

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ABS GLOBAL, INC. and GENUS PLC,
Petitioner,

v.

XY, LLC,
Patent Owner.

Case IPR2014-01550
Patent 7,820,425 B2

Before JACQUELINE WRIGHT BONILLA,¹
GRACE KARAFFA OBERMANN, and MICHELLE R. OSINSKI,
Administrative Patent Judges.

OBERMANN, *Administrative Patent Judge.*

FINAL WRITTEN DECISION
35 U.S.C. § 318 and 37 C.F.R. § 42.73

¹ Judge Bonilla replaces Judge Mitchell on the panel.

I. INTRODUCTION

This is a Final Written Decision in an *inter partes* review of claims 1–4, 6–9, 11–13, 15, 21–28, and 31–34 (“the challenged claims”) of U.S. Patent No. 7,820,425 B2 (Ex. 1001, “the ’425 patent”). We instituted review on the following grounds stated in the Petition (Paper 1, “Pet.”):

Claims	Basis	References
1–4, 6–9, 11–13, 15, 21–28, and 31–34	§ 103(a)	Seidel ² and Salisbury ³
1–4, 6, 25, 26, 31, and 32	§ 103(a)	Fugger ⁴
7–9, 11–13, 15, 21–24, 27, 28, 33, and 34	§ 103(a)	Fugger and Salisbury

Patent Owner filed a Response (Paper 15, “Resp.”) and Petitioner filed a Reply (Paper 17, “Reply”). The record includes a transcript of the final oral hearing conducted on January 11, 2016. Paper 24 (“Tr.”). We have jurisdiction under 35 U.S.C. § 6(c). For the reasons that follow, we determine that Petitioner shows by a preponderance of the evidence that the challenged claims are unpatentable.

² Seidel et al., US 7,195,920 B2, issued March 27, 2007 (Ex. 1005).

³ 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”).

⁴ 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”).

A. Related Proceedings

Petitioner indicates that the '425 patent was asserted in *XY, LLC v. Trans Ova Genetics, L.C.*, No. 13-CV-00876-WJM-BNB (D. Colo.). Pet. 2.

B. The '425 Patent and the Field of Invention

The '425 patent is titled "Method of Cryopreserving Selected Sperm Cells." Ex. 1001, Title. The challenged claims are directed to a method of selecting (that is, sorting) non-human sperm for a specific characteristic, such as sex-selection, then freezing the sorted sperm for later use to fertilize an egg. Ex. 1001, Abstract, 1:17–21, 31:64–32:11.

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

1. A method of freezing separated sperm cells, comprising the steps of:
 - a) obtaining sperm cells from a male of a species of non-human mammal;
 - b) differentiating said sperm cells based upon at least one property which allows a portion of said sperm cells to be identified as bearing either an X-chromosome or a Y-chromosome;
 - c) separating said sperm cells into a discrete population based upon said at least one property;
 - d) establishing from said discrete population a selected sperm sample having a sufficient number of sperm cells to fertilize an egg of a female of said species of non-human mammal;
 - e) freezing said selected sperm sample.

Id. at 31:64–32:11.

The remaining challenged claims depend directly or indirectly from claim 1 and further limit the method of freezing, except that claim 31 specifies a frozen separated cell sample in accordance with the method of claim 1. *Id.* at 32:12–34:50.

According to the '425 patent, “[a] wide variety” of sorting techniques were available in the prior art. *Id.* at 4:16–40; Ex. 1003 ¶ 46. The '425 patent discloses that the preferred sorting method for use in the invention is conventional flow cytometry, which uses “differential staining with fluorescent dyes or binding to fluorescently labeled molecules, such as antibodies or nucleic acids.” *Id.* at 4:41–44. Because an X chromosome contains slightly more DNA than a Y chromosome, an X-chromosome bearing sperm absorbs more dye than a Y-chromosome bearing sperm, allowing for separation based on sex-selection. *Id.* at 4:47–52.

The '425 patent also states that “techniques for freezing unselected sperm” were “well known.” *Id.* at 2:10–11; Ex. 1003 ¶¶ 52–59 (and citations therein to Ex. 1009, Ex. 1010). The '425 patent identifies conventional methods of freezing sperm as suitable for use in the invention, explaining in an example that sorted sperm is “frozen conventionally.” *Id.* at 17:2.

C. The Asserted Prior Art

The asserted prior art includes Seidel and Salisbury. Seidel discloses a technique for sorting non-human sperm for sex-selection. Ex. 1005, 1:62–2:4, 6:12–30. Salisbury discloses a technique for successfully freezing non-human sperm for later use in fertilizing an egg. Ex. 1006, 443–538⁵; *see* Ex. 1003 ¶¶ 199–212 (summarizing Salisbury’s disclosure). Patent Owner’s own witness could articulate

⁵ We follow the parties’ convention of referring to the original page numbers of documents, not those added by the parties to the exhibits.

no difference between the method of claim 1 and the method of Seidel, as modified to include the freezing step of Salisbury.
Ex. 1035, 171:17–174:5, 179:8–24, 182:11–16.

The asserted prior art also includes Fugger. Fugger shows that, at the time of the invention, *human* sperm had been successfully frozen for later use to fertilize an egg. Specifically, Fugger disclose a method of sorting and freezing human sperm to produce “normal and healthy” human babies. Ex. 1007, 2368. That sets up the central dispute; whether a person of ordinary skill in the art would have had the desire and technical acumen to sort and freeze *non-human* sperm with a reasonable expectation of success.

II. DISCUSSION

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). Claim terms are given their ordinary and customary meaning as understood by one of ordinary skill in the art in the context of the entire disclosure. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). 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).

