UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

FLUIDIGM, CORP.,
Petitioner,

v.

THE BOARD OF TRUSTEES OF
THE LELAND STANFORD JUNIOR UNIVERSITY,
Patent Owner.

Case IPR2017-00014
Patent 7,695,926 B2


FRANKLIN, Administrative Patent Judge.

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


We have jurisdiction under 35 U.S.C. § 314, which provides that an inter partes review may not be instituted “unless . . . 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). Upon considering the Petition, we determine that Petitioner has shown a reasonable likelihood that it would prevail in showing the unpatentability of claims 1–9 and 11–12. Accordingly, we institute an inter partes review of those claims.

A. Related Proceedings

Petitioner and Patent Owner affirm that they are not aware of any judicial proceeding involving the ’926 patent. Pet 3, Paper 4, 1.

B. The ’926 Patent

The claims of the’926 patent are directed to a kit comprising first and second activation state-specific antibody, wherein each of those antibodies binds to an activation form of respective first and second proteins within one

of the recited signaling pathways, i.e., MAPK, AKT, NFkB, STAT, or WNT. Ex. 1001, 51:20–33. Additionally, the kit comprises instructions for using those antibodies. Id. at 51:21–22. In some embodiments, claims 6–9, the antibodies are uniquely labeled. Id. at 52:44–55. In other embodiments, claims 11–12, the antibodies are immobilized in a solid surface. Id. at 52:58–63.

C. Illustrative Claim

Claim 1 of the ’926 patent is the only independent claim and it is reproduced below:

1. A kit comprising a first activation-state specific antibody and a second activation-state specific antibody and instructions for use of the antibodies, wherein at least one of the antibodies is specific for a phosphorylation site, wherein said first activation state-specific antibody binds to an activation form of a first protein within the MAPK (mitogen activated protein kinase), AKT (homolog of V-akt murine thymoma viral oncogene), NFkB (nuclear factor kappa B), PKC (protein kinase C), STAT (signal transducers and activators of transcription) or WNT (Wingless/Int) signaling pathways, and said second activation state-specific antibody binds to an activation form of a second protein within the MAPK, AKT, NFkB, PKC, STAT or WNT signaling pathways, and wherein said first and second proteins are different proteins.

Ex. 1001, 51:20–33.

D. The Asserted Grounds of Unpatentability

Petitioner challenges the patentability of claims 1–9 and 11–12 of the ’926 patent on the following grounds:
Petitioner also relies upon the Declaration of Tom Huxford, Ph.D. (Ex. 1002).

II. ANALYSIS

A. Claim Construction

In an inter partes review, 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. § 42.100(b); Cuozzo Speed Techs., LLC v. Lee, 136 S. Ct. 2131, 2142 (2016) (affirming applicability of broadest reasonable construction standard to inter

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2 Petitioner asserts that Shen is prior art under pre-AIA 35 U.S.C. § 102(a) or § 102(b). Pet. 18.
partes review proceedings). Under that standard, and absent any special definitions, we give claim terms 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). Any special definitions for claim terms must be set forth with reasonable clarity, deliberateness, and precision. *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994).

The Specification explains, “the term ‘activation state-specific antibody’ or ‘activation state antibody’ or grammatical equivalents thereof, refer to an antibody that specifically binds to a corresponding and specific antigen.” Ex. 1001, 26:55–58. Petitioner recognizes that definition as the broadest reasonable construction of the claim term. Pet. 6–7. Petitioner also asserts, however, that definition encompasses “virtually any antibody, as all antibodies bind to a specific antigen.” *Id.* at 7. Based on that reasoning, Petitioner proposes to construe the term more narrowly to mean “an antibody that specifically binds to a corresponding and specific isoform of an activatable protein.” *Id.* (citing Ex. 1002 ¶¶ 54–55).

