discloses conditions of lyophilization that result in less than 5%, 4%, and 2% degradation.” *Id.* (citing Ex.1005, 7:6–17; Ex. 1001 ¶ 83). Petitioner contends that Holthuis discloses stability of a peptide hormone at 4° C for at least 9 months. *Id.*

(citing Ex.1005, 6:50–58, 7:6–17; Ex.1001 ¶ 83). Petitioner further relies on Osterberg for its teaching that "samples freeze-dried with a thermal cycle (stored at 2–8°C for 2 years) revealed some crystallinity, which decreased as the pH decreased (Fig. 7)." Pet. 43 (citing Ex. 1030, 306).

We note that the formulations and "conditions of lyophilization" disclosed in Holthuis are not substantially identical to the formulations and conditions disclosed in the '886 patent and recited in the challenged claims. Pet. 34–35. For example, the protein preparation disclosed in Holthuis contains a different protein and does not contain L-histidine. *See* Ex. 1005, 6:6–10 ("Aqueous PTH preparations were first prepared for subsequent freeze-drying by mixing human PTH(1–84), as hormone; mannitol, as excipient; and a citrate source, as buffering agent."). With regard to Petitioner's reliance on Osterberg, we note that Osterberg measures crystallinity, and there is insufficient information provided in the Petition to establish a link between reduced crystallinity, disclosed in Osterberg, with the reduced protein degradation seen in Holthuis. Accordingly, we are not persuaded that reliance on Holthuis or Osterberg, without more, is sufficient to establish that the results achieved by Holthuis necessarily would be achieved with a GLP-2 formulation prepared from a combination of the cited references. *Cf. Perricone v. Medicis Pharm. Corp*., 432 F.3d 1368, 1378 (Fed. Cir. 2005) (where prior art reference "discloses the very same methods" as the invention, "then the particular benefits" of the invention "must naturally flow from those methods even if not recognized as benefits" in the reference).

Petitioner further relies on the declaration of Dr. Palmieri to support their argument that formulations having less than about 5%, 4%, or 2% degradation were known in the art. Pet. 42; Palmieri Decl., ¶¶ 83–84. Dr. Palmieri testified as follows:

> While specific percentages are not set forth, it is my opinion that the combination of the Osterberg and Holthuis disclosures describing no significant decrease in purity would correspond to percentages of degradation less than 5%, 4%, and 2%.

Palmieri Decl., ¶ 84. Dr. Palmieri, however, fails to provide sufficient underlying data such that one of ordinary skill in the art would have a reasonable basis to believe that his opinion is correct. Absent some underlying facts or data to support this conclusory testimony, such testimony is entitled to little, if any, weight. *See* 37 C.F.R. § 42.65 ("Expert testimony that does not disclose the underlying facts or data on which the opinion is based is entitled to little or no weight.").

Accordingly, we conclude that Petitioner does not supply us with sufficient information to establish that the lyophilized formulation suggested by the combination of Drucker '379, Kornfelt, and Osterberg necessarily achieves the results required by claims 28–30 and 41–43. As such, we conclude that Petitioner has failed to establish a reasonable likelihood of prevailing on its assertion that claims 28–30 and 41–43 would have been obvious over the combination of Drucker '379, Kornfelt, Osterberg, and Holthuis.

b. Claims 39 and 40

Claims 39 and 40 are directed to lyophilized formulations comprising

less than 5% or 2% water by weight. Ex. 1003, 14:10–13. With regard to claims 39 and 40, Petitioner contends that Holthuis discloses a lyophilized formulation of a peptide hormone that has 2% water or less. Pet. 43 (citing Ex.1005, 7:19–23; Ex.1001 at ¶ 85). Specifically, Holthuis discloses that:

> Residual moisture in the PTH preparation was determined by the standard Karl-Fischer technique and indicated that the water content of all freeze-dried preparations remained below 2% by weight, and typically at about 1% by weight, throughout the storage period.

Ex. 1005, 7:19–24.

Petitioner further relies on the on the declaration of Dr. Palmieri, who testifies that "[t]he level of moisture required by claims 38 and 39 were standard in the art the time of the invention." Ex. 1001 ¶ 85 (citing Ex. 1031, 1545[9] ("The [freeze-drying] process continues until the product is dry (usually 1% or less of moisture).")).

