

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

GENUS PLC,
Petitioner,

v.

INGURAN, LLC,
Patent Owner.

IPR2021-01027
Patent 10,542,734 B2

Before ULRIKE W. JENKS, SUSAN L. MITCHELL, and
ROBERT A. POLLOCK, Administrative Patent Judges.

JENKS, *Administrative Patent Judge*.

DECISION

Granting Institution of *Inter Partes* Review
35 U.S.C. § 314, 37 C.F.R. § 42.4

I. INTRODUCTION

Genus plc (“Petitioner”) filed a Petition to institute an *inter partes* review of claims 1–5 (“the challenged claims”) of U.S. Patent No. 10,542,734 B2 (Ex. 1001, “the ’734 patent”), pursuant to 35 U.S.C. §§ 311–319. Paper 3 (“Pet.”). Inguran, LLC (“Patent Owner”) filed a Patent Owner Preliminary Response to the Petition. Paper 7 (“Prelim. Resp.”).

We have authority, acting on the designation of the Director, to determine whether to institute an *inter partes* review under 35 U.S.C. § 314 and 37 C.F.R. § 42.4(a)(2020). *Inter partes* review may not be instituted unless “the information presented in the petition filed under section 311 and any response filed under section 313 shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.” 35 U.S.C. § 314(a). The Supreme Court held that a decision to institute under 35 U.S.C. § 314 may not institute on fewer than all claims challenged in the petition. *SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1359–60 (2018).

For the reasons set forth below, upon considering the Petition, Preliminary Response, and supporting evidence of record, we determine that Petitioner has sufficiently shown for the purpose of institution that the information presented in the Petition establishes a reasonable likelihood that Petitioner will prevail with respect to at least one of the challenged claims. Accordingly, we institute *inter partes* review on all of the challenged claims based on all of the grounds identified in the Petition.

Our findings of fact, conclusions of law, and reasoning discussed below are based on the evidentiary record developed thus far, and made for the sole purpose of determining whether the Petition meets the threshold for

initiating review. This decision to institute trial is not a final decision as to the patentability of any challenged claim or the construction of any claim limitation. Any final decision will be based on the full record developed during trial.

A. Real Parties-in-Interest

Petitioner identifies itself and ABS Global, Inc., as real parties-in-interest to this proceeding. Pet. 3. Patent Owner identifies itself as real party-in-interest. Paper 5, 1.

B. Related Proceedings

The parties state that they are not aware of any other judicial or administrative matter that would affect, or be affected by, a decision in this proceeding. Pet. 3; Paper 5, 1. The parties indicate that pending U.S. Application No. 16/708,007 claims priority to the '734 patent. *Id.*

C. The '734 Patent (Ex. 1001)

The '734 patent issued on Jan. 28, 2020 from Application No. 16/248,569 ("the '569 application"), filed Jan. 15, 2019, which is a continuation of U.S. Application No. 15/655,663, filed on July 20, 2017, now U.S. Patent No. 10,188,082, which is a continuation of U.S. Application No. 14/406,186, filed as Application No. PCT/US2013/044521 on June 6, 2013, now U.S. Patent No. 9,743,645, which is a continuation of U.S. Application No. 13/840,598, filed on Mar. 15, 2013, now U.S. Patent No. 9,433,195, which claims priority from U.S. Provisional Application No. 61/656,446, filed on June 6, 2012. Ex. 1001, codes (21), (22), (45), (60), (63). The '734 patent is titled "Methods for Increasing Genetic Progress in a

Line or Breed of Swine Using Sex-selected Sperm Cells.” *Id.* at code (54). The ’734 patent discloses “methods of increasing the genetic progress of a line, breed or herd of swine through the use of sex-selected sperm cells in artificial insemination techniques.” *Id.* at 1:17–20. As background, the ’734 patent indicates that there is “a need in the swine industry to increase the rate of desirable genetic change in lines and breeds as well as to lower operational costs on breeding and commercial swine farms.” *Id.* at 1:27–30. The ’734 patent purports to achieve these goals by allowing an operator of a breeding or commercial farm to “select the sex of offspring swine using sex-selected sperm cell samples and/or by allowing the use of far fewer genetically superior boars through the use of reduced sperm cell doses for artificial insemination procedures.” *Id.* at 1:30–35.

The “line” or “breed” is “a group of animals having a common origin and similar identifying characteristics.” *Id.* at 3:3–5. The ’734 patent describes that “any desirable genotypic or phenotypic trait can be used to construct a selection index for a line or breed of swine” and that such phenotypic traits include “feed efficiency, average daily gain, carcass lean, carcass quality, fertility, litter size and milk production.” *Id.* at 3:18–23. Feed efficiency is “a measure of an animal’s efficiency in converting feed mass into increased body mass (also known as feed conversion or feed to gain ratio)” and average daily gain is “the average daily weight gain for an animal.” *Id.* at 9:5–9. The rate of desirable genetic change of a herd or line can be increased by selecting the sex of the offspring in a line. *Id.* at 7:28–35. A genetic change, or a “genetic progress” means that for a given desired trait or a given undesirable trait, “the individuals in the successive generation will express the desired trait more strongly than the previous

generation” or “the individuals in the successive generation will express the [undesirable] trait less strongly than the previous generation.” *Id.* at 7:30–36.

The ’734 patent discloses that swine production “can be represented by a multilevel pyramid, with certain offspring at each level used in the next lower level for breeding.” *Id.* at 9:41–43. The top level of the pyramid is the “nucleus herd” and the next levels from top to bottom are the “daughter nucleus herd,” the “multiplier herd” and finally the “commercial farm,” respectively. *Id.* at 9:43–46. In such a pyramid, the nucleus herd “is typically comprised of 12 to 15 lines, although any number of lines may be represented, with each line comprising a number of desirable traits.” *Id.* at 9:47–49. The daughter nucleus level is a “line multiplication” level in which “sows from a line are inseminated with boar semen derived from the nucleus herd.” *Id.* at 10:17–19. In the next lower level of the multiplier herd level, “the resulting sows are typically crossed with boars of a different line.” *Id.* at 10:19–21. Here, a multiplier herd “is typically either a gilt multiplier or boar multiplier.” *Id.* at 10:21–22. A gilt is a young female pig that has not yet fallowed. *Id.* at 6:20–21. Gilt multipliers are then used to “produce parent gilts” and boar multipliers are then used to “produce parent boars.” *Id.* at 10:22–23. “Parent gilts are sent to commercial farms to replace old or dead gilts and sows, and parent boars are sent to boar studs to produce the sperm cells for use in artificial insemination.” *Id.* at 10:23–26.

According to the ’734 patent, its method of increasing the profitability of a swine herd or farm includes “collecting a semen sample from a boar” and “sorting said semen sample into at least two subpopulations of sperm cells, wherein at least 80% of a first subpopulation bears (i) X-chromosomes if the female pig results in a higher net income per pig, or

(ii) Y-chromosomes if the male pig results in a higher net income per pig.”