To the extent that any term requires express construction for the purposes of this decision, we discuss that construction in our analysis of the grounds of unpatentability. *See 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.’” (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999))).

B. Principles of Law

Petitioner bears the burden of proving unpatentability of the challenged claims, and that burden never shifts to Patent Owner. *Dynamic Drinkware, LLC v. Nat’l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015). To prevail, Petitioner must establish facts supporting its challenge by a preponderance of the evidence. 35 U.S.C. § 316(e); 37 C.F.R. § 42.1(d).

A patent claim is unpatentable under 35 U.S.C. § 103(a) if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person of ordinary skill in the art. *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). Obviousness is resolved based on underlying factual determinations, including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of skill in the art; and (4) objective evidence of nonobviousness, i.e., secondary considerations. *See Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

C. Level of Ordinary Skill in the Art

The prior art in this case is representative of the level of ordinary skill in the art. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001). Patent Owner contends that Petitioner’s witness, Dr. Marvin M. Pace,⁶

⁶ Dr. Pace began researching the cryopreservation of sperm in the 1960’s and has been actively involved in the field for his entire adult life. He has performed research and published in the field of sperm freezing. For

opines from the viewpoint of a hypothetical person of ordinary skill in the art who “may have no background in sperm cell sorting at all.” Resp. 12 (citing Ex. 1003 ¶ 41). Patent Owner contends that this is an erroneous viewpoint, because an ordinary artisan must have “at least . . . 3 years of experience working in the field of sperm cell sorting” in addition to experience freezing sperm. *Id.* (citing Ex. 2015 ¶ 91).

We find that Dr. Pace’s testimony is keyed to the knowledge and understanding of a person of ordinary skill in the art. A full and fair reading of Dr. Pace’s testimony reveals that, in fact, he opines from the perspective of a hypothetically ordinary artisan who has “at least 3 years experience with methods of freezing sperm” (Ex. 1003 ¶ 41) and, additionally, is familiar with conventional sperm sorting techniques, as described in the prior art, including Seidel and Fugger. *See, e.g., id.* ¶¶ 41, 46–51, 230, 233–34, 248, 305–308. A hypothetical person of ordinary skill in this art need not acquire their understanding of sperm sorting through hands-on experience, as proposed by Patent Owner. Resp. 12; Ex. 2015 ¶ 91. Knowledge acquired through familiarity with the prior art is sufficient. “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).

example, he developed “a straw freezing system” for cryopreserving sperm. He conducted over 300 laboratory experiments on semen physiology and cryopreservation of sperm. Ex. 1003 ¶¶ 2–9. We find that Dr. Pace is qualified to opine from the perspective of an ordinary artisan in the field of the invention.

D. Analysis

Three obviousness grounds are at issue in this review, based on the following prior art references: (1) the combined disclosures of Seidel and Salisbury; (2) Fugger alone; and (3) the combined disclosures of Fugger and Salisbury. We address each ground in turn below.

1. The Ground Based on Seidel and Salisbury

Petitioner asserts that the subject matter of claims 1–4, 6–9, 11–13, 15, 21–28, and 31–34 would have been obvious over the combined disclosures of Seidel and Salisbury. Pet. 15–36. The thrust of Patent Owner’s opposition is that Seidel teaches away from freezing sperm cells that have already been compromised by the damaging effects of sorting. Resp. 14–23. We first address the ground as applied against claim 1, then turn to the challenged claims that depend directly or indirectly from claim 1.

a. Analysis of Claim 1

(1) Seidel Discloses Steps (a) Through (d) of Claim 1

Seidel relates to a method of sorting non-human sperm cells—for example, by separating cells bearing an X chromosome from those bearing a Y chromosome—to facilitate sex-selection in non-human mammalian offspring produced by artificial insemination. Ex. 1005, 1:12–29; 5:41–42. Seidel expressly discloses the step of obtaining sperm from a non-human mammal by collecting bull semen through the use of an artificial vagina. Pet. 17–18 (citing Ex. 1005, 13:17–21; Ex. 1003 ¶¶ 182, 226). In other words, Seidel discloses “obtaining sperm cells from a male of a species of non-human mammal” as specified in step (a) of claim 1.

Step (b) of claim 1 requires “differentiating said sperm cells based upon at least one property which allows a portion of said sperm cells to be identified as bearing either an X-chromosome or a Y-chromosome.”

Ex. 1001, 32:1–4. Seidel is directed to separating non-human sperm via conventional flow cytometry, which the ’425 patent identifies as “a preferred method for separating cells.” *Id.* at 4:41; Ex. 1005, 5:53–7:33; Ex. 1003 ¶¶ 186–89, 227. We find that Seidel discloses step (b) of claim 1.

Step (c) of claim 1 requires “separating said sperm cells into a discrete population based upon said at least one property.” Ex. 1001, 32:5–6. Both the ’425 patent and Seidel discuss the method pioneered by Larry Johnson, in which a sample stream of X- and Y-chromosome bearing cell streams are distinguished and separated by a flow cytometer. *Compare* Ex. 1005, 1:62–2:4, 6:12–30 (Seidel, applauding Larry Johnson’s “seminal” work in developing the flow cytometry technique for sorting sperm cells), *with* Ex. 1001, 4:41–60 (the ’425 patent, identifying Johnson’s flow cytometry technique as “preferred” for separating cells in the method of the invention).