Petitioner makes the point that, based on the disclosure of the Specification, a person of ordinary skill in the art at the time of the invention would consider an “activation state-specific antibody” as referring to an “antibody that specifically binds to a corresponding and specific isoform of an activatable protein.” *Id.* We decline, however, to substitute that construction for the definition expressly provided by the Specification, as it is set forth with reasonable clarity, deliberateness, and precision. *See In re Paulsen*, 30 F.3d at 1480. Moreover, independent claim 1 further describes an “activation state-specific antibody” in a manner that identifies such
antibody as one that binds to an activation form of a protein within a specific signaling pathway. Ex. 1001, 51:6–32.

B. Level of Ordinary Skill in the Art


According to Petitioner, a person of ordinary skill in the art at the time of the invention would have had “a Ph.D. in the areas of chemistry, biochemistry, cell biology or molecular biology including five or more years of experience in dealing with antibodies, protein labeling, protein interaction, and protein detection.” Pet. 17 (citing Ex. 1002 ¶¶ 12–13).

At this stage in the proceeding, we determine that Petitioner’s description of the level of ordinary skill in the art is accurate and supported by the current record. Moreover, we have reviewed Dr. Huxford’s credentials (Ex. 1003) and, at this stage in the proceeding, we consider him to be qualified to provide his opinion on the level of skill and the knowledge of a person of ordinary skill in the art at the time of the invention. 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. Anticipation by Shen

Petitioner asserts that claims 1–5 and 11–12 are unpatentable as anticipated by Shen. Pet. 18–28.

1. Shen

Shen discloses a method for detecting protein modification in a sample. Ex. 1016, 1:10–11. Specifically, Shen describes simultaneously assessing the protein modification status of a plurality of target proteins “by contacting the plurality of target proteins with an immobilized capture molecule, or a plurality of immobilized capture molecules, simultaneously” on a solid support. Id. at 1:15–16, 19:24–27. Shen explains that the protein modification can be a phosphorylation, and the capture molecules can be antibodies. Id. at 51. Further, Shen explains that the antibody array may be produced on any suitable solid surface, including in the form of beads, silicon chips, microplates, and a variety of membranes. Id. at 40:11–16.

Shen also discloses kits of the invention comprising “a solid support of 2 or more capture molecules immobilized on the solid support, each of which can specifically bind a target protein that is capable of a subject protein modification,” as well as “a detection molecule specific for the subject protein modification in order to detect whether or not a captured target protein comprises the subject protein modification,” and instructions for using the kit. Id. at 50:22–26.

2. Analysis

“A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” Verdegaal Bros., Inc. v. Union Oil Co. of Cal., 814 F.2d 628, 631 (Fed. Cir. 1987).
Independent claim 1 is directed to a kit comprising a first and a different second activation state-specific antibody, along with instructions for using the antibodies, wherein those antibodies respectively bind to an activated form of a first and a second protein within one of the recited signaling pathways. Petitioner asserts that Shen anticipates the claimed invention. Pet. 19–28. Based on the information presented at this stage of the proceeding, as discussed below, we determine that Petitioner has sufficiently established a reasonable likelihood of prevailing in that regard.

Petitioner describes how Shen discloses each limitation of the claimed invention. *Id.* For example, Petitioner refers to Shen’s disclosure of a kit comprising “2 or more capture molecules immobilized on a solid support, each of which can specifically bind a target protein that is capable of a subject protein modification; . . . and instructions for use of the kit.” *Id.* at 20 (quoting Ex. 1016, 50:21–28). Petitioner refers also to Shen’s disclosure that “[t]he capture molecules on the solid support can be antibodies,” and “[t]he subject protein modification on the solid support can be a phosphorylation.” *Id.* (quoting Ex. 1016, 51:21–22, 13–15).

