

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ABS GLOBAL, INC.
Petitioner,

v.

XY, LLC
Patent Owner.

IPR2018-01224
Patent 9,365,822 B2

Before ROBERT A. POLLOCK, MICHELLE N. ANKENBRAND, and
DAVID COTTA, *Administrative Patent Judges*.

COTTA, *Administrative Patent Judge*.

JUDGMENT
Final Written Decision
Determining Challenged Claim Unpatentable
35 U.S.C. § 318(a)

I. INTRODUCTION

ABS Global, Inc. (“Petitioner”) filed a Petition requesting an *inter partes* review of claim 11 of U.S. Patent No. 9,365,822 B2 (Ex. 1001, “the ‘822 patent”).¹ Paper 1 (“Pet.”). XY, LLC (“Patent Owner”) filed a Preliminary Response to the Petition. Paper 7 (Prelim. Resp.).² We determined, based on the information presented in the Petition and Preliminary Response, that there was a reasonable likelihood that Petitioner would prevail in showing that claim 11 was unpatentable under 35 U.S.C. § 103(a) as obvious over the cited art. Pursuant to 35 U.S.C. § 314, we instituted trial on December 10, 2018. Paper 8 (“Institution Decision” or “Inst. Dec.”).

Following our Institution Decision, Patent Owner filed a Response to the Petition (Paper 12, “PO Resp.”), Petitioner filed a Reply to Patent Owner’s Response (Paper 17, “Reply”), and Patent Owner filed a Sur-Reply (Paper 19, “Sur-Reply”). Patent Owner also filed a Motion to Exclude Evidence (Paper 21, “Mot.”), to which Petitioner filed an Opposition (Paper 23, “Mot. Opp.”), and Patent Owner filed a Reply (Paper 25, “Mot. Reply”). On September 11, 2019, the parties presented arguments at an oral hearing. The transcript of the hearing has been entered into the record. Paper 27 (“Tr.”).

We have jurisdiction under 35 U.S.C. § 6. We issue this Final Written Decision pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73. Based on the record before us, we conclude that Petitioner has demonstrated by a

¹ Petitioner identifies ABS Global, Inc., and Genus plc as real parties in interest. Pet. 1.

² Patent Owner identifies XY, LLC, and Inguran, LLC as real parties in interest. Paper 5, 1.

preponderance of the evidence that claim 11 of the '822 patent is unpatentable. We grant Patent Owner's Motion to Exclude.

A. Related Proceedings

Petitioner and Patent Owner identify *Inguran, LLC d/b/a STGenetics v. ABS Global, Inc.*, Civil Action No. 17-cv-00446 (W.D. Wis.), and *XY, LLC v. Trans Ova Genetics, LC*, Civil Action No. 1:17-cv-00944-WJM-NYW (D. Colo.), as litigations involving the '822 patent. Pet. 1; Paper 5, 1.

B. The '822 Patent (Ex. 1001)

The '822 patent issued June 14, 2016, identifying George E. Seidel, Lisa A. Herickhoff, and John L. Schenk as co-inventors. Ex. 1001, codes (45), (72). The patent discloses “systems for sorting sperm via flow cytometry for sex-specific and low dose efforts at artificial insemination or the like.” *Id.* at 1:19–21.

The '822 patent teaches that “flow cytometry involves sorting items, such as cells, which are provided to the flow cytometer instrument through some type of cell source.” *Id.* at 5:48–50. Figure 1 of the '822 patent is reproduced below.

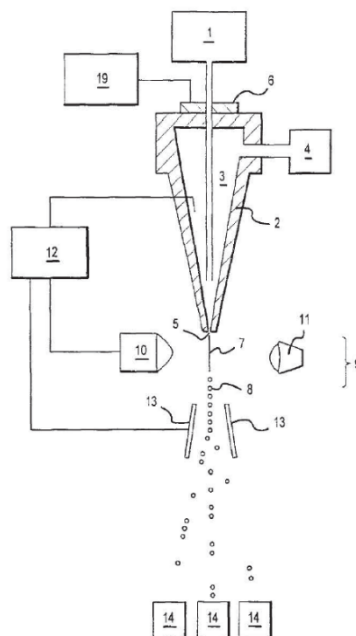


Figure 1 is a “schematic diagram of a sorter system according to [Patent Owner’s] invention.” *Id.* at 5:10–11.

As shown in Figure 1, the flow cytometer includes “cell source (1)” that supplies cells to “nozzle (2) in a manner such that the cells are surrounded by a sheath fluid (3)” that “sheath fluid source (4)” supplies. *Id.* at 5:51–56. Oscillator (6) acts upon the cells, which causes stream of cells (7) exiting through “nozzle orifice (5)” to regularly form “drops (8).” *Id.* at 5:62–6:3. Because the drops contain isolated cells, “sensing system (9)” can “distinguish and separate droplets based upon whether or not the appropriate cell or cells is/are contained within the drop.” *Id.* at 6:5–8. “[S]orter discrimination system (12) . . . can differentially charge each drop (8) based upon whether it has decided that the desired cell does or does not exist within that drop (8).” *Id.* at 6:25–28. The sorter discrimination system then causes “electrostatic deflection plates (13) to deflect drops (8) based on whether or not they contain the appropriate cell.” *Id.* at 6:29–32. By sensing a property of the cells, the flow cytometer can discriminate between cells based on a particular characteristic of the cells and “place them in the appropriate collector (14).” *Id.* at 6:33–37.

The ’822 patent discloses that sperm are “extremely delicate cells.” *Id.* at 2:46–47. Because of their fragility, “processing through normal flow cytometer techniques may . . . be unacceptable for cytometric sorting of sperm cells in certain applications.” *Id.* at 2:54–56.

According to the ’822 patent, “[a]n object of the invention is . . . to achieve better sorting for substances such as sperm cells” and “minimize the impact the sorting function itself has on the cells.” *Id.* at 4:45–48. More particularly, the inventors of the ’822 patent sought to “minimize the impact

the sheath fluid imposes upon the cells and to potentially provide a sheath fluid which affirmatively acts to assist the cells in handling the various stresses involved.” *Id.* at 4:48–52. A further goal is to “minimize the impacts that the collection phase (e.g., after sorting) has upon the cells and to minimize the physical impact as well as chemical impacts on such sex sorted sperm cells.” *Id.* at 4:56–59. The ’822 patent discloses that “[b]y selecting certain metabolic chemical compositions, most notably citrates or chemicals which are within the citric acid cycle, great advances appear possible.” *Id.* at 8:50–52.

C. Challenged Claims

Petitioner challenges claim 11 of the ’822 patent. Claim 11 is reproduced below:

11. A method of producing at least one sexed embryo comprising:
 - producing a stream containing sperm cells, wherein the stream comprises sperm cells from a cell source surrounded by sheath fluid, wherein the sheath fluid surrounding the sperm cells includes a citric acid;
 - identifying X-chromosome bearing sperm cells and/or Y-chromosome bearing sperm cells in the stream;
 - collecting X-chromosome bearing sperm cells and/or Y-chromosome bearing sperm cells in at least one collector having a collector fluid which includes a citric acid; and
 - fertilizing at least one egg with the collected sperm cells to form at least one sexed embryo.

Ex. 1001, 30:22–35.

D. The Instituted Ground of Unpatentability

We instituted trial based on Petitioner’s challenge to the patentability of claim 11 as obvious over the combination of Johnson,³ Salisbury,⁴ and Garcia.⁵ Petitioner submits the Declaration of Dr. Marvin M. Pace (Ex. 1003) in support of the Petition. Patent Owner submits the Declaration of Dr. R. Vishwanath (Ex. 2003) in support of its Response to the Petition.

Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis
11	103(a)	Johnson, Salisbury, Garcia

II. ANALYSIS

A. Person of Ordinary Skill in the Art

Factual indicators of the level of ordinary skill in the art include “the various prior art approaches employed, the types of problems encountered in the art, the rapidity with which innovations are made, the sophistication of the technology involved, and the educational background of those actively working in the field.” *Jacobson Bros., Inc. v. United States*, 512 F.2d 1065, 1071 (Ct. Cl. 1975); *see also Orthopedic Equip. Co. v. United States*, 702 F.2d 1005, 1011 (Fed. Cir. 1983) (quoting with approval *Jacobson Bros.*).