Seidel discloses that “the only quantitative technique used to achieve the separation of X- and Y-chromosome bearing sperm has been that involving individual discrimination and separation of the sperm through the techniques of flow cytometry.” Ex. 1005, 1:62–66. Seidel informs that “by sensing the degree of dye present in the sperm cells it is possible to discriminate between X-bearing sperm and Y-bearing sperm by their differing emission levels.” *Id.* at 6:24–30; Pet. 18 (citing Ex. 1003 ¶¶ 188, 228); *see* Ex. 1005, 7:1–25 (Seidel, reporting that “rates of sorting in the thousand and twelve hundred ranges have already been achieved” for non-human sperm by using a MoFlo® high speed flow cytometer). Seidel also

explains that flow cytometry allows one to “discriminate between cells based on a particular characteristic and place them in the appropriate collector.” Ex. 1005, 6:40–45; *see* Pet. 18 (citing Ex. 1003 ¶¶ 189, 228). We are persuaded that Seidel discloses step (c) of claim 1.

We next address whether Seidel discloses “establishing from said discrete population a selected sperm sample having a sufficient number of sperm cells to fertilize an egg of a female of said species of non-human mammal” as required by step (d) of claim 1. Ex. 1001, 32:7–10. Seidel discloses establishing a population of X-bearing sperm, diluting the sperm to the desired concentration, and placing the sperm into a straw. Ex. 1005, 14:26–28; Ex. 1003 ¶¶ 190–91, 194, 196–97. Seidel describes using that selected sperm sample to successfully artificially inseminate a female bovine. Ex. 1005, 15:16–16:9; Ex. 1003 ¶¶ 198, 229. On this record, we are persuaded that Seidel discloses step (d) of claim 1.

Petitioner acknowledges that Seidel does not teach expressly freezing the sorted non-human sperm sample as required by step (e) of claim 1. Pet. 19. As explained in the next section, however, Petitioner persuasively shows that an ordinary artisan would have had the desire and skill to freeze Seidel’s sorted sperm, by applying Salisbury’s conventional freezing technique to cryopreserve the sample for later use in fertilizing an egg.

(2) Salisbury Discloses Freezing Step (e) of Claim 1

The ’425 patent states that “techniques for freezing unselected sperm are well known” and, further, that advances in cryopreservation and sperm storage “have facilitated widespread distribution and commercialization of sperm intended for artificial insemination or in vitro fertilization.” Ex. 1001, 2:10–11, 1:29–32. In describing the equilibration and freezing of sperm,

the '425 patent states that, “[f]ollowing equilibration, any standard freezing method can be employed, provided the freezing rate is not too rapid (i.e., not in excess of about 0.5°C./minute).” *Id.* at 10:54–57. Salisbury describes principles and techniques of freezing non-human spermatozoa (Ex. 1006, 494–539), and recognizes the problems that may occur when the freezing rate is too rapid, *id.* at 508–12, Fig. 17-6. Salisbury does not expressly describe freezing sperm that have been subjected to a cell sorting process.

*(3) Reasons to Combine the
Disclosures of Seidel and Salisbury*

Petitioner argues that one of ordinary skill in the art would have been led to combine the teachings of Seidel and Salisbury in view of the known commercial benefits of separated, frozen non-human sperm:

A person of ordinary skill in the art would have been motivated to freeze separated sperm in light of the commercial benefits to separated, frozen sperm. For example separated sperm allows farmers to vary the male to female offspring ratio. Female dairy cows are normally more valuable than males because only females can produce milk and because female calves have a lower incidence of difficult births (female calves tend to be smaller than male calves). And, because fresh sperm quickly loses viability, frozen sperm allows breeders to store sperm over long periods of time and to use it to artificially inseminate cows at the optimal time. Frozen sperm can be shipped long distances, permitting producers to take advantage of the genetic attributes of bulls located far away from the heifers to be impregnated.

Pet. 16 (citing Ex. 1003 ¶¶ 43, 92, 230 (Pace Declaration)).

Patent Owner confirms that “[t]he benefits of freezing were well-known in the industry and easily appreciated by those of skill in the art well before” the time of the invention. Resp. 22 (citation omitted). In Patent

Owner's view, however, Seidel teaches away from freezing sorted sperm, in disclosures which acknowledge that sorting imposes stresses on the already-delicate sperm cells. *Id.* at 14–15 (citing Ex. 1005, 2:24–25, 45–49, 56–67; 7:48–51, 62–64; 9:52–57; Ex. 2015 ¶¶ 20, 114). Patent Owner submits that a person of ordinary skill in the art would not have been led to apply a damaging method of freezing to a cell population that is already compromised by the deleterious effects of a sorting process. *Id.* at 16.

A reference teaches away if it “criticize[s], discredit[s], or otherwise discourage[s]” modifying the reference to arrive at the claimed invention. *In re Fulton*, 391 F.3d 1195, 1201 (Fed. Cir. 2004). Patent Owner directs us to no disclosure in Seidel that mentions freezing, much less a teaching that “criticize[s], discredit[s], or otherwise discourage[s]” the application of a freezing step to sorted sperm. *Id.*; see Resp. 14–16 (teaching away argument). We will not “read into a reference a teaching away from a process where no such language exists.” *DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co.*, 464 F.3d 1356, 1364 (Fed. Cir. 2006). Patent Owner's evidence that freezing “would exacerbate the deleterious effects of sorting” does not persuade us that Seidel teaches away from the proposed combination with Salisbury. Resp. 20 (quoting Ex. 2015 ¶ 126).

We are persuaded that “nothing inherent in the process of separating sperm cells” would have discouraged an ordinary artisan from combining Seidel's sorting technique with Salisbury's freezing technique. *See, e.g.*, Ex. 1003 ¶ 90. Petitioner persuasively argues that “the prior art is full of examples where sperm was subjected to the stresses of a sorting process, frozen, and then used to produce pregnancies.” Reply 2. Specifically, Petitioner directs us to evidence that artisans in the field had been applying

sorting and freezing, in combination, for decades to obtain non-human sperm populations suitable for fertilization. *Id.* at 3–5; *see* Ex. 1003 ¶¶ 81–90 (Dr. Pace, discussing prior art methods in which non-human sperm was sorted, frozen, and then used for insemination (citing Exs. 1018–1026)). For example, one prior art process achieved a “very high conception rate” using non-human sperm that was first subjected to a stressful series of sorting steps, then frozen according to conventional cryopreservation methods. Reply 3–4 (quoting Ex. 1019, 14:39–43) (citing Ex. 1019, 12:50–60; 15:37–46; Ex. 1035 72:7–18; 73:15–81:6; 82:16–83:15; 899–90:15).