Petitioner asserts that Shen discloses that at least one of the antibodies is specific for a phosphorylation site by explaining that “[t]he subject protein modification on the solid support can be a phosphorylation and the phosphorylation can comprises [sic] tyrosine, serine or threonine phosphorylation.” *Id.* at 20–21 (alterations in original) (quoting Ex. 1016, 51:13–15). Petitioner asserts also that Shen discloses that the antibodies are specific to 2 or more proteins within the MAPK or AKT signaling pathway by teaching that “the capture molecules [e.g., antibodies] are specific for 2 or more phosphorylated proteins selected from the group consisting of
On the current record, we discern no deficiency in Petitioner’s characterization of Shen’s teachings. Thus, based on the information presented at this stage of the proceeding, Petitioner has shown sufficiently that there is a reasonable likelihood that it would prevail in showing the unpatentability of independent claim 1 as anticipated by Shen. We have considered also Petitioner’s arguments and evidence with respect to the challenged dependent claims. See Pet. 24–28. Based on the current record, we determine that Petitioner has made a sufficient showing that Shen discloses each element of those claims, as well. Accordingly, we institute an inter partes review of claims 1–5 and 11–12 of the ’926 patent as anticipated by Shen.

D. Obviousness over Fleisher

Petitioner asserts that claims 1–9 are unpatentable as obvious over Fleisher. Pet. 28–40.

1. Fleisher

Fleisher is a journal article discussing an investigation of interferon-\(\gamma\) activation of human monocytes using flow cytometry and monoclonal antibodies that distinguish between the native and phosphorylated forms of signal transducer and activator of transcription (1) proteins (“STAT-1”). Ex. 1004, 425. Fleisher explains that its approach “enables rapid and quantitative assessment of STAT-1 phosphorylation on a discrete cell basis
and is both more sensitive and less time consuming than immunoblotting.”

*Id.* In particular, Fleisher describes the method as follows:

Peripheral blood mononuclear cells (PBMC) were . . . prepared in phosphate-buffered saline (PBS) with 2% fetal calf serum and 400 μl aliquots were cultured without or with interferon-γ (100 or 1000 IU/ml in the standard assay) at 37°C for the times indicated. Following incubation, the cells were either treated with specific antibodies or subjected to fixation and permeabilization before antibody addition . . . 100 μl of permeabilization medium . . . together with a specific antibody was added to each cell pellet followed by a 30-min incubation at room temperature. The tubes were then washed, incubated with the appropriate second antibody for 30 min at room temperature, and again washed before being resuspended in 200 μl of PBS for flow cytometry. An augmented fixation and permeabilization method involved the addition of 3 ml of cold methanol while vortexing in between the addition of Reagents A and B (3). The tubes were held for 10 min at 4°C, centrifuged, washed in PBS, and resuspended in permeabilization medium (Reagent B) with antibody as described above.

The precultured unmodified PBMC, fixed and permeabilized (F/P) PBMC, and fixed and permeabilized including methanol (F/P 1 MeOH) PBMC were incubated with 1 μg of murine monoclonal anti-human STAT-1 cytoplasmic terminus (Transduction Laboratories, Lexington, KY), 1 μg of murine IgG2b, 0.1 μg of rabbit anti-human phosphorylated STAT-1 (New England Biolabs, Beverly, MA), or 0.1 μg of rabbit IgG for 30 min as above. The second antibody consisted of either 1 μg of FITC-conjugated F(ab′)2 goat anti-murine IgG (Caltag) or 1 μg of FITC conjugated F(ab′)2 goat anti-rabbit IgG (Caltag) with a 30-min incubation at room temperature as above. Following a final wash step, the cells were resuspended in 200 μl of PBS and analyzed with a flow cytometer.

*Id.* at 425–426. Fleisher also describes using a FACScan, i.e., a fluorescent activated cell sorting (“FACS”) flow cytometer. *Id.* at 426. According to
Fleisher, the disclosed “technique should find applications in the study of multiple phosphorylation-dependent pathways such as those involving other Jak-STAT combinations, IκB, and MAP kinases.” Ex. 1004, 429. Further, Fleisher explains that its approach “should be valuable in studying any activation pathway for which antibody reagents exist that discriminate between a native and an activation modified protein.” Id.

