

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

10X GENOMICS, INC.
Petitioner,

v.

BIO-RAD LABORATORIES, INC.
Patent Owner

Case IPR2020-00086
U.S. Patent No. 9,562,837

**PATENT OWNER'S PRELIMINARY RESPONSE
PURSUANT TO 35 U.S.C. § 313 AND 37 C.F.R. § 42.107**

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I. INTRODUCTION

Pursuant to 35 U.S.C. § 313 and 37 C.F.R. § 42.107(a), Patent Owner Bio-Rad Laboratories, Inc. (“Patent Owner”) respectfully submits this Preliminary Response to the Petition for *Inter Partes* Review (Paper No. 02) (“the 086 Petition” or “Pet.”) filed by Petitioner 10X Genomics, Inc. (“Petitioner”). The Petition seeks *Inter Partes* Review (“IPR”) of claims 1-4, 7-13, and 19-20 of U.S. Patent No. 9,562,837 (“the ’837 patent”), which Petitioner alleges are invalid in light of U.S. Patent No. 7,129,091 to Ismagilov *et al.* (“Ismagilov”) (Ex. 1004) either alone or in combination with U.S. Published Application 2002/0058332 to Quake *et al.* (“Quake”) (Ex. 1006); and/or in light of U.S. Published Application 2006/0094119 to Ismagilov *et al.* (“Ismagilov 119”) (Ex. 1005) either alone or in combination with one or more of U.S. Published Application 2007/0243634 to Pamula *et al.* (“Pamula 634”) and U.S. Published Application 2015/0148238 to Pamula *et al.* (“Pamula 238”) (Ex. 1008) (collectively “Pamula”). The Board should deny the Petition for several reasons.

First, the Board should deny the 086 Petition because Petitioner failed to construe the claims of the ’837 patent as required by 37 C.F.R. § 42.104(b). In the Petition, Petitioner explains that Grounds 1 and 2 are based entirely on Patent Owner’s alleged interpretation of the claims in the pending Delaware district court action. (Pet. at 24). Petitioner does not proffer its own constructions in Grounds 1

or 2, however, let alone explain why the ‘837 claims are allegedly invalid under those constructions. Further, Petitioner makes clear that it does not agree with the constructions it attributes to Patent Owner. (*See* Pet. at 18-20 (disclosing alleged Patent Owner and Petitioner constructions that are different from each other)). The Board has held that a Petitioner does not satisfy § 42.104(b) under these circumstances. *See, e.g., Hologic, Inc. v. Enzo Life Sciences, Inc.*, IPR2018-00019, Paper No. 21 (“Petitioner does not satisfy Rule 42.104(b)(3) when, in a proceeding applying the *Phillips* claim-construction standard, it ‘expressly disagree[s] with its proffered constructions.’”) (citing *Western Digital Corp. v. SPEX Techs., Inc.*, IPR2018-0084, Paper No. 14 and *CareFusion Corp. v. Baxter Int’l, Inc.*, IPR2016-01456, Paper No. 9 (“petitioner has failed to prove a sufficient statement of how the challenged claims are to be construed” because “it relies on constructions advanced by Patent Owner in the related litigation” but “also states that it *does not agree that those constructions are in fact correct.*”) (emphasis in original)).

Further, given the deficiencies in Grounds 1 and 2, the Board should deny all grounds of the 086 Petition. After *SAS Institute, Inc. v. Iancu*, the Board must evaluate the 086 Petition as “a binary choice – either institute review or don’t.” *SAS Institute, Inc. v. Iancu*, 138 S. Ct. 1348, 1359 (2018). Since institution would require the Board to conduct a trial and issue a written decision on grounds that do

not satisfy § 42.104(b), *i.e.* Grounds 1 and 2, the Board should deny institution of the entire petition.

Second, the Board should deny the 086 Petition because it is both horizontally and vertically redundant. The former occurs when “a plurality of references [are] applied not in combination to complement each other but as distinct and separate alternatives . . . Because the references are not identical, each reference has to be better in some respect or else the references are collectively horizontally redundant.” *Liberty Mutual Ins. Co. v. Progressive Casualty Ins. Co.*, , CBM2012-00003, Paper 7 at 3. The latter occurs when “a plurality of prior art [is] applied both in partial combination and in full combination.” *Id.* In that case, “[t]here must be an explanation of why the reliance in part may be the stronger assertion as applied in certain instances **and** why the reliance in whole may also be the stronger assertion in other instances.” *Id.* (emphasis in original). Although Petitioner included a Notice Ranking Petitions explaining why it believes the 086 Petition is stronger than IPR2020-00087 (“the 087 Petition”), it did not explain under what circumstances the various grounds recited in the 086 Petition are stronger or weaker than the other grounds within the 086 Petition. Presentation of multiple, overlapping grounds in a single petition without a sufficient explanation of their relative strengths and weaknesses is an inefficient use of the Board’s resources. *Interthinx, Inc. v. Corelogic Solutions, LLC*, CBM2012-00007,

Paper No. 20 at 4 (“Multiple grounds presented in a redundant or cumulative manner are contrary to the regulatory and statutory mandates of efficiency, patent system integrity, economy and timely completion of proceedings, and therefore are not all entitled to consideration.”).

Third, the Board should deny institution of the 086 Petition because Petitioner filed two separate petitions – the 086 and 087 Petitions – challenging largely the same claims in the same way on the same day, albeit with different but duplicative prior art references. This is exactly the type of cumulative filing that the Board discourages. *See, e.g., TRIAL PRACTICE GUIDE UPDATE* (July 2019) at 26; *TRIAL PRACTICE GUIDE UPDATE* (August 2018) at 11; *Comcast Cable Commc’ns, LLC v. Rovi Guides, Inc.*, IPR2019-00224, -00225, -00226, -00227, -00228, -00229 (P.T.A.B. April 3, 2019) (Paper 10).

