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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ABS GLOBAL, INC.,
Petitioner,

v.

INGURAN, LLC,
Patent Owner.

Case IPR2015-00001
Patent 8,206,987 B2

Before GRACE KARAFFA OBERMANN, MICHELLE R. OSINSKI, and SUSAN L. C. MITCHELL, *Administrative Patent Judges.*

OBERMANN, *Administrative Patent Judge*.

DECISION
Denying Institution of *Inter Partes* Review
37 C.F.R. § 42.108

Petitioner requests an *inter partes* review of claims 1, 2, and 5–8 of U.S. Patent No. 8,206,987 B2 (Ex. 1001, "the '987 patent"). Paper 6 ("Pet."). Patent Owner filed a Preliminary Response. Paper 11 ("Prelim. Resp."). Applying the standard set forth in 35 U.S.C. § 314(a), which requires demonstration of a reasonable likelihood that Petitioner would

prevail with respect to at least one challenged claim, we deny the Petition and do not institute an *inter partes* review of claims 1, 2, and 5–8.

I. BACKGROUND

A. Related Proceedings

Petitioner identifies no co-pending related proceedings involving the ’987 patent. Pet. 1.

B. The ’987 Patent (Ex. 1001)

The ’987 patent relates to a method of sorting sperm cells to yield populations that are “enriched” with cells having a desired characteristic, for example, a gender characteristic. Ex. 1001, 213:7 (claim 1); *see id*. at 1:25–29; 4:24–45 (explaining nature of the enrichment). The sorting method provides viable populations of sperm that are useful for preselecting the sex of animal offspring produced by artificial insemination. *Id*. at 1:29–38.

An enriched population of cells is obtained from a mixture of stained sperm cells. *Id*. at 24:16–21. Uptake of dye results in a mixture of stained cells having differing and measurable fluorescence intensity, based on their X-chromosome or Y-chromosome content, which permits sorting the cells based on the sex characteristic. *Id*. at 26:9–15. A photodetector distinguishes the fluorescence emissions and classifies the cells according to their X or Y content. *Id*. at 28:46–51. Laser light then is used to “ablate (kill or otherwise damage) selected particle sets to provide a collected population having a desired content.” *Id*. at 80:6–8. Photo-damage selection, or “laser ablation,” of sperm cells is described in the ’987 patent and required by each challenged claim. *Id*. at 126:59; *see id*. at 213:6–8 (claim 1, the only independent claim); *see generally id*. at 126:44–127:54 (describing method of photo-damage selection).

The ’987 patent also describes a conventional flow cytometry apparatus, which distinguishes and sorts sperm cells based on their X or Y content. *Id*. at Fig. 2 (depicting conventional droplet sorter); *id*. at 4:55–57, 28:18–58; 46:8–47:28. That apparatus produces a stream of droplets, in which each droplet ideally contains an individual sperm cell. *Id*. at 28:22–23, 28–29 (describing flow cytometry apparatus that delivers a fluid stream “with the cells substantially in single file” and a “conventional” method of causing “the stream to break into droplets containing individual cells”) (internal numbering omitted). A pair of electrostatic charged deflector plates sorts and deflects droplets into separate streams, maintaining “the segregation of the different populations” during collection. *Id*. at 28:57–58; 46:8–47:28 (explaining process by which droplets are deflected “in respective groups . . . by supplying the appropriate number of collection vessels, each being positioned to collect a different population of droplets”); *see id*. at Fig. 2 (depicting physical separation of cell populations).

A droplet sorter thus distinguishes and segregates cell populations into separate collection containers based on their X or Y content. *See id*. at 47:26–27. The ’987 patent discloses a modification of the droplet sorter, in which “the droplet sorting components are eliminated” and “replaced by a laser to ablate undesired particles in the fluid stream.” *Id*. at 127:1–9 (internal numbering omitted). “As a result, the stream collected in a collection receptacle contains a desired population of particles.” *Id*. at 127:9–11 (internal numbering omitted).