Based on the current record, we are persuaded that a person of ordinary skill in the art would recognize that lyophilization of a protein formulation inherently results in the formulation having 2% water or less. Accordingly, we conclude that Petitioner has established a reasonable likelihood of prevailing on its assertion that claims 39–40 would have been obvious over the combination of Drucker '379, Kornfelt, Osterberg, and Holthuis, as evidenced by Ex. 1031.

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[9] *Remington: The Science and Practice of Pharmacy*, Vol. II, 19th edition, Mack Publishing Co., Easton, PA. 1995 (Ex. 1031).

D. Patent Owner's Additional Contentions

1. Petition Should Be Denied Because It Fails to Identify All Real Parties-in-Interest

A petition for *inter partes* review may be considered "only if" it identifies all real parties in interest ("RPIs"). 35 U.S.C. § 312(a)(2) ("A petition filed under section 311 may be considered only if . . . the petition identifies all real parties in interest . . . ."). That statutory requirement, thus, defines a "threshold issue" for substantive review of the merits of the challenges presented in the petition. *See ZOLL Lifecor Corp. v. Philips Elec. N. Am. Corp.*, Case IPR2013-00606, slip op. at 8 (PTAB Mar. 10, 2014) (Paper 13). The identification of RPIs must be made as part of a petitioner's mandatory notices, which are required to be filed as a part of the petition. 37 C.F.R. § 42.8(a)(1). The only provision made in our Rules for subsequently updating the identification of RPIs is "within 21 days of a change in the information," i.e., a change in the status of a party as RPI. 37 C.F.R. § 42.8(a)(3). Otherwise, we have held that correcting the identification of RPI listed in a petition results in a loss of the petition's filing date. *See Askeladden LLC v. McGhie*, Case IPR2015-00122, slip op. at 2 (PTAB Mar. 6, 2015) (Paper 34).

We generally accept a petitioner's identification of real parties in interest at the time of filing the petition. *See* Changes to Implement *Inter Partes* Review Proceedings, Post-Grant Review Proceedings, and Transitional Program for Covered Business Method Patents; Final Rule, 77 Fed. Reg. 48,680, 48,695 (Aug. 14, 2012). Thus, there is a rebuttable presumption that a petitioner's identification of real parties in interest is

accurate. However, when a patent owner provides sufficient rebuttal evidence that reasonably brings into question the accuracy of the petitioner's identification, the ultimate burden of proof remains with the petitioner to establish that it has complied with the statutory requirement of 35 U.S.C. § 312(a)(2) to identify all real parties in interest. *Zerto, Inc. v. EMC Corp.*, Case IPR2014-01254, slip op. at 6–7 (PTAB Feb 12, 2015) (Paper 32).

"Whether a party who is not a named participant in a given proceeding nonetheless constitutes a 'real party-in-interest' . . . to that proceeding is a highly fact-dependent question." 77 Fed. Reg. 48,756, 48,759 (Aug. 14, 2012) (Trial Practice Guide). "[T]he spirit of that formulation as to IPR . . . proceedings means that, at a general level, the 'real party-in-interest' is the party that desires review of the patent. Thus, the 'real party-in-interest' may be the petitioner itself, and/or it may be the real party or parties at whose behest the petition has been filed." *Id*. (emphasis added). "Courts invoke the terms 'real party-in-interest' and "privy' to describe relationships and considerations sufficient to justify applying conventional principles of estoppel and preclusion." *Id*. The determination of whether a non-party is a real party-in-interest involves a consideration of "control." *Id*.; *see also, Benson & Ford, Inc. v. Wanda Petroleum Co*., 833 F.2d 1172, 1174 (5th Cir. 1987) ("To have control of litigation requires that a person have effective choice as to the legal theories and proofs to be advanced in behalf of the party to the action. He must also have control over the opportunity to obtain review.") (quoting *Restatement (Second) of Judgments* 39, comment c (1982)).

The non-party's participation may be overt or covert, and the evidence

may be direct or circumstantial—but the evidence as a whole must show that the non-party possessed effective control from a practical standpoint. *Gonzalez v. Banco Cent. Corp*., 27 F.3d 751, 759 (1st Cir. 1994). The inquiry is not based on isolated facts, but rather must consider the totality of the circumstances. *Id*.