Petitioner contends that the person of ordinary skill in the art (“POSA”) at the time of the ’822 patent would have been “someone with at least a bachelor’s degree in the biological sciences or a relevant field of engineering, and at least 3 years of experience in a field relating to sperm

³ Johnson, US Patent No. 5,135,759, issued Aug. 4, 1992 (Ex. 1005, “Johnson”).

⁴ Salisbury et al., *Physiology of Reproduction and Artificial Insemination of Cattle*, 2d ed. (1978) (Ex. 1006, “Salisbury”).

⁵ Garcia et al., *Development of a Buffer System for Dialysis of Bovine Spermatozoa Before Freezing*, 31(5) THERIOGENOLOGY, 1039–1048 (1989) (Ex. 1007, “Garcia”).

cell physiology.” Pet. 32. Patent Owner contends that a POSA would have had “(1) a bachelors or a graduate degree in at least one of the biological sciences (such as biology, biochemistry, or biomedical engineering), (2) at least five years of experience with flow cytometers, and (3) at least some experience working with non-human, mammalian sperm cell physiology and sexual reproduction.” PO Resp. 21. Alternatively, Patent Owner contends that someone without a degree in the biological sciences but who “ha[d] worked extensively in the field of semen physiology or in semen technology for at least five years would possess enough knowledge to be classified as a person of ordinary skill in the art.” *Id.*

Both parties agree that the POSA would have had a degree in the biological sciences and work experience relating to sperm cell physiology. The parties’ definitions of the POSA differ, however, in whether the POSA must have had experience working with flow cytometers. Accordingly, in identifying the POSA, we focus our analysis on the extent of flow cytometry knowledge or experience required of the POSA.

Petitioner contends that “the sole technical issue disputed in this proceeding concerns the effects of dilution on sperm cell viability, not the technical details of flow cytometry” and thus, “[a]ll that is necessary . . . is a general understanding of the basics of flow cytometry.” Reply 4. Patent Owner argues that “[b]ecause the patentability of the ’822 patent depends almost entirely on the components included in the *sheath and collector fluids*—fluids that are used in the context of sorting sperm cells using flow cytometry—[Petitioner’s] definition . . . lack[s] the necessary level of skill required to understand the field of the ’822 patent.” PO Resp. 22.

Patent Owner's proposal that the POSA would have had five years of experience in the field of flow cytometry seems to overstate the amount of flow cytometry experience required given that the focus of the '822 patent, and of the claim at issue, is on the buffer fluids in which the sperm cells are sorted and collected. *See* Ex. 1001, 4:33–5:6 (“Summary of the Invention” portion of Specification, focusing on improved sheath and collector fluids that minimize the stress on sperm cells), 30:22–35 (claim 11, reciting the claimed method and specifying the components of the sheath and collector fluids without specifying any of the other components that make up a flow cytometer); *see also* Tr. 33 (“The novelty really was in the inventors discovering compatibility [In the prior art] the sheath fluid had different components, and then the collector fluid had different components, and the extender had different components, and that’s how it was seen. What the '822 Patent really did was make a component consistent in all the fluids. So citric acid is not just in the sheath fluid, it’s in the sheath fluid, the collector fluid, and would be expected to be an extender, as well.”), 32 (“that brings us to the innovation, the '822 Patent, while seemingly simple differences in the sheath and the collector fluids, they actually had a very novel impact on the viability of sperm cells”).

Based on our review of the '822 patent and the relevant art, we find that the POSA would have had a bachelors or a graduate degree in at least one of the biological sciences (such as biology, biochemistry, or biomedical engineering), at least 3 years of experience in a field relating to sperm cell physiology, and sufficient knowledge of flow cytometry to understand the role and requirements of the sheath and collector fluids. This determination

is consistent with the level of skill in the art that is reflected in the prior art of record. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001).

The parties rely on the testimony of Drs. Pace and Vishwanath to support their positions in this case. Neither witness indicates that his opinion would change under a different definition of the level of ordinary skill in the art. *See* Ex. 2003 ¶ 30 (Dr. Vishwanath testifying: “I have also considered the level of skill proposed by Dr. Pace in my analysis, and it is my opinion that my conclusions would not change even under that level of skill.”). Similarly, our opinion that the claims would have been obvious over the cited art would not change had we adopted Patent Owner’s proposed definition.

Having identified the POSA, we next consider whether the parties’ witnesses, Dr. Pace and Dr. Vishwanath, are qualified to provide opinions as to the perspective and knowledge of a POSA. Patent Owner criticizes Dr. Pace, Petitioner’s expert, for his lack of experience with flow cytometry, citing testimony that Dr. Pace lacked personal experience using flow cytometry to sort sperm cells. PO Resp. 27. Patent Owner does not contend that Dr. Pace lacks the qualifications to testify from the perspective of the POSA, but contends that Dr. Pace’s lack of experience with flow cytometry goes to the weight of his testimony. Tr. 46–47. Petitioner does not challenge the qualifications of Dr. Vishwanath.

We find that Dr. Pace has sufficient understanding of the role and requirements of sheath and collector fluids to testify from the perspective of the POSA. Ex. 1003 ¶ 10; Ex. 2006, 267:20–268:6; *see also generally id.* ¶¶ 2–9; Ex. 1004. We also find that Dr. Vishwanath is qualified to provide opinions as to the perspective and knowledge of a person of ordinary skill in

the art. See Ex. 2003 ¶¶ 4–17; Ex. 2004. We acknowledge that Dr. Pace lacks personal experience with flow cytometry (see Ex. 2006, 24:13–25, 25:21–25, 35:2–19, 37:5–16), and have considered this factor in weighing his testimony. We find the testimony of Dr. Pace cited in this decision credible for the reasons discussed herein, including that Dr. Pace’s testimony is consistent with the cited art.

B. Claim Construction

The ’822 patent expired on December 31, 2017. Prelim. Resp. 10. The Board interprets claims of an expired patent using the principles set forth in *Phillips*. See *In re CSB-Sys. Int’l, Inc.*, 832 F.3d 1335, 1340–42 (Fed. Cir. 2016) (“[C]onsistent with our prior precedent and customary practice, we reaffirm that once a patent expires, the PTO should apply the *Phillips* standard for claim construction.”); *Black & Decker, Inc. v. Positec USA, Inc.*, 646 F. App’x 1019, 1024 (Fed. Cir. 2016); see also Amendments to the Rules of Practice for Trials before the Patent Trial and Appeal Board, 81 Fed. Reg. 18,750, 18,750 (Apr. 1, 2016) (amending 37 C.F.R. § 42.100(b) to allow a district court-style claim construction approach “for claims of patents that will expire before entry of a final written decision”). Accordingly, in this proceeding, we give claim terms their ordinary and customary meaning, as would be understood by a person of ordinary skill in the art, at the time of the invention, in light of the language of the claims, the specification, and the prosecution history of record. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005). We also consider any extrinsic evidence presented. *Id.* at 1317.

Claim 11 of the ’822 patent requires that “the sheath fluid . . . includes a citric acid” and that the “collector fluid . . . includes a citric acid.”

Ex. 1001, 30:22–35. The dispute with respect to these claim limitations centers on whether they encompass fluids in which citric acid molecules are present because a citrate (e.g., the citric acid salt, sodium citrate) was added to an aqueous solution.⁶ Petitioner contends that we should construe the requirement that the fluids “include[] a citric acid” to encompass sheath and collector fluids produced by dissolving a citrate in water. Pet. 27–28; see Ex. 1003 ¶ 172. Petitioner thus proposes that the requirement that the claimed fluids “include[] a citric acid” means that the fluids “comprise[] citric acid molecules.” *Id.* at 28. Patent Owner contends “citric acid molecules [that] are naturally present in the ‘solution’ based on the addition of a citrate” do not meet the “includes a citric acid” limitations. PO Resp. 23. Patent Owner thus proposes:

[T]he language “includes a citric acid” must mean that a citric acid is specifically included as a component of the sheath fluid. Accordingly, the term “includes a citric acid” means “includes a citric acid as at least one component of the sheath fluid composition” or “includes a citric [acid] as at least one component of the collection fluid composition.”

Id. at 25.⁷ We find that Petitioner has the better position.

