

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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ABS GLOBAL, INC.,  
Petitioner,

v.

XY, LLC,  
Patent Owner.

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Case IPR2017-02184  
Patent 7,208,265 B1

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Before GRACE KARAFFA OBERMANN, SUSAN L. C. MITCHELL, and  
ROBERT A. POLLOCK, *Administrative Patent Judges*.

OBERMANN, *Administrative Patent Judge*.

Instituting *Inter Partes* Review  
35 U.S.C. § 314 and 37 C.F.R. § 42.108

## I. INTRODUCTION

Petitioner filed a Petition for *inter partes* review of claims 1–4, 8–20, 22, and 26–28 of U.S. Patent No. 7,208,265 B1 (Ex. 1001, “the ’265 patent”). Paper 1 (“Pet.”). Patent Owner filed a Preliminary Response. Paper 8 (“Prelim. Resp.”).

The Petition asserts two grounds of unpatentability against claims 1–4, 8–20, 22, and 26–28:

Basis	References
§ 103(a)	Seidel <sup>1</sup> , Salisbury <sup>2</sup> , Spaulding <sup>3</sup>
§ 103(a)	Fugger <sup>4</sup> , Salisbury

The Petition is supported by the Declaration of Dr. Marvin M. Pace. Ex. 1003. Patent Owner, by contrast, waived its opportunity to file declaration testimony in support of the Preliminary Response. *See* Ex. 2001 (sole exhibit filed by Patent Owner, consisting of an excerpt from a “Farmers Weekly” publication dated July 3-9, 1998). Based on the information presented at this stage of the proceeding, we find that Dr. Pace is qualified to opine from the perspective of a person of ordinary skill in the art at the time of the invention. *See* Ex. 1003 at ¶¶ 2–10 (Dr. Pace’s

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<sup>1</sup> George E. Seidel et al., US 7,195,920 B2, issued March 27, 2007 (Ex. 1005) (“Seidel”).

<sup>2</sup> G. W. SALISBURY, N. L. VANDEMARK, AND J. R. LODGE, PHYSIOLOGY OF REPRODUCTION AND ARTIFICIAL INSEMINATION OF CATTLE 442–554 (W.H. Freeman & Co. 2d ed. 1978) (Chapters 16 and 17) (Ex. 1006) (“Salisbury”).

<sup>3</sup> Glenn F. Spaulding, US 5,021,244, issued June 4, 1991 (Ex. 1031) (“Spaulding”).

<sup>4</sup> E. F. Fugger et al., *Births of Normal Daughters after MicroSort Sperm Separation and Intrauterine Insemination, In-Vitro Fertilization, or Intracytoplasmic Sperm Injection*, 13 HUMAN REPRODUCTION 2367–70 (Sept. 1998) (Ex. 1007) (“Fugger”).

statement of qualifications); Ex. 1004 (Dr. Pace's curriculum vitae). Any final determination on that point shall be based on the full trial record.

We have discretion to institute an *inter partes* review only upon a showing that Petitioner is reasonably likely to prevail at trial with respect to at least one challenged patent claim. *See* 35 U.S.C. § 314(a). Applying that standard, we institute a review of all challenged claims (that is, claims 1–4, 8–20, 22, and 26–28) on the asserted ground of unpatentability based on obviousness over Fugger and Salisbury. We decline to institute review on the ground based on Seidel, Salisbury, and Spaulding.

We provide the following preliminary findings of fact and conclusions of law for the sole purpose of determining whether Petitioner meets the threshold for institution of review. Any final decision shall be based on the full trial record. Arguments not raised by Patent Owner in a timely filed Response will be deemed waived, even if presented in the Preliminary Response. The time for filing the Response is set forth in the Scheduling Order filed concurrently herewith.

#### *A. Related Proceedings*

Petitioner states that the '265 patent is the subject of a co-pending district court action in Colorado, which “was transferred from an earlier” case filed in Texas. Pet. 2 (citing *XY, LLC v. Trans Ova Genetics, LC*, No. 1:17-cv-00944 (D. Colo.) (transferred on April 18, 2017)). Petitioner does not identify the patent claims asserted in that action or indicate whether Petitioner, its real party-in-interest, or its privy is a party to that action. *Id.*

In addition to the action presently pending in Colorado, Patent Owner identifies a district court action filed in Wisconsin in which Patent Owner asserts the '265 patent against Petitioner's real party-in-interest. Paper 4, 2

(citing *Inguran, LLC d/b/a STGenetics, XY, LLC and Cytonome/ST, LLC v. ABS Global, Inc., Genus PLC, and Premium Genetics (UK) Ltd.*, Civil Action No. 17-cv-00446 (W.D. Wis.) (filed June 7, 2017)).<sup>5</sup>

Neither party identifies an administrative proceeding in their respective statements of related proceedings. Pet. 2; Paper 4. However, in the body of the briefs, both parties refer to the Final Written Decision previously entered by the Board in Case IPR2014-01550 (“IPR550”), involving the same parties and U.S. Patent No. 7,820,425 B2 (“the ’425 patent”), which shares substantially the same written description with the ’265 patent. *See* Pet. 3–4, 9–12, 16–18, 24, 29, 45–47, 50 (examples pertaining to claim 1 of the ’265 patent); Prelim. Resp. 7; Ex. 1033 (the ’425 patent). In IPR550, we held unpatentable certain claims of the ’425 patent based on obviousness over Fugger and Salisbury—the same combination of prior art references asserted in the instant proceeding. *See* IPR550, Paper 25, 24–26 (Final Written Decision).