2. Analysis

A conclusion that claimed subject matter is obvious must be supported by evidence, as shown by some objective teaching in the prior art or by knowledge generally available to one of ordinary skill in the art that would have led that individual to combine the relevant teachings of the references to arrive at the claimed invention. In re Fine, 837 F.2d 1071, 1074 (Fed. Cir. 1988).

Petitioner asserts that a person of ordinary skill in the art would have found it obvious to provide the claimed kit comprising materials needed to carry out the methods taught by Fleisher. Pet. 28–40. Based on the information presented at this stage of the proceeding, as discussed below, we determine that Petitioner has sufficiently established a reasonable likelihood of prevailing in that regard.

According to Petitioner, Fleisher teaches a method of detecting the activation state of a first activatable protein, i.e., STAT-1, in single cells using a labeled activation state-specific antibody that is specific for a STAT-1 phosphorylation site, wherein the antibody binds to an activation form of STAT-1. Pet. 29–31. Petitioner acknowledges that Fleisher does not expressly teach using a state-specific antibody to detect the activation state of a second activatable protein. Id. at 28. Petitioner asserts, however, that
Fleisher explains that its method may apply generally to evaluate other activatable signaling proteins, where activation state-specific antibodies exist. *Id.* (citing Ex. 1004, 425; Ex. 1002 ¶ 74).

Further, Petitioner asserts that the following statement in Fleisher suggests other activatable proteins for evaluation: “This technique should find applications in the study of multiple phosphorylation-dependent pathways such as those involving other Jak-STAT combinations, IκB, and MAP kinases.” *Id.* at 28–29 (quoting Ex. 1004, 429). Based on that statement, Petitioner asserts that Fleisher teaches one of skill in the art that its method may be used to analyze multiple different activatable proteins. *Id.* at 29.

Petitioner asserts also that Fleisher’s instruction that its “technique should find application in the study of multiple phosphorylation-dependent pathways,” along with its discussion that the technique may be applied to MAP kinases, would have provided a person of ordinary skill in the art a reason to perform Fleisher’s method using activation state-specific antibodies to detect MAP kinases (ERK1/2 and MEK1/2), in addition to using an activation state-specific antibody to detect the activated STAT-1. Pet. 30 (quoting Ex. 1004, 425, 429) (citing Ex. 1002 ¶¶ 80, 82). Petitioner asserts that Fleisher informed a skilled artisan that such a modification would have only required “the existence of an antibody specific to the activated form of the [additional] proteins of interest.” *Id.* (citing Ex. 1004, 429; Ex. 1002 ¶ 79). Petitioner’s declarant, Dr. Huxford, explains that a person of skill in the art would have known that antibodies specific to the phosphorylated form of ERK1/2 and MEK1/2 were commercially available, e.g., anti-phospho-p44/42 MAPK (Thr202/Tyr204) known to detect
activated ERK 1/2, and anti-phospho-MEK1/2 (Ser217/221) known to detect activated MEK1/2. Ex. 1002 ¶¶ 22–24, 81, 83.

According to Petitioner and Dr. Huxford, a skilled artisan would have understood that applying Fleisher’s method in this manner would provide “a better understanding of the MAPK signaling pathway.” Pet. 31; Ex. 1002 ¶ 82. Petitioner asserts that goal is consistent with Fleisher’s statement describing a benefit of its technique as “permit[ting] dissection of a full range of cellular signaling pathways.” Pet. 32–33 (quoting Ex. 1004, 425, 429).