Even if those prior art sorting techniques were less reliable at sorting sperm than flow cytometry, Petitioner shows persuasively that, at the time of the invention, it was routine in the field of the invention to apply sorting and freezing techniques in tandem to non-human sperm cell populations with success. *See* Reply 3–4 (discussing the disclosures of Exs. 1019 and 1025); Ex. 1003 ¶¶ 81–90 (and citations to prior art therein). Patent Owner’s own witness confirms that the references advanced by Petitioner, in fact, disclose examples in which non-human sperm was subjected to the stresses of both sorting and freezing, then used to fertilize an egg. Reply 4–6 (citing Ex. 1035, 73:15–81:6, 82:16–83:15, 88:4–89:2, 89:9–90:15).

Research conducted by Dr. Chris Polge would have further encouraged an ordinary artisan to combine Seidel’s method of sorting for sex-selection with Salisbury’s method of freezing in order to achieve the benefits of cryopreserving sorted non-human sperm for later use in fertilization. Ex. 1003 ¶ 93 (citing Ex. 1027, 10 (discussing “preliminary experiments . . . carried out on freezing sperm after sorting” for non-human animal breeding)); Resp. 22 (contesting import of Ex. 1027); Reply 8–9

(reasserting import of Ex. 1027). The evidence shows that an ordinary artisan, seeking to extend Dr. Polge's work, would have combined Seidel's sorting and Salisbury's freezing techniques. As explained in *KSR*:

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

Reply 2 (quoting *KSR*, 550 U.S. at 421); *see id.* at 8–9 (further discussing Dr. Polge's work).

In light of the known commercial benefits of freezing sorted non-human sperm, the evidence of a decades-long practice of freezing sorted non-human sperm, the encouraging work of Dr. Polge, and Dr. Pace's persuasive testimony on the issue, we find that an ordinary artisan, reading Seidel and Salisbury, would not have been "led in a direction divergent from the path" taken by the inventor of the '425 patent. *In re Mouttet*, 686 F.3d 1322, 1333–34 (Fed. Cir. 2012) (quotations omitted); *Ricoh Co. v. Quanta Computer Inc.*, 550 F.3d 1325, 1332 (Fed. Cir. 2008) (quotations omitted).

On the contrary, a person of ordinary skill in the art would have been led to combine Seidel's method of sorting non-human sperm, based on sex-selection, with Salisbury's method of freezing to cryopreserve the sorted sample for later use in fertilizing an egg. The knowledge of the art suggests the utility of freezing non-human sperm, after sorting for sex-selection, to facilitate distribution and commercialization of sperm for non-human animal breeding. Even if we accept Patent Owner's counterview—that the sorting process would have been understood to make sperm more vulnerable to the

damaging effects of freezing—we are not persuaded that the mere possibility of failure makes unobvious the successful sorting and freezing of non-human sperm. *See In re Moreton*, 129 USPQ 288 (CCPA 1961) (“An argument that if one slavishly following the prior art . . . will sometimes succeed and sometimes fail, then he is always entitled to a patent in case of success [is] not the intention behind 35 U.S.C. 103. Obviousness does not require absolute predictability. Where . . . the knowledge of the art clearly suggests” something “as useful . . . , the mere possibility of failure does not render the [] successful use ‘unobvious.’”).

Seidel uses a sorted sperm sample to successfully inseminate a female bovine; in other words, Seidel discloses a sorted sperm sample that includes “a sufficient number of sperm cells to fertilize an egg.” Ex. 1001, 32:7–11; Pet. 19 (citing Ex. 1005, 15:16–16:9; Ex. 1003 ¶¶ 198, 229). Here, it is useful to highlight that, in claim 1, it is the *sorted* sperm sample of step (d)—not the *sorted and frozen* sperm sample of step (e)—that must have “a sufficient number of sperm cells to fertilize an egg.” Ex. 1001, 32:7–11. No express terms in claim 1 require the sorted sperm sample to retain any utility for use in fertilization, after it is frozen in step (e).⁷ *Id.*

Nevertheless, we cannot ignore that the entire thrust of the ’425 patent disclosure is directed toward freezing a sperm sample that “can be thawed and used for fertilization.” Ex. 1001, Abstract, 2:35–67; *see also, e.g., id.* at 10:29–11:45, 17:11–27. That persuades us that a person of ordinary skill in

⁷ Patent Owner asserts an argument based on a misconception that the term “having a sufficient number of cells to fertilize an egg” modifies the “selected sperm sample” after freezing step (e) of claim 1. Ex. 1001, 32:8–9, 11; Resp. 20–21 (bridging paragraph).

the art, reading the claim language in light of the specification, would have understood that the “selected sperm sample” of claim 1 must have some utility for fertilization, at the conclusion of the freezing step of claim 1(e). *Id.* at 32:11. Not even Petitioner, who would benefit from the broader construction, advocates reading claim 1 so broadly as to yield “nothing, no viable sperm at the end of the process.” Tr. 10:1–9.