Appeals in IPR550, as well as related Case IPR 2014-01161 (“IPR161”), presently are pending before the U.S. Court of Appeals for the Federal Circuit (“Federal Circuit”). *See XY, LLC v. ABS Global, Inc.*, No. 2016-1897 (Fed. Circ. argued Dec. 5, 2017) and *XY, LLC v. ABS Global, Inc.*, No. 2016-2228 (Fed. Cir. argued Dec. 5, 2017). In IPR161, we held unpatentable claims 1 and 3 of U.S. Patent 7,195,929 B2, which is the Seidel reference asserted in the obviousness challenge on which we decline to institute review in this proceeding. IPR161, Paper 26 (Final Written Decision); Pet. 5.

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<sup>5</sup> Patent Owner identifies Inguran as its real party-in-interest. Paper 4, 2.

The Federal Circuit heard oral arguments in IPR550 and IPR161 on December 5, 2017, but, to date, appellate decisions have not issued in either case. Given that the appeal in IPR550 has not concluded, at this time we assign no preclusive effect to the Final Written Decision entered in that proceeding, which resolved an obviousness challenge based on the same two prior art references—Fugger and Salisbury—that are asserted in the challenge upon which we institute review in this case. Prelim. Resp. 7 (citing 37 C.F.R. § 42.73(d)); *SDI Techs., Inc. v. Bose Corp.*, IPR2014-00343, Paper 32, 8–9 (P.T.A.B. Jun. 11, 2015) (non-precedential) (estoppel does not attach until all appeal rights have terminated).

We direct the parties to request jointly, by email to [Trials@uspto.gov](mailto:Trials@uspto.gov) within five (5) business days of entry of a Federal Circuit decision in IPR550, a teleconference with the Board to discuss the extent to which issue preclusion applies in this review.

*B. The '265 Patent and the Field of Invention*

The '265 patent is titled “Method of Cryopreserving Selected Sperm Cells.” Ex. 1001, Title. The challenged claims are directed to a method of cryopreserving (that is, freezing) sex-selected non-human sperm cells that are sorted “without the presence of protective compounds in seminal plasma.” Ex. 1001, 32:31–32 (claim 1). After sorting, but before freezing, the sperm cells are suspended “in an extender to provide a concentration of sperm cells of about 5 million per milliliter of extender to about 10 million per milliliter of extender.” *Id.* Those two quoted steps distinguish the independent claim at issue here from those at issue in IPR550. *See* Pet. 4 (representation on that point); Prelim. Resp. 7–8 (bridging paragraph,

confirming that those two method steps distinguish the claims at issue in this review from those involved in IPR550).

Claim 1, the only independent challenged claim, is reproduced below:

1. A method of cryopreserving sex-selected sperm cells, comprising:
  - a. obtaining sperm cells from a species of a non-human male mammal;
  - b. sorting said sperm cells, without the presence of protective compounds in seminal plasma, and based upon sex-type to provide a collection of sex-selected sperm cells obtained using flow cytometry or fluorescence-activated cell sorting;
  - c. cooling said sex-selected sperm cells;
  - d. suspending said sex-selected sperm cells in an extender to provide a concentration of sperm cells of about 5 million per milliliter of extender to about 10 million per milliliter of extender; and
  - e. freezing said sex-selected sperm cells in said extender.

*Id.* at 32:27–40.

According to the '265 patent, “[a] wide variety” of sorting techniques were available in the prior art. *Id.* at 4:15–39. The claimed method, however, requires that the “sex-selected sperm cells” be “obtained using flow cytometry or fluorescence-activated cell sorting.” *Id.* at 32:34–35. In that regard, the specification describes conventional flow cytometry, which uses “differential staining with fluorescent dyes or binding to fluorescently labeled molecules, such as antibodies or nucleic acids.” *Id.* at 4:40–43. Fluorescence-activated cell sorting (“FACS”) permits sorting based on sex type by distinguishing “the fluorescence intensity” of individual cells “upon irradiation.” *Id.* at 4:43–46. Because an X chromosome contains

slightly more DNA than a Y chromosome, an X-chromosome bearing sperm absorbs more fluorescent dye than a Y-chromosome bearing sperm, allowing for sex-type separation by FACS. *Id.* at 4:46–52.

The specification identifies two prior art patents that describe the FACS technique, which was developed by Mr. Larry Johnson (who is not an inventor of the '265 patent (Ex. 1001 [75])), for obtaining sex-selected sperm cell populations. *Id.* at 4:52–54. As explained above, the claims at issue here, unlike those challenged in IPR550, require “sorting said sperm cells, without the presence of protective compounds in seminal plasma,” a requirement that we discuss in more detail below. *Id.* at 32:31–32.

The specification describes cooling the sorted sperm sample “by reducing the temperature at a controlled rate” prior to freezing and, further, explains that “[c]ooling too rapidly can cause cold shock, which can result in a loss of membrane integrity and cell function.” *Id.* at 7:47–51. The '265 patent informs that “techniques for freezing unselected sperm” were “well known.” *Id.* at 2:6–8. On that point, the '265 patent indicates that, in the claimed method, sorted sperm is “frozen conventionally.” *Id.* at 17:17.