Id. at 6:6–17. A sow is then inseminated with sperm cells from the first subpopulation to produce offspring. *Id.* at 6:17–19. Further, an embryo or a zygote is selected “based on the presence or absence of a genetic marker” and the “genetic marker can be a marker for, or associated with, for example, any of the swine traits disclosed herein.” *Id.* at 2:30–38.

D. Illustrative Claim

Claim 1 of the ’734 patent is illustrative and reproduced below:

1. [preamble] A method of increasing the genetic progress of a line or breed of swine within a genetic nucleus comprising the steps of:
 - [a] providing a boar from a genetic nucleus and a sow from a genetic nucleus, wherein said boar and said sow are from a line or breed within said genetic nucleus and wherein said line or breed of said boar and said sow are the same line or breed;
 - [b] collecting a semen sample from said boar;
 - [c] sorting said semen sample into at least two subpopulations of sperm cells, wherein at least 80% of a first subpopulation bears X-chromosomes or Y-chromosomes;
 - [d] inseminating said sow with sperm cells from said first subpopulation to produce offspring from said sow;
 - [e] genotyping said offspring to identify one or more genetic markers;
 - [f] selecting one or more of said offspring as a parent in the line or breed in the genetic nucleus based on the one or more identified genetic markers.

Ex. 1001, 25:8–26:8 (lettering and bracketing added for reference convenience).

E. Prior art

Petitioner relies upon the following prior art references (Pet. 26–59):

References	Patent / Reference	Date	Exhibits
Dekkers, J.C.M. et al. (“Dekkers”)	<i>16 Genetic Improvement of the Pig</i> , THE GENETICS OF THE PIG, 2 ND ED., Rothchild, M.F., Ruvinsky, A. (eds.), CAB Int’l, Cambridge, MA.	2011	Ex. 1004
Maxwell, W.M.C. et al. (“Maxwell”)	<i>Integration of sperm sexing technology into the ART toolbox</i> , ANIMAL REPRODUCTION SCIENCE 82–83: 79–95	2004	Ex. 1005
Garner, D.L. (“Garner”)	<i>Flow cytometric sexing of mammalian sperm</i> , THERIOGENOLOGY 65:943–57	2006	Ex. 1006
Kim, S.K. et al. (“Kim”)	<i>A missense variant of the porcine melanocortin-4 receptor (MC4R) gene is associated with fatness, growth, and feed intake traits</i> , MAMMALIAN GENOME 11:131–35	2000	Ex. 1007
Okere, C. et al. (“Okere”)	<i>Novel Reproductive Techniques in Swine Production – A Review</i> , ASIAN-AUST. J. ANIM. SCI. 15:445–52	2002	Ex. 1008
Buttram	US 2008/0028478 A1	Jan. 31, 2008	Ex. 1009

Petitioner also relies upon the Declaration of Dr. Christine Baes (Ex. 1002) to support its contentions.

F. Asserted Grounds of Unpatentability

Petitioner challenges the patentability of claims 1–5 of the ’734 patent on the following grounds. Pet. 4.

Claim(s) Challenged	Basis ¹	References
1–5	§ 102(b)/103(a) ²	Dekkers, Maxwell, Garner, Kim
1–5	§ 103(a)	Dekkers, Okere
1–5	§ 103(a)	Buttram, Maxwell, Kim ³

II. ANALYSIS

A. *Person of Ordinary Skill in the Art*

Petitioner asserts that a person of ordinary skill in the art would have had at least “an undergraduate or graduate degree in genetics, genomics, and/or animal breeding, along with several years of relevant applied research and/or industry work experience in the same fields, including in swine” and “would have been well-acquainted with methods of commercial breeding of lines and breeds within a genetic nucleus for the purpose of promoting genetic progress, the use of sex-selected semen in breeding schemes, including those within the genetic nucleus, genetic evaluation of livestock for desirable and undesirable traits, and the use of genetic markers, *e.g.*, SNPs, and various other genotype data, to guide selection strategies to

¹ The relevant sections of the Leahy-Smith America Invents Act (“AIA”), Pub. L. No. 112–29, 125 Stat. 284 (Sept. 16, 2011), took effect on March 16, 2013. Because the priority application from which the ’734 patent issued was filed before that date, our citations to Title 35 are to its pre-AIA version.

² Petitioner contends that claims 1–5 are anticipated by Dekkers, as evidenced by either Maxwell, Garner, or Kim. Pet. 26–41. Alternatively, Petitioner contends that claims 1–5 are obvious over Dekkers and either Maxwell, Garner, or Kim. Pet. 41–45.

³ In the table identifying ground III, Petitioner does not list Kim. Pet. 4. However, in the arguments provided for this ground in regard to claim 5, Petitioner includes Kim. Pet. 48.

improve desirable traits and/or minimize undesirable traits.” Pet. 13 (citing Ex. 1002 ¶ 22). Patent Owner states, “[s]olely for purposes of this Preliminary Response, Patent Owner and its expert apply this portion of Petitioner’s proposal, while reserving the right to dispute it later.” Prelim. Resp. 17.

On this record, we adopt Petitioner’s definition of the level of ordinary skill in the art as Patent Owner also does. We also note that the prior art itself demonstrates the level of skill in the art at the time of the invention. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) (explaining that specific findings regarding ordinary skill level are not required “where the prior art itself reflects an appropriate level and a need for testimony is not shown”) (quoting *Litton Indus. Prods., Inc. v. Solid State Sys. Corp.*, 755 F.2d 158, 163 (Fed. Cir. 1985)).

B. Principles of Law

To prevail in its challenge to Patent Owner’s claims at trial, Petitioner must demonstrate by a preponderance of the evidence⁴ that the claims are unpatentable. 35 U.S.C. § 316(e); 37 C.F.R. § 42.1(d). To establish anticipation under 35 U.S.C. § 102, each and every element in a claim, arranged as recited in the claim, must be found in a single prior art reference. *See Net MoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359, 1369 (Fed. Cir. 2008); *Karsten Mfg. Corp. v. Cleveland Golf Co.*, 242 F.3d 1376, 1383 (Fed.

⁴ The burden of showing something by a preponderance of the evidence requires the trier of fact to believe that the existence of a fact is more probable than its nonexistence before the trier of fact may find in favor of the party who carries the burden. *Concrete Pipe & Prods. of Cal., Inc. v. Constr. Laborers Pension Tr. for S. Cal.*, 508 U.S. 602, 622 (1993).

Cir. 2001). Although the elements must be arranged or combined in the same way as in the claim, “the reference need not satisfy an *ipsissimis verbis* test,” i.e., identity of terminology is not required. *In re Gleave*, 560 F.3d 1331, 1334 (Fed. Cir. 2009) (accord *In re Bond*, 910 F.2d 831, 832–33 (Fed. Cir. 1990)).