In this case, the Petitioner names Coalition For Affordable Drugs II LLC ("CFAD"), Hayman Credes Master Fund, L.P. ("Credes"), Hayman Orange Fund SPC – Portfolio A ("HOF"), Hayman Capital Master Fund, L.P. ("HCMF"), Hayman Capital Management, L.P. ("HCM"), Hayman Offshore Management, Inc. ("HOM"), Hayman Investments, L.L.C. ("HI"), nXn Partners, LLC ("nXnP"), IP Navigation Group, LLC ("IPNav"), J Kyle Bass, and Erich Spangenberg as the real parties in interest (collectively, "named RPI"). Pet. 3. Petitioner further represents as follows:

> Other than HCM and J Kyle Bass in his capacity as the Chief Investment Officer of HCM and nXnP and Erich Spangenberg in his capacity as the Manager/CEO of nXnP, no other person (including any investor, limited partner, or member or any other person in any of CFAD, Credes, HOF, HCMF, HCM, HOM, HI, nXnP or IPNav) has authority to direct or control (i) the timing of, filing of, content of, or any decisions or other activities relating to this Petition or (ii) any timing, future filings, content of, or any decisions or other activities relating to the future proceedings related to this Petition. All of the costs associated with this Petition will be borne by HCM, CFAD, Credes, HOF and/or HCMF.

Pet. 4.

Patent Owner contends that the shareholders of Petitioner should have been designated as real parties in interest. Prelim. Resp. 31–43. Patent

Owner alleges that Mr. Bass successfully pitched "wealthy individuals and institutions to invest in a dedicated fund that would bet against, or short, the shares of [target] companies . . . and wager on rivals that could benefit." Prelim. Resp. 34–35 (citing Ex. 2035, 4). The strategy allegedly involves 80% of the profits resulting from the investments to be returned to investors, while "Mr. Bass's firm will keep 20% of all profits earned." *Id.* (quoting Ex. 2035, 4). Patent Owner contends that this strategy renders Petitioner a "nominal petitioner for high net worth investors who profit by bringing IPRs and manipulating stocks." *Id.* at 34. We disagree.

Based on the record before us, Patent Owner does not point to sufficient evidence indicating that any entity, other than the named RPIs, was involved in the filing of the present Petition or had the opportunity to direct the filing or conduct of the present Petition. Rather, the evidence tends to suggest that the shareholders identified by Patent Owner are passive investors who contributed funds to be invested at the behest of, for example, Mr. Bass, a named RPI. As explained by Patent Owner, Mr. Bass sought investments from certain entities, but such evidence does not suggest he was paid by any entity to initiate any particular *inter partes* review. That is, the evidence does not suggest that any investor in a named RPI directed Petitioner or a named RPI, such as Mr. Bass, to challenge the '886 patent. Rather, evidence indicates that a business strategy of Mr. Bass involves seeking investment funds where he is paid 20% of any profits earned off the investment of those funds, which he directs. *Id.* at 34–35 (citing Ex. 2035, 4). The evidence of record does not support sufficiently a finding that an unnamed party controlled the investment decisions prompting the filing of

the present Petition.

Further, while the expenses associated with the present cases are being paid for by funds contributed by investors (Prelim. Resp. 33), the funding of an *inter partes* review, absent other indicia of control, is not necessarily sufficient to render a party a real party in interest. 77 Fed. Reg. at 48759–60 (citing *Taylor v. Sturgell*, 553 U.S. 880 (2008)); *Wavemarket Inc. v. Locationet Sys. Ltd*., IPR2014-00199, Paper 34, 5 (Aug. 11, 2014). Here, for example, Patent Owner has not shown sufficiently that an unnamed party co-authored the present Petition or exerted control over its content, or could exert any control over any aspect of the current case, in particular.

Finally, Patent Owner argues that "hedge fund investors often can negotiate their individual rights as conditions to their investment." Paper 8, 3. We granted Patent Owner's request for additional discovery on this issue, requiring Petitioner to identify any agreements affecting control of this proceeding. Paper 13. No such agreements were identified. Prelim. Resp. 32 n.14.

Based on the particular facts of this case, in view of the evidence before us, we are not persuaded that Patent Owner has provided sufficient rebuttal evidence to show that the present Petition fails to satisfy the requirement of § 312(a)(2) to identify all real parties in interest.