Moreover, Petitioner notes that Fleisher explains that its technique is “applicable in any setting where immunoblotting has already been useful to dissect intracellular signaling pathways.” Id. at 33 (quoting Ex. 1004, 425). Petitioner asserts that one of skill in the art would have been aware of “numerous immunoblot assays that detected multiple different intracellular signaling proteins at the [same time].” Id. Thus, we understand Petitioner explains that Fleisher’s teachings would have provided a skilled artisan with a reasonable expectation of successfully detecting multiple different activatable proteins by applying Fleisher’s method.

Petitioner asserts that it would have been obvious to provide the necessary first and second activation state-specific antibodies, discussed supra, in a kit because doing so would beneficial in assisting practitioners who only occasionally need to perform an assay such as the one suggested by Fleisher, and providing a kit would likely increase the reliability and ease of performing the assay. Pet. 29 (citing Ex. 1002 ¶ 85).

With respect to the claim recitation that the kit comprises “instructions for use of the antibodies,” Petitioner asserts that claim element should not be
given patentable weight as such “instructions” constitute printed matter. *Id.* at 30 (citing *In re Ngai*, 367 F.3d 1336, 1337–38 (Fed. Cir. 2004) (characterizing kit instructions as printed matter). Alternatively, Petitioner asserts that it would have been obvious for a person of ordinary skill in the art to include instructions with a kit comprising materials to perform Fleisher’s assay to provide a detailed protocol for the use of the included antibodies. *Id.* (citing Ex. 1002 ¶ 85).

On the current record, we discern no deficiency in Petitioner’s characterization of the knowledge in the art at the time of the invention, Fleisher’s teachings, or in Petitioner’s assertions as to the reasonable inferences an ordinary artisan would make from Fleisher. Thus, based on the information presented at this stage of the proceeding, Petitioner has shown sufficiently that there is a reasonable likelihood that it would prevail in showing the unpatentability of independent claim 1 as obvious over Fleisher. We have considered also Petitioner’s arguments and evidence with respect to the challenged dependent claims. *See* Pet. 34–40. Based on the current record, we determine that Petitioner has made a sufficient showing as to those claims, as well. Accordingly, we institute an *inter partes* review of claims 1–9 of the ’926 patent as obvious over Fleisher.

**E. Obviousness over Darzynkiewicz and Yen**

Petitioner asserts that claims 1–9 are unpatentable as obvious over Darzynkiewicz and Yen. Pet. 40–54.

1. *Darzynkiewicz*

Darzynkiewicz is directed to methods, reagents and kits that “permit the concurrent and discriminable detection of discrete functional conformations of proteins within a single cell.” Ex. 1005, 7:2–6. The
invention focuses on the protein encoded by the retinoblastoma susceptibility gene (“pRB” or “pRb”) “which plays a pivotal role in the regulation of the cell cycle.” Id. at 2:23–26. pRB restrains cell cycle progression in a manner that allows tumor suppression. Id. at 2:26–30. Darzynkiewicz explains that pRB activity is controlled by changes in phosphorylation. Id. at 3:4–5. For example, phosphorylated pRB discharges transcription factors, and those factors in turn activate transcription of genes coding for proteins regulating DNA replication and cell proliferation. Id. at 3:13–16. The invention provides methods and materials for “the flow cytometric determination of multiple pRB phosphorylation states in individual cells” using anti-pRB antibodies that distinguish the phosphorylation state of pRB and that may be conjugated to fluorophores to allow concurrent detection of such functional conformations of pRB in single cells. Id. at 7:6–25.

In addition to comprising contacting a cell with a first and a second antibody specific for two different phosphorylation conformations of pRB, id. at 9, Darzynkiewicz explains that the method may further comprise contacting the cell with a third antibody, wherein the third antibody is “specific for a second protein and [is] distinguishable from each of said first and second antibodies, and then detecting the concurrent binding of each of said antibodies to said cell,” id. at 10:8–13. Darzynkiewicz discloses preferred embodiments wherein “the second protein may be a cyclin, a cyclin dependent kinase, or a cyclin dependent kinase inhibitor.” Id. at 10:13–16. Darzynkiewicz teaches that “multiparametric flow cytometric techniques permit more than two antibodies to be discriminably detected in a single assay.” Id. at 27:22–24. As an example, Darzynkiewicz explains that
its methods may be used, along with such antibodies, “to report, concurrently with the phosphorylation status of pRB, the concurrent levels of other proteins that participate in the regulation of the cell cycle.” Id. at 27:28–33.