⁶ There is no dispute that some citric acid molecules must be present when a citrate is added to an aqueous solution. Ex. 2003 ¶ 112 (Dr. Vishwanath testifying: “I do not dispute that when a citrate, such as sodium citrate, is added to an aqueous solution, a small number of citric acid molecules may exist”); Tr. 62 (Patent Owner’s counsel: “We -- I think, Dr. Vish agreed and we agree, that if you take citrate and put it in aqueous solution, there will be a small number of citric acid molecules that will form.”); Ex. 1003 ¶¶ 168, 171–172.

⁷ Our claim construction analysis treats Patent Owner’s proposed construction as if it would exclude citric acid molecules that come to be present in the sheath or collector fluid based on the addition of citrate to an aqueous solution. We note, however, that it is not clear that Patent Owner’s proposed construction would exclude such molecules because they would

The language of claim 11 is plain on its face. It requires that the claimed fluids “include[] a citric acid.” There is nothing in the language of the claim that restricts the manner in which citric acid came to be present in the claimed fluids; it is not a product-by-process claim. Accordingly, the plain language of the claim supports that the claim encompasses fluids that include citric acid that came to be present through the addition of a citrate.

This interpretation is consistent with the Specification, which describes the preparation of a sheath fluid by adding a citrate to an aqueous solution. Indeed, the only example of a citric-acid-containing sheath fluid described in the Specification is a sheath fluid prepared using sodium citrate. *See* Ex. 1001, 8:52–9:5 (describing preparation of sheath fluid comprising 2.9% sodium citrate), *id.* at 14:66 (disclosing an example “using 2.9% Na citrate as sheath fluid”); *see also* Ex. 1003 ¶ 170 (explaining, with citations to the Specification, how the ’822 patent describes producing a sheath fluid by adding sodium citrate dehydrate to water). Accordingly, the Specification also supports that the claim encompasses fluids that include citric acid that came to be present through the addition of a citrate.

Patent Owner argues that the doctrine of claim differentiation supports its proposed construction because claim 1 and claim 11 must have different scope. The sheath fluid limitations of claims 1 and 11 are recited below:

Claim 1: “wherein the sheath fluid surrounding the sperm cells includes an amount of citrate”

appear to be a “component of the sheath [or collector] fluid composition” as Patent Owner’s proposed construction requires. As we have declined to adopt Patent Owner’s proposed construction, we need not determine whether Patent Owner’s construction would, in fact, exclude citric acid molecules created when citrate is added to an aqueous solution.

Claim 11: “wherein the sheath fluid surrounding the sperm cells includes a citric acid”

Patent Owner contends that “a citric acid and a citrate are not the same thing” and that construing the “includes a citric acid” limitation as Petitioner proposes is incorrect under the doctrine of claim differentiation because it gives claims 1 and 11 the same scope. PO Resp. 23–24. We are not persuaded.

As an initial matter, it is not clear that giving the “includes a citric acid” limitation its plain meaning would cause it to have the same scope as the “includes an amount of citrate” limitation in claim 1. As previously noted, there is no dispute that adding citrate to an aqueous solution will necessarily cause some amount of citric acid to be present. *See supra* n.6. However, the parties do not direct us to evidence from which we can determine whether the converse is true, i.e., whether citrate is always present when a citric acid is present in an aqueous solution. During oral argument, counsel for Petitioner asserted that “scientifically, you can make a solution which contains a citric acid without using citrate; and if you do that, you don’t necessarily have citrate present in the solution.” Tr. 13; *see also id.* at 78. Petitioner, however, did not direct us to evidence supporting that statement. Similarly, Patent Owner did not direct us to evidence supporting its position that Petitioner’s construction would result in the two limitations having the same scope. *Id.* at 66 (Patent Owner’s counsel responding to question about whether it was possible to have a citric acid without a citrate: “I don’t think that’s in the record anywhere, so I can’t agree with that because Dr. Vish won’t opine on that, Dr. Pace won’t opine on that; that’s attorney argument today. So I, honestly, can’t answer that.”).

Even accepting the premise of Patent Owner’s argument that construing claim 11 as Petitioner proposes would cause the “includes a citric acid” limitation in claim 11 to have the same scope as the “includes an amount of citrate” limitation in claim 1, Patent Owner’s argument is not persuasive because claim 11 is not otherwise identical to claim 11. More specifically, claim 11 restricts the content of the collector fluid – requiring that it “include[] a citric acid” – whereas claim 1 imposes no restriction on the content of the collector fluid. *Compare* Ex. 1001, 29:11–12 (claim 1 requiring “at least one collector having a collector fluid”), *with id.* at 30:31–33 (claim 11 requiring “at least one collector having a collector fluid which includes a citric acid”). Accordingly, construing the “includes a citric acid” limitation to encompass fluids that include a citric acid because a citrate was added to an aqueous solution does not render claim 11 redundant of claim 1. This diminishes the justification for applying the doctrine of claim differentiation to these claims. *See Anderson Corp. v. Fiber Composites, LLC*, 474 F.3d 1361, 1370 (Fed. Cir. 2007) (“A further reason for not applying the doctrine of claim differentiation in this case is that the Group I claims are not otherwise identical . . . and thus the district court’s construction does not make the composite composition claims redundant.”).

Moreover, the doctrine of claim differentiation cannot justify giving the “includes a citric acid” limitations a scope that is not warranted in view of the Specification. *See Fromson v. Anitec Printing Plates, Inc.*, 132 F.3d 1437, 1445 (Fed. Cir. 1997) (holding that the doctrine of claim differentiation “can not, of itself, restore to [patentee’s] claims a scope that has been shown to be unwarranted”); *Tandon Corp. v. United States Int’l Trade Comm’n*, 831 F.2d 1017, 1024 (Fed. Cir. 1987) (“Whether or not

claims differ from each other, one can not interpret a claim to be broader than what is contained in the specification and claims as filed.”). As discussed above, the language of the limitations at issue is clear and is consistent with the disclosure of the Specification. Accordingly, the inclusion of a limitation in claim 1 requiring the presence of “an amount of citrate” does not mandate a construction of the “includes a citric acid” limitation in claim 11 that excludes citric acid created by adding an amount of citrate. *Multiform Desiccants, Inc. v. Medzam, Ltd.*, 133 F.3d 1473, 1480 (Fed. Cir. 1998) (“claims that are written in different words may ultimately cover substantially the same subject matter”); *Kraft Foods, Inc. v. Int’l Trading Co.*, 203 F.3d 1362, 1368 (Fed. Cir. 2000) (“That the patentee chose several words in drafting a particular limitation of one claim, but fewer (though similar) words in drafting the corresponding limitation in another, does not mandate different interpretations of the two limitations, since ‘defining a state of affairs with multiple terms should help, rather than hinder, understanding.’”). As the Federal Circuit has explained, claim differentiation “is not a hard and fast rule of construction” and the presumption that claims differ in scope “does not mean that every limitation must be distinguished from its counterpart in another claim, but only that at least one limitation must differ.” *Kraft Foods*, 203 F.3d at 1368. Here, as discussed above, claim 1 and claim 11 meet the requirement that “at least one limitation must differ.”

Accordingly, we construe the limitations requiring that the sheath and collector fluids “include[] a citric acid” to mean that the sheath fluid

comprises citric acid molecules without regard as to how those molecules came to be present in the claimed fluids.

Although the parties offer briefing regarding several additional claim terms (Pet. 26–31; PO Resp. 22–25), the only claim limitations in dispute in this case are the citric acid limitations. PO Resp. 26–54; Tr. 60 (Patent Owner’s counsel agreeing that “the citric acid requirements” are the only claim elements in dispute). Accordingly, we determine that no explicit construction of any other claim terms is necessary to decide this case. See *Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (“[W]e need only construe terms ‘that are in controversy, and only 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))); *Wellman, Inc. v. Eastman Chem. Co.*, 642 F.3d 1355, 1361 (Fed. Cir. 2011) (“[C]laim terms need only be construed ‘to the extent necessary to resolve the controversy’”).