Finally, the Board should deny the Petition because Petitioner fails to show a reasonable likelihood of success on the merits of its invalidity arguments. Neither of the Ismagilov references, either alone or in combination with any of the secondary references, discloses all of the elements of the ’837 claims, including at least a “downstream separation chamber”; “wherein the separation chamber is upright to the microchannel and out of the horizontal plane”; “wherein the droplet formation chamber and the separation chamber are in fluid communication with each other via the microchannel”; or, “wherein the separation chamber has a wider

cross-section than the microchannel cross-section to accumulate a plurality of droplets . . . and is of a volume sufficient to separate the plurality of droplets . . . within the separation chamber.” Further, a person of ordinary skill in the art (“POSA”) would not have been motivated to combine the Ismagilov references with the secondary references to address their shortcomings. Moreover, several secondary considerations weigh in favor of a finding of nonobviousness of the ’837 claims. Petitioner is well aware of these secondary considerations from a previous litigation at the International Trade Commission, but nevertheless asserts in the 086 Petition that it “is aware of no secondary considerations of non-obviousness, let alone any with the required nexus, to rebut [Petitioner’s] strong showing on obviousness.” (Pet. at 2). This statement is not true, and the Board should deny the 086 Petition for this reason as well.

II. BACKGROUND

A. Microfluidics

Microfluidics is the study of the behavior and flow of liquids inside micrometer-sized channels or other structures. It has practical application in a number of fields, in particular, biotechnology where biomedical applications are increasingly relying on high throughput assays of small amounts of sample material and reagents. For example, high throughput genetic tests may combine a small amount of genetic or biological material with reagents to provide high-

quality information about samples for drug discovery, biomarker discovery, and clinical diagnostics, among other things.

Emulsions have helped to revolutionize the field of high throughput assays. Emulsification can create tens to hundreds of thousands of aqueous droplets formed when a water based substance (such as a biological sample) becomes surrounded by a hydrophobic substance (such as oil). Each tiny droplet formed through emulsification has the ability to act as a separate, miniature test tube in which biological reactions may occur.

A microfluidic “chip” or “plate” can contain a set of micro-reservoirs and channels formed into a material (typically, glass, silicon or a polymer such as polydimethylsiloxane (“PDMS”)) and connected together according to the needs of the particular assay or other biomedical application. The chip or plate can be small and be held in one hand. Due to its ability to precisely and accurately control the movement of small amounts of fluid, however, a “chip” is capable of integrating several laboratory functions into a very small space.

The technology at issue here involves microfluidic assemblies with a “separation chamber” that facilitates the collection and transfer of droplets for further “off chip” processing. By substantially separating the droplets from the immiscible carrier fluid and directing them to a desired location, the novel chips of

the '722 patent make collection of the droplets much easier to allow for further downstream processing.

B. The '837 Patent

The '837 patent is entitled “Systems for Handling Microfluidic Droplets” and issued on February 7, 2017. The '837 patent was filed on April 2, 2013, and claims priority to several provisional applications, the earliest of which (Provisional Application Nos. 60/799,833 and 60/799,834) were filed on May 11, 2006.

The '837 patent is directed generally to systems and methods for forming emulsions. The '837 patent has 1 independent claims and 19 dependent claims.

Independent claim 1 recites:

1. An assembly, the assembly comprising:

a microchannel in a horizontal plane;

at least one droplet formation module comprising a sample inlet, an immiscible fluid inlet, and a junction, wherein the junction is located between the sample inlet and the microchannel and the droplet formation module is configured to produce droplets comprising the sample surrounded by the immiscible fluid; and

at least one downstream separation chamber comprising a droplet receiving chamber inlet and at least one droplet receiving outlet, wherein the separation chamber is upright to the microchannel and out of the horizontal plane;

wherein the droplet formation module and the separation chamber are in fluid communication with each other via the microchannel; and wherein the separation chamber has a wider cross-section than the

microchannel cross-section to accumulate a plurality of droplets comprising the sample and is of a volume sufficient to separate the plurality of droplets comprising the sample from the immiscible fluid within the separation chamber.

As recited in claim 1, the '837 patent covers systems for generating sample-containing droplets, or emulsions, through the use of “a microchannel in a horizontal plane” with “at least one droplet formation module.” Emulsions are formed when the instrument drives fluids through the microchannel into a droplet formation module that contains both a “sample inlet” and an “immiscible fluid inlet” to a “junction” that creates droplets comprising the sample fluid surrounded by the immiscible fluid. The patent further teaches the use of a novel “separation chamber” that is “out of the horizontal plane” of the microchannel and has a wider cross-section than the microchannel cross-section. The “separation chamber” is designed to be of a volume “sufficient to separate the plurality of droplets comprising the sample from the immiscible fluid.”

III. CLAIM CONSTRUCTION

For purposes of this Preliminary Response, and as set out in further detail below, Patent Owner asserts that Petitioner has failed to comply with 37 CFR § 42.104(b)(3) and (4), the rule provisions requiring a petition to contain an explanation as to how the challenged claim should be construed and how the claim so-construed is allegedly unpatentable. For Grounds 1 and 2, Petitioner fails to propose any of its own constructions but instead conducts its analysis under a set

of constructions that it alleges Patent Owner will use and with which Petitioner expressly disagrees. For Grounds 3 and 4, Petitioner proffers its own set of claim constructions, which it then uses to argue in the alternative to Patent Owner's alleged constructions. Patent Owner notes that the parties have exchanged their preliminary proposed constructions in the parallel Delaware district court action but are not due to submit their Joint Claim Construction brief until May 25, 2020, with a *Markman* hearing scheduled for June 17, 2020. Patent Owner reserves the right to challenge Petitioner's proposed alternative constructions or propose its own constructions of terms in dispute in its §42.120 Response if any trial is instituted.

IV. LEGAL STANDARDS

In an IPR, claims are to be “construed using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. 282(b), including construing the claim in accordance with the ordinary and customary meaning of such claim as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent.” *See* 37 C.F.R. § 42.100(b). Claim terms are also to be given their ordinary and customary meaning as would be understood by a POSA, in the context of the entire patent's disclosure, at the time of the invention. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007); *see also* MPEP § 2111.

In order to anticipate a claimed invention, a prior art reference must “disclose all elements of the claim within the four corners of the document,” and it must “disclose those elements ‘arranged as in the claim.’” *Net MoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359, 1369 (Fed. Cir. 2008) (quoting *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 1548 (Fed. Cir. 1983)).