2. *Yen*

Yen is a journal article describing a study revealing that retinoic acid (“RA”) “augments MEK-dependent ERK2 activation that is needed for subsequent RB hypophosphorylation, cell differentiation, and G0 arrest.” Ex. 1006 Abstract. In the study, Western blotting of RB, MAPK, and activated MAPK was performed, wherein cell membranes were “probed with antibodies detecting the phosphorylated and unphosphorylated forms of RB, ERK2, and ERK1.” Id. at 3165.

3. *Analysis*

Petitioner asserts that a person of ordinary skill in the art would have found it obvious to provide the claimed kit comprising materials needed to carry out the methods taught or suggested by combined teachings of Darzynkiewicz and Yen. Pet. 40–47. Based on the information presented at this stage of the proceeding, as discussed below, we determine that Petitioner has sufficiently established a reasonable likelihood of prevailing in that regard.

In particular, Petitioner asserts that Darzynkiewicz describes providing kits comprising materials needed to perform its assay. Pet. 42. Specifically, Petitioner refers to Darzynkiewicz’s explanation that “any one clinical laboratory may have only sporadic need to perform the assay [of the invention], and there is thus a need for compositions and kits that permit the assay readily to be performed on an as-needed basis,” and its description of
meeting that need, i.e., “the present invention provides reagents and kits that permit the assay readily to be performed on an as-needed basis.” *Id.* at 42–43 (quoting Ex. 1005, 39:28–40:2). With respect to the materials needed in the kit, Petitioner asserts that Darzynkiewicz teaches a method of detecting two different proteins in a single cell. *Id.* at 43 (citing Ex. 1005, 10:13–16). Petitioner acknowledges that Darzynkiewicz does not describe the second protein to be an activated isoform. *Id.* at 40. Petitioner, however, contends that a person of skill in the art would understand from Darzynkiewicz that its method of using distinguishable antibodies inclusively applies to using activation state-specific antibodies specific for an activated isoform of the second protein. *Id.* at 40–41 (citing Ex. 1002 ¶¶ 16–17). Further, according to Petitioner and Dr. Huxford, doing so would not require any change to Darzynkiewicz’s approach. *Id.* at 41 (citing Ex. 1002 ¶ 17).

Petitioner asserts also that Darzynkiewicz applies its method to the human promyelocytic leukemic cell line, HL-60. *Id.* at 43; Ex. 1005, 24:15–16. According to Petitioner and Dr. Huxford, a person of skill in the art would have understood that the HL-60 cell line contains many different activatable and distinct proteins, including retinoblastoma, Ras, ERK1/2 and MEK1/2. Pet. 43 (citing Ex. 1002 ¶¶ 96–97). In further support of that contention, Petitioner refers to Yen’s discussion relating to detecting retinoblastoma in addition to activated ERK1/2, using an activation state-specific antibody specific for activated ERK1/2, to analyze the effect of those proteins on cell cycle regulation. *Id.* at 43–46 (citing Ex. 1006, 3163, 3165).
Petitioner asserts also that Darzynkiewicz describes using “multiparametric flow cytometric techniques to permit more than two antibodies to be discriminably detected in a single assay.” *Id.* at 41–42 (emphasis omitted) (quoting Ex. 1005, 27:22–24). Petitioner refers also to statement in Darzynkiewicz that “these further antibodies may, for example, be used to report, concurrently with the phosphorylation status of pRB, the concurrent levels of other proteins that participate in the regulation of the cell cycle.” *Id.* (quoting Ex. 1005, 27:29–33).