Therein lies a conundrum. There is no particular number of viable sperm cells that will ensure fertilization; accordingly, neither party proposes a number, or even a numerical range, of viable sperm cells that will successfully fertilize an egg. Reply 12. It is possible to achieve fertilization using low numbers of viable sperm, and it is also possible to achieve complete failure (no fertilization) using high numbers of viable sperm. *Id.* at 12–15. But this much is clear: A sample having no viable sperm cells cannot fertilize an egg. *Id.* For the reasons that follow, we find that a sperm sample is useful for fertilization if it contains at least one viable sperm cell.

At the time of the invention, an ordinary artisan would have understood that conventional procedures for fertilizing an egg included not only artificial insemination (in which sperm are introduced into the uterus or cervix), but also in vitro fertilization (“IVF”), in which the egg is combined with sperm in a laboratory dish outside the body. Ex. 2015 ¶¶ 52–54; Resp. 5 (Patent Owner’s overview of fertilization methods).

Intracytoplasmic sperm injection (“ICSI”) was a known method of IVF that required just one viable sperm cell, which is injected directly into the egg. Ex. 2015 ¶ 55; Reply 5–6 (citing Ex. 1035, 121:3–4; Ex. 1003 ¶ 51). Although the ’425 patent does not refer expressly to ICSI, claim 1

contains no terms that limit the fertilization technique for which the sorted and frozen sperm must be useful. Ex. 1001, 32:11 (step 1(e)).

Patent Owner's own witness confirms that, in "ICSI, a single cell can be sufficient to fertilize an egg." Ex. 1035, 121:5–7; *see* Resp. 5 (Patent Owner's overview of fertilization procedures, including ICSI). Not even Patent Owner goes "so far as to suggest that one of ordinary skill in the art would have expected the combination of Seidel and Salisbury to kill all of the cells." Reply 6; *see* Resp. 19–20 (arguing that sperm sorting imposes "severe deleterious effects" on sperm, but stopping short of arguing that Seidel's improved sorting method would kill all of the sperm in a sample).

On this record, at the time of the invention, a sperm sample containing at least one viable sperm cell would have been understood to be useful in a fertilization procedure, namely, ICSI. Even if we exclude ICSI from the universe of known fertilization procedures, however, the result remains the same. Seidel discloses that the pregnancy rate of heifers inseminated with sorted sperm cells was not significantly different from the rate achieved with unsorted sperm cells. Pet. 31 (citing Ex. 1005, 15:16–16:9; Ex. 1003 ¶¶ 198, 281). Patent Owner's own witness agrees that, "if you use Seidel's disclosure and then freeze the cells, they will survive the process and produce a sufficient number to fertilize eggs." Reply 10 (quoting Ex. 1035, 182:11–16). In other words, one led to combine Seidel and Salisbury, to achieve the well-known benefits of freezing, would have attained a sorted, frozen sperm sample having the same level of utility for artificial insemination that is reported in the '425 patent.

For the foregoing reasons, we find that Petitioner has set forth reasoning with a rational underpinning as to why a person of ordinary skill

in the art would have combined the teachings of Seidel and Salisbury to arrive at the invention of claim 1.

b. Analysis of Dependent Challenged Claims

Petitioner presents detailed arguments and evidence that dependent claims 6–9, 11–13, 15, 21–24, 28, 31, 33, and 34 are unpatentable as obvious over the combined disclosures of Seidel and Salisbury. *See* Pet. 20–36 (and citations to record therein). Patent Owner does not address the patentability of those claims separately from claim 1. Resp. 14 (“The dependent claims, therefore, are also not obvious because they depend from claim 1.”). The information presented in the Petition satisfies Petitioner’s burden with respect to those dependent claims.

Petitioner also presents detailed arguments and evidence that dependent claims 2–4, 25–27, and 32 are unpatentable as obvious over the combined disclosures of Seidel and Salisbury. *See* Pet. 20–22, 31–35 (and citations to record therein). Patent Owner raises additional arguments, as to those claims, that are separate from the arguments presented as to claim 1. Resp. 24–30. We first address claims 25–27, then turn to claims 2–4 and 32.

Claims 25–27 require establishing, by the freezing method of claim 1, “an insemination sample having a sufficient number of sperm cells to inseminate a female.” Ex. 1001, 34:14–16. That limitation of claim 25 modifies the sorted, frozen sperm sample. *Id.* We agree with Patent Owner that the term “insemination” excludes an IVF procedure, such as ICSI, in which fertilization occurs outside the female body. Resp. 27–29 (and citations to record therein). For the reasons stated above, however, even if ICSI and other IVF techniques are excluded from the universe of known fertilization procedures, the result does not change. A person of ordinary

skill in the art would have had the desire and skill to combine Seidel and Salisbury and, thereby, would have attained a frozen sample having the same level of utility for artificial insemination that is reported in the '425 patent.

Claim 27 additionally requires an “insemination sample” that “contains between about one million and about three million sex-selected sperm cells.” Ex. 1001, 34:22–25. Nothing in the terms of claim 27 specifies that the same number of cells must be viable; accordingly, this limitation refers to the absolute number of cells (whether viable or not) contained in the sample. *See* Reply 11–12 (citing Ex. 1035, 151:22–153:10). Petitioner directs us to persuasive evidence that Seidel’s sorting technique produces samples having between about one million and three million sex-selected sperm cells. Pet. 32 (citing Ex. 1005, 14:11–12; Ex. 1003 ¶¶ 194, 287). We agree with Petitioner that Patent Owner does not genuinely “dispute that Seidel discloses sorting at rates that will produce doses of more than 1 million cells.” Reply 12; *see* Resp. 27–30. Seidel discloses that sorted and unsorted sperm samples produce similar pregnancy rates in heifers and, further, uses a sorted sperm sample to successfully fertilize a female bovine via artificial insemination. Ex. 1005, 15:16–16:9; Ex. 1003 ¶¶ 198, 229, 281.