### *C. The Prosecution History of the '265 Patent (Ex. 1002)*

We provide a discussion of the prosecution history of the '265 patent for context, given that two of the prior art references asserted in this proceeding (Salisbury and Spaulding) were analyzed by the Examiner. During patent prosecution, the Examiner entered a final rejection based on obviousness over the disclosures of Salisbury and Spaulding in combination with a third reference (“Shrimpton”) not of

record here. Ex. 1002, 433–434.<sup>6</sup> The inventor, Mr. John L. Schenk, submitted an affidavit, asserting that the method of claim 1 (which was designated as claim 38 at that point in the prosecution) was distinguished from the applied prior art by two method steps. Specifically, Mr. Schenk directed the Examiner’s attention to the same two method steps discussed above, which require “sorting the sperm cells without the presence of protective compounds in seminal plasma” in combination with “suspending at dilutions of at least about 5 million per milliliter of extender to at least about 10 million per milliliter of extender.” Ex. 1002, 496 (at ¶ 12).

The Examiner expressed concerns about the “suspending at dilutions” limitation, questioning how the required concentration range is supported by the specification, and whether the limitation even refers to a concentration of sperm cells in an extender. *See id.* at 431–432 (Examiner’s concern that there is “no support in the specification for the ranges of sperm cells claimed”); 433 (Examiner, questioning whether the limitation even refers “to the number of sperm cells” in an extender), 700 (Examiner, addressing Table 1 in the specification, stating that “it is not clear what this signifies”).

In response to those concerns, the applicant provided further information. *See, e.g., id.* at 747 (applicant’s argument that “Table 1 values support the claimed ranges as one skilled in the art can appreciate”); *see also* Ex. 1001, 12:50–62 (Table 1). The applicant emphasized that the claims “are distinguished from the references

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<sup>6</sup> We refer to page numbers added by the parties instead of the original page numbers of the exhibits.



through their inclusion” of two method steps in combination; (1) “the element of sorting the sperm cells without the presence of protective compounds in seminal plasma;” and (2) the step of “suspending” sperm cells in extender “at dilutions,” for example, “of about 5 million per milliliter of extender to about 10 million per milliliter of extender.” *Id.* at 749; Ex. 1001, 32:37–40 (claim 1 limitation pertaining to concentration per milliliter before freezing).

The Examiner relied on Spaulding for disclosure of the step that requires “sorting said sperm cells, without the presence of protective compounds in seminal plasma.” Ex. 1002, 433–434. Mr. Schenk, however, in his affidavit, attested that “I have never personally observed a successful accomplishment of the techniques described in the Spaulding reference” and averred that he was unaware “of any credible evidence suggesting a single instance in which the techniques of the Spaulding reference were successfully reproduced to achieve effective sperm cell discrimination techniques.” *Id.* at 496 (at ¶ 13). The applicant further argued that neither Spaulding nor Salisbury individually discloses the combination of elements specified in the asserted claims and that neither of those references is “capable of being successfully reproduced.” *Id.* at 762–763.

The Examiner thereafter allowed the claims to issue, providing the following explanation of the “reasons for allowance: [T]he declaration of Mr. Schenk filed January 20, 2006, proves that the references were inoperable and thus cannot be used in a 35 U.S.C. 103 rejection against the claims.” *Id.* at 783; *see id.* at 493–498 (Mr. Schenk’s declaration).

## II. ANALYSIS

We organize our analysis into four parts. First, we discuss claim construction. Second, we address the level of ordinary skill in the art at the time of the invention. Third, we analyze the ground based on Fugger and Salisbury (instituting review on that ground). Fourth, we analyze the ground based on Seidel, Salisbury, and Spaulding (declining to institute review on that ground).

### A. Claim Construction

In an *inter partes* review, claim terms in an unexpired patent are assigned their broadest reasonable interpretation in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b). Under that standard, we interpret claim terms using “the broadest reasonable meaning of the words in their ordinary usage as they would be understood by one of ordinary skill in the art, taking into account whatever enlightenment by way of definitions or otherwise that may be afforded by the written description contained in the applicant’s specification.” *In re Morris*, 127 F.3d 1048, 1054 (Fed. Cir. 1997). “Under a broadest reasonable interpretation, words of the claim must be given their plain meaning, unless such meaning is inconsistent with the specification and prosecution history.” *Trivascular, Inc. v. Samuels*, 812 F.3d 1056, 1062 (Fed. Cir. 2016). In that regard, if an inventor acts as his or her own lexicographer, the definition must be set forth with reasonable clarity, deliberateness, and precision. *Renishaw PLC v. Marposs Societa’ per Azioni*, 158 F.3d 1243, 1249 (Fed. Cir. 1998).

Only terms in controversy need be construed and only to the extent necessary to resolve the controversy. *Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999). One term requires discussion at

this stage; namely, the claim 1 term that requires “sorting said sperm cells, without the presence of protective compounds in seminal plasma.”

Ex. 1001, 32:31–32. The plain meaning of the term requires the removal of “protective compounds in seminal plasma” *before* the step of sorting the sperm cells by sex type. *Id.* Petitioner directs us to a single-sentence disclosure within the ’265 patent specification that refers to a process that removes “seminal plasma” and leaves the sperm cells in a “pellet,” but which contains no information about when that step is performed in relation to sorting. Pet. 20 (citing Ex. 1001, 13:7–10); Prelim. Resp. 9 (declining to contest Petitioner’s position regarding the construction of this term).