In other words, unlike a conventional droplet sorter, the modified apparatus does not depend on physical separation of cells; instead of separating cells from the fluid stream, undesired cells are made “ineffective”

and collected in the same container as desired cells. *Id*. at 127:11–17. The result is an "enriched" population of desired cells. *Id*. at 1:28.

The '987 patent specification, in its discussion of "photodamage (laser ablation)," incorporates by reference the disclosure of Shapiro, one of the references applied against the challenged claims in the Petition. *Id*. at 126:49–61; *see* Pet. 42. As discussed below, Shapiro uses laser light to kill "acute lymphoblastic leukemia cells" in a fluid stream. Ex. 1007, 2:13–14 (sole experimental example); *see id*. at 1:5–32. Shapiro explains that, by killing undesired cells in the fluid stream, instead of sorting them in droplets, laser ablation provides "superior speed as well as reliability" for the removal of cancer cells in a cell population. *Id*. at 1:27–32.

C. Illustrative Claim

Claim 1, the only independent claim, is illustrative of the subject matter at issue in this proceeding:

> 1. A method of sorting a mixture of stained sperm cells having either characteristic A or characteristic B into at least one population, the method comprising the steps of:
>
> a. flowing a fluid stream containing stained sperm cells through a flow path at a fluid delivery rate;
>
> b. exciting fluorescence emissions from the stained sperm cells having characteristic A and the stained sperm cells having characteristic B flowing in the flow path;
>
> c. detecting the fluorescence emissions from the excited sperm cells;
>
> d. classifying the stained sperm cells as either having characteristic A or characteristic B based upon the fluorescence emissions;

e. selecting stained sperm cells in the flow path based on their classification; and

f. photo-damaging the selected sperm cells to produce an enriched population of sperm with respect to either characteristic A or characteristic B.

D. Prior Art Relied Upon

Petitioner relies upon the following prior art references:

Jan F. Keij, et al., *High-Speed Photodamage Cell Sorting: An Evaluation of the ZAPPER Prototype*, Methods in Cell Biology, vol. 42, 371–386 (1994) (Ex. 1005) (hereinafter "Keij").

L.A. Johnson and G.R. Welch, *Sex Preselection: High-Speed Flow Cytometry Sorting of X and Y Sperm for Maximum Efficiency*, Theriogenology 52: 1323–1341 (1999) (Ex. 1006) (hereinafter "Johnson").

Shapiro, US Patent 4,395,397, issued July 26, 1983 (Ex. 1007) (hereinafter "Shapiro").

E. The Asserted Grounds of Unpatentability

Petitioner challenges the patentability of claims 1, 2, and 5–8 of the '987 patent on the grounds set forth in the chart below. *See* Pet. ii.

References	Basis	Claims Challenged
Keij	§ 102(b)	1, 2, 5–8
Johnson and Keij	§ 103	1, 2, 5–8
Johnson and Shapiro	§ 103	1, 2, 5, 7, 8
Johnson, Shapiro, and Keij	§ 103	6

II. ANALYSIS

A. Claim Construction

In an *inter partes* review, claim terms in an unexpired patent are interpreted according to their broadest reasonable construction in light of the specification of the patent in which they appear. 37 C.F.R. § 100(b); Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48,766 (Aug. 14, 2012); *see In re Cuozzo Speed Tech., LLC*, 778 F.3d 1271, 1278–82 (Fed. Cir. 2015). 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 in the specification with reasonable clarity, deliberateness, and precision. *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1249 (Fed. Cir. 1998). The construction that stays true to the claim language, and most naturally aligns with the inventor's description, is likely the correct interpretation. *Id.* at 1250.

For the purposes of this decision, only one claim term requires express construction—the term "enriched" in claim 1. Ex. 1001, 213:6–7. We begin with the claim language itself: Claim 1 specifies "photo-damaging the selected sperm cells to produce an enriched population of sperm with respect to either characteristic A or characteristic B." *Id.*

The claim language unequivocally requires that "selected sperm cells" are subjected to "photo-damaging." Ex. 1001, 213:6. The specification explains that photo-damaging, or "laser ablation," is accomplished by "a laser" that "is used to ablate (kill or otherwise damage) selected particles" so as to "render them ineffective." *Id*. at 80:6–7; 126: 58–59; 127:11–17.