A claim is unpatentable under 35 U.S.C. § 103(a) if the differences between the claimed subject matter and the prior art are such that the subject matter, as a whole, would have been obvious at the time of the invention to a person having ordinary skill in the art. *KSR Int’l Co. v. Teleflex, Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of underlying factual determinations, including “the scope and content of the prior art”; “differences between the prior art and the claims at issue”; and “the level of ordinary skill in the pertinent art.” *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

A patent claim “is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art.” *KSR*, 550 U.S. at 418. An obviousness determination requires finding “both ‘that a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success in doing so.’” *Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1367–68 (Fed. Cir. 2016) (citation omitted); *see KSR*, 550 U.S. at 418 (for an obviousness analysis, “it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does”). Further, an assertion of obviousness “cannot be sustained by mere conclusory statements; instead,

there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” *KSR*, 550 U.S. at 418 (quoting *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006)); *In re NuVasive, Inc.*, 842 F.3d 1376, 1383 (Fed. Cir. 2016) (a finding of a motivation to combine “must be supported by a ‘reasoned explanation’” (citation omitted)).

C. Claim Construction

In an *inter partes* review for a petition filed on or after November 13, 2018, “claim[s] of a patent . . . shall be construed using the same claim construction standard that would be used to construe the claim[s] in a civil action under 35 U.S.C. [§] 282(b), including construing the claim[s] in accordance with the ordinary and customary meaning of such claim[s] as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent.” 37 C.F.R. § 42.100(b); *see* Changes to the Claim Construction Standard for Interpreting Claims in Trial Proceedings Before the Patent Trial and Appeal Board, 83 Fed. Reg. 51,340 (Oct. 11, 2018) (codified at 37 C.F.R. § 42.100(b) (2019)) (amending 37 C.F.R. § 42.100(b) effective November 13, 2018). A term’s ordinary and customary meaning “is its meaning to the ordinary artisan after reading the entire patent.” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1321 (Fed. Cir. 2005) (en banc). Nevertheless, “it is always necessary to review the specification to determine whether the inventor has used any terms in a manner inconsistent with their ordinary meaning,” because “[t]he specification acts as a dictionary when it expressly defines terms used in the claims or when it defines terms by implication.” *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996).

Petitioner requests construction of the terms “genetic progress,” “line or breed,” “genetic nucleus,” “feed efficiency,” “average daily gain,” and “carcass lean.” Pet. 9–12. Patent Owner does not presently dispute Petitioner’s proposed construction of “genetic progress,” “line or breed,” “feed efficiency,” “average daily gain,” or “carcass lean.” Prelim Resp. 19–20. Patent Owner, however, argues that to the extent a construction of “genetic nucleus is necessary, the term should be given its plain and ordinary meaning.” *Id.* at 20. For purposes of this decision on institution, we provide a construction of the term “genetic nucleus.”

1. genetic nucleus

According to Petitioner, “[t]he ’734 patent discloses that ‘[s]wine production can be represented by a multilevel pyramid, with certain offspring at each level used in the next lower level for breeding,’ that the ‘top level of the pyramid is the nucleus herd,’ and that ‘any number of lines may be represented’ in a nucleus herd.” Pet. 10 (citing Ex. 1001, 9:41–49) (second alteration in original). Petitioner contends that this provides an incomplete description of genetic nucleus because “commercial breeders must also use offspring of the genetic nucleus for breeding within the genetic nucleus itself.” *Id.* (citing Ex. 1004, 410 (“Most genetic improvement in pigs is based on selection within pure breeds or lines.”), 417 (Fig. 16.4); Ex. 1002 ¶ 32).

Patent Owner, however, argues that one of ordinary skill in the art would not find the additional language in Petitioner’s proposed definition accurate in describing a genetic nucleus. Prelim Resp. 21 (citing Ex. 2001 ¶ 21). Patent Owner contends “that the plain and ordinary meaning of ‘genetic nucleus’ is ‘an animal herd comprising one or more lines and

positioned at the top of a multi-level pyramidal hierarchy of herds in a commercial herd breeding structure.” *Id.* (citing Ex. 2001 ¶ 24 (“The ’734 Patent does not specify this additional requirement as part of the meaning of ‘genetic nucleus,’ nor would the additional language be accurate in describing every genetic nucleus.”)).

On the present record, Petitioner has the better argument. The ’734 specification describes pig breeding as pyramid with the “nucleus herd” at the top of the pyramid and commercial farms at the bottom. Ex. 1001, 9:43–44. “A nucleus herd is typically comprised of 12 to 15 lines, although any number of lines may be represented, with each line comprising a number of desirable traits. . . . Only the offspring with the highest measured selection index are retained in the nucleus herd.” *Id.* at 9:47–49. The retention of offspring with the most desirable features in the nucleus herd reasonably implies that these individuals are selected to propagate the desirable trait in the nucleus heard. Accordingly, at this stage of the proceeding, we construe “genetic nucleus” as “an animal herd comprising one or more lines and positioned at the top of a multi-level pyramidal hierarchy of herds in a commercial herd breeding structure, wherein certain offspring of the herd are used for breeding within the herd.”

The parties are invited to brief this issue further at trial, if deemed necessary.

2. Remaining Claim Terms

At this stage of the proceeding, it is unnecessary to expressly construe any remaining claim terms for purposes of this Decision. *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)).

D. Ground 1A: Anticipation of Claims 1–5 by Dekkers, as evidenced by either Maxwell, Garner, or Kim

Petitioner contends that claims 1–5 are unpatentable as anticipated by Dekkers, as evidenced by either Maxwell, Garner, or Kim. Pet. 26–41. Patent Owner opposes. Prelim. Resp. 24–34.

1. Overview of Dekkers (Ex. 1004)

Dekkers teaches “[g]enetic improvement in pigs.” Ex. 1004, 390. According to Dekkers, the general principles of genetic improvement includes an objective of a breeding program that produces “most improvement per unit of time.” *Id.* at 391. A “goal is then to maximize genetic change over generations or over time.” *Id.* at 392. Dekkers indicates that in most countries, pig breeding programs “operate in a three-tier pyramidal structure.” *Id.* at 393. Dekkers discloses that at the peak of the pyramid are the “nucleus breeding farms that actually generate the genetic changes.” *Id.* (emphasis omitted). Below that tier are “multiplier farms that carry out specific matings or crossbreeding for the production of large numbers of females.” *Id.* (emphasis omitted). These females are then sold, under the lower tier, to “commercial producers for piglet production and finishing to produce market pigs” for slaughterhouses. *Id.* (emphasis omitted). Variations of the tiers of the pyramid are possible. *Id.*

Dekkers further discloses that one of the most used reproduction technologies “is AI,” or artificial insemination. *Id.* at 395–96. Another includes sperm sexing technology that allows “the production of either male

or female offspring for sire or dam lines,” which can be very useful for the nucleus and multiplication tiers. *Id.* at 396. “The technique involves the separation of spermatozoa carrying either X or Y chromosomes (Maxwell *et al.*, 2004; Garner, 2006)” in which the “sorted sperm can then be used for AI or embryo transfer.” *Id.* Further, molecular genetics have discovered new classes of DNA polymorphisms that allow for direct selection of “an individual’s genotype for genes or genetic markers that are associated” with a trait. *Id.* at 407. Certain types of genetic markers are applied “*for within-breed genetic improvement.*” *Id.* Dekkers discloses that genetic selection (GS) is an enhanced version of marker assisted selection (MAS) “that involves the selection of animals for breeding on the basis of their genotype for tens of thousands of ‘random’ SNPs [(single nuclear polymorphisms)] that cover the genome.” *Id.* at 414.