The specification contains three examples (Examples 1, 2, and 3) but none discloses removal of seminal plasma *before* a sorting step. Example 1 contains the disclosure, relied upon by Petitioner, which describes a “non-frozen, non-sorted, but highly diluted sperm” sample that is concentrated “by centrifugation” in “a swinging bucket centrifuge” followed by aspiration of the supernatant from the sample, thereby “removing most of the seminal plasma and leaving the sperm in a 900µl pellet.” Ex. 1001, 11:56–57, 12:11–19, 13:6–10. Example 1 does not include a cell sorting step. *Id.*

Examples 2 and 3, by contrast, combine a cell sorting step with a centrifugation step (and describe removing supernatant after bucket centrifugation to produce “sperm pellets”). *Id.* at 17:6 (Example 3); *see id.* at 15:11 (Example 2, referring to “sperm pellet”). In Examples 2 and 3, however, centrifugation (including supernatant removal and, accordingly, seminal plasma removal) is accomplished *after* cell sorting. *Compare id.* at 14:35–15:21 (Example 2); 16:56–17:13 (Example 3), *with* 32:27–40 (claim 1, requiring removal of seminal plasma *before* cell sorting).

At this stage of the proceeding, we determine that the claim 1 step, which requires removal of seminal plasma *before* cell sorting, is met by the technique disclosed in the examples, which describe “seminal plasma” that is “removed by centrifugation” and where supernatant is subsequently removed by aspiration. Pet. 20–21 (Ex. 1003 ¶ 111); Ex. 1001, 13:6–10. On this record, that finding is consistent with the specification (Ex. 1001, 13:6–10) and aligns with arguments presented by both parties at this stage of the proceeding. Pet. 20–21 (asserting that “the term ‘without the presence of protective compounds in seminal plasma’” encompasses “a sample that has had nearly all of the seminal plasma removed by centrifugation”); Prelim Resp. 4 (asserting that the term “sorting the sperm cells ‘without the presence of protective compounds in seminal plasma’” in claim 1 “encompasses centrifuging the sperm cells before sorting”), 9 (Patent Owner, declining to contest Petitioner’s construction of that term).

To the extent that the meaning of any other claim term requires discussion, for the purposes of this decision, we discuss that construction in the following analysis of the challenges. We provide preliminary claim constructions based on the current record. Any final claim constructions will be based on the full trial record.

*B. Level of Ordinary Skill in the Art*

Petitioner submits that a “person of ordinary skill in the art” at the time of the invention would have held “at least a bachelor’s degree in the biological sciences or a relevant field of engineering, and at least three years of experience with methods of freezing sperm.” Pet. 18 (citing Ex. 1003 ¶ 17). At this stage, Patent Owner does not advance a different definition.

On this record, we determine that the asserted prior art references are representative of the level of ordinary skill in the art. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001). “The person of ordinary skill is a hypothetical person who is presumed to be aware of all the pertinent prior art.” *Custom Accessories, Inc. v. Jeffrey-Allan Indus., Inc.*, 807 F.2d 955, 962 (Fed. Cir. 1986). To the extent that a more specific definition is required, however, at this stage we adopt the definition set forth in the Petition, which is supported by the declaration of Dr. Pace. Pet. 18 (citing Ex. 1003 ¶ 17). Any final determination, pertaining to the level of ordinary skill in the art, however, shall be made on the full trial record.

### *C. The Ground Based on Fugger and Salisbury*

The Petition asserts that claims 1–4, 8–20, 22, and 26–28 are unpatentable as obvious over the combined disclosures of Fugger and Salisbury. Pet. 4–5, 45–65. First, we analyze claim 1 (the only independent challenged claim) in view of the disclosures of Fugger and Salisbury. Second, we discuss claims 2–4, 8–20, 22, and 26–28, which depend directly or indirectly from claim 1. Third, we address Patent Owner’s request that we exercise our discretion under 35 U.S.C. § 325(d) to deny review. *See* Prelim. Resp. 39–43 (Patent Owner, discussing that issue); *see also* Pet. 6–7 (Petitioner, preemptively addressing that issue).

#### *1. Independent Claim 1*

Fugger discloses that, at the time of the invention, an ordinarily skilled artisan would have known how to obtain **human** sperm cells, sort them based on sex-type using the FACS technique discussed in the ’265 patent, collect the sex-selected sperm cells, freeze them for later use, and, subsequently, employ them in successful fertilization

procedures. Ex. 1007, 2367–2368; Pet. 47–50 (and citations therein to Dr. Pace’s declaration (Ex. 1003)).

Petitioner directs us to disclosure and testimony that is sufficient to establish that Fugger’s method included centrifugation of sperm samples under conditions that “would have removed all, or nearly all, of the seminal plasma prior to the sorting” step. Pet. 48 (citing Ex. 1007, 2367 (Fugger); Ex. 1003 ¶¶ 165, 247 (Dr. Pace’s declaration testimony pertaining to Fugger’s pre-sorting centrifugation disclosure)); *see especially* Ex. 1003 ¶ 247 (Dr. Pace’s testimony, explaining Fugger’s pre-sort conditions, including Fugger’s citation to an earlier paper that describes “sequential centrifugation” and “removal of supernatant” under “conditions [that] would have removed the seminal plasma”).