Against that backdrop, we must resolve what is "an enriched" sperm population in claim 1. *Id*. at 213:6–7. The specification describes a photo-damaging step in which all of the cells are collected in the same collection container. *Id*. at 127:6–11; *see* Pet. 17 (concurring in that assessment); Prelim. Resp. 11 (concurring in that assessment). The collection container receives the undesired cells, which have been laser ablated, along with the desired cells. In other words, the number of undesired cells in the collection container has not changed relative to the starting number, nor does the ratio of desired to undesired cells change: It is the status of the undesired cells—as viable or not—that changes as a result of laser ablation.

On this record, we conclude that claim 1 is directed to killing, or otherwise rendering ineffective, selected sperm cells to obtain a population that is "enriched" with "viable" sperm cells having a desired characteristic, that is, "characteristic A or characteristic B." *Id*. at 1:25–32; 213:7–8; *see id*. at 1:51; 4:32, 42; 47:11–13; 53:58–54:2; 60:55; 72:2–15; 73:61–74:63; 75:6–11 (some of the numerous disclosures indicating the importance of viability of desired cells); *see also id*. at 59:31–45 (comparing pulse intensities of "non-viable cells" to "live" cells in the population).

The broadest reasonable interpretation of "an enriched population of sperm" in claim 1 is a population in which the ratio of viable sperm cells, having the A or B characteristic, to total viable sperm cells, has been increased as a result of photo-damaging selected cells. *Id*. at 213:6–8.

B. The Applied Prior Art

We next turn to the prior art references raised in the Petition, and in particular, to our analysis of what those references convey about the state of the art at the time of the invention of the '987 patent.

i. Keij

Keij discloses a high-speed cell sorter (identified as "the ZAPPER") as an alternative to a droplet sorter for ablating murine and human progenitor cells, and other rare cells, such as stem cells from bone marrow grafts. Ex. 1005, 2, 3. The ZAPPER is described as a photo-damage sorter obtained by modifying a conventional flow sorter. *Id*. at 3. Acknowledging the work of Shapiro, among others, Keij states that "[p]hotodamage cell sorters were first suggested as a high-speed alternative to droplet sorters more than a decade ago." *Id*. at 2.

Keij does not describe an example, or otherwise disclose an experimental technique, for applying the ZAPPER to the sorting of sperm cells. *See id*. The sum total of Keij's disclosure, relating to the sorting of sperm cells, is this: "Sorting of X or Y chromosome bearing sperm cells for insemination (Johnson *et al*., 1989) is an interesting possibility." *Id*. at 3.

ii. Johnson

Johnson discloses a flow cytometry droplet sorter that distinguishes and collects sperm cells, based on their X or Y content. Ex. 1006, 1. Petitioner shows sufficiently that Johnson discloses each limitation of claim 1, but for the limitation that requires photo-damaging selected sperm cells to produce an enriched population of sperm with respect to either characteristic A or B. Pet. 32–34 (and citations therein).

Petitioner acknowledges that Johnson does not disclose a photo-damage sorter to attain an enriched population of sperm: "Instead, Johnson discloses the use of charged plates to deflect charged droplets into separate containers." *Id*. at 34–35 (citing Ex. 1006, 1329; Ex. 1003 ¶ 137).

iii. Shapiro

Shapiro discloses a method and apparatus for selectively destroying, within a population of living cells, a subpopulation of unwanted cells. Ex. 1007, 1:5–7. Shapiro contains a detailed description of the removal of unwanted cells, "not by sorting, but rather by killing them by means of laser light." *Id*. at 1:29–30. In Shapiro's experimental example, cancerous cells are distinguished in a fluid stream from non-cancerous cells by a fluorescence label, and laser light is used to kill the cancerous cells so labeled. *Id*. at 2:12–3:11. Because unwanted cells are destroyed, instead of separated out of the population, Shapiro's method "provides superior speed as well as reliability, and is particularly advantageous for the removal of cancer cells from a cell population." *Id*. at 1:30–33.