Figure 16.4 of Dekkers is reproduced below.

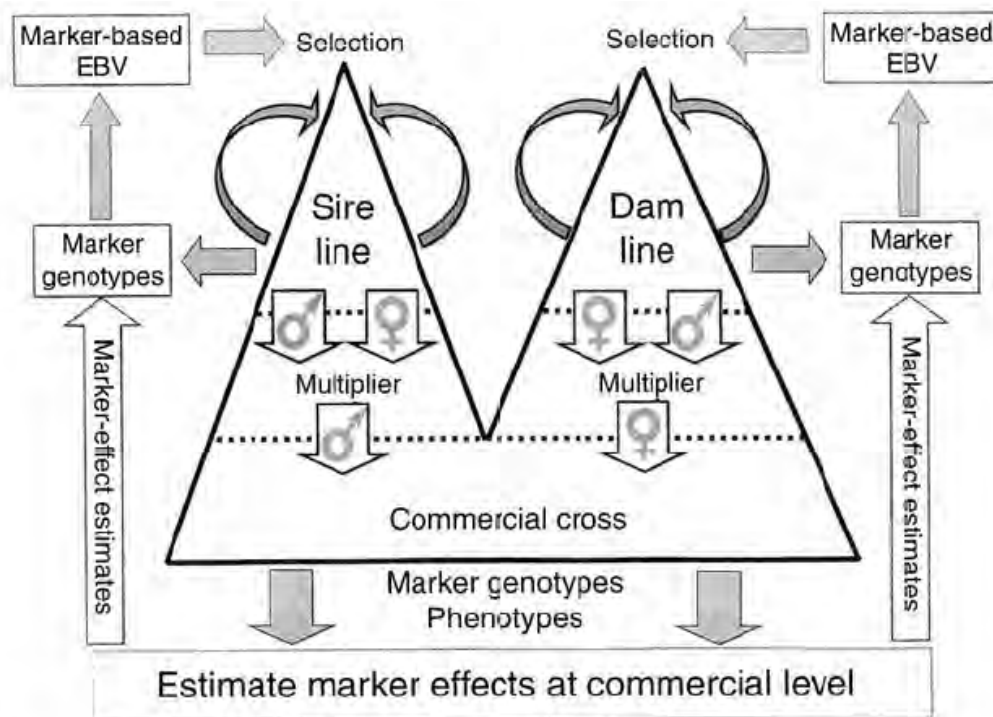


Figure 16.4 shows selection of “pure lines for commercial crossbred performance based on estimates of marker effects estimated on crossbreds.” *Id.* at 417. A sire line and a dam line, each at the top of a pyramid, are used to produce a female and a male offspring for the multiplier tier, which are then used for “Commercial cross,” and assessed for “Marker genotypes” and “Phenotypes” below in the pyramids. Estimated breeding value (EBV) is determined based on marker genotypes and an offspring is selected to be a parent as shown from the arrows surrounding the pyramids. *Id.* Dekkers states that the “nucleus breeding farms typically maintain specific breeds or breeding lines” and breeding companies “further line breeding within the crossbreds for several generations to combine and stabilize the desirable characteristics.” *Id.* at 394. As an example of genetic markers and genes used in swine, Dekkers discloses that the *MC4R* gene targets the melanocortin-4 receptor which affects the traits of lean growth, fatness, and feed intake. *Id.* at 413, Table 16.6. Thus, genetic improvement within sire or dam lines can be “targeted towards improvement in specific characteristics that are important to the producers and consumers.” *Id.* at 394.

2. Overview of Maxwell (Ex. 1005)

Maxwell teaches sex-sorting of mammalian spermatozoa “for genetic improvement of farm animals.” Ex. 1005, 79. Maxwell discloses that sex pre-selection before insemination to produce a specific sex in livestock offspring results in “faster genetic progress” for “the production of male and female crossbred lines in the pig industry.” *Id.* at 80. In sperm sexing, the “greater the difference in DNA content between X- and Y-chromosome bearing (X and Y) spermatozoa, the more efficiently the two populations can be resolved and separated by flow cytometric sorting.” *Id.* at 80–81.

According to Maxwell, generally, “X and Y purities of more than 85% can be achieved in most species, depending on the rate of sorting.” *Id.* at 81.

3. *Overview of Garner (Ex. 1006)*

Garner teaches parameters that are “needed for optimization of flow cytometric sexing mammalian sperm” and updates for “the current status of sperm sexing for various species.” Ex. 1006, 943. Garner discloses that the precise measurement of “the DNA content difference between X- and Y-chromosome bearing sperm of mammals has provided an effective means of separating viable gametes carrying either the X- or Y- chromosome with an accuracy of 85–95%.” *Id.* at 944. According to Garner, “swine was the first large animal species where the feasibility of using” the technology of predetermination of sex using flow cytometry/cell sorting, was demonstrated. *Id.* at 952. Consequently, the “adoption of sperm sexing for production of founder animals with superior genetic qualities” can be used to increase the availability of animals with superior genetic traits for swine producers. *Id.*

4. *Overview of Kim (Ex. 1007)*

Kim teaches a missense variant of the porcine melanocortin-4 receptor (*MC4R*) gene that is associated with fatness, growth, and feed intake traits. Ex. 1007, 131. Identification of this missense mutation in the pig *MC4R* gene was confirmed by sequence of the PCR product. *Id.* at 133.

5. *Analysis*

Petitioner asserts that Dekkers discloses every element of the claimed invention either expressly or inherently. Pet. 26–41. Petitioner relies on the teachings of Maxwell, Garner, or Kim, each of which is cited in Dekkers, as evidencing certain knowledge attributable to one of ordinary skill in the art

at the time the invention was made. *See* Pet. 34 (“Dekkers expressly cites Maxwell and Garner as the two examples of technologies to use for sperm sexing”), 40 (“the missense variant of porcine *MC4R* described in Kim is a single SNP that correlates with carcass lean, feed efficiency and average daily gain.”). Petitioner provides an element-by-element comparison of the asserted art to the challenged claims. *Id.* at 29–41. Patent Owner opposes. Prelim. Resp. 24–39. We focus below on the elements of claim 1.

a. Claim 1 (preamble) “A method of increasing the genetic progress of a line or breed of swine within a genetic nucleus”

Petitioner asserts that Dekkers “discloses methods of increasing genetic progress in swine. . . . Dekkers explains that in pig breeding programs, selection response depends on, *inter alia*, selection accuracy, selection intensity or standardized selection differential, and generational interval.” Pet. 27–28 (citing Ex. 1004, 391; Ex. 1002 ¶¶ 30, 55, 56, 100, 101, 102, 103). Petitioner further asserts that “Dekkers also teaches that the disclosed methods of genetic improvement are carried out in a line or breed at the level of the genetic nucleus (aka, nucleus breeding farms).” Pet. 29 (citing Ex. 1004, 391–392, 394).