C. Motion to Exclude

Before considering whether the method recited in claim 11 would have been obvious over the cited art, we consider the scope of available evidence. Patent Owner has moved to exclude Exhibits 1029 and 1032 “as hearsay under Federal Rules of Evidence 801 and 802, and as irrelevant and highly prejudicial under Rules 401, 402, and 403.” Mot. 1. Patent Owner also argues that Petitioner “improperly rel[ies] on Dr. Seidel’s lay testimony as expert opinion on the ultimate issue of obviousness” without “seek[ing] to qualify Dr. Seidel as an expert in this proceeding.” *Id.* at 5. Petitioner argues that the cited testimony does not qualify as hearsay because it is not offering the testimony for the truth of the matter asserted. Mot. Opp. 2. In

the alternative, Petitioner argues that even if the cited testimony is offered for the truth of the matter asserted, and thus qualifies as hearsay, it meets the residual exception to the hearsay rule. *Id.* at 2–3. Petitioner further argues that “Dr. Seidel does not need to be formally qualified as an expert in this proceeding for his testimony to be highly relevant.” *Id.* at 5. We find that Patent Owner has the better position.

Exhibit 1029 is the testimony of co-inventor Dr. George E. Seidel, Jr. in a related district court proceeding, and Exhibit 1032 is Dr. Seidel’s *curriculum vitae*. Petitioner cites Dr. Seidel’s testimony in five places in its Petition:

1. To support Petitioner’s claim construction position that there is “no functional consequence of using a citrate rather than citric acid.” Pet. 27 (citing Ex. 1029, 81:12–83:15, 84:1–7);
2. To support Petitioner’s contention the skilled artisan working in the field of bull semen processing and handling before 1997 would have been aware of the advantages of using an extender containing citric acid instead of a phosphate. Pet. 51 (citing Ex. 1029, 39:11–40:10, 68:19–69:17, 70:19–25, 72:6–73:12, 73:16–74:7);
3. To support Petitioner’s contention that a POSA would have known before 1997 that citric acid-based extenders were known to keep bovine sperm healthy. Pet. 54–55 (citing Ex. 1029, 39:11–40:10, 68:19–69:17, 70:19–25, 72:6–73:12, 73:16–74:7);
4. To support Petitioner’s contention that a POSA would have recognized that buffered solutions including a citric acid were as good, or better, than buffered solutions containing phosphates in maintaining the viability of fresh and frozen-thawed sperm. Pet. 60 (citing Ex. 1029, 39:11–40:10, 68:19–69:17, 70:19–25, 72:6–73:12, 73:16–74:7); and

5. To support Petitioner’s position on the ultimate issue that it would have been obvious to adapt a flow cytometry technique disclosed in the prior art to “sort bovine sperm to select a buffer to use in the extender and sheath fluids that includes a citric acid.” Pet. 62, 63–64 (both citing Ex. 1029, 138:6–139:15).

Petitioner cites Exhibit 1032 in its Reply to support its position that “Dr. Seidel, the lead named inventor upon whose testimony Petitioner relies, is undeniably a skilled person, under any proposed definition.” Reply 5.

Petitioner contends that Dr. Seidel’s testimony supporting these five contentions is not hearsay because it is not being offered for the truth of the matter asserted. According to Petitioner, it cites Dr. Seidel’s testimony “to show that a skilled person (one of the inventors, no less) holds an opinion on these issues, not to prove that they are necessarily true.” Mot. Opp. 2. We are not persuaded. Although the fact that Dr. Seidel is “a skilled person,” and “one of the inventors” may lend credibility to his assertions, it does not, by itself, convey relevance to his testimony independent of the truth of the matters asserted. Petitioner does not identify, and we do not find, any relevance to the above assertions other than to prove that what the inventor said was true — i.e., that citrate and citric acid are interchangeable (contention 1), that the benefits of citrate with respect to bull semen were known (contentions 2–4), and that the alleged innovation of the claimed method would have been obvious (contentions 5). Accordingly, we agree with Patent Owner that the above statements are hearsay.

Petitioner argues that “[e]ven if the inventor statements were used for a hearsay purpose, they should be admitted under Rule 807.” Mot. Opp. 2. Federal Rule of Evidence 807 provides:

(a) In General. Under the following circumstances, a hearsay statement is not excluded by the rule against hearsay even if the

statement is not specifically covered by a hearsay exception in Rule 803 or 804:

- (1) the statement has equivalent circumstantial guarantees of trustworthiness;
- (2) it is offered as evidence of a material fact;
- (3) it is more probative on the point for which it is offered than any other evidence that the proponent can obtain through reasonable efforts; and
- (4) admitting it will best serve the purposes of these rules and the interests of justice.

(b) Notice. The statement is admissible only if, before the trial or hearing, the proponent gives an adverse party reasonable notice of the intent to offer the statement and its particulars, including the declarant's name and address, so that the party has a fair opportunity to meet it.

Fed. R. Evid. 807.

We are not persuaded that the facts of this case merit application of Rule 807, the residual exception to the rule against hearsay. In particular, it is not clear that the testimony at issue is “more probative on the point for which it is offered than any other evidence that proponent can obtain through reasonable efforts,” as Federal Rule of Evidence 807 requires. Although the fact that the declarant is a named inventor may lend considerable weight to his testimony, the testimony at issue appears to be cumulative of other evidence Petitioner identifies. As this testimony is cumulative, it is not “more probative on the point for which it is offered than any other evidence that the proponent can obtain through reasonable efforts.” Accordingly, we exclude the testimony cited in the Petition from Exhibit 1029, as well as the portions of the Petition and Reply that rely solely on that testimony, as hearsay.

We also exclude Exhibit 1032 as irrelevant. Petitioner relies on Exhibit 1032 to establish that Dr. Seidel is qualified to offer the cited testimony. Reply. 5. As we have excluded Dr. Seidel's testimony, Exhibit 1032 lacks relevance. Accordingly, we exclude Exhibit 1032 as well as the portions of the Petition and Reply that rely solely on Exhibit 1032, as irrelevant.

D. Obviousness

Petitioner asserts that claim 11 would have been obvious over the combination of Johnson, Salisbury, and Garcia. See Pet. 41–67. We have considered the question of patentability in view of all the evidence and arguments presented in this proceeding. Based on the record developed during this proceeding, we determine that Petitioner has shown by a preponderance of the evidence that claim 11 would have been obvious over the combination of the combination of Johnson, Salisbury, and Garcia.

1. Disclosures of the Asserted Prior Art

Johnson

Johnson discloses:

the separation, by flow sorting, of intact, viable X and Y chromosome-bearing rabbit and swine sperm populations based on relative DNA content; surgical insemination of the sorted sperm into does; and the subsequent birth of sexed offspring with a phenotypic sex ratio consistent with predictions based on the relative DNA content of the sorted sperm populations.

Ex. 1005, 2:64–3:3.

Johnson further discloses:

It is, of course, of critical importance to maintain high viability of the intact sperm during the sorting process and during storage after sorting but prior to insemination.

Of the factors involved in maintaining sperm viability, the method of staining, the sheath fluid, and the collecting fluid have been found to be especially important.

Id. at 4:19–26.

Johnson exemplifies sorting rabbit and swine sperm. *Id.* at 4:65–66, 7:1–41. With respect to the sheath fluid, Johnson teaches the use of “10 mM phosphate-buffered saline (PBS) containing 0.1% bovine serum albumin (BSA).” *Id.* at 6:38–41. With respect to the collecting fluid, Johnson teaches the use of an egg yolk extender comprising “N-tris(hydroxymethyl)-methyl-2-amino ethane sulfonic acid, 2.16 g; tris hydroxymethyl aminomethane, 0.51 g; dextrose 0.1 g; streptomycin sulfate, 0.13 g; penicillin G, 0.08 g; egg yolk, 12.5 ml; Equex STM . . . , 0.5%; and distilled water, 50 ml.” *Id.* at 6:42–47. Johnson “expected that the sperm of most mammals could be effectively sorted by following these procedures” but recognized that “minor modifications may be made in the procedure without departing from the spirit and scope of the invention.” *Id.* at 4:67–5:3.