Patent Owner argues that additional reasons support the patentability of claims 2–4 and 32 over Seidel and Salisbury. Resp. 24–27. First, Patent Owner points out that Seidel is directed to the same flow cytometry sorting method, involving fluorescence-activated cell sorting (“FACS”), that is useful to sort cells according to the method of claims 2–4 and 32. *Id.* at 24–26. Second, Patent Owner argues that “Seidel’s disclosure regarding the stresses that sperm cells must endure during sorting by flow cytometry and

FACS” show that “a person of ordinary skill in the art would not have had a reasonable expectation of success in combining the freezing method of Salisbury with the sorting method of Seidel.” *Id.* at 26. We agree with Petitioner that this argument is essentially the same as the teaching away argument presented in the context of claim 1. Reply 11. For reasons stated above in connection with claim 1, Patent Owner’s alleged additional arguments pertaining to claims 2–4 and 32 are not persuasive.

Petitioner satisfies its burden with respect to the obviousness of the subject matter of claims 2–4, 25–27, and 32 over the disclosures of Seidel and Salisbury. We next turn to Petitioner’s assertion that the challenged claims are invalid based on Fugger alone or in combination with Salisbury.

2. The Ground Based on Fugger Alone

Petitioner asserts that claims 1–4, 6, 25, 26, 31, and 32 are unpatentable as obvious over Fugger. Pet. 36–44. The Petition includes detailed explanations of how each claim limitation is met by that reference, as well as rational reasons for modifying the reference, and directs us to the declaration of Dr. Pace (Ex. 1003). *Id.* Patent Owner responds that Fugger does not demonstrate the obviousness of a method for freezing sorted *non-human* sperm, because Fugger freezes sorted *human* sperm. Resp. 31–32.

Fugger uses the conventional flow cytometry method to separate human sperm cells for preconception sex-selection, which results in a desired female sex-selection in 92.9% of births. Ex. 1007, 2367 (Abstract). The introduction section in Fugger, however, also discusses the use of flow cytometric separation (“FCS”) to sort non-human X- and Y-bearing sperm:

In 1987, Johnson et al. reported flow cytometric separation (FCS) of animal X- and Y-bearing spermatozoa into two enriched populations based on total DNA difference (United

States Patent #5,135,759). Subsequently, pregnancies and births have been reported in the rabbit (Johnson et al., 1989), swine (Johnson, 1991), ovine (Morrell and Dresser, 1989), and bovine (Cran et al., 1993) species using such flow sorted spermatozoa. Over 400 offspring, all normal, have been born using flow sorting technology, including three successive generations in swine (L.A. Johnson, personal communication) and five successive generations in rabbits (Morrell and Dresser, 1989).

Id. at 2367.

Fugger's examples relate to sorted human sperm. In that regard, Fugger discloses that sorted human sperm samples are placed into cryotubes or straws "and subsequently frozen in a programmable rate freezer." Pet. 37–38 (quoting Ex. 1007, 2368) (citing Ex. 1003 ¶¶ 223, 309). Frozen human sperm samples "were thawed at room temperature, centrifuged, and resuspended" prior to use. Ex. 1007, 2368. "Pregnancies [were] attained with the use of frozen sorted sperm cells." *Id.* at 2369.

Fugger compares human sperm to bovine sperm in the FCS separation process. Fugger states that "[s]everal characteristics specific to human sperm cells present unique challenges for FCS compared with domestic animal spermatozoa." *Id.* at 2369. Those characteristics include the percentage total DNA difference between X- and Y-bearing spermatozoa, physical shape and morphology, variation in the size of the Y chromosome, heterogeneity of the sperm cells, and the range of individual variability. *Id.* Fugger notes that pregnancies using intrauterine insemination with less than 1×10^6 motile sperm cells have been achieved in bovine and human species. *Id.* (citations omitted).

We find that Fugger discloses each method step of claim 1, except that claim 1 requires non-human sperm, and Fugger's method is applied to

human sperm. *See* Pet. 36–39 (and citations to record therein). The crux of Patent Owner’s counter argument is that a person of ordinary skill in the art would not have been prompted to apply Fugger’s combined sorting and freezing method to non-human sperm cells, because “human sperm exhibit differences from sperm cells of other species.” Resp. 33.

Petitioner asserts that it would have been obvious to apply Fugger’s method to the sperm of non-human mammals with a reasonable expectation of success. Pet. 38–39. Specifically, Petitioner asserts that a person of ordinary skill in the art would have been led to apply the teachings of Fugger to sperm cells of non-human species, such as bovine, because of the known commercial benefits of doing so, which included increasing the percentage of milk-producing offspring, reducing the number of difficult births, and taking advantage of optimal times for insemination of the female with genetic attributes of high quality bulls that may be located away from the female to be inseminated. *Id.* (citing Ex. 1003 ¶¶ 43, 92, 305).

Patent Owner responds that Fugger teaches away from combining sorting and freezing processes on non-human sperm samples, by discussing differences between human and non-human sperm cells. Resp. 31–33. Patent Owner directs us to this disclosure in Fugger: “Concerns regarding embryo development in bovine and rabbit species were not observed in our experience with humans.” *Id.* at 32 (quoting Ex. 1007, 2369) (citations omitted). That language does not rise to the level of a teaching away. A reference does not teach away if it merely expresses a general preference for an alternative invention from amongst options available to the ordinarily skilled artisan, and the reference does not discredit or discourage investigation into the invention claimed. *Fulton*, 391 F.3d at 1201.