2. Abuse of Inter Partes Review Process

In its Preliminary Response, Patent Owner argues that the Petition was filed for an improper purpose and should be denied. Prelim. Resp. 41–42. Patent Owner contends that Petitioner is not using *inter partes*

review (IPR) as an alternative to court proceedings, as Congress intended, because Petitioner could never commence a district court case involving the '886 patent due to Petitioner's lack of standing. *Id*. Rather, according to Patent Owner, Petitioner is misusing the IPR process as part of a "short activist" investment strategy "coupled with a deceptive marketing plan" that amounts to "[m]isrepresentations [that] defraud the entire market and, consequently, affect the [Patent Owner's] stock price." Paper 21, 4–6.[10]

We take no position on the merits of short-selling as an investment strategy and note only that Patent Owner does not contend that such a strategy is illegal or unregulated. The purposes of the America Invents Act ("AIA") are not limited to providing a less costly alternative to court proceedings. Another purpose of the AIA is to encourage the filing of legitimate patentability challenges in an effort to further improve patent quality. *See In re Cuozzo Speed Technologies, LLC*, 793 F.3d 1297, 1300 (Fed. Cir. 2015) ("Congress created IPRs as a 'new post-grant review procedure' that would provide 'a more efficient and streamlined patent system that will improve patent quality and limit unnecessary and counterproductive litigation costs.'") (quoting H.R. Rep. No. 112–98, pt. 1, at 40, 45 (2011), 2011 U.S.C.C.A.N. 67; *see also*, 77 Fed. Reg. 48,680 (Aug. 14, 2012) (codified at 37 C.F.R. §§ 42.100, *et seq*.)); *see also, Coalition For Affordable Drugs VI, LLC, v. Celgene Corp.*, Case IPR2015-01092 (PTAB

[10] In the Order of September 23, 2015, we asked the parties to submit briefs addressing whether the Petition should be dismissed for abuse of process. Paper 19. Patent Owner submitted a brief (Paper 21), and Petitioner filed an opposition (Paper 22).

Sept. 25, 2015) (Paper 19) (denying a motion for sanctions that alleges abuse of the IPR process).

Along those lines, providing a forum for legitimate patentability challenges serves a strong public interest in facilitating the removal of poor quality patents from the public arena. *See Lear v. Adkins*, 395 U.S. 653, 656 (1969) (emphasizing a "strong federal policy favoring free competition in ideas which do not merit patent protection"); *Pope Manufacturing Co. v. Gormully*, 144 U.S. 224, 234 (1892) ("It is as important to the public that competition should not be repressed by worthless patents."); *SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331, 1354 (Fed. Cir. 2005) ("Both this court and the Supreme Court have recognized that there is a significant public policy interest in removing invalid patents from the public arena.").

Here, Patent Owner does not allege that Petitioner filed a non-meritorious patentability challenge that amounts to abuse. Prelim. Resp. 44–46; *see also*, Paper 21 ("[T]he merits (if any) of the IPR are irrelevant, because an improper purpose cannot be cured by arguing a potentially proper one, i.e., any IPR might be said to touch upon patent quality."). As discussed herein, we find the Petition raises challenges having a reasonable likelihood of prevailing. Accordingly, based on the record before us, we decline to deny the Petition for abuse of process under our rules.

3. Board Should Exercise Its Discretion under 35 U.S.C. § 325(d) to Deny the Petition Because It Relies on Substantially the Same Art and Arguments Previously Considered by the Office

Patent Owner requests that we exercise our discretion under 35 U.S.C.

§ 325(d) to deny the Petition because it relies upon prior art and arguments that are the same or substantially the same as considered during the prosecution of the '886 patent. Prelim. Resp. 8–21. According to Patent Owner, the Examiner considered Kornfelt during prosecution. *Id*. at 9. Patent Owner states that Drucker '379 was not before the Examiner, but that the technology disclosed by Drucker '379 was considered by the Examiner because Drucker '379 is merely cumulative of Knudsen[11]—that is, "the substance of the Examiner's prior art rejections is unchanged by Petitioner." *Id.* at 8–9.

Patent Owner acknowledges that Petitioner adds another secondary reference, Osterberg, but contends that Osterberg "is less relevant than Kornfelt" as it "merely discloses that L-histidine functioned as a buffer and stabilizer in lyophilized recombinant factor VIII formulations and how to prevent L-histidine from crystallizing." *Id.* at 9.

During prosecution, the Examiner rejected the subject matter of the challenged claims explaining that:

> Knudsen et al. teach a pharmaceutical composition comprising a GLP-2 derivative or analog, an isotonic agent such as mannitol, a buffer of histidine or sodium phosphate, a pharmaceutical [sic] acceptable carrier, a preservative and a surfactant . . . However, Knudsen et al. do not disclose using histidine as a stabilizing agent.