“An analysis of obviousness must be based on several factual inquiries: (1) the scope and content of the prior art; (2) the differences between the prior art and the claims at issue; (3) the level of ordinary skill in the art at the time the invention was made; and (4) objective evidence of nonobviousness, if any.” *Leo Pharm. Prods. v. Rea*, 726 F.3d 1346, 1353 (Fed. Cir. 2013) (citing *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966)). Further, “there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” *KSR, Int’l. Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007). And while the approach to obviousness is flexible, a patent challenger still must provide a colorable explanation why a POSA would modify its asserted reference in the manner it proposes. See *Kinetic Concepts, Inc. v. Smith & Nephew, Inc.*, 688 F.3d 1342, 1366-67 (Fed. Cir. 2012) (citing *Innogenetics, N.V. v. Abbott Labs.*, 512 F.3d 1363, 1374 (Fed. Cir. 2008)). Moreover, the patent challenger must demonstrate a reasonable expectation of success of combining the prior art references to achieve the claimed invention. MPEP 2143.02.

In evaluating these references, a POSA must avoid the trap of hindsight. *See KSR*, 550 U.S. at 421 (“A factfinder should be aware . . . of the distortion caused by hindsight bias and must be cautious of arguments reliant upon ex post reasoning.”). Further, a reference that teaches away cannot serve as a basis for obviousness. *See, e.g., In re Gurley*, 27 F.3d 551, 553 (Fed. Cir. 1994). “A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant.” *Id.*

Finally, “evidence rising out of so-called ‘secondary considerations’ must always when present be considered en route to a determination of obviousness.” *Stratoflex v. Aeroquip Corp.*, 713 F.2d 1530, 1538 (Fed. Cir. 1983). “The objective considerations, when considered with the balance of the obviousness evidence in the record, guard as a check against hindsight bias.” *In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*, 676 F.3d 1063, 1079 (Fed. Cir. 2012).

V. ARGUMENT

A. The Board Should Deny Institution of the 086 Petition Because Petitioner Failed to Construe the Claims in Grounds 1 and 2

A petition for IPR must “[p]rovide a statement of the precise relief requested for each claim challenged,” which “statement must identify . . . [h]ow the

challenged claim is to be construed” and “[h]ow the construed claim is unpatentable.” 37 C.F.R. § 42.104(b)(3)–(4). “If a petitioner believes that a claim term requires an express construction, the petitioner must include a statement identifying a proposed construction of the particular term and where the intrinsic and/or extrinsic evidence supports that meaning.” *CONSOLIDATED TRIAL PRACTICE GUIDE* (November 2019) at 44. “On the other hand, a petitioner may include a statement that the claim terms require no express construction.” *Id.*

Here, the Board should deny institution of the 086 Petition because Petitioner did not include either statement in Grounds 1 and 2 of the Petition. Instead, Petitioner provided a set of constructions that Petitioner believes Bio-Rad will assert based on Bio-Rad’s infringement contentions and Complaint in the parallel Delaware district court action. (*See* Pet. at 18-20). Petitioner makes clear that it believes these constructions are incorrect (*see id.* (also setting forth a set of Petitioner’s constructions that are different from Patent Owner’s alleged constructions)), but states that the entirety of its arguments in Grounds 1 and 2 are based on this set of allegedly incorrect constructions (*id.* at 24 (explaining that Grounds 1 and 2 are based solely on Patent Owner’s alleged claim constructions)). The Board should deny the 086 Petition because numerous panels have held that a Petitioner does not satisfy § 42.104(b) by proffering constructions with which it expressly disagrees in a proceeding applying the *Phillips* claim construction standard, as is

the case here. *See, e.g., Hologic, Inc. v. Enzo Life Sciences, Inc.*, IPR2018-00019, Paper 21; *Western Digital Corp. v. SPEX Techs., Inc.*, IPR2018-0084, Paper 14; *CareFusion Corp. v. Baxter Int’l, Inc.*, IPR2016-01456, Paper 9; *Intel Corp. v. Qualcomm Inc.*, IPR2018-01326, Paper 8; *Orthopediatrics Corp. v. K2M, Inc.*, IPR2018-01548, Paper 9.

For example, in *Hologic, Inc. v. Enzo Life Sciences, Inc.*, the Board denied institution of the petition because the Petitioner conducted its unpatentability analysis only under a claim construction with which it expressly disagreed. IPR2018-00019, Paper 21 at 2. In its petition, the petitioner set forth both its own proposed constructions and the constructions of the patent owner in a related infringement litigation. *Id.* at 3. The petitioner, however, conducted all of its analyses based on patent owner’s claim construction positions. *Id.* at 4. The Board concluded that this approach “created a situation in which the Petition either did not identify ‘how the challenged claim[s] [were] to be construed’ or did not identify ‘[h]ow the construed claim[s] [are] unpatentable’” as required by Rules 42.104(b)(3) and (b)(4). *Id.* The petitioner requested rehearing of the decision denying institution, arguing that it “improperly interpreted Rules 42.104(b)(3) and (b)(4).” *Id.* The Board rejected each of petitioner’s arguments, explicitly holding that “Petitioner does not satisfy Rule 42.104(b)(3) when, in a proceeding applying

the *Phillips* claim construction standard, it ‘expressly disagree[s] with its proffered constructions.’” *Id.* at 6.

Likewise, in *OrthoPediatrics Corp. v. K2M, Inc.*, the Board denied institution of the petition because the Petitioner failed to set forth proposed constructions for certain terms. IPR2018-1549, Paper 9. Despite urging the district court to construe two terms as invoking means-plus function claiming in litigation regarding the same patent, the petitioner argued in its petition that “no specific claim term[s] of the Challenged Claims require[] construction for the purpose of this petition.” *Id.* The petitioner justified not providing any proposed constructions by stating that “Patent Owner has not requested any constructions under § 112 ¶ 6, and Petitioner has no reason to believe that Patent Owner will do so for purposes of this petition.” *Id.* at 8. The petitioner also stated that “[i]n essence, [its] petition is based on the claim constructions urged by Patent Owner in the related district court litigation.” *Id.* at 6-7.