Patent Owner contends that the method steps of claim 1 “are not disclosed within the four corners of Dekkers, nor are they arranged in Dekkers as they are claimed.” Prelim. Resp. 24.

On the record at the stage of the proceeding, Petitioner has made an adequate showing that Dekkers meets the preamble limitation.⁵ In particular,

⁵ We do not reach the question whether the preamble is limiting. *Cf. Allen Eng’g Corp. v. Bartell Indus., Inc.*, 299 F.3d 1336, 1346 (Fed. Cir. 2002) (“Generally, the preamble does not limit the claims.”). Petitioner at this

Dekkers discloses that the “objective of a breeding programme is to produce the ‘most improvement per unit of time.’” Ex. 1004, 391. Dekkers discloses that “[t]he nucleus farms [in a pyramid scheme] actually conduct breeding and selection for the genetic improvement of specific breeds or lines.” Ex. 1004, 393–394; Ex. 1002 ¶ 101. Dekkers describes that “[g]enetic improvement within sire or dam lines is then targeted towards improvement in specific characteristics that are important to the producers and consumers.” Ex. 1004, 394; Ex. 1002 ¶ 101. Dekkers explains that “[t]he nucleus breeding farms typically maintain specific breeds or breeding lines. . . . Furthermore, within a breed, specific lines are developed to advance certain traits of interest, while keeping up the main breed characteristics.” Ex. 1004, 394. “It is important to note that the breeding objective is actually implemented at the nucleus level, but it is targeted to the production level and to future markets.” *Id.* at 397. According to Dekker:

The sire lines are mainly selected for genetic improvement in production traits such as growth rate, carcass quality, meat quality, feed conversion and conformation. The breeding goal for dam lines typically includes the same production traits, but in addition female reproductive traits, such as litter size, piglet survival, age at puberty, conception rate, number weaned and weaning to oestrus interval.

Id. “The choice of breeding goals and successful breeding have led to the genetic improvement of economically important traits such as daily gain, backfat thickness, feed efficiency and litter size.” *Id.* at 398. Dekkers explains that “[m]ost genetic improvement in pigs is based on selection

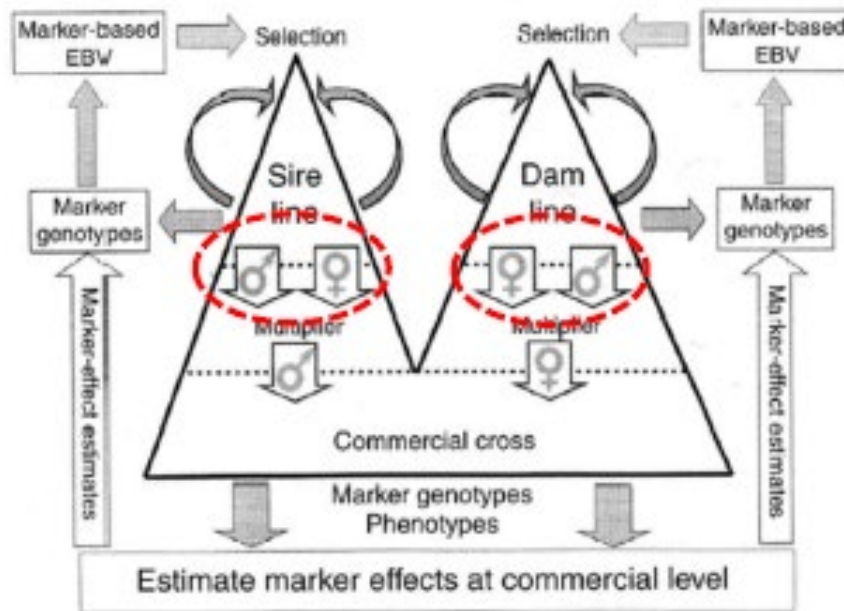
stage of the proceeding shows sufficiently for purposes of institution that the recitation in the preamble is satisfied by the prior art.

within pure breeds or lines. Within breed selection can be improved with availability of genotype on markers that are associated with the trait(s) of interest.” *Id.* at 410. According to Petitioner’s expert, Dr. Baes, genetic progress is synonymous with genetic improvement. Ex. 1002 ¶ 102.

Applying the claim construction of “genetic nucleus” as set forth above, Petitioner shows that on this record at this stage of the proceeding that Dekkers meets the preamble limitation of increasing genetic progress in a breeding program targeting specific breeds or lines in a nucleus farm.

b. (element 1a) “providing a boar from a genetic nucleus and a sow from a genetic nucleus”

Petitioner asserts that Dekkers discloses the element of providing a boar for the purpose of breeding the animals. Pet. 29. Specifically, Petitioner directs our attention to Dekkers teaching of using nucleus farms to conduct breeding and selection for the genetic improvement of the specific breed of pig. *Id.* (citing Ex. 1004, 393–394). Petitioner asserts that Dekkers teaches that these nucleus breeding farms maintain specific breeding lines and notes that genetic improvements in the pigs is usually based on selection within pure breeds or lines. *Id.* at 30 (citing Ex. 1004, 393, 404). Petitioner directs our attention to Dekkers’ annotated Figure 16.4, reproduced below.



Dekkers annotated Figure 16.4 illustrates pure sire and dam lines used for the production of animal within the line as well as for the lower tiers.

Pet. 31. Petitioner asserts that

the breeding method described by Fig. 16.4 involves a sire line and a dam line within a genetic nucleus herd. The element “providing a boar from a genetic nucleus and a sow from a genetic nucleus” is described in the figure by, *e.g.*, the pair of downward arrows in the sire line which are labeled with male and female symbols (highlighted in the red ovals above), and would be understood by a [person of ordinary skill in the art] to represent a boar and a sow.

Pet. 31 (citing Ex. 1004, 417; Ex. 1002 ¶¶ 32, 59, 106–110). Petitioner’s expert, Dr. Baes, attests that a person of ordinary skill in the art at the time the invention was made “would understand Dekkers to teach the claim element ‘providing a boar from a genetic nucleus and a sow from a genetic nucleus,’ as all methods of breeding swine within a genetic nucleus herd necessarily provide a boar from the genetic nucleus and a sow from the

genetic nucleus.” Ex. 1002 ¶ 110. With reference to Figure 16.4, reproduced above, Petitioner’s expert explains that “the curved arrows shown in connection with the sire and dam lines within the genetic nucleus illustrate that boars and sows from a line or breed within a genetic nucleus are selected for breeding within the genetic nucleus.” Ex. 1002 ¶ 109.

Patent Owner does not dispute that Dekkers teaches mating between boars and sows to generate offspring. *See generally* Prelim. Resp. 24–34.