According to Petitioner, the combined teachings of Darzynkiewicz and Yen would have motivated a person of ordinary skill in the art to analyze the effects of cell cycle regulation by concurrently analyzing the activated state of retinoblastoma protein, ERK1/2, MEK1/2, or RAS using the multiparametric flow cytometric method taught by Darzynkiewicz. *Id.* at 42. Further, Petitioner asserts that, when providing the kit described by Darzynkiewicz for performing the assay, it would have been obvious to a person of ordinary skill in the art to include the required and known activation state-specific antibodies specific for the activated proteins of interest. Pet. 44. For example, Petitioner asserts that when analyzing ERK1/2 and MEK1/2, two proteins within the MAPK signaling pathway, it would have been obvious for a skilled artisan to select and include in the kit: (a) a first activation state-specific antibody, anti-phospho-p44/42 MAPK (Thr202/Tyr204) known to detect activated ERK 1/2, and (b) anti-phospho-MEK1/2 (Ser217/221) known to detect activated MEK1/2. Pet. 47 (citing Ex. 1002 ¶¶ 22–24, 99). Dr. Huxford explains that those antibodies, each specific for a phosphorylation site, were commercially available at the time of the invention. Ex. 1002 ¶¶ 22–24, 99.
With respect to the claim recitation that the kit comprises “instructions for use of the antibodies,” Petitioner asserts that claim element should not be given patentable weight as such “instructions” constitute printed matter. Pet. 43 (citing In re Ngai, 367 F.3d 1337–38 (characterizing kit instructions as printed matter)). Alternatively, Petitioner asserts that it would have been obvious for a person of ordinary skill in the art to include instructions with Darzynkiewicz’s kit, as Darzynkiewicz explained the kit was being provided to assist practitioners who “only sporadically need to perform the assay.” Id. at 44 (citing Ex. 1005, 18:16–19; Ex. 1002 ¶ 100). According to Petitioner and Dr. Huxford, those practitioners who only sporadically perform the assay would likely benefit from instructions. Id.

On the current record, we discern no deficiency in Petitioner’s characterization of the knowledge in the art at the time of the invention, the teachings of Darzynkiewicz and Yen, or in Petitioner’s assertions as to the reasonable inferences an ordinary artisan would draw from those combined teachings. Thus, based on the information presented at this stage of the proceeding, Petitioner has shown sufficiently that there is a reasonable likelihood that it would prevail in showing the unpatentability of independent claim 1 as obvious over the combined teachings of Darzynkiewicz and Yen. We have considered also Petitioner’s arguments and evidence with respect to the challenged dependent claims. See Pet. 47–54. Based on the current record, we determine that Petitioner has made a sufficient showing as to those claims, as well. Accordingly, we institute an inter partes review of claims 1–9 of the ’926 patent as obvious over Darzynkiewicz and Yen.
III. CONCLUSION

For the foregoing reasons, we determine that the information presented in the Petition establishes that there is a reasonable likelihood that Petitioner would prevail in showing that claims 1–9 and 11–12 of the ’926 patent are unpatentable.

At this stage of the proceeding, the Board has not made a final determination as to the patentability of any challenged claim.

ORDER

In consideration of the foregoing, it is hereby:

ORDERED that pursuant to 35 U.S.C. § 314(a), an inter partes review is instituted as to claims 1–9 and 11–12 of the ’926 patent on the following grounds of unpatentability:

A. Claims 1–5 and 11–12 under 35 U.S.C. § 102 as anticipated by Shen;

B. Claims 1–9 under 35 U.S.C. § 103(a) as obvious over Fleisher;

C. Claims 1–9 under 35 U.S.C. § 103(a) as obvious over Darzynkiewicz and Yen; and

FURTHER ORDERED that 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 commencing on the entry date of this Decision.
IPR2017-00014
Patent 7,695,926 B2

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