The Board held that “[g]iven Petitioner’s prior factual and legal positions as to these limitations being subject to § 112 ¶ 6, Petitioner should have known that the question of whether or not the limitations . . . are means-plus-function limitations was likely to be at issue in this proceeding. Accordingly, Petitioner should have either provided reasons why these limitations are not governed by 35 U.S.C. § 112 ¶ 6, or Petitioner should have provided an explicit claim construction

as required by our rules.” *Id.* at 10. Thus, despite petitioner’s claim construction position being consistent with the patent owner’s position in the district court, the Board denied institution.

Further, in *CareFusion Corp. v. Baxter Int’l, Inc.*, the Board denied institution of the petition in part because the “Petitioner [] failed to indicate that it agrees with, proposes, or adopts the constructions attributed to Patent Owner.” IPR2016-01456, Paper 9 at 7 (citing *Toyota Motor Corp. v. Blitzsafe Texas, LLC*, Case IPR2016-00422, slip op. at 26–27 (PTAB July 6, 2016) (Paper 12)). Similar to *Hologic*, the Petitioner relied on the patent owner’s interpretations of the claims but stated that it did not “agree that those constructions are in fact correct[.]” *Id.* at 6. The Board found that because it expressly disagreed with the constructions it was proposing, the Petitioner “failed to provide a sufficient statement of how the challenged claims are to be construed as required by 37 C.F.R. § 42.104(b)(3).” *Id.* at 6-7.

Finally, denial of the 086 Petition is also consistent with *Intel Corp. v. Qualcomm Inc.*, In that case, the Board found that “[a] petitioner may satisfy 37 C.F.R. § 42.104(b)(3) ‘by identifying claim constructions it proposes as the basis for requesting review of the challenged claims,’ without ‘express[ing] its subjective agreement regarding correctness of its proffered claim constructions or [] tak[ing] ownership of those constructions.” IPR2018-01326, Paper 8 at 11

(quoting *Hologic, Inc. v. Enzo Life Sciences, Inc.*). The Board made clear however that this applied to *inter partes* reviews “where the broadest reasonable interpretation applies,” which is not the case here. Further, the Board relied on *Hologic, Inc. v. Enzo Life Sciences, Inc.*, which held that although Petitioner did not have to adopt Patent Owner’s proffered constructions, it did have to proffer a set of constructions that it believed to be correct:

The dissent asserts that our interpretation of these rules “force[s] Petitioner into . . . adopting – as its own – Patent Owner’s proposed constructions from the district court proceeding (which may not necessarily be favorable to its non-infringement positions in order to be allowed to present its unpatentability arguments in this proceeding.” But, our interpretation of 37 C.F.R. § 42.104(b)(3) and (4) does not, in fact, force Petitioner to adopt Patent Owner’s construction as its own in order to request an *inter partes* review. Rather, under our interpretation, Petitioner was free to advocate unpatentability under a claim construction it considered to be correct. It did not do so. If Patent Owner’s construction in a related lawsuit is erroneous, Petitioner should respond accordingly there, not here. At the Patent Trial and Appeal Board, petitioners should bring petitions for *inter partes* review asserting unpatentability based on constructions that their petitions seek.

IPR2018-00019, Paper 17 at 9.

In addition to the case law cited above, judicial efficiency weighs in favor of the Board denying institution of the 086 Petition. Although Petitioner has provided the Board with what Petitioner believes to be the constructions that Patent Owner will assert, Petitioner’s argument ignores the fact that the parties have already

exchanged proposed constructions in the parallel Delaware district court action, and the constructions proposed by Patent Owner there are different than those set forth by Petitioner in the 086 Petition. Further, Petitioner fails to inform the Board that the parties are not due to submit their Joint Claim Construction brief in the parallel Delaware district court action until May 25, 2020, with a *Markman* hearing scheduled for June 17, 2020. Thus, Patent Owner is several weeks (if not months) away from having to offer its final claim constructions in the district court action. There is no reason for the Board to spend time and resources analyzing a set of claim constructions that neither the District Court nor the parties have adopted. The better practice is the one advocated for by the Board in *Hologic, Inc. v. Enzo Life Sciences, Inc.*, that is, to require petitioners to set forth what they believe to be the *correct* constructions. If petitioners want to offer alternative constructions in addition for each of their grounds, that is fine. But that is not what happened here, where Petitioner offers in Grounds 1 and 2 only a set of constructions with which it expressly disagrees.

The fact that Petitioner offers its own alternative constructions in support of Grounds 3-5 should not save the 086 from denial. After *SAS Institute, Inc. v. Iancu*, the Board must evaluate the 086 Petition as “a binary choice – either institute review or don’t.” *SAS Institute, Inc. v. Iancu*, 138 S. Ct. 1348, 1359 (2018). Since institution would require the Board to conduct a trial and issue a

written decision on grounds that do not satisfy § 42.104(b), *i.e.* Grounds 1 and 2, the Board should deny institution of the entire 086 Petition.

B. The Board Should Deny Institution of the 086 Petition Because Petitioner Included Multiple, Redundant Grounds With No Meaningful Distinction Between Them

“Part 42 of Title 37, Code of Federal Regulations, governs proceedings before the Board and 37 C.F.R. § 42.1(b) provides that ‘[t]his part shall be construed to secure the just, speedy, and inexpensive resolution of every proceeding.’” *Liberty Mutual Ins. Co.*, CBM2012-00003, Paper 7 at 2. “When promulgating the regulations, the Board considered ‘the effect of the regulations on the economy, the integrity of the patent system, the efficient administration of the Office, and the ability of the Office to timely complete proceedings’ as mandated by 35 U.S.C. § 326(b).” *Id.* “[M]ultiple grounds, which are presented in a redundant manner by a petitioner who makes no meaningful distinction between them, are contrary to the regulatory and statutory mandates, and therefore are not all entitled to consideration.” *Id.* This is especially true after *SAS Institute, Inc. v. Iancu*, where the United States Supreme Court held that once instituted, “[petitioner] is entitled to a final written decision addressing all of the claims it has challenged.” *SAS Institute, Inc. v. Iancu*, 138 S. Ct. 1348, 1359 (2018). In other words, after *SAS Institute*, the Board must institute on all grounds or none. When,

as here, a petition includes multiple, redundant grounds, the Board should deny institution rather than waste Office resources addressing redundant grounds.