On the record at the stage of the proceeding, Petitioner has made an adequate showing that Dekkers supports claim element 1a.

c. (element 1b) “collecting a semen sample from said boar”

Petitioner contends that Dekkers teaches sex sorting the semen and artificial insemination. Pet. 32. Petitioner contends that one of ordinary skill in the art at the time the invention was made would have understood that, artificial insemination of the sow in a sire line with sperm from a boar in the same line “necessarily requires first collecting the boar sperm from said boar.” Pet. 33 (citing Ex. 1002 ¶ 111). Petitioner contends that one of ordinary skill in the art would recognize that in order to perform artificial insemination or to sort sperm requires that the semen be collected in the first place. *See* Pet. 33 (citing Ex. 1002 ¶ 111 (“Dekkers states that, among the assisted reproduction technologies, ‘[o]ne of the most used among these is AI [(artificial insemination)]’ . . . , which a POSA would understand to entail the initial collection of a boar semen sample. In fact, AI requires ‘collecting a semen sample’ since boar sperm cannot be used for artificial insemination, much less sorted by sex, without first collecting a semen sample from a boar.” (first alteration in original))).

Patent Owner does not dispute that Dekkers teaches collecting semen samples. *See generally* Prelim. Resp. 24–34.

On this record at this stage of the proceeding, Petitioner has sufficiently shown that Dekkers meets the claim limitation of element 1b.

d. (element 1c) “sorting said semen sample into at least two subpopulations of sperm cells, wherein at least 80% of a first subpopulation bears X-chromosomes or Y-chromosomes”

Petitioner asserts that Dekkers teaches sorting boar semen, which means sorting the sample into at least 2 subpopulations of sperm cells where one subpopulation contains X chromosome and the other subpopulation contains Y chromosomes. *See* Pet. 33–35 (“The ‘separation of spermatozoa,’ as described in Dekkers, by definition, produces at least two subpopulations (e.g., a subpopulation of predominantly X-chromosome bearing sperm cells and another subpopulation of predominantly Y-chromosome bearing sperm cells).”). Petitioner’s expert testifies that one of ordinary skill in the art at the time the invention was made would have understood that “[f]rom a commercial pig production perspective, using semen with less than 80% sex skew (i.e., purity for X or Y chromosomes) would not be efficient or economical, and consumers (e.g., pig producers) would not purchase such poorly enriched samples.” Ex. 1002 ¶ 113; Pet. 34.

Patent Owner disputes that Dekkers discloses sorting semen samples having “at least 80%” of a population of sperm cells that carry either X-chromosomes or Y-chromosomes. Prelim. Resp. 25. Patent Owner contends that this element is missing, therefore, Dekkers cannot anticipate the claims. *Id.* (citing *Continental Can Co. USA, Inc. v. Monsanto Co.*, 948 F.2d 1264 (Fed. Cir. 1991)). Patent Owner’s expert avers that “Dekkers does

not expressly or inherently disclose sorting semen at any specific skew ratio, 80% or otherwise.” Ex. 2001 ¶ 50.

On the record at this stage of the proceeding, Petitioner has made an adequate showing that Dekkers discloses the claim limitation of element 1c. In particular, Dekkers discloses that “[a] combination of reproduction technologies with advancements in molecular genetics is particularly expected to deliver a powerful impact in increasing the rate of genetic progress and to allow for efficient use of genetic variation and reduce genetic lag.” Ex. 1004, 397. Dekkers discloses “that the breeding objective is actually implemented at the nucleus level, but it is targeted to the production level and to future markets.” Ex. 1004, 397.

The sire lines are mainly selected for genetic improvement in production traits such as growth rate, carcass quality, meat quality, feed conversion and conformation. The breeding goal for dam lines typically includes the same production traits, but in addition female reproductive traits, such as litter size, piglet survival, age at puberty, conception rate, number weaned and weaning to oestrus interval.

Ex. 1004, 397.

Dekkers discloses that

sperm sexing technology allow[s] for the production of either male or female offspring for sire or dam lines, and this can be very useful for the nucleus and multiplication tiers. The technique involves the separation of spermatozoa carrying either X or Y chromosomes (Maxwell *et al.*, 2004; Garner, 2006). The sorted sperm can then be used for AI or embryo transfer.

Ex. 1004, 396.

The issue is what one of ordinary skill in the art at the time the invention was made would have understood about using sex sorted semen in

the context of artificial insemination for the purpose of directing piglet production toward creating predominantly male or female offspring.

Petitioner's expert explains that the state of the art at the time the invention was made required at least an 80% or better sex sorted semen in order to be able to use the sorted semen in to skew the piglet production in a littler to be either predominantly female or male offspring. *See* Ex. 1002 ¶ 113.

Specifically, Petitioner's expert avers that one of ordinary skill in the art would have understood that “[f]rom a commercial pig production perspective, using semen with less than 80% sex skew (i.e., purity for X or Y chromosomes) would not be efficient or economical, and consumers (e.g., pig producers) would not purchase such poorly enriched samples.” Ex. 1002 ¶ 113. Petitioner's expert testimony is supported by the teachings of Maxwell (Ex. 1005) and Garner (Ex. 1006), both of which are expressly cited in Dekkers as evidencing “sperm sexing technology . . . for the production of either male or female offspring for sire or dam lines.” *See* Ex. 1004, 396, 420, 422. In particular, Maxwell teaches that “[i]n combination with the orientating nozzle and changes in the design of the sorter electronics, this allowed significant increases in sorting rates (15 million spermatozoa per hour) to be achieved while maintaining more than 85% purity.” Ex. 1005, 81. In addition, Gardner teaches that “acceptable sperm sexing efficiency, usually at 90% accuracy.” Ex. 1006, Abstract.

Based on the current record, Petitioner's expert testimony reasonably supports the position that Dekkers application of sex sorting technology at the level of the nucleus or multiplication tiers would require at least an 80% sex sorting efficiency.

Patent Owner contends that Petitioner is improperly relying on Maxwell and Garner in order to support its anticipation argument over Dekkers. Prelim. Resp. 26 (citing *Callaway Golf Col. v. Acushnet Co.*, 576 F.3d 1331, 1346 (Fed. Cir. 2009)). On the record at the stage of the proceeding, Petitioner has made an adequate showing to supports its anticipation argument. In particular, Dekkers disclosure of using sex sorted semen to allow for the production of either male or female offspring for sire or dam lines, reasonably suggests that the sorted sperm is at a sufficient purity level to achieve the stated result. Ex. 1004, 396. Petitioner relies on the testimony of its expert to establish that at the time the invention was made one of ordinary skill in the art would have understood that 80% or better sex sorted semen is a necessary level in order to skew the sex of the litter. *See* Ex. 1002 ¶ 113. Here, Petitioner’s expert testimony is supported by the teachings of either Maxwell (Ex. 1005) or Garner (Ex. 1006) to establish the knowledge of one of ordinary skill in the art at the time of Dekkers publication. Accordingly, we are not persuaded by Patent Owner’s contention that Petitioner is improperly relying on Maxwell and Garner.