Salisbury

Salisbury discloses that adding an “extender” to sperm cells may “preserve the fertility of sperm cells and . . . increase the total volume so that the proper dose of cells for insemination can be conveniently packaged and used.” Ex. 1006, 442. According to Salisbury, “[t]here are countless recipes for media that will preserve bull spermatozoa.” *Id.* Salisbury reports that the “most widely used medium for artificial insemination in cattle” is the “yolk-citrate extender,” which provides “equal fertility, higher spermatozoan motility during prolonged storage, and improved visibility” as compared to a previously used extender comprising “equal volumes of egg yolk and

phosphate buffer.” *Id.* at 443; *see also id.* at 448 (“In general, yolk-citrate has been the standard against which new extenders have been compared.”).

Salisbury discloses three extender formulations that comprise citric acid and egg yolk: the “standard” egg-yolk citrate formulation (*id.* at 447–448); the Cornell University extender (“CUE”) (*id.* at 450–455); and the TRIS-egg-yolk-citric acid formulation (*id.* at 455–457). The below table summarizes the composition of these three extenders.

Table 1. Most Commonly Used Bovine Extenders

Bovine Extender	Components	Reference
CUE	sodium citrate dihydrate 1.45g/100ml citric acid monohydrate 0.09g/100ml sodium bicarbonate 0.21g/100ml potassium chloride 0.0 g/100ml glucose 0.3g/100ml glycine 0.94g/100ml sulfanilamide 0.30g/ml 20 parts egg yolk	Salisbury-1978, 452.
Tris-egg yolk-citric acid	tris 3.028g citric acid monohydrate 1.675g fructose 1.25g egg-yolk 25ml glycerol 8.0ml Glass redistilled water 92.0ml	Salisbury-1978, 456.
Egg yolk-citrate	sodium citrate dihydrate 2.9% (w/v) egg yolk 20-25% (v/v)	Salisbury-1978, 447-448.

Pet. 53. Table 1 (above) is a summary Petitioner provides identifying the components of the three citric-acid containing bovine extenders Salisbury discloses. Patent Owner does not contest the accuracy of Table 1 in its Patent Owner’s Response.

Salisbury discloses:

A major breakthrough in semen extenders came when Phillips reported the value of hen’s egg yolk. In the original formula the extender contained equal volumes of egg yolk and phosphate buffer. Salisbury et al. showed that, by replacing the phosphate with sodium citrate, equal fertility, higher

spermatozoan motility during prolonged storage, and improved visibility resulted.

Ex. 1006, 443.

Garcia

Garcia reports the results of three experiments “conducted to study the effect of inorganic and organic acids on survival of dialyzed bovine spermatozoa.” Ex. 1007, Abstract. The experiments analyze sperm motility in samples before and after thawing and record the ability of spermatozoa in post-thaw samples to pass through a Sephadex column. *Id.* Garcia concludes that:

post[-]thaw sperm motility in solutions containing 35% isosmotic Na citrate (V/V) in the extender and dialysate was statistically superior to any other buffer solution studied. Sperm motility of fresh and frozen thawed samples was high in potassium phosphate and was not different from motility in samples containing Na citrate. However, the evaluation of the number of cells that passed through the Sephadex column showed statistical differences between the use of phosphate containing dialysates and Na citrate. All data obtained for carbonate and chloride solutions were significantly lower ($P < 0.05$) than the data obtained for phosphate buffers.

Id. at 1046.

2. Analysis

Petitioner directs us to substantial evidence that Johnson discloses all of the limitations of claim 11, with the exception of limitations requiring that the sheath and collector fluids “include[] a citric acid.” Pet. 41–46. Patent Owner does not contest that Johnson discloses these limitations. *See* PO Resp. 26–54; Tr. 60. Patent Owner, therefore, has waived any arguments against Petitioner’s assertions as to these limitations. *See* Paper 9, 4 (Scheduling Order cautioning Patent Owner that “any arguments for

patentability not raised in the response will be deemed waived”); *cf. In re NuVasive, Inc.*, 842 F.3d 1376, 1381 (Fed. Cir. 2016) (explaining that a patent owner waives an argument presented in the preliminary response if it fails to renew that argument in the patent owner response after trial is instituted). Based on the arguments and evidence presented during this review, we determine that Petitioner has shown by a preponderance of the evidence that Johnson discloses all of the limitations of claim 11, with the exception of the limitations requiring that the sheath and collector fluids “include[] a citric acid,” for the reasons set forth in the Petition. *NuVasive, Inc.*, 841 at 974 (explaining that the Board need not make specific findings as to claim limitations that Patent Owner does not dispute are disclosed in the prior art). The remainder of our analysis focuses on the disputed limitations of claim 11, i.e., the requirement that the sheath and collector fluids “include a citric acid.”

i. The Parties’ Arguments as to the Includes Citric Acid Limitations

With respect to the requirement that the collector fluid include a citric acid, Petitioner contends that “[t]he ordinary artisan would have known that extender solutions can have different effects on different species of sperm, and that certain extenders were more effective in extending the viability of particular species of sperm.” *Id.* at 54 (citing Ex. 1003 ¶ 235). Petitioner further contends that “[t]he ordinary artisan also would have understood the importance of selecting an extender suitable for bull semen [because] . . . samples take several hours to be processed and once sorted, the cells remain in the collection fluid, heavily diluted by the sheath fluid, for many hours longer.” *Id.* (citing Ex. 1003 ¶ 238).

Based on the teachings of Salisbury, Petitioner contends that the skilled artisan would have understood that “the CUE, Tris-egg yolk-citric acid and egg yolk citrate extenders were the most effective and proven extenders being used in processing of bovine sperm.” *Id.* According to Petitioner, the ordinary artisan also would have known that “citrate and citric acid-based extenders provide better results than phosphate-based extenders for bovine sperm.” *Id.* at 54–55 (citing Salisbury and Garcia). Petitioner thus concludes that an ordinary artisan, considering how to adapt Johnson to sort bovine sperm, would have found it obvious to “use one of the well-known bovine semen extenders that contain a citric acid in the collection fluid when sex-sorting bovine sperm, such as CUE, Tris-egg-yolk-citric acid or egg yolk-citrate.” *Id.* at 55 (citing Ex. 1003 ¶¶ 239–241).

With respect to the requirement that the sheath fluid include a citric acid, Petitioner contends that “sheath fluid can affect sperm viability when it dilutes the collection fluid containing the sperm.” *Id.* at 60 (citing Johnson).⁸ Petitioner further contends that

the ordinary artisan would have found it logical to not only select a sheath fluid that had been shown to maintain the viability of the type of sperm being sorted but also to use a sheath fluid that would be compatible with the constituents of the extender media being used in the collection fluid.

Id. at 61. As support, Petitioner cites Dr. Pace’s testimony (Ex. 1003 ¶¶ 248–49) and Leary’s disclosure,⁹ which states:

⁸ Sheath fluid propels a sample through the flow cytometer, but does not mix with the sample layer until the sheath and collection fluids combine in the collection unit. Ex. 1003 ¶ 243.

⁹ Leary, *Methods in Cell Biology Volume 42: Flow Cytometry* (2d ed. 1994) (Ex. 1021, “Leary”).

Since the sorted sample will be highly diluted in sheath fluid, make certain that the cells can tolerate the sheath fluid. While phosphate-buffered saline (PBS) (and many cells dislike PBS!) is commonly used for sheath fluid in cell sorters other fluids can be used provided that they provide proper ion charges for cell sorting and do not disturb the viscosity for fluidic requirements or refractive index for optical requirements.

Ex. 1021, 350.

Petitioner contends that “although PBS was used as a sheath fluid in the rabbit and swine examples in Johnson[], it would have been recognized as not being the optimal buffer media to use for bovine sperm.” Pet. 62. Petitioner argues that the ordinary artisan, seeking to apply Johnson’s sorting method to bovine sperm, would have found it obvious to “select a buffer to use in the extender and sheath fluids that includes a citric acid, as it was known that such buffers would maintain the viability of bovine sperm.” *Id.* According to Petitioner, the ordinary artisan would have understood that “buffered solutions based on citric acid showed equivalent or better results with respect their effects on bovine sperm than buffered solution based on phosphates.” *Id.* at 63 (citing Pace Declaration, Garcia, and Salisbury). Therefore, Petitioner argues, the ordinary artisan “would have found it obvious to use a buffer solution including a citric acid as the sheath fluid when using the Johnson technique to sort bovine sperm, particularly when the extender used in the collection fluid also included a citric acid.” *Id.*

Patent Owner contends that the cited art does not render the claimed method obvious because none of the asserted references disclose a sheath or collector fluid that includes a citric acid. PO Resp. 26–30. Patent Owner further argues that Johnson teaches away from the claimed method by discouraging the use of citric acid. *Id.* at 30–37. Finally, Patent Owner argues that Petitioner has failed to establish a motivation to use a citric acid

in the sheath and collector fluids and a reasonable expectation of success in doing so. *Id.* at 38–55.