Petitioner also shows sufficiently that an ordinarily skilled artisan would have been led to apply Fugger’s method to a sperm cell population obtained from ***non-human*** mammals. Pet. 47 (citing Ex. 1003 ¶ 244). Specifically, Petitioner directs us to information that such an artisan would have been aware of “the commercial benefits” of separating non-human sperm by sex type, which “allows farmers to vary the male to female offspring ratio,” for example, to “increase the percentage of milk-producing offspring.” *Id.* at 46 (citing Ex. 1003 ¶ 19). Petitioner further identifies information that an ordinarily skilled artisan, seeking to apply Fugger’s method to non-human mammalian sperm cell populations, would have turned to Salisbury—“one of the most respected texts in the field of artificial insemination of cattle.” Pet. 13 (citing Ex. 1006, 1, 442–443; Ex. 1003 ¶¶ 144–

152); *see id.* at 48 (arguing that an ordinarily skilled artisan “would have understood that slightly different methods may be required when freezing sperm” obtained from non-human mammals) (citing Ex. 1003 ¶¶ 52, 146, 248).

Salisbury would have informed the ordinarily skilled artisan that non-human sperm “should be cooled to 5° C before freezing ‘for maximum livability of the cells.’” Pet. 14 (citing Ex. 1006, 509). Like the ’265 patent, Salisbury recommends slow cooling to avoid the deleterious effects of “cold shock.” Ex. 1006, 508–509; *see* Ex. 1001, 7:47–51 (“[c]ooling too rapidly can cause cold shock, which can result in a loss of membrane integrity and cell function”). Salisbury further discloses that non-human sperm cells, in concentrations of, for example, 10 million sperm cells per milliliter of extender, “had been frozen and subsequently used for successful inseminations.” Pet. 49 (citing Ex. 1006, 517–518; Ex. 1003 ¶¶ 157, 249). Thus, on this record, Salisbury suggests a concentration of sperm cells in extender that falls squarely within the concentration range specified in claim 1 and, further, suggests that this concentration would have been useful when applying Fugger’s method to non-human sperm cell populations. Petitioner identifies additional evidence sufficient to show that an ordinarily skilled artisan “would have expected success” in applying Fugger’s method to Salisbury’s non-human sperm cell populations because “[i]ndividuals had been freezing animal sperm since the 1950’s and,” further, “numerous individuals had reported successfully freezing separated animal sperm” cell populations. *Id.* at 47 (citing Exs. 1008, 1018–1026; Ex. 1003 ¶¶ 30, 69, 72, 244).

Patent Owner, for its part, argues that the Examiner, during patent prosecution, fully considered Salisbury and credited “Mr. Schenk’s conclusion” (as set forth in the inventor’s affidavit) “that Salisbury lacks the claimed concentration limitation.” Prelim. Resp. 43. That is a mischaracterization of the record. Mr. Schenk stated in his affidavit that none of three prior art references (Shrimpton, Spaulding, and Salisbury) discloses or suggests *the combination* of *two specified features* of the claimed method. Ex. 1002, 496 (affidavit at ¶ 12). Specifically, Mr. Schenk asserted that none of those references discloses or suggests “sorting the sperm cells without the presence of protective compounds in seminal plasma *and* suspending at dilutions of at least about 5 million per milliliter of extender to at least about 10 million per milliliter of extender.” *Id.* (emphasis added); *see* Ex. 1002, 749 (applicant’s argument, during patent prosecution, that the applied prior art failed to disclose the combination of those two features). Patent Owner quotes that very same paragraph of Mr. Schenk’s affidavit but selectively highlights the second identified feature in an attempt to persuade us of its position. Prelim. Resp. 42–43 (quoting Ex. 1002, 496 (Mr. Schenk’s affidavit at ¶ 12)). On this record, we discern no evidence that Mr. Schenk represented, or the Examiner found, “that Salisbury lacks the claimed concentration limitation.” Prelim. Resp. 43.

Further, we find that the applicant expressly admitted before the Examiner that Salisbury discloses sperm cell samples that were “extended [] to 5, 10, and 15 million motile cells per milliliter.”



Ex. 1002, 762.<sup>7</sup> The referenced portion of Salisbury discusses the minimum number of sperm cells necessary for optimum insemination of cows. *See* Ex. 1006, 476–77 (referencing the “curvilinear relationship between number of sperm inseminated and fertility” in Figure 16-1). Specifically, Salisbury discloses that

an extension rate of more than 100 X was possible before too few sperm were present for maximum conception rates. Bratton et al. (208) took initial sperm cell concentration and motility into account and extended samples to 5, 10, and 15 million motile cells per milliliter. This resulted in 60–90-day NR<sup>8</sup> figures of 66.7, 70.9, and 70.5 percent respectively. Therefore 10 X 10<sup>6</sup> motile sperm were recommended for insemination.

*Id.* at 477; *see also id.* at 517, Table 17-6 (reporting NR rate for inseminations at 10 x 10<sup>6</sup> spermatozoa per ml).

Based on our own review of the reference and the prosecution history, we find, for the purposes of trial institution, that Salisbury expressly discloses concentrations (including 10 million motile cells per milliliter (*id.* at 476–477, 417)), as admitted by the applicant during prosecution (Ex. 1002, 762)) that fall squarely within the range of concentrations specified in claim 1. Ex. 1006, 517 (Table 17-6,

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<sup>7</sup> We view the applicant’s reference to “[p]age 477 of Spaulding,” rather than Salisbury, as a clear typographical error as Spaulding (Ex. 1031) is only 17 pages long and the corresponding information appears on page 477 of Salisbury (Ex. 1006).