Shapiro does not mention sperm cells. *See generally* Ex. 1007.

C. Analysis of Grounds of Unpatentability

We next turn to Petitioner's asserted grounds of unpatentability. The first ground is based on anticipation by Keij. The remaining grounds are based on obviousness over Johnson in combination with one or more of Keij and Shapiro.

i. Anticipation by Keij

Keij describes a photo-damage sorter ("the ZAPPER"), useful for laser ablation of photosensitized cells, as an alternative to a droplet sorter for murine and human progenitor cells, and other rare cells, such as stem cells from bone marrow grafts. Ex. 1005, 2, 3. Keij explains that, unlike droplet sorters, photo-damage sorters are not limited in sort rate by droplet frequency. *Id*. at 2. In fact, "the modulation of the lethal laser beam can be achieved in 100 nsec." *Id*. Keij describes applying the ZAPPER to "the

purging of leukemic cells from bone marrow grafts, the isolation of hybrid cells obtained through fusion procedures, and the isolation of hybridoma class switches and mutant cells." *Id*. at 3.

Keij does not describe an application of the ZAPPER to the sorting of sperm cells. *Id*. On that point, Petitioner directs us to the sole disclosure in Keij that expressly refers to sperm cells: "Sorting of X or Y chromosome bearing sperm cells for insemination (Johnson *et al*., 1989) is an interesting possibility." *Id*.; *see* Pet. 23–24.

"It is axiomatic that anticipation of a claim under § 102 can be found if the prior art reference discloses every element of the claim." *In re King*, 801 F.2d 1324, 1326 (Fed. Cir. 1986). Petitioner does not show sufficiently that Keij discloses, with anticipatory specificity, the method of claim 1, which requires, among other things, "photo-damaging [] selected sperm cells to produce an enriched population of sperm with respect to either characteristic A or characteristic B." Ex. 1001, 213:6–8.

Keij contains no example of a method of sperm sorting, much less a method that produces an "enriched population of sperm," in which the ratio of viable sperm cells, having the characteristic A or B, to total viable sperm cells, has been increased as a result of photo-damaging selected cells. *Id*.; *see* Pet. 23 (citing Ex. 1005, 3 for proposition that Keij discloses a method that "could be used for" sperm cell sorting). On this record, Petitioner does not show a reasonable likelihood of prevailing at trial on the ground that Keij anticipates claim 1.

Because each of the other challenged claims depends from claim 1, Petitioner also fails to carry its burden of showing a reasonable likelihood that any claim of the '987 patent is anticipated by Keij.

ii. Obviousness over Johnson and Keij or Shapiro

We next turn to the grounds of unpatentability that are based on obviousness over Johnson and Keij or Shapiro. Pet. 31–49. Even if we accept that a person of ordinary skill in the art would have been led to modify Johnson's droplet sorter to incorporate the photo-damage elements of Keij or Shapiro, Petitioner fails to show a likelihood of prevailing at trial on this record. *See* Pet. 31–37, 42–46. That is because the information presented in the Petition does not establish adequately that one would have reasonably expected success in applying the modified apparatus to obtain the "enriched population of sperm" required by each challenged claim. Ex. 1001, 213:7.

The claims are directed to "[a] method of sorting a mixture of stained sperm cells having either characteristic A or characteristic B into at least one population," comprising a step of "photo-damaging [] selected sperm cells to produce an enriched population of sperm with respect to either characteristic A or characteristic B." Ex. 1001, 212:58–213:8 (claim 1, from which each of the other challenged claims depends).

Petitioner argues that Keij "specifically suggests that the methods disclosed" in Keij "could be used for '[s]orting of X or Y chromosome bearing sperm cells.'" Pet. 35 (quoting Ex. 1005) (citing Ex. 1003 ¶ 138 (Lopez Declaration)). That is not what the reference discloses: Keij states that "[s]orting of X or Y chromosome bearing sperm cells for insemination (Johnson *et al.*, 1989) is an interesting possibility." Ex. 1005, 3.