Based on the arguments and evidence presented during this review, we find that Petitioner has shown by a preponderance of the evidence that it would have been obvious to have included a citric acid in the sheath and collector fluids of a flow cytometer like that disclosed in Johnson.

ii. Collector Fluid that Includes a Citric Acid

We begin our analysis by considering the collector fluid. According to Dr. Vishwanath, “[a] collector fluid is a solution that is deposited into a collection vessel before the sperm cells are sorted and collected.” Ex. 2003 ¶ 48. “The purpose of the collector fluid was to provide a liquid cushion to reduce the impact of the sperm cells hitting a glass wall once it exits the flow cytometer nozzle at speeds up to 50 mph.” *Id.* ¶ 49. “In 1997, commonly-used collector fluids were simple buffers (TEST Yolk) containing egg yolk that were understood to reduce dilution effects and protect sperm cells from physical damage when sorted into the designated collection vessel.” *Id.* ¶ 50; *see also* Ex. 1005, 2:56–58 (“It is a further object of this invention to provide a collecting fluid capable of maintaining the viability of sorted sperm cells.”). In 1997, “it was understood that the collector fluid needed to be of the right pH and osmotic strength and supportive of sperm health, but had to be simple enough to not exacerbate sperm metabolism.” Ex. 2003 ¶ 48. Collector fluids also “required components that also reduced the dilution effect on sperm.” *Id.* ¶ 49.

The evidence of record supports that before 1997, it was known that different buffer solutions could have different effects on different species of

sperm. For example, Dr. Pace testifies that “[d]ifferent extender¹⁰ formulations provide optimal results for different types of sperm – what worked well to maintain viability of bovine sperm did not necessarily work well for equine or swine sperm.” Ex. 1003 ¶ 106; *see also id.* ¶ 235 (“The ordinary artisan would have known that extender solutions can have different effects on different species of sperm, and that particular extenders were known to be more effective in extending the viability of particular species of sperm.”). This testimony is consistent with the prior art of record, which reflects that different extenders may be optimal for different species of sperm. *See, e.g.,* Ex. 1021, 350 (disclosing that although PBS is “commonly used [as] sheath fluid in cell sorters,” “many cells dislike PBS!”); Ex. 1013, 900 (disclosing different buffers for use in bull, boar, and human sperm).

The evidence of record also supports that it was well known to use citric acid in buffers for bovine sperm. Indeed, Dr. Pace testifies that extenders containing citric acid were the “most common” extenders suitable for bovine sperm. Ex. 1003 ¶ 246. Consistent with Dr. Pace’s testimony, Salisbury teaches that “[t]he yolk-citrate extender, with various modifications, has been the most widely used medium for artificial insemination of cattle.” Ex. 1006, 443; *see also* Ex. 1007, 1046 (“Na citrate has been used as an extender for many years”). The evidence further supports that the skilled artisan would have known citrate and citric acid-based extenders provide equivalent or better results than phosphate-based extenders when used with bovine sperm. *Id.* (“post[-]thaw sperm motility in

¹⁰ An “extender” is a medium in which raw ejaculate is diluted to extend the sperm’s viability outside the body. Ex. 1003 ¶ 101.

solutions containing 35% isosmotic Na citrate (V/V) in the extender and dialysate was statistically superior to any other buffer solution studied”); Ex. 1006, 443 (“[B]y replacing the phosphate with sodium citrate, equal fertility, higher spermatozoan motility during prolonged storage, and improved visibility resulted.”); Ex. 1003 ¶ 240 (Dr. Pace’s testimony, consistent with the cited art that “[t]he ordinary artisan also would have known before 1997 that citrate and citric acid-based extenders provide better results than phosphate-based extenders for bovine sperm.”).

The record thus supports that the POSA would have had reason to customize the collector fluid to the species of sperm being sorted and, when sorting bovine sperm, reason to substitute a collector fluid containing a citric acid for Johnson’s phosphate-based collector fluid. The record further supports that the POSA would reasonably have expected such substitution to be successful because extenders containing citrates were known to be equivalent to or better than extenders containing phosphates for sorting bovine sperm. Accordingly, the record supports that the POSA would have found it obvious to use a buffer including a citric acid as the collector fluid when adapting the flow cytometry process disclosed in Johnson, which sorts rabbit sperm (Ex. 1001, 4:65–5:1), to instead sort bovine sperm.

iii. Sheath Fluid that Includes a Citric Acid

We turn next to the sheath fluid. “Sheath fluid is a chemical or solution that provides an outer core surrounding the sample stream (sperm cells).” Ex. 2003 ¶ 42. “[T]he role of the sheath fluid is to propel the sample through the flow cytometer.” Ex. 1003 ¶ 243. “Because the sheath fluid forms an outer core surrounding the sample of sperm cells, the sheath fluid does not excessively mix with the sample until the sperm cells exit the

nozzle, forming droplets. Once a droplet is charged and selected for deflection into a particular collection vessel, the sheath fluid mixes with sperm cells and the collector fluid.” Ex. 2003 ¶ 44.

The evidence of record supports that even though sheath fluid does not interact with cells in the flow cytometer, it was known that sheath fluid can affect sperm viability when it combines with and dilutes the collection fluid in the collection unit. Ex. 1003 ¶ 82 (Dr. Pace’s testimony, consistent with the art, that “before 1997, it was well understood that the sheath fluid will dilute the concentration of agents and sperm in the collection container, and that steps need to be taken to mitigate any stress that dilution may cause on the sperm after they have been sorted”), ¶¶ 76–82, 243–245; Ex. 1013, 900 (“The TEST-egg yolk extender into which the sperm are received is critical to their survival after sorting because of the excessive dilution caused by the presence of the sheath fluid in the flow sorting process.”); Ex. 1005, 4:51–52 (“Dilution of sperm as occurs in sorting tends to reduce viability of the cells.”); Ex. 1021, 350 (“Since the sorted sample will be highly diluted with sheath fluid, make certain that the cells can tolerate the sheath fluid.”).

The evidence also supports that the skilled artisan would have selected a sheath fluid that was known to maintain the viability of the type of sperm being sorted. Ex. 1003 ¶¶ 248–249; Ex. 1005, 4:23–26 (“Of the factors involved in maintaining sperm viability, the method of staining, the sheath fluid, and the collecting fluid have been found to be especially important.”). More specifically, the evidence supports Dr. Pace’s testimony that the POSA would have “found it logical to select a sheath fluid that had been shown to maintain the viability of the type of sperm being sorted and which would be compatible with the constituents of the extender media being used in the

collection fluid.” Ex. 1003 ¶ 249. For example, Leary teaches: “[s]ince the sorted sample will be highly diluted in sheath fluid, make certain that the cells can tolerate the sheath fluid.” Ex. 1021, 350.

As discussed above, the evidence supports that different buffers are optimal for different species of sperm and that, for bovine sperm, buffers containing citric acid are equivalent to or better than buffers that, like the buffer disclosed in Johnson, contain phosphates. This, combined with the knowledge that the sheath fluid can affect sperm viability when it combines with and dilutes the collector fluid, provides reason to use a sheath fluid containing a citric acid when sorting bovine sperm. The record further supports that the POSA reasonably would have expected such substitution to be successful because extenders containing citrates were known to be equivalent to or better than extenders containing phosphates for sorting bovine sperm. Ex. 1003 ¶ 255 (Dr. Pace’s testimony that “[b]uffer solutions including a citric acid would have been considered by the ordinary artisan to be a known and predictable equivalent[of] the PBS sheath fluid used in the examples in Johnson-1992, particularly when sorting bovine sperm.”). Accordingly, the record supports that the POSA would have found it obvious to use a buffer including a citric acid as the sheath fluid when adapting the flow cytometry process disclosed in Johnson to sort bovine sperm, particularly if one were using a citric acid-containing collector fluid. See Ex. 1003 ¶ 249 (“Using a common buffer system . . . would reduce the possibility of the two fluid systems altering the isotonicity, osmolarity, pH or some other aspect of the fluid environments to which sperm are exposed during sorting.”).

iv. *Patent Owner's Arguments*

We turn now to Patent Owner's arguments. Patent Owner argues that "[n]one of the references discloses a sheath fluid or a collector fluid that includes a citric acid." PO Resp. 26. We do not find this argument persuasive.