<sup>8</sup> Absent evidence to the contrary, we understand “NR” or “Non return rate” as used in Salisbury to indicate “the proportion of cows not seen to come back into estrus within a specified period after breeding, and are thus considered to be pregnant.” *See* The Free Dictionary, <https://medical-dictionary.thefreedictionary.com/nonreturn+rate>, last visited Mar. 3, 2018. Ex. 3001.

reporting “number of spermatozoa” “in 1.0-milliliter ampules” as “10<sup>6</sup>”); Pet. 49 (citing Ex. 1006, 517–518; Ex. 1003 ¶¶ 157, 249).

Patent Owner also argues that a person of ordinary skill in the art at the time of the invention would have been discouraged from applying the series of steps specified in claim 1 because such a person would have understood that each step is potentially damaging to delicate sperm cells. *See, e.g.*, Prelim. Resp. 5 (“Piling these damaging processing steps, one on top of the other, is what makes the ’265 [p]atent an important, non-obvious advance in the field of livestock management.”), 17 (“The claimed invention” represents “a complex and lengthy combination of many individual processing steps, each of which is potentially fatal or injurious to uniquely fragile sperm cells.”). At this stage, however, that argument rests on conclusory assertions of counsel aimed at establishing the perspective of a hypothetical person of ordinary skill in the artisan. *Id.* Patent Owner directs us to no evidence that counsel is competent to testify from that perspective, or any other evidence explaining adequately how or why a person—aware of the disclosures of the prior art and exercising ordinary skill—would have been led away from the claimed invention. *Id.*

We next turn to Patent Owner’s proffered evidence of secondary considerations of nonobviousness. Pet. 31–36. Patent Owner identifies two pieces of evidence, which we address in turn. First, Patent Owner identifies an excerpt from an edition of “Farmers

Weekly” in which “Genus’s senior veterinarian, Stuart Revell,”<sup>9</sup> allegedly “expressed his conclusion that sperm cells sex-selected by flow cytometry are ‘unsuitable for freezing’ because of the low output of flow cytometers and because the sperm cells have ‘been knocked about by a centrifuge.’” Prelim. Resp. 30 (citing Ex. 2001, 3); *see id.* at 33–34 (relying on that article for evidence of teaching away and failure of others). That isolated statement in the Farmers Weekly article (published in July of 1998 (Ex. 2001, 3)) is insufficient to establish secondary considerations of nonobviousness that outweigh the disclosure of Fugger (published several months later, in September of 1998 (Ex. 1007, Cover)). Patent Owner does not show sufficiently that Mr. Revell’s statement reflects the perspective of a person of ordinary skill in the art at the time of the invention. Such a person would have been aware of Fugger’s disclosure, indicating that, by the time of the invention, others in the field had subjected sperm cell populations to centrifugation, sorted those cells by sex type using the FACS technique, frozen the sorted cells, and, subsequently, used the cells successfully to achieve pregnancies and live births. Ex. 1007, 2367–2368.

Second, Patent Owner directs us to evidence that “the inventor himself was surprised by the unexpectedly good results of the claimed procedure.” Prelim. Resp. 34–35 (citing Ex. 1001, 2:48–53) (the ’265 patent, disclosing that “the result was surprising because of the well-documented fragility of sperm” and “[p]rior researchers had

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<sup>9</sup> Petitioner identifies Genus as its real party-in-interest. Pet. 1.

demonstrated that the stresses associated with various selection methods or with cryopreservation resulted in significant losses in fertility and/or viability”). A showing of unexpected results requires evidence “that the claimed invention exhibits some superior property or advantage that a person of ordinary skill in the relevant art would have found surprising or unexpected.” *In re Soni*, 54 F.3d 746, 750 (Fec. Cir. 1995). Patent Owner does not address adequately, on this record, how the inventor’s assertion within the ’265 patent establishes that any results obtained would have been truly surprising to the hypothetical person of ordinary skill in the art in view of the combined disclosures of Fugger and Salisbury. Prelim. Resp. 34–35.

Based on the information presented, we determine that Petitioner demonstrates a reasonable likelihood of prevailing at trial in showing that the subject matter of claim 1 would have been obvious at the time of the invention over the combined disclosures Fugger and Salisbury.

*2. Dependent Claims 2–4, 8–20, 22, and 26–28*

Having determined that Petitioner satisfies the threshold showing under 35 U.S.C. § 314(a) for institution of trial with respect to at least one challenged claim of the ’265 patent, we exercise our discretion under 37 C.F.R. § 42.108(a) and order that the trial shall proceed on all claims challenged in this ground as obvious over Fugger and Salisbury. Without reaching any preliminary findings or conclusions pertaining to the merits of the challenge directed to dependent claims 2–4, 8–20, 22, and 26–28, upon consideration of the information presented in the Petition and Preliminary Response, we

determine that inclusion of the dependent claims will not unduly complicate the trial. Pet. 50–65; Prelim. Resp. 17–38, 41. We further determine that inclusion of the dependent claims promotes our overarching goal of securing the just, speedy, and inexpensive resolution of the parties’ dispute. 35 U.S.C. § 314 (a) (authorizing institution of an *inter partes* review where Petitioner demonstrates a reasonable likelihood of prevailing at trial with respect to at least one challenged patent claim); 37 C.F.R. §§ 42.1(b), 42.108 (reflecting the Board’s mission of securing “the just, speedy, and inexpensive resolution” of patentability disputes).

### 3. *Consideration of 35 U.S.C. § 325(d)*

We have discretion to deny review when “the same or substantially the same prior art or arguments previously were presented to the Office.” 35 C.F.R. § 325(d). Patent Owner invites us to enter a discretionary denial under that provision because Salisbury was before the Examiner during patent prosecution. Prelim. Resp. 39–43. We decline to do so for two reasons.