Accordingly, having considered the arguments and evidence presented by the parties at this stage, Petitioner has made a sufficient showing that Dekkers discloses the claim limitations of element 1c.

e. (element 1d) “inseminating said sow with sperm cells from said first subpopulation to produce offspring from said sow”

Petitioner asserts that Dekkers discloses the use of sorted sperm for artificial insemination, which a person of ordinary skill in the art would have understood to mean inseminating the sow with the sex sorted semen. Pet. 35 (citing Ex. 1004, 417; Ex. 1002 ¶¶ 115, 116).

Patent Owner does not dispute that Dekkers teaches artificial insemination in order to impregnate sows. *See generally* Prelim. Resp. 24–39.

On this record at this stage of the proceeding, Petitioner has sufficiently shown that Dekkers meets the claim limitation of element 1d.

f. (element 1e) “genotyping said offspring to identify one or more genetic markers”

Petitioner contends that Dekkers teaches the use of genetic markers for improvements within the nucleus herd. Pet. 36 (citing Ex. 1004, 407–408; Ex. 1002 ¶¶ 117, 118).

Patent Owner does not dispute that Dekkers teaches genotyping offspring. *See generally* Prelim. Resp. 24–34.

On the record at the stage of the proceeding, Petitioner has made an adequate showing that Dekkers meets the limitation of element 1e. In particular, Dekkers discloses the use of marker-assisted selection (MAS). Ex. 1004, 407. Dekkers explains that “[o]nce markers associated with the trait have been identified and validated, they can be used for genetic improvement.” *Id.* at 408. “Most genetic improvement in pigs is based on selection within pure breeds or lines. Within-breed selection can be improved with availability of genotype on markers that are associated with the trait(s) of interest.” *Id.* at 410. Dekkers Table 16.6, reproduced below, discloses a listing of exemplary genetic markers in swine.

Table 16.6. Examples of genetic markers and genes used in swine.

Gene (action/target)	Traits affected	Reference(s)
<i>RYR1</i> (halothane sensitivity)	Lean growth, porcine stress syndrome, meat quality	Fuji <i>et al.</i> , 1991
<i>RN</i> (Rendement Napole)	Meat quality	Milan <i>et al.</i> , 2000
<i>ESR</i> (estrogen receptor)	Litter size	Rothschild <i>et al.</i> , 1996; Chen <i>et al.</i> , 2001
<i>PRLR</i> (prolactin receptor)	Nursing performance and litter size	Vincent <i>et al.</i> , 1997; Farmer, 2000
<i>RBP4</i> (retinol binding protein 4)	Litter size	Messer <i>et al.</i> , 1996
<i>MC4R</i> (melanocortin-4 receptor)	Lean growth, fatness, feed intake	Kim <i>et al.</i> , 2000
<i>IGF2</i> (insulin-like growth factor 2)	Lean growth, litter size	Van Laere <i>et al.</i> , 2003; Jungerius <i>et al.</i> , 2004; Liu <i>et al.</i> , 2006
<i>HFABP/AFABP</i>	Intramuscular fat	Gerbens <i>et al.</i> , 1999
<i>c-KIT</i> receptor	Coat and skin colour	Andersson-Eklund <i>et al.</i> , 1996
<i>MC1R</i> (melanocortin-1 receptor)	Red/black coat colour	Kijas <i>et al.</i> , 1998
<i>PRKAG3</i> (protein kinase AMP-activated gamma 3-regulatory subunit)	Meat quality	Ciobanu <i>et al.</i> , 2001
<i>HMGA1</i> (high mobility group AT hook 1)	Backfat thickness	Kim <i>et al.</i> , 2004
<i>CCKAR</i> (cholecystokinin type A receptor)	Feed intake and growth	Houston <i>et al.</i> , 2006
<i>CAST</i> (calpain inhibitor)	Tenderness	Ciobanu <i>et al.</i> , 2004
<i>EPOR</i> (erythropoietin)	Litter size	Vallet <i>et al.</i> , 2005
<i>F18</i>	<i>Escherichia coli</i> diarrhoea	Vogeli <i>et al.</i> , 1997
<i>K88</i>	<i>E. coli</i> diarrhoea	Meijerink <i>et al.</i> , 1996, 2000 Jørgensen <i>et al.</i> , 2003

Table 16.6 of Dekkers, reproduced above, provides a list of genetic markers and their traits. Ex. 1004, 413.

Dekkers discloses two strategies using marker based selection (MAS) and describes that one of the strategies “gave 24% greater response than conventional selection.” *Id.* at 411. In that strategy, “[a] random two of four members of each full-sib family are slaughtered to record meat quality data. The remaining individuals are selected on the basis of a marker-assisted EBV [(estimated breeding value)] for meat quality, once data on their sibs are recorded.” *Id.* Dekkers discloses that one way to incorporate genetic markers into breeding decisions includes the “preselection of candidates based on genetic markers.” *Id.* at 412.

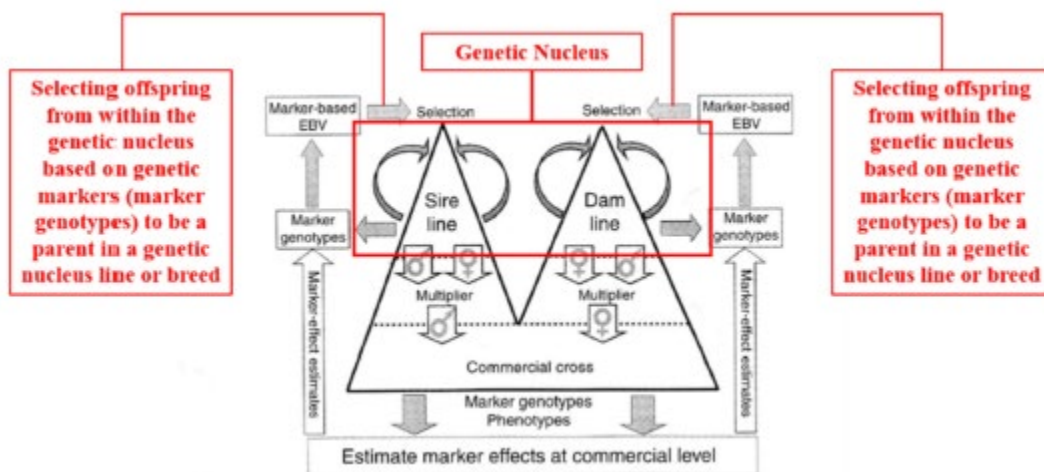
g. (element 1f) “selecting one or more of said offspring as a parent in the line or breed in the genetic nucleus based on the one or more identified genetic markers”

Petitioner asserts that Dekkers discloses selecting offspring from the mating of boars and sows in a sire or dam line and using the offspring to further improve the sire or dam line by having the offspring become parents for the next generation in the nucleus heard. Pet. 36–37. In particular, Petitioner asserts that Dekkers discloses

that a sow and boar in the sire line (or the dam line) are bred to produce offspring. The offspring are genotyped to identify genetic markers, as shown by the arrows from the genetic nucleus sire line and dam line, to the boxes titled “Marker genotypes.” An estimated breeding value (“EBV”) is calculated based on genotype results, as indicated by the arrows from the “Marker genotypes” box to the “Marker-based EBV” box. A selection of the offspring to be the parents of the next generation is made based on the EBVs, which were based on the genetic markers.