The 086 Petition includes five different grounds: (1) anticipation based on Ismagilov, (2) obviousness based on the combination of Ismagilov and Quake, (3) obviousness based on Ismagilov 119, (4) obviousness based on the combination of Ismagilov 119 and Pamula 634 and (5) obviousness based on Ismagilov 119 and Pamula 238. The Board should deny institution of the 086 Petition because these grounds are both horizontally and vertically redundant of each other without sufficient explanation as to why all grounds are necessary, *i.e.* the circumstances under which each ground is stronger or weaker than the others.

First, Grounds 3-5 are horizontally redundant of Ground 2 because they rely on a different set of references to argue obviousness without a sufficient explanation from Petitioner as to the circumstances under which each ground is stronger or weaker. Petitioner states that Ismagilov 119 “incorporates by reference in its entirety Ismagilov” (Pet. at 24) but provides no explanation as to why Grounds 1-2 (Ismagilov as primary reference) is necessary. Nor does Petitioner explain why the various secondary references (Quake, Pamula 634 and Pamula 238) are necessary or how they are stronger or weaker relative to each other.

Second, Grounds 3-5 are vertically redundant of each other because they each rely on Ismagilov 119 in combination with different secondary references.

Petitioner states that Grounds 4 and 5 are necessary because the Pamula references include “additional information regarding [the density sorter allegedly disclosed in Ismagilov 119] (*id.*), but provides no explanation as to what that additional information is or how it advances Petitioner’s arguments in a way that could not be articulated in Ground 3 alone.

Petitioner should not be allowed to present multiple, redundant grounds because it is worried that one or more of its grounds may not succeed. That sort of “shot gun” approach to *inter partes* review petitions is a waste of Office resources and contrary to the regulatory requirement of a “just, speedy, and inexpensive resolution of every proceeding.” 37 C.F.R. § 42.1(b).

C. The Board Should Deny the 086 Petition Because Petitioner Filed Parallel Petitions on the Same Day

Petitioner’s filing of the 086 and 087 Petitions on the same day attacking largely the same claims of the same patent (the ’837 patent) also places a substantial and unnecessary burden on the Board and Patent Owner. The Board has stated that “one petition should be sufficient to challenge the claims of a patent in most situations.” *CONSOLIDATED TRIAL PRACTICE GUIDE* (November 2019) at 59. *See also Comcast Cable Commc’ns, LLC v. Rovi Guides, Inc.*, IPR2019-00224, -00225, -00226, -00227, -00228, -00229 (P.T.A.B. April 3, 2019) (Paper 10). “Two or more petitions filed against the same patent at or about the same time (e.g., before the first preliminary response by the patent owner) may place a

substantial and unnecessary burden on the Board and the patent owner and could raise fairness, timing, and efficiency concerns.” *CONSOLIDATED TRIAL PRACTICE GUIDE* (November 2019) at 59. Further, to aid the Board in determining whether a second petition is necessary, the Petitioner must identify “(1) a ranking of the petitions in the order in which it wishes the Board to consider the merits, if the Board uses its discretion to institute any of the petitions, and (2) a succinct explanation of the differences between the petitions, why the issues addressed by the differences are material, and why the Board should exercise its discretion to institute additional petitions if it identifies one petition that satisfies petitioner’s burden under 35 U.S.C. § 314(a).” *Id.* at 59-60. The Board should deny the 086 Petition because Petitioner did not explain sufficiently why the Board should exercise its discretion and institute both the 086 and 087 Petitions.

Petitioner also argues that both petitions are necessary because the 086 Petition includes claim constructions that are different than the 087 Petition, in that it includes grounds based on both Patent Owner’s “expected” claim constructions with which it disagrees as well as Petitioner’s own proposed claim constructions. As explained above in section IV(A), the Board should not exercise its discretion to institute the 086 Petition on this basis. Petitioner failed to satisfy § 42.104(b) because it did not proffer its own claim constructions with respect to Grounds 1 and 2 but rather relied only on what it believes will be Patent Owner’s

constructions, with which Petitioner expressly disagrees. Petitioner should not get the benefit of two petitions because it failed to comply with § 42.104(b).

In sum, Petitioner cites no authority that would justify multiple attacks on the same claims in order to try “different” ways of attacking the claims. These serial attacks on the same claims that merely provide Petitioner with several options is exactly the approach that is most burdensome for the Board and unfair to patent owners. Every petitioner would like multiple bites at the apple via what is essentially a “backup” Petition, but in fairness the *inter partes* proceeding should allow only one. See *TRIAL PRACTICE GUIDE UPDATE* (July 2019) at 26.

D. The Board Should Deny the 086 Petition Because Petitioner Failed to Show a Likelihood of Success on the Merits

As explained above, the 086 Petition includes five different grounds: (1) anticipation based on Ismagilov, (2) obviousness based on the combination of Ismagilov and Quake, (3) obviousness based on Ismagilov 119, (4) obviousness based on the combination of Ismagilov 119 and Pamula 634 and (5) obviousness based on Ismagilov 119 and Pamula 238. The Board should deny the 086 Petition because Petitioner failed to satisfy its burden of showing a likelihood of success on the merits for any of these grounds. The Ismagilov references, Quake and the Pamula references are missing critical elements of the '837 claims, and a POSA would not have been motivated to combine Ismagilov with either Quake or the Pamula references.

1. Ismagilov, Quake and Pamula Are Missing Critical Elements of the '837 Claims

Ismagilov, Quake and Pamula are missing several critical elements of the '837 claims related to the requirement of a “separation chamber,” including the mere existence of a “separation chamber” as well as the recited configuration and dimensions.

For example, Petitioner asserts that the “outlet port” disclosed in Ismagilov constitutes a separation chamber “under Bio-Rad’s interpretations,” but the portion of Ismagilov cited by Petitioner demonstrates that the sole purpose of the “outlet port” is to facilitate collection of a “flow of solution” after the reaction plugs have moved through “different analysis units” that are disposed across “mainfolds” that are “preferably fabricated into the substrate at different depth levels.” (Ismagilov at 17:18-30). In other words, the “outlet ports” of Ismagilov typically act as extensions of the tubing or pipettes that collect the entirety of the “solution” following analysis within the manifolds, not as a “chamber” that maintains the entirety of the solution contents and droplets.