First, the prior art asserted in this review is significantly different from the prior art that was before the Examiner. Fugger was not made of record during patent prosecution. Our review of the prosecution history persuades us, moreover, that Fugger is not cumulative of the references that were analyzed by the Examiner. On the contrary, as explained below, Fugger differs in several key respects when compared to the references considered and assessed during patent prosecution. *See, e.g.*, Ex. 1002, 201–202, 353, 406–407, 433–434 (Examiner, discussing disclosures of Shrimpton, Spaulding, and Salisbury); Ex. 1007, 2367–2369 (Fugger’s disclosure).

In that regard, the Examiner analyzed Salisbury in combination with Spaulding and Shrimpton. *See, e.g.*, Ex. 1002, 433. The Examiner, however, determined that Spaulding and Shrimpton were inoperable. *Id.* at 496–496 (affidavit of Mr. Schenk, nowhere asserting that Salisbury was inoperable; expressly limiting his arguments pertaining to inoperability to Spaulding and Shrimpton) (*see especially id.* ¶¶ 12–18)), 669–701 (Examiner, discussing inventor’s affidavit that Spaulding and Shrimpton are inoperable), 749 (applicant, arguing “that the techniques taught in the Spaulding and Shrimpton references are not capable of being successfully reproduced”), 762–763 (applicant, admitting that Salisbury discloses the required concentration limitation, but arguing that Spaulding and Shrimpton “are inoperable”), 783 (reasons for allowance, stating that “the references were inoperable”).

That left Salisbury as the sole operable reference actually analyzed by the applicant and evaluated by the Examiner prior to entry of the notice of allowance. *Id.* Unlike Fugger, Salisbury does not disclose sorting sperm cells by sex type. *See generally* Ex. 1006 (Salisbury); *see* Prelim. Resp. 12–13 (bridging sentence, averring “the sole mention of sex-selected sperm in the Salisbury reference is a two-sentence dismissal of claims that any meaningful sex-selection can be accomplished”). In contrast to Salisbury, Fugger discloses sorting sperm cells by sex type using the very same technique that is disclosed in the ’265 patent. *Compare* Ex. 1007, 2367–2368 (describing “[a] reliable method for preconception gender selection” and discussing sperm cell samples that “were sorted by FCS as previously described (Johnson *et al.*, 1993)”, *with* Ex. 1001, 4:40–59 (describing

“preferred method for separating cells from missed populations” using the FACS method described in a patent “issued to Johnson”).

In addition, Petitioner advances the declaration of Dr. Pace, which was not available to the Examiner, and which explains the significance of Fugger’s disclosure. Ex. 1003¶¶ 243–251 (Dr. Pace’s declaration) (explaining Fugger’s disclosure in the context of claim 1); *see* Pet. 7 (citing *Amneal Pharmaceuticals LLC v. Purdue Pharma L.P.*, IPR2016-01413, Paper 9 at 23 (P.T.A.B. Jan. 18, 2017) (declining to apply § 325(d) where “[t]he Petition presents additional arguments and evidence beyond what was already considered by the Examiner,” including witness testimony)).

Second, the arguments presented in this review are significantly different from the arguments that were presented during patent prosecution. Our review of the prosecution history persuades us that a central focus of examination was whether Spaulding and Shrimpton (which will form no part of the trial in this *inter partes* review) were operable. *See, .e.g.*, Ex. 1002, 496 (Mr. Schenk’s affidavit), 783 (Examiner’s reasons for allowance). That conclusion is supported by the Examiner’s single-sentence explanation of the “reasons for allowance,” specifically: “[T]he declaration of Mr. Schenk filed January 20, 2006, proves that the references<sup>[10]</sup> were inoperable and

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<sup>10</sup> Significantly, the prosecution history makes plain that “the references” that the Examiner deemed “inoperable” were Spaulding and Shrimpton—not Salisbury, which is a textbook in the field of the invention, and which the applicant never characterized as “inoperable” during prosecution. *Id.* at 496–496 (affidavit of Mr. Schenk, nowhere asserting that Salisbury was inoperable; limiting his arguments pertaining to inoperability to Spaulding and Shrimpton) (*see especially* affidavit at ¶¶ 12–18)).

thus cannot be used in a 35 U.S.C. 103 rejection against the claims.” *Id.* at 783; *see id.* at 493–498 (Mr. Schenk’s declaration).

Further, during patent prosecution, the applicant repeatedly argued that the inventor had demonstrated “***for the first time***, that frozen selected sperm cell products . . . can be thawed and used to inseminate female mammals and successfully achieve pregnancies.” *Id.* at 253; *see id.* at 221 (applicant’s argument that the inventor had “***demonstrated, for the first time, that pregnancies can be achieved with sperm that have been selected and then frozen and that the resulting offspring exhibit the selected characteristic***”).

The Examiner was called upon to assess that argument without the benefit of Fugger, which discloses that, well before the invention of the ’265 patent, others in the field had successfully sorted mammalian sperm cells by sex type, frozen the sorted sperm cells, and used those cells to produce “29 clinical pregnancies” and “11 normal healthy babies” with a desired sex selection rate of “92.9%.” Ex. 1007, 2368–2369. Patent Owner identifies no persuasive information that Spaulding, Shrimpton, or Salisbury similarly disclosed or suggested Fugger’s combination of sorting mammalian sperm cells by sex type, freezing the sorted cells, and, subsequently, using those cells to produce pregnancies or live births of the desired sex.