Ex. 1015, 5–6; Prelim. Resp. 13–14. The Examiner relied on Kornfelt for the disclosure of a stabilizing amount of histidine in a pharmaceutical

[11] Knudsen et al., WO 99/43361. Ex. 1025 ("Knudsen").

preparation comprising glucagon and concluded as follows:

> At the time the invention was made, it would have been obvious that a person of ordinary skill in the art is motivated to prepare a pharmaceutical composition of GLP-2 as indicated by Knudsen et al. with the addition of histidine as a stabilizing agent as taught by Kornfelt et al. because [sic, a] stabilizing amount of histidine has been shown to stabilize glucagon in the formulation.

Ex. 1015, 6.

According to Patent Owner, Applicants overcame the Examiner's rejection by arguing that

> [t]here is no teaching or suggestion in the prior art to combine the teachings of Knudsen with the teachings of Kornfelt to obtain the claimed invention. Kornfelt is directed to a pharmaceutical composition comprising glucagon and a stabilizing amount of a pharmaceutically acceptable ampholyte including, for instance, histidine. Despite similarities in their names, glucagon and a naturally occurring GLP-2, or an analog thereof, are not interchangeable and have different properties, characteristics, and functionality.

Prelim. Resp. 15 (quoting Ex. 1016, 15–17).

Petitioner acknowledges that the Examiner considered Knudsen and Kornfelt during prosecution of the '886 patent, but argues that the Examiner did not consider the combination set forth in the Petition. Pet. 11–14, 19–21.

35 U.S.C. § 325(d) states: "In determining whether to institute or order a proceeding . . . , the Director may take into account whether, and reject the petition or request because, the same or substantially the same prior art or arguments previously were presented to the Office." We are not

persuaded, however, that the same or substantially the same prior art or arguments were previously presented to the Office. Rather, we observe that Petitioner presents different arguments and new supporting evidence that were not before the Examiner during the *ex parte* prosecution of the application that issued as the '886 patent.

Notably, Osterberg was not considered by the Examiner. We find Osterberg to be relevant art, as it provides a study on the use of L-histidine as a protein stabilizer in protein drug formulations. Ex. 1030. In addition to the use of L-histidine as a buffer and stabilizer in freeze-dried formulations of recombinant factor VII and recombinant factor IX, Osterberg provides guidance on the use of L-histidine generally as a multifunctional protein stabilizer in protein formulations. *Id.; cf.* Prelim. Resp. 8–9 (attempting to limit the relevance of Osterberg to recombinant factor VIII formulations). Furthermore, Dr. Palmieri's testimony was not considered by the Examiner.

We are not persuaded that Osterberg is irrelevant to our analysis here, nor that Petitioner's contentions regarding Osterberg are superfluous or repetitive to arguments and prior art addressed during prosecution of the '886 patent. Accordingly, we decline to exercise our discretion under 35 U.S.C. § 325(d).

III. SUMMARY

We conclude that Petitioner has established a reasonable likelihood of prevailing on its assertions that claims 1–27, 31–40, and 44–45 of the '886 patent are unpatentable as obvious. We further conclude that Petitioner has not established a reasonable likelihood of prevailing on its assertions that

claims 28–30 and 41–43 of the ’886 patent are unpatentable as obvious.

IV. ORDER

For the reasons given, it is

ORDERED that the Petition is granted with regard to the following alleged grounds:

(i) Claims 1–27, 33–35, 38, and 45 as obvious over the combination of Drucker ’379, Kornfelt, and Osterberg;

(ii) Claims 31, 32, and 44 as obvious over the combination Drucker ’379, Kornfelt, Osterberg, and Munroe;

(iii) Claims 39–40 as obvious over the combination of Drucker ’379, Kornfelt, Osterberg, and Holthuis; and

(iv) Claims 36 and 37 as obvious over the combination Drucker ’379, Kornfelt, Osterberg, and Drucker ’574;

FURTHER ORDERED that pursuant to 35 U.S.C. § 314(a), *inter partes* review of the ’886 patent is hereby instituted commencing on the entry date of this Order, and pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4, notice is hereby given of the institution of a trial; and

FURTHER ORDERED that the trial is limited to the grounds listed in the Order. No other grounds are authorized.

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