Petitioner’s argument that the outlet ports in Ismagilov meets the configuration and dimension limitations of claim 1 rests solely on the assumption that an “outlet port” in Ismagilov would require a sufficient volume “deep enough for the pipette to extend into it.” (Pet. at 41; *see also id.* at 44-45). Notably, the only support Petitioner cites for these statements is the testimony of its expert, not

any disclosure in Ismagilov. *Id.* There is simply no disclosure in Ismagilov that teaches any chamber with the dimensions and configuration claimed in the '837 patent, which is unsurprising given that the only functionality disclosed for the “outlet ports” is solution extraction, as explained above.

Petitioner also fails to show that Quake discloses the required “separation chamber.” Petitioner cites paragraphs 198-200 as disclosing wells intended for separation but this portion of Quake teaches nothing of the sort. Instead it teaches “sorting experiments” where “cells can be directed to either side of the ‘T’ channels depending upon the voltage potential settings” created by inserting platinum electrodes into the disclosed “wells.” (Quake at ¶¶ 198-200). Moreover, Figures 6 and 8 cited by Petitioner fail to show that any of the “well” structures, which Petitioner asserts to be a separation chamber have both an inlet and an outlet. To the contrary, the figures make clear that the “wells” in Quake are part of a closed system, which Quake makes clear by disclosing that “pneumatically-driven syringes” are used to introduce fluids into the device. (Ex. 1004 ¶¶ 288, 300; *see also id.* ¶¶ 65, 81.) These syringes are not part of the device and are not structures of the device that are capable of holding fluid until ready for use, or for purposes of separation. (*Id.*) Thus, even if a POSA were motivated to combine Ismagilov with Quake, which Petitioner has failed to establish as explained further

below, the combination would still fail to teach the claimed separation chamber of the '837 patent.

Finally, Petitioner also fails to show that the Pamula references disclose a “downstream separation chamber.” Petitioner argues that this element is present due to Pamula’s reference to a “vertical configuration” that may exploit the density between the two phases. Pamula, however, fails to disclose how the vertical configuration relates to any “microchannel” or whether there is even a “microchannel in a horizontal plane” that includes a “droplet formation module” that is in “fluid communication” with the portion of Pamula that contains a vertical configuration. Furthermore, absent from the Petition are any citations in Pamula that describe the dimensions of the “vertical configuration” in Pamula, let alone dimensions that would allow droplets to sink relative to the immiscible fluid.

2. A POSA Would Not Have Been Motivated to Combine Ismagilov With Either Quake or Pamula

The Board should also deny institution of the 086 Petition because a POSA would not have been motivated to combine Ismagilov with either Quake or Pamula, as necessary to support Petitioner’s obviousness arguments.

For example, Petitioner argues that “[a] skilled artisan would have been motivated to combine Ismagilov with Quake.” (Petition at 26). But Petitioner provides no explanation of *why* a POSA would have been motivated other than that both researchers were known in the field. Further, Petitioners provide no

explanation for how a POSA would go about combining the disparate elements of the references, or what modifications a POSA would necessarily have made in order to combine the disparate elements. Conclusory arguments such as this are insufficient to show a likelihood of success on the merits in the context of an IPR. *See, e.g., Harmonic v. Avid Technology*, 815 F.3d 1356,1364-65 (2016) (holding that Petitioner’s “single sentence without any elaboration” was improperly conclusory); *In re Magnum Oil Tools Int’l Ltd.*, 829 F.3d 1364, 1380 (Fed. Cir. 2016) (finding petitioner’s “mere conclusory statements” insufficient to satisfy its burden of proving obviousness); *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006) (a rejection on the ground of obviousness must include “articulated reasoning with some rational underpinning to support the legal conclusion of obviousness”).

Petitioner also argues that a POSA would have been motivated to combine Ismagilov with Quake because “[t]he differences between Ismagilov and Quake are minor and relate to additional structural details provided by Quake.” (Pet. at 39). The identification of similarities between two prior art references, however, is also not enough to satisfy Petitioner’s burden. *Free-Flow Packaging Int’l, Inc. v. Automated Packaging Sys.*, IPR2016-00350, Paper 7 at 3 (June 27, 2016).

Finally, Petitioner attempts to explain to the Board what a combination of the wells and channels of Ismagilov and Quake would look like when combined and then states that “[b]ased on this combination, a droplet receiving chamber inlet

was obvious.” (Pet. at 40). This is impermissible hindsight. As the Federal Circuit has explained, “it is impermissible to use the claimed invention as an instruction manual or ‘template’ to piece together the teachings of the prior art so that the claimed invention is rendered obvious.” *In re Fritch*, 972 F.2d 1260 Fed. Cir. 1992); *InTouch Techs., Inc. v. VGO Commc’ns, Inc.*, 751 F.3d 1327, 1338 (Fed. Cir. 2014) (holding that Defendant’s expert testimony was nothing more than impermissible hindsight by “rel[ying] on the patent itself as her roadmap for putting what she referred to as pieces of a ‘jigsaw puzzle’ together... consist[ing] of conclusory references to her belief that one of ordinary skill in the art could combine these references, not that they would have been motivated to do so.”).

Petitioner similarly offers conclusory assertions that both Ismagilov and Pamula were well known in the field and thus a POSA would know to pick and choose between the references to derive the claimed invention in the ‘837 patent. (Pet. at 29-30, 56-60). This conclusory and hindsight-based reasoning for why a POSA would be motivated to combine Ismagilov with the Pamula references should be rejected for the reasons explained above.

3. Several Secondary Considerations Support a Finding of Non-obviousness

Several secondary considerations weigh in favor of a finding of nonobviousness of the ‘837 claims, including long-felt need, commercial success, praise, and acquiescence and licensing. Despite asserting in the 086 Petition that

it “is aware of no secondary considerations of non-obviousness, let alone any with the required nexus, to rebut [Petitioner’s] strong showing on obviousness” (Pet. at 2), Petitioner is well aware of these secondary considerations from a previous litigation at the International Trade Commission. Since Petitioner has not offered any rebuttal to secondary considerations that it was already aware of, the Board should deny the 086 Petition for this reason as well.