That statement in Keij in insufficient to show that an ordinary artisan would have reasonably expected that photo-damage sorting would produce the specified "enriched population of sperm"—that is, an enriched

population of viable sperm having either the A or B characteristic. Ex. 1001, 213:7; *see infra* (discussing broadest reasonable interpretation of "enriched," and why that term includes a requirement of cell viability).

"[I]t has always been known that the sperm themselves are extremely delicate cells." Ex. 2008, 2:45–47. Petitioner sets forth no persuasive argument or information, based on the prior art, showing that an ordinary artisan would have had a reasonable expectation of success in applying a photo-damage sorting method to sperm cells, or that an enriched population of viable sperm, having either the A or B characteristic, would have been the expected result of doing so. Pet. 11–12, 31–37, 42–46. We decline to institute review absent information showing that one reasonably would have expected sperm to survive, as viable, the relatively high sort speeds disclosed in Keij or Shapiro.

The information presented, in fact, suggests that increasing sort speed decreases sperm viability. Prelim. Resp. 21–22 (and citations to Johnson therein); *see* Ex. 2008, 5:1–4 (acknowledging "goals of minimizing the stress or potential damage upon the sperm cells" to attain "both high speed and low stress sorting"). The droplet sorter disclosed in Johnson operates at "collection rates of flow" of up to about 5,000 sperm cells per second. Ex. 1006, 11 (disclosing "18 x 10^6" as the "[n]umber of sperm sorted per [hour]"); *see* Prelim. Resp. 21 (explaining that "18 x 10^6" equates to 5,000 cells per second). Keij, by contrast, discloses a photo-damage sorter that functions at "[a] rate of 25,000 cells/sec." Ex. 1005, 6–7, *see id*. at 12 (cell samples "were sorted at a rate of 25,000 cells/sec."). Shapiro discloses a method in which acute lymphoblastic leukemia cells pass by the lethal laser

beam at a rate of "approximately 60,000 cells per second." Ex. 1007, 3:10–11; *see id*. at 3:2–5.

Keij states that "cell survival is of critical importance in sorting," therefore, "several cell types were tested for their ability to survive increased sheath velocities." Ex. 1005, 8. Based on that data, Keij concludes "that cell death was caused by the shear forces endured during the acceleration in the nozzle tip" of the sorting apparatus. *Id*. Keij further discloses that "[t]he high-speed capabilities of the ZAPPER can be fully exploited for *small and sturdy cells* which survive passage through the nozzle at increased velocities." *Id*. at 12 (emphasis added). Petitioner does not argue, or identify information sufficient to show, that one reasonably would have expected "extremely delicate cells," such as sperm cells, to survive the stresses that attend photo-damage sorting. Ex. 2008, 2:45–47; *see* Pet. 11–12, 31–37, 42–46.

Petitioner at best shows that the combined teachings of Johnson, Keij, and Shapiro suggest that photo-damage sorting, at the time of the invention, was emerging as "an interesting possibility" for increasing sperm cell sort rates as compared to conventional droplet sorting. Ex. 1005, 3; *see* Pet. 11–12, 35–36, 42–46. Petitioner, however, directs us to no argument or information supporting an inference that an ordinary artisan reasonably would have expected, at the time of the invention, that any sperm cells would survive photo-damage sorting to retain their viability. *Id*. at 11–12, 31–37, 42–46. Keij's disclosure, that applying photo-damage sorting to sperm cells "is an interesting possibility," is too slender a reed to support such an inference. Ex. 1005, 3.

We decline to institute review on this record.

III. CONCLUSION

Based on the information presented in the Petition and Preliminary Response, Petitioner has not demonstrated a reasonable likelihood of prevailing on its assertion that any challenged claim of the '987 patent is unpatentable. Accordingly, we decline to institute an *inter partes* review based on any ground of unpatentability stated in the Petition.

IV. ORDER

It is

ORDERED that the Petition is denied and no *inter partes* review is instituted.

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