We recognize that both Salisbury and Garcia do not expressly disclose citric acid, instead disclosing solutions containing citrate. However, as discussed above (*see supra* p. 11 n.6), there is no dispute that aqueous solutions containing citrate would necessarily include some amount of citric acid. As also discussed above, we construe the "includes a citric acid" limitations of claim 11 to encompass citric acid that comes to be present in an aqueous solution by adding citrate to an aqueous solution. Accordingly, we find that Salisbury and Garcia both disclose buffers "including a citric acid" within the meaning of claim 11.

We also recognize that the buffers disclosed in Salisbury and Garcia were not used as sheath or collector fluids. We do not find this deficiency fatal because it is the combination of Johnson, Salisbury, and Garcia, not any single reference alone, that Petitioner asserts renders the claims obvious. "Non-obviousness cannot be established by attacking references individually where the rejection is based upon the teachings of a combination of references." *In re Merck & Co.*, 800 F.2d 1091, 1097 (Fed. Cir. 1986).

Patent Owner argues that Petitioner's obviousness argument is "based entirely on an assumption made by its expert that extenders used to store conventional, unsorted bovine semen for long-term preservation (as in Salisbury) or used in dialysis experiments on conventional bovine semen (as in Garcia) could be substituted for the sheath fluid or the collector fluid" and

that Petitioner relies only on the testimony of Dr. Pace to support this assumption. PO Resp. 27. Patent Owner then argues that Dr. Pace was “personally unfamiliar” with sheath and collector fluids (*id.* at 27–29) and that Dr. Vishwanath explained that the superior performance of Salisbury’s citrate-based buffers “related only to long-term storage and visibility – not to maintain sperm cells temporarily or to aid with hydrodynamic flow as with the sheath fluid, or to limit the negative impact of dilution or to cushion the cells as with the collector fluid.” *Id.* at 29. We are not persuaded.

As an initial matter, we find Dr. Pace’s testimony credible and supported by the art of record. In particular, we credit Dr. Pace’s testimony that the “ordinary artisan would have . . . known, based on the guidance in Salisbury-1978 and Garcia-1989-III and from that person’s experience using bovine extenders in various part of the AI [artificial insemination] process, that extenders and buffer solutions containing a citric acid maximize the viability of bovine sperm.” Ex. 1003 ¶ 225; *see also id.* ¶¶ 112, 115, 165. We also credit Dr. Pace’s testimony that the “ordinary artisan would have . . . expected, based on this knowledge, that the use of sheath and collection fluids containing a citric acid would be as or more effective in obtaining viable bovine sperm as the exemplary conditions described in Johnson-1992.” *Id.* ¶ 226.

With respect to the specific arguments Patent Owner raises as to why the POSA would have considered the teachings of Salisbury and Garcia inapplicable to flow cytometry, we acknowledge that the benefits of using a buffer containing a citrate taught in Salisbury were in the context of “prolonged storage.” Ex. 1006, 443. However, it is not clear why a buffer taught as useful for prolonged storage of bovine sperm would not also be

useful in situations where bovine sperm is exposed to the buffer for shorter durations. At a minimum, a POSA would have expected that a buffer that was not harmful for prolonged storage would also not be harmful when sperm were exposed to it for a shorter period of time. The absence of harm is among the factors a POSA would have considered in selecting buffers for use as sheath and collector fluids. Ex. 2003 ¶ 156 (Dr. Vishwanath's testimony: "When determining what to use for the sheath and collector fluids, the emphasis was on selecting chemicals that would facilitate the sorting method but that were known at the same time to not harm the sperm.").

Moreover, Garcia supports that using a buffering system including a citric acid would have helped to address the negative impact of dilution. In Garcia, a bovine semen sample was first extended using an extender containing 20% egg yolk and one of the buffer systems being tested. Ex. 1007, 1041. The extended semen was then dialyzed at 1:50 ratio with the same buffer system without the egg yolk. *Id.* at 1039. We agree with Petitioner and Dr. Pace that, at least with regard to the dilution problem, this situation is analogous to when sheath fluid dilutes the collector fluid in flow cytometry. Ex. 1003 ¶ 163. We do not agree with Patent Owner that the presence of egg yolk in Garcia's dialysis extender and the absence of egg yolk in flow cytometry sheath fluid renders Garcia's dilution step non-analogous to the dilution that occurs in flow cytometry. PO Resp. 47. In both cases, a buffered solution not containing egg yolk (in Garcia, the dialyzing buffer; in flow cytometry, the sheath fluid) dilutes a sample of sperm extended with a semen extender containing egg yolk (in Garcia, the extender; in flow cytometry, the collector fluid).

We recognize that, in aspects other than dilution, Garcia's buffers are used differently from how the sheath and collector fluids are used in flow cytometry. Dr. Vishwanath testifies that unlike the dialysis described in Garcia, in flow cytometry the sperm cells are stained, subjected to shear forces, illuminated by laser light, and deflected at high speed into a collection vessel. Ex. 2003 ¶¶ 161–163. Patent Owner, however, does not direct us to persuasive evidence in the record that these differences would have caused the ordinary artisan to consider Garcia's teachings regarding buffer solutions for bull semen inapplicable to flow cytometry. Nor do these differences diminish the teaching in Garcia that, with respect to bovine sperm dilution, buffers including citrates were equivalent to or better than phosphate-based buffers.

We acknowledge that citric acid in a buffer system used as a collector fluid may not, by itself cushion the cells when they are deflected into the collector fluid. However, this does not provide a reason to disregard Salisbury's and Garcia's teachings regarding citrate buffers, particularly as the claims do not require that citric acid itself cushion cells. Moreover, Petitioner and Dr. Pace contend that it would have been obvious to use "one of the well-known bovine semen extenders that contain a citric acid in the collection fluid . . . such as CUE, Tris-egg-yolk-citric acid or egg yolk-citrate." Pet. 55; Ex. 1003 ¶¶ 234–241. Each of these buffers contained egg yolk. *Id.* ¶ 148 (Dr. Pace's testimony summarizing components of extenders disclosed in Salisbury). The evidence supports that it was known that egg yolk helped to cushion cells when they impacted the collector fluid at high

speed.¹¹ PO Resp. 8 (“Dr. Vishwanath explains that in 1997, egg yolk was a common constituent of collector fluids because of its ability to address the negative side effects of dilution and its ability to cushion the cells when they impacted the collector fluid at high speeds.”) (citing Ex. 2003 ¶ 50); Ex. 1003 ¶ 82 (Dr. Pace’s testimony that it was known to add an extender containing egg yolk to the collector fluid); Ex. 2006, 110:8–17 (Dr. Pace’s testimony that egg yolk performs a cushioning function).

Patent Owner argues that Johnson teaches away from the use of a citrate in the sheath fluid by teaching that sugars and salts must be avoided. The relevant passage in Johnson states:

Sheath fluid used in sorting cells must be electrically conductive and isotonic. A concentration of 10 mM phosphate buffered saline provided the necessary electrical properties, and 0.1% bovine serum albumin was added to enhance sperm viability by providing protein support for metabolism and viscosity for the sperm. ***The sheath fluid must be free of sugars and excess salts.***

Ex. 1005, 4:44–50 (emphasis added). Patent Owner contends that the POSA would have understood that this teaching was consistent with the understanding in the art – to which Dr. Vishwanath attests – that adding sugars increases the metabolic activity of sperm, which leads sperm to more quickly enter a capacitation phase in which sperm cells “must fertilize an egg within a certain period or else they will degrade and die.” PO Resp. 33; Ex. 2003 ¶ 136. According to Patent Owner and Dr. Vishwanath, a POSA

¹¹ Dr. Pace testifies that the POSA would have understood that egg yolk did not need to be in the sheath fluid since it does not interact with sperm until it combines with the collection fluid. Ex. 1003 ¶ 254. This testimony is consistent with the art. See, e.g., Ex. 1005, 6:38–48 (Johnson’s disclosure of sheath fluid lacking egg yolk and collector fluid containing egg yolk).

would have understood adding salt to have a similar effect. PO Resp. 31; Ex. 2003 ¶ 137. Thus, Patent Owner argues, “Johnson’s teaching that ‘[t]he sheath fluid must be free of sugars and excess salts’ would have discouraged a skilled artisan from replacing Johnson’s phosphate-based buffer with the citric acid-based extenders of Salisbury or the citrate-based buffer of Garcia because all of those buffers include sugars or salts.” PO Resp. 34.