(a) Long-Felt Need

The ’837 patent includes numerous novel elements, including multi-step processes designed to improve the ability to easily and reliably remove the droplets from the separation chamber while minimizing the removal of unwanted continuous phase fluid. This ability is facilitated by a particular orientation for the separation chamber (one that is upright or perpendicular to the microchannel) of a certain width. This design is used to enhance separation and collection of the sample-containing droplets. When RainDance Technologies, Inc. (“RainDance”) was founded, it helped transform disease research by making innovative tools using its proprietary technologies that simplify complex genetic analysis. RainDance’s patented droplet system fundamentally enhances the way researchers and scientists study cell-based and cell-free biomarkers in cancer, infectious disease, and inherited disorders.

Bio-Rad's ddPCR™ platform—including the QX100 and QX200 Droplet Digital PCR systems and AutoDG Droplet Generator—practices the '837 patent and was heralded as a breakthrough that greatly advanced the capabilities of PCR. Bio-Rad's new system offered unprecedented precision, sensitivity, and reproducibility that was not available with existing PCR products. Bio-Rad ddPCR™ products quickly became and remain the gold standard for droplet-based PCR systems. Shortly after its launch, Bio-Rad's first-generation ddPCR™ product, the QX100, was widely acknowledged as an innovative design that contributed to the progression of PCR technology. The new product was an easy-to-use alternative to the existing technology, such as real-time or quantitative digital PCR, for users looking for more precise and accurate methods of detecting rare mutations and small copy number variations. (*See, e.g., Erica Mazaika & Jason Homsy, Digital Droplet PCR: CNV Analysis and Other Applications*, 82 *Current Protocols in Hum. Genetics* 7.24.1 (2014) (Ex. 2001)). Bio-Rad's ddPCR™ products were rapidly adopted in the industry and led to an explosion of research. Just one year after the QX100 launch, the number of cancer research papers citing ddPCR™ nearly quintupled. (Press Release, Bio-Rad, *Bio-Rad's Droplet Digital™ PCR Technology Highlighted at the 2014 AACR Annual Meeting* (Apr. 5, 2014), <https://www.bio-rad.com/en-us/life-science-research/news/bio-rads-droplet-digital-pcr-technology-highlighted-at-2014-aacr-annual->

meeting?ID=Bio-Rad-s-Droplet-Di_1396030479 (Ex. 2002)). Since launching Bio-Rad's ddPCR™ platform, there have been more than 4,400 published studies describing research breakthroughs using this technology, including 1034 publications in 2019. (*See Droplet Digital Polymerase Chain Reaction Publication*, Bio-Rad, <https://www.bio-rad.com/ddPCR/publications> (last visited Jan. 28, 2020) (Ex. 2003)). With the help of ddPCR™, researchers were able to detect rare targets with a level of precision that was just not possible with previous technologies. (*See, e.g., Droplet Digital™ PCR (ddPCR™) Technology*, Bio-Rad, <https://www.bio-rad.com/en-us/applications-technologies/droplet-digital-pcr-ddpcr-technology?ID=MDV31M4VY> (last visited Jan. 28, 2020) (Ex. 2004)). The inventions of the '837 patent fulfilled a long-term need for a means of isolating sample from the surrounding environment for further analysis using microfluidic droplets by means of the claimed separation chamber.

(b) Commercial Success

Bio-Rad's products, the ddPCR and ddSEQ systems, embody the '837 patent and have been a commercial success, as evident by the high sales volume and revenues generated by Bio-Rad's sales of ddPCR. The inventions disclosed in the '837 patent have contributed to this success. They allow for the utilization of differences in density of the different fluids to concentrate the droplets in a particular part of the chamber. This greatly improved the ability to easily and

reliably remove the droplets from the separation chamber while minimizing the removal of unwanted continuous phase fluid. These developments represented a significant improvement on the prior art that greatly advanced the capability of PCR and NGS. (*See, e.g., R&D 100 Archive of Winners* (2012), <https://www.rdworldonline.com/rd-100-archive/2012> (Ex. 2005); Bio-Rad's QX100™ Droplet Digital PCR System Wins 2012 *Laboratory Equipment* Readers' Choice Award (Ex. 2006); Bio-Rad's QX200™ Droplet Digital PCR System Wins the SelectScience Scientists' Choice Award for Best New Life Sciences Product of 2013 at AACR (Ex. 2007); Frost & Sullivan Recognizes Bio-Rad's Digital PCR Platform, the QX200™ AutoDG™ Droplet Digital™ PCR System for New Product Innovation (Ex. 2008); Editorial Article: Winners of the 2018 Scientists' Choice Awards for Life Sciences Announced at AACR (Ex. 2009)).

These patented features are repeatedly referenced in Bio-Rad's instruction manuals and are critical to the Bio-Rad products' workflows. (*See, e.g., ddSEQ™ Single-Cell Isolator*, Instruction Manual, at 18 (instructing users on how to transfer droplets out of the separation chamber of the ddSEQ cartridge) (Ex. 2010); QX200™ Droplet Generator, Instruction Manual, at 18 (instructing users on how to transfer droplets out of the separation chamber of the DG8 cartridge) (Ex. 2011)).

Similarly, 10X's products embodying the invention have been a commercial success. (See, e.g., 10X Genomics, *Prospectus: 10,000 Shares Class A Common Stock* at 75-76 (Sept. 11, 2019), <https://investors.10xgenomics.com/static-files/ad03dcbd-2c62-49f8-916b-917918056567> ("Since launching our first product in mid-2015, and as of June 30, 2019, we have sold 1,284 instruments to customers around the world, including 93 of the top 100 global research institutions by publications, and 13 of the top 15 global pharmaceutical companies by 2018 revenue. . . . Revenue increased 106% to \$146.3 million in the year ended December 31, 2018 as compared to \$71.1 million in the prior year, and increased 85% to \$109.4 million for the six months ended June 30, 2019 as compared to \$59.2 million for the six months ended June 30, 2018, primarily due to the adoption of our platform by customers as reflected by the doubling in size of our installed base to more than 1,000 instruments as of December 31, 2018 and more than 1,280 instruments as of June 30, 2019, and the associated consumables pull-through on those instruments.")) (Ex. 2012)).