Patent Owner's teaching away argument also is unpersuasive for other reasons. Fugger describes a method of employing flow cytometry to sort non-human sperm for sex-selection, resulting in the birth of over 400 offspring, all normal, "including three successive generations in swine." Ex. 1007, 2367. Fugger points out the problems in using flow cytometry for human sperm, which were not issues for non-human sperm, such as bovine. *Id.* at 2369. From Fugger's description, using flow cytometry for non-human sperm, such as bovine, did *not* present the "unique challenges" of using that method for human sperm cells. *Id.* ("Several characteristics specific to human sperm cells present unique challenges for" flow cytometric separation "compared with domestic animal spermatozoa."). Based on the full trial record, we are persuaded that Fugger does not teach away from using flow cytometry to sort non-human sperm samples.

Nor does Fugger teach away from freezing sorted non-human sperm cells. We agree with Patent Owner that the occurrence of "cold shock," caused by a sudden change in temperature, was not a concern with human sperm, but was known to lead to non-viability and cell death in non-human sperm. Resp. 4, 34–35. We find, however, that it was well within the level of ordinary skill in the art to protect non-human sperm from the effects of "cold shock" by controlling the change in temperature during freezing. Reply 17–18 (citing Ex. 1003 ¶ 74; Ex. 1035, 224:12–20). That finding is consistent with the disclosure of the '425 patent, which states that "[s]perm from any species can be selected and frozen according to the method of the invention," including "[h]uman sperm, bovine, equine, porcine, ovine, elk and bison sperm." Ex. 1001, 4:1–8. Fugger reports seven pregnancies out of 27 patients in 33 cycles using frozen human sperm sorted for sex-

selection. Ex. 1007, 2368. That data establishes that Fugger obtained a sorted sperm sample having a sufficient number of sperm to fertilize an egg. Patent Owner's counterview that "the data set in Fugger was too small to lead to any conclusions" is unpersuasive. Resp. 35; Reply 19.

Patent Owner raises one other contention—that the evidence cited in the Petition fails to establish that Fugger's method establishes an "insemination sample" within the meaning of claims 25 and 26. Resp. 38–42. As explained in our analysis of the ground based on Seidel and Salisbury, *see supra*, we agree with Patent Owner that the term "insemination" excludes IVF procedures, including ICSI, in which fertilization occurs outside the female body. We, therefore, find unpersuasive Petitioner's argument that Fugger discloses an "insemination sample" used for IVF. Pet. 42. On that point, Fugger discloses "[f]rozen specimens used for IVF or ICSI," without any mention of frozen samples used for intrauterine insemination. Ex. 1007, 2368. Petitioner fails to identify persuasive evidence that Fugger froze the sorted samples that were used for intrauterine insemination. Reply 19–20. Patent Owner, by contrast, directs us to evidence that Fugger's frozen samples were not used for intrauterine insemination. Resp. 38–39 (and evidence cited therein).

Petitioner fails to carry its burden of proving that Fugger discloses or suggests a frozen, sorted "insemination sample" as required by claims 25 and 26. Ex. 1001, 34:14–15. Petitioner fails to carry its burden as to claims 25 and 26, but carries its burden of proof as to claims 1–4, 6, 31, and 32.

3. The Ground Based on Fugger and Salisbury

Petitioner challenges claims 7–9, 11–13, 15, 21–24, 27, 28, 33, and 34 as unpatentable under 35 U.S.C. § 103(a) over the combined disclosures of

Fugger and Salisbury. Pet. 44–59. Petitioner provides detailed explanations of how each claim limitation is met by the references. Petitioner shows persuasively that a person of ordinary skill in the art would have recognized that the method taught in Fugger could be improved when applied to other animals, using the teachings of Salisbury. And Petitioner provides rational reasons why the combined disclosures of Fugger and Salisbury would have led an ordinarily skilled artisan to the subject matter of claims 7–9, 11–13, 15, 21–24, 28, 33, and 34. Pet. 44–59 (and citations to record therein). The Petition is supported by the declaration of Dr. Pace. Ex. 1003).

Dr. Pace states that

A person of ordinary skill in the art also would have been motivated to combine Fugger 1998 (which pertains to freezing human sperm) with Salisbury 1978. There would have been a strong motivation to freeze separated animal sperm due to the benefits of both separated and frozen sperm. A person of skill looking to apply the teachings of Fugger 1998 to other animals would have recognized that the method taught in Fugger 1998 could be improved when applied to other animals by modifying that method in modest respects. Such a person would have turned to references such as Salisbury 1978, one of the most respected texts in the field of artificial insemination. Furthermore, in light of the long history of freezing animal sperm and the numerous reports of successful freezing of animal sperm, such a person would have expected to be successful in freezing animal sperm separated by the methods disclosed in Fugger 1998.

Ex. 1003 ¶ 336 (citation omitted).

We credit Dr. Pace’s testimony, as it is consistent with the teachings disclosed in the cited references. Although Fugger describes using flow cytometry for human sperm cells, Fugger also discusses using the process for non-human sperm cells, and the success in doing so. Ex. 1007, 2367–69.

We are persuaded that one of ordinary skill in the art would have been led to look to the teachings of Salisbury, which focus on cattle. Ex. 1006, Title.