We recognize that citrates may be salts, but Johnson does not teach against the inclusion of all salts. Indeed, Johnson’s phosphate buffered saline sheath fluid includes some salt. Ex. 1005, 6:38–41 (describing the sheath fluid as “saline” and disclosing that the collector fluid includes dextrose); PO Resp. 34 (“PBS with BSA already included a minimal amount of salt—saline”) (citing Ex. 2003 ¶ 137). Rather, Johnson cautions against “excess salt,” which we understand to mean salt beyond the amount included to render the solution isotonic, or put another way, salt beyond the amount in Johnson’s phosphate buffered saline sheath fluid. *Id.*; Ex. 1005, 4:44–50; Tr. 48:23–25 (Patent Owner’s counsel explaining “Johnson uses the term excessive salts because, obviously, PBS, the phosphate-based saline is a salt.”).

Patent Owner’s argument that Johnson teaches away from using Salisbury or Garcia’s buffers as sheath fluid is not persuasive because Petitioner does not contend that it would have been obvious to substitute the buffers in Salisbury or Garcia, in their entirety, for Johnson’s sheath fluid. Rather, Petitioner simply contends that it would have been obvious “to select a buffer to use in the . . . sheath fluids that includes a citric acid.” Pet. 62. There is nothing in the record to suggest that such a sheath fluid would contain “excess salt.” For the same reason, we are not persuaded by Patent

Owner's argument that Johnson teaches "against adding any type of salt to the sheath fluid" and thus, the POSA would not have added citrate to Johnson's sheath fluid, which already contains a minimal amount of salt. PO Resp. 34 (citing Ex. 2003 ¶ 137). Simply put, Petitioner does not contend that it would have been obvious to *add* citrate to Johnson's sheath fluid. Pet. 62. Rather, Petitioner contends it would have been obvious to *substitute* Johnson's phosphate-buffered saline with a citrate buffer.

Patent Owner argues that Petitioner cannot circumvent Johnson's teaching away by contending only that the citric acid component of the sheath fluid would have been obvious without identifying other components that would also be present. PO Resp. 35. Patent Owner points out that "neither Petitioner nor Dr. Pace identifies what buffer system would have replaced Johnson's sheath fluid," leaving the POSA to "guess as to what components a person of ordinary skill in the art would have included." *Id.* at 36. This argument is not persuasive because the claims do not require that the sheath fluid include any other components. Ex. 1001, 30:22–35. All the claims require with respect to the composition of the sheath fluid is that it "includes a citric acid." *Id.* For the reasons discussed above, Petitioner has demonstrated by a preponderance of the evidence that it would have been obvious to include a citric acid (via dissolution of a citrate) in the sheath fluid. With respect to the sheath fluid, nothing more was required.

Patent Owner argues that "Johnson himself sorted bovine sperm cells yet did not consider the teaching of Salisbury or Garcia in his choice of sheath fluid and collector fluid." PO Resp. 38. According to Patent Owner, this "refutes Petitioner's implication that Johnson used a phosphate-based sheath fluid because of the particular species he was sorting" (*id.* at 48) and

shows that the POSA would “not have been motivated by Salisbury or Garcia to use a citric acid or a citrate-based buffer in the sheath fluid or in the collector fluid to sort bovine sperm cells.” *Id.* at 38–39.

We do not find this argument persuasive because the POSA is not a specific individual, but a hypothetical construct. *In re Metz*, No. 97-1263, 1998 WL 670185, at *4 (Fed. Cir. Nov. 17, 1998) (“[T]he test is not whether a particular individual, or two individuals as in this case, of ordinary skill in the art could or did make the connection, but rather if it would have been obvious to the hypothetical person of ordinary skill in the art.”). In addition, Patent Owner does not point to any specific teaching in Johnson explaining why he did not use citric acid buffers or the same buffer in the sheath and collection fluids. Absent an explanation as to why Johnson chose to use a phosphate-based buffer with bovine sperm rather than a citric acid-based buffer, we accord little weight to his decision. There are many possible explanations for this decision beyond Patent Owner’s implication that Johnson did not see citric acid-based buffers as viable alternatives to phosphate-based buffers. *Cf. DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co.*, 464 F.3d 1356, 1364 (Fed. Cir. 2006) (“[M]ere failure to discuss immediate use of his leuco indigo *solution* for dyeing is not the same thing as Brochet stating in his article that . . . his leuco indigo solution may only be concentrated in paste form. We will not read into a reference a teaching away from a process where no such language exists.”); *In re Fulton*, 391 F.3d 1195, 1201 (Fed. Cir. 2004) (“The prior art’s mere disclosure of more than one alternative does not constitute a teaching away from any of these alternatives because such disclosure does not criticize, discredit, or otherwise discourage the solution claimed . . .”).

Finally, Patent Owner argues that the POSA would not have expected success in using citric acid-based buffers in the sheath and collector fluids because the POSA would have “understood that citric acid renders sperm cells non-viable.” PO Resp. 54. We do not find this argument persuasive because it is contrary to the evidence that buffers including citric acid were commonly used as extenders for bovine sperm. *See, e.g.*, Ex. 1006, 443 (“The yolk-citrate extender, with various modifications, has been the most widely used medium for artificial insemination in cattle.”). Patent Owner relies on the testimony of Dr. Pace that citric acid would destroy sperm cells to support this argument. PO Resp. 54. But in context, Dr. Pace’s testimony is reasonably understood as relating to the use of citric acid by itself without a buffer. Ex. 2006, 101:16–25. Petitioner does not contend that it would have been obvious to use citric acid alone. Rather Petitioner contends that it would have been obvious to use a buffer including citric acid.

For the reasons set forth above, we find that Petitioner has established by a preponderance of the evidence that claim 11 would have been obvious over the combination of Johnson, Salisbury, and Garcia.

III. CONCLUSION

Upon consideration of the Petition, Response, Reply, Sur-Reply, the briefing on Patent Owner’s Motion to Exclude, and the evidence before us, we determine that Petitioner has proven by a preponderance of the evidence that claim 11 would have been obvious over either the combination of Johnson, Salisbury, and Garcia.¹² We grant Patent Owner’s motion to exclude.

¹² Should Patent Owner wish to pursue amendment of the challenged claims in a reissue or reexamination proceeding subsequent to the

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that Petitioner has proven by a preponderance of the evidence that claim 11 of U.S. Patent No. 9,365,822 is unpatentable.

ORDERED that Patent Owner's motion to exclude is granted.

ORDERED that, pursuant to 35 U.S.C. § 318(b), upon expiration of the time for appeal of this decision, or the termination of any such appeal, a certificate shall issue canceling claim 11 of U.S. Patent No. 9,365,822; and

ORDERED that, because this is a Final Written Decision, parties to the proceeding seeking judicial review of the decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

Claims	35 U.S.C. §	Reference(s)/Basis	Claims Shown Unpatentable	Claims Not Shown Unpatentable
11	103(a)	Johnson, Salisbury, Garcia.	11	
Overall Outcome			11	

issuance of this decision, we draw Patent Owner's attention to the April 2019 *Notice Regarding Options for Amendments by Patent Owner Through Reissue or Reexamination During a Pending AIA Trial Proceeding*. See 84 Fed. Reg. 16,654 (Apr. 22, 2019). If Patent Owner chooses to file a reissue application or a request for reexamination of the challenged patent, we remind Patent Owner of its continuing obligation to notify the Board of any such related matters in updated mandatory notices. See 37 C.F.R. § 42.8(a)(3), (b)(2).

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