(c) Praise by Others

Bio-Rad's innovative ddPCR™ products have received repeated accolades for their contributions to the field. In 2012, just one year after its launch, the QX100 ddPCR™ product was awarded *R&D Magazine's* 100 Award, which is given to the 100 most technologically significant products introduced into the

marketplace over the past year. (Ex. 2005). The QX100 ddPCR™ product was also awarded the *Laboratory Equipment* Readers' Choice Award in the biotech category, which is given to celebrate excellence in product design and performance for the tools and materials used by scientists and engineers in research laboratories. (See Ex. 2006). Similarly, the QX200 ddPCR™ product—Bio-Rad's second-generation ddPCR™ system—received the Scientists' Choice Award for Best New Life Sciences Product of 2013 from *SelectScience* because of its significant contribution in 2013. (See Ex. 2007). The following year, the QX200 ddPCR™ product received the 2014 Frost & Sullivan New Product Innovation Award for the Digital PCR Market in recognition of its innovation, value-added features/benefits, and the return on investment to customers. (See Ex. 2008).

Bio-Rad's investment and development efforts led to a new generation of products to be used in the preparatory steps of creating thousands of microdroplets that are then evaluated in Next Generation Sequencing ("NGS") applications, such as in those provided by Illumina Corporation. Bio-Rad's next generation product that is used in NGS is called the ddSEQ™ system. It was launched in January 2017 and it consists of both a newly-optimized microfluidic device (cartridge/chip) and a droplet generator instrument. As with its prior droplet products, the ddSEQ™ system has also received wide acclaim. (See, e.g., Ex. 2009).

Both Bio-Rad's and 10X's products have received praise because of their turn-key, easy-to-use workflows. (See, e.g., Sonia Nicholas, *Editorial Article: Technology Showcase: How to Use Bio-Rad's Droplet Digital PCR* (May 12, 2017), <https://www.selectscience.net/editorial-articles/technology-showcase-how-to-use-bio-rads-droplet-digital-pcr/?artID=43650> (customer reviews noting the ease-of-use of the QX200) (Ex. 2013)). The patented inventions allow users to easily remove the droplets by collecting them on the microfluidic chip, where they can separate from the continuous fluid. This feature allows users to more efficiently and easily subject the contents of the droplets to further downstream reactions and analysis.

(d) Acquiescence and Licensing

Evidence of licensing supports the nonobviousness of the '837 patent. Bio-Rad acquired RainDance and all of its intellectual property in January 2017, including the '837 patent, demonstrating the value that third-parties have placed on acquiring rights to the '837 patent. (See, e.g., Bio-Rad to *Acquire RainDance Technologies*, *genomeweb* (Jan. 16, 2017), <https://www.genomeweb.com/pcr/bio-rad-acquire-raindance-technologies> (Ex. 2014).

E. AIA Does Not Apply

Petitioner argues that the '837 patent "is a transition application and is subject to the America Invents Act ("AIA"). (Pet. at 5). In particular, Petitioner

argues that the '837 patent is subject to the AIA because the related utility application (Application No. 13/855,318) “contained new matter and claims to that new matter with an effective filing date of April 2, 2013. For example, at least Claims 5 and 6 covering particular connections to a slide have an effective filing date after March 16, 2013.” (*Id.*). Petitioner is incorrect. Both claims 5 and 6 of the '837 patent have support in, at least, Application No. 11/803,104 (“the '104 application”), which was filed on May 11, 2007. For example, the limitations in claims 5 and 6 of the '837 patent are supported in the '104 application at column 77, line 30 through column 78, line 12. Thus, there is support prior to March 13, 2013 for the only claims that Petitioner identifies as lacking support as of that date. Accordingly, Petitioner has failed to meet its burden of showing that the AIA applies. Even if the AIA is found to apply, however, none of Petitioner’s invalidity grounds have merit for the same reasons identified above.

VI. CONCLUSION

In view of the foregoing, Patent Owner respectfully submits that the Board should deny institution of all grounds of the 086 Petition.¹

¹ Patent Owner expressly reserves its right to present constitutional arguments under *Arthrex, Inc. v. Smith and Nephew, Inc.*, No. 2018-2140, where the Federal Circuit is currently considering multiple petitions for rehearing *en banc*.

Date: January 29, 2020

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CERTIFICATE OF COMPLIANCE

I, the undersigned, certify that the above Patent Owner Preliminary Response complies with the applicable type-volume limitations of 37 C.F.R. § 42.24 (b)(1). Exclusive of the portions exempted by 37 C.F.R. § 42.24(a), this Preliminary Response, including footnotes, contains 8,091 words, as counted by the word count function of Microsoft Word. This is less than the limit of 18,700 words as specified by 37 C.F.R. § 42.24(a)(ii).

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CERTIFICATION OF SERVICE (37 C.F.R. §§ 42.6(E), 42.105(A))

The undersigned hereby certifies that the foregoing document was
served in its entirety on January 29, 2020 upon the following parties via
Electronic Mail.

<p>Samantha A. Jameson USPTO Reg. No. 57,609 Azra Hadzimehmedovic <i>Pro Hac Vice</i> motion to be submitted Aaron M. Nathan <i>Pro Hac Vice</i> motion to be submitted Tensegrity Law Group LLP 8260 Greensboro Dr., Suite 260 McLean, VA 22102</p> <p>samantha.jameson@tensegritylawgroup.com azra@tensegritylawgroup.com aaron.nathan@tensegritylawgroup.com 10X_TLG_IPR_Service@tensegritylawgroup.com</p>	<p>Matthew D. Powers <i>Pro Hac Vice</i> motion to be submitted Robert L. Gerrity <i>Pro Hac Vice</i> motion to be submitted Gina Cremona USPTO Reg. No. 74,844 Daniel M. Radke USPTO Reg. No. 69,820 Tensegrity Law Group LLP 555 Twin Dolphin Drive, Suite 650 Redwood Shores, CA 94065</p> <p>matthew.powers@tensegritylawgroup.com robert.gerrity@tensegritylawgroup.com gina.cremona@tensegritylawgroup.com daniel.radke@tensegritylawgroup.com</p>
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