Pet. 36–37 (citing Ex. 1004, 417 (Fig. 16.4); Ex. 1002, ¶¶ 54, 60, 120, 121).

Petitioner provides an annotated version of Dekkers Figure 16.4, reproduced below:

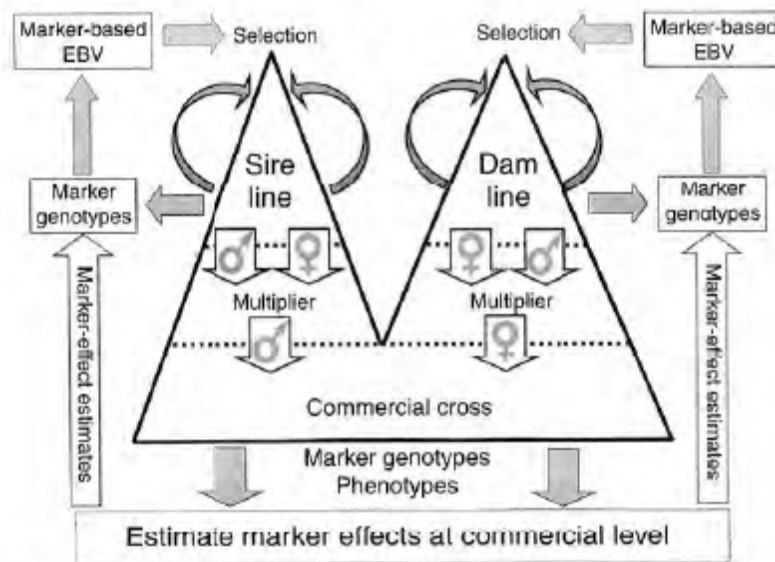


Petitioner's annotations, shown in red above, identify the genetic nucleus and selection based on marker genotypes and estimated breeding values.

Pet. 37 (citing Ex. 1004, 417 (Fig. 16.4)).

Patent Owner disputes that Dekkers teaches “selecting one or more of said offspring as a parent in the line or breed *in the genetic nucleus*.” Prelim. Resp. 26, 32 (citing Ex. 2001 ¶¶ 26–29, 40–44, 50). Specifically, Patent Owner contends that Dekkers describes disseminating genetics from the genetic nucleus to others outside the nucleus. *Id.* at 27 (citing Ex. 1004, 392; Ex. 2001 ¶¶ 26–29, 40–44, 50). In particular, Patent Owner contends that rather than providing improvements in the genetic nucleus, Dekkers is directed to the commercial crossbreeding of pigs, which occurs at a lower tier. *Id.* at 28 (citing Ex. 1004, 400 (Fig. 16.2); Ex. 2001 ¶¶ 26–29, 40–44, 50). Patent Owner contends that Dekkers discusses reducing genetic lag, but asserts that, “reducing genetic lag is fundamentally different from improving genetic progress within a genetic nucleus.” *Id.* at 33 (citing Ex. 2001 ¶¶ 26–29, 40–44, 50.). Patent Owner further contends that Dekkers does not disclose the use of sexed semen for improving genetic progress in a line in a genetic nucleus. *Id.* at 33 (citing Ex. 2001 ¶ 50).

On the record at this stage of the proceeding, Petitioner has made an adequate showing. In particular, Dekkers discloses “that the breeding objective is actually implemented at the nucleus level, but it is targeted to the production level and to future markets.” Ex. 1004, 397. Dekkers Figure 16.4, reproduced below, shows a breeding schematic for genotype selection in either a sire line or dam line.



Dekkers Figure 16.4, reproduced above, shows a breeding schematic that introduces identifying estimated markers effects at the commercial level to estimate breeding values of individuals at the purebred level.

Marker data can also be used to address the problem associated with the genetic improvement of crossbred performance in commercial environments based on pure-line selection in nucleus environments by estimating effects on phenotypes and genotypes collected on crossbred individuals in the field, and using the resulting estimates to estimate breeding values of individuals in the purebred nucleus populations based on their marker genotypes, as illustrated in Fig. 16.4 [shown above]. . . . By analysing data from crossbreds in the field, estimates of marker effects will be for performance of crossbreds under field conditions, rather than for purebred performance in nucleus herds.

Ex. 1004, 411.

Here, the identification of estimate breeding values of individuals in the purebred nucleus populations based on their marker genotypes reasonably supports Petitioner's position that this is "[a] selection of the offspring to be the parents of the next generation is made based on the

EBVs, which were based on the genetic markers.” Pet. 37 (citing Ex. 1004, 417 (Fig. 16.4); Ex. 1002 ¶¶ 54, 60, 120, 121); Ex. 1002 ¶¶ 41–42.

On the record at the stage of the proceeding, Petitioner has made an adequate showing that Dekkers discloses the claim limitation of element 1f.

h. Summary of Claim 1

To summarize, having considered the arguments and evidence presented by the parties at this stage in the proceeding, we find that Petitioner has established a reasonable likelihood of prevailing on its assertion that claim 1 is anticipated by Dekkers.

i. Claims 2 and 3

Petitioner asserts that Dekkers discloses a line or breed is a guilt line (claim 2) or a boar line (claim 3). Pet. 38–39.

Patent Owner does not address the limitations of claims 2 and 3 separately, relying instead on the contention that limitations of claim 1 are missing in Dekkers. *See generally* Prelim. Resp. 24–34.

On the record at the stage of the proceeding, we determine that Petitioner has made an adequate showing that Dekkers meets the limitation of claims 2 and 3. In particular, Dekkers discloses that breeding at the nucleus level is divided into sire and dam lines.

It is important to note that the breeding objective is actually implemented at the nucleus level, but it is targeted to the production level and to future markets.

In commercial breeding, breeding goals are defined separately for sire and dam lines. The sire lines are mainly selected for genetic improvement in production traits such as growth rate, carcass quality, meat quality, feed conversion and conformation. The breeding goal for dam lines typically includes the same production traits, but in addition female

reproductive traits, such as litter size, piglet survival, age at puberty, conception rate, number weaned and weaning to oestrus interval.

Ex. 1004, 397. Dekkers discloses that “new developments in sperm sexing technology allow for the production of either male or female offspring for sire or dam lines, and this can be very useful for the nucleus and multiplication tiers.” Ex. 1004, 396.

Accordingly, having considered the evidence and arguments presented at this stage of the proceeding, Petitioner shows a reasonable likelihood of prevailing on its assertion that claims 2 and 3 are anticipated by Dekkers.

j. Claims 4 and 5

Petitioner asserts that Dekkers discloses genetic markers including single nucleotide polymorphisms (SNPs) (claim 4), that are correlated with feed efficiency, average