Patent Owner disagrees based on arguments made in connection with the ground based on Fugger alone. Resp. 42–43. Specifically, Patent Owner argues that “the addition of Salisbury in combination with Fugger does not alter . . . that Fugger teaches away from extending the Fugger method to non-human species or attempting to use separated, frozen sperm for artificial insemination.” *Id.* at 43. For the reasons stated above in connection with the ground based on Fugger alone, those arguments are unpersuasive, with one exception: Petitioner has not carried its burden of showing that claim 27—which, like claim 25, requires a freezing method that establishes an “insemination sample”—is unpatentable over Fugger and Salisbury. Ex. 1001, 34:23. Petitioner carries its burden, however, with respect to claims 7–9, 11–13, 15, 21–24, 28, 33, and 34

4. Secondary Considerations

Factual inquiries for an obviousness determination include secondary considerations based on objective evidence of nonobviousness. *See Graham*, 383 U.S. at 17–18. The totality of the evidence submitted may show that the challenged claims would not have been obvious to one of ordinary skill in the art. *In re Piasecki*, 745 F.2d 1468, 1471–72 (Fed. Cir. 1984). Secondary considerations may include long-felt but unsolved need, failure of others, unexpected results, commercial success, copying, licensing, and praise. *Graham*, 383 U.S. at 17; *Transocean Offshore Deepwater Drilling, Inc. v. Maersk Drilling USA, Inc.*, 699 F.3d 1340, 1349, 1355 (Fed. Cir. 2012). “[E]vidence rising out of the so-called ‘secondary considerations’ must always when presented be considered en route to a

determination of obviousness.” *Stratoflex v. Aeroquip Corp.*, 713 F.2d 1530, 1538 (Fed. Cir. 1983).

Patent Owner presents evidence of secondary considerations, which we weigh en route to ruling on Petitioner’s obviousness challenges. Resp. 43–49. Specifically, Patent Owner presents evidence that “leading scientists” employed by Petitioner’s own parent company “expressed initial skepticism that a separated sperm sample could be frozen.” Resp. 44 (citing Ex. 2012); *see* Ex. 2015 ¶¶ 202–05 (opinion testimony relating to Patent Owner’s asserted evidence of industry skepticism). Petitioner responds that the statements advanced by Patent Owner are not shown to relate to the technique disclosed in the ’425 patent. Reply 21–23. We are persuaded, however, that Patent Owner’s evidence is not entirely without merit, and we weigh it against the strength of the evidence supporting a conclusion of obviousness.

Patent Owner also asserts that an article, which appeared in *Beef Magazine*, demonstrates the commercial success of the invention claimed in the ’425 patent. Resp. 47–49 (citing Ex. 2022). Sales information, in the absence of evidence as to market share or what sales would normally be expected in the market, does not support an inference that the sales represent a substantial share of any definable market, and thus, is insufficient to show commercial success. *Cable Elec. Prod., Inc. v. Genmark, Inc.*, 770 F.2d 1014, 1027 (Fed. Cir. 1985) (reversed on other grounds). Patent Owner does not point us to any actual sales data, or evidence that any commercial success was driven by the claimed invention—as opposed, for example, to the inventions of other patents controlled by Patent Owner, such as the break-through flow cytometry method developed by Larry Johnson, and

intellectual property relating to the revolutionary high speed sorter known as the MoFlo®, which both are discussed in Seidel. Reply 24–25; Ex. 1005, 2:1–8. Seidel lauds Johnson’s work as “so significant an advancement that it has for the first time made the commercial separation of” sex-selected sperm cells “feasible.” Ex. 1005, 2:1–8. Seidel also reveals MoFlo® cell sorters “have increased sorting speeds extraordinarily and have thus made flow cytometry a technique which is likely to make feasible the commercial application of sperm sorting.” *Id.* at 7:6–9. Patent Owner fails to show that its asserted evidence of commercial success reflects the merits of the invention of the ’425 patent, instead of other intellectual property readily available in the prior art. *See, e.g., J.T. Eaton & Co. v. Atl. Paste & Glue Co.*, 106 F.3d 1563, 1571 (Fed. Cir. 1997) (“asserted commercial success of the product must be due to the merits of the claimed invention *beyond what was readily available in the prior art*” (emphasis added)).

Patent Owner also alleges that there was a long-felt but unsolved need for the invention of the ’425 patent. Resp. 45–47. That evidence is unpersuasive for the same reasons stated above. Petitioner persuasively argues that any long felt but unsolved need “was solved in the prior art, not in the ’425 patent, which admittedly relies on prior art techniques to produce a ‘sufficient number of cells.’” Reply 23–24. We are persuaded that the actual force behind any evidence of long-felt need relates to Patent Owner’s control over Larry Johnson’s break-through flow cytometry method for sex-selecting sperm, and the MoFlo® high speed flow cytometer that revolutionized the commercialization of such sorting. *Id.* at 24–25. On this record, it appears that any long-felt need was solved in the prior art, not the invention of the challenged claims of the ’425 patent.

Even affording it some weight, Patent Owner's evidence of secondary considerations is insufficient to overcome the strong showing of obviousness made out by Petitioner in this review. *See Süd-Chemie, Inc. v. Multisorb Techs., Inc.*, 554 F.3d 1001, 1009 (Fed. Cir. 2009) ("evidence of unexpected results and other secondary considerations will not necessarily overcome a strong prima facie showing of obviousness").

III. CONCLUSION

Taking account of the arguments and evidence presented during trial, including all evidence of secondary considerations, we determine that Petitioner establishes by a preponderance of the evidence that claims 1–4, 6–9, 11–13, 15, 21–28, and 31–34 of the '425 patent are *unpatentable* based on the following grounds of obviousness under 35 U.S.C. § 103(a):

A. Claims 1–4, 6–9, 11–13, 15, 21–28, and 31–34 are unpatentable as obvious over the combination of Seidel and Salisbury;

B. Claims 1–4, 6, 31, and 32 are unpatentable as obvious over Fugger; and

C. Claims 7–9, 11–13, 15, 21–24, 28, 33, and 34 are unpatentable as obvious over the combination of Fugger and Salisbury.

IV. ORDER

For the foregoing reasons, it is
ORDERED that claims 1–4, 6–9, 11–13, 15, 21–28, and 31–34 of
the '425 patent are *unpatentable*; and

FURTHER 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.

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