For the above reasons, on this record, based on the particular factual circumstances presented in this case, we are unpersuaded that “the same or substantially the same prior art or arguments previously were presented to the Office” during patent prosecution. 35 U.S.C. § 325(d). Accordingly, we decline to exercise our discretion to deny review under that provision.



*D. The Ground Based on Seidel, Salisbury, and Spaulding*

The Petition further asserts that claims 1–4, 8–20, 22, and 26–28 are unpatentable as obvious over the combined disclosures of Seidel, Salisbury, and Spaulding. Pet. 24–45. We specifically decline to institute trial on that ground for reasons that follow.

Petitioner fails to show sufficiently that the combined disclosures of the asserted references would have suggested a method that, like claim 1, includes the step of removing seminal plasma from the sperm cell population prior to sorting. Ex. 1001, 32:31–32 (claim 1, requiring “sorting said sperm cells, without the presence of protective compounds in seminal plasma”). As explained above in our discussion of claim construction, on this record, that claimed step embraces centrifugation followed by aspiration of supernatant when carried out prior to sorting by sex type. *See supra*.

Petitioner argues that “removal of seminal plasma using centrifugation is taught by both Spaulding and Seidel.” Pet. 28. However, as Petitioner acknowledges, Seidel describes the “use of a centrifuging step *after sorting*.” *Id.* (emphasis added). Petitioner fails to explain adequately how or why Seidel’s disclosure of a centrifugation step *after sorting* would have led an ordinarily skilled artisan to apply the centrifugation step *prior to sorting* as required by claim 1. *Id.* Although the Petition asserts that this “is a matter of process design choice and an obvious variant,” Petitioner directs us to no persuasive objective proof on that point. *Id.* (citing Ex. 1003, ¶ 178 (Dr. Pace’s similarly conclusory opinion testimony)).

Nor does Petitioner adequately explain how or why a person of ordinary skill in the art would have been led to apply Spaulding’s centrifugation step to the teachings of Seidel or Salisbury in a manner that

would have achieved the method of claim 1. Spaulding does not sort sperm cells to achieve a population useful in fertilization procedures. On the contrary, Spaulding applies a sorting step in a process that involves the “complete[] removal of plasma membranes from the sperm cells.” Prelim. Resp. 22 (citing Ex. 1031, 10:24–29); Ex. 1031, 1:16–29 (Spaulding, disclosing a process for isolating proteins and antibodies from sex-selected “sperm plasma membranes and components thereof”), 9:17–36 (Spaulding, disclosing centrifugation step), 10:18–43 (Spaulding, disclosing cavitation step that separates sperm plasma membranes into component parts).

After sorting the sperm cells, Spaulding uses “the X-sperm or Y-sperm enriched cell subpopulations” “to isolate plasma membrane vesicles,” which are subjected to cavitation to separate plasma membrane vesicles into component parts; “plasma membrane vesicles consisting mostly (e.g., 80% (boar sperm data)) head plasma membrane and some (e.g., 20% (boar sperm data)) tail plasma membrane from sperm heads.” *Id.* at 10:14–29. Petitioner does not explain adequately how or why an ordinarily skilled artisan would have been led to apply Spaulding’s centrifugation step, with a reasonable expectation of success, to the very different processes, and for the very different purposes, disclosed in Seidel and Salisbury. In that regard, Petitioner identifies Spaulding’s objective for applying a centrifugation step (“to match the refractive indices between sheath and sample fluid”) but directs us to no persuasive reason why an ordinarily skilled artisan would have recognized that objective as applicable to Seidel’s or Salisbury’s method. Pet. 28–29.

On this record, Petitioner fails to demonstrate a reasonable likelihood of showing at trial that the subject matter of claim 1 would have been

obvious over the combined disclosures of Seidel, Salisbury, and Spaulding. Because each of the other challenged claims depends directly or indirectly from claim 1, our above analysis is dispositive of this ground.

On this record, we determine that Petitioner fails to make out the threshold showing for institution of review based on the combined disclosures of Seidel, Salisbury, and Spaulding. Accordingly, we decline to institute review on this ground.

### III. CONCLUSION

Based on the information presented in the Petition and Preliminary Response, we determine that Petitioner meets the threshold for institution of an *inter partes* review of claims 1–4, 8–20, 22, and 26–28 of the '265 patent on the ground based on obviousness over Fugger and Salisbury. We determine that Petitioner fails to meet the threshold for institution of an *inter partes* review of claims 1–4, 8–20, 22, and 26–28 of the '265 patent on the ground based on Seidel, Spaulding, and Salisbury.

### IV. ORDER

Accordingly, it is

ORDERED that an *inter partes* review of claims 1–4, 8–20, 22, and 26–28 of the '265 patent is instituted and trial shall proceed on the ground based on obviousness over Fugger and Salisbury;

FURTHER ORDERED that no other ground of unpatentability is authorized during the trial;

FURTHER ORDERED that the parties shall jointly request, by email to [Trials@uspto.gov](mailto:Trials@uspto.gov) within five (5) business days of entry of a Federal Circuit decision in IPR550, a teleconference with the Board to discuss the extent to which issue preclusion applies in this review; and

FURTHER ORDERED that pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4, notice is hereby given of the institution of a trial, which will commence on the entry date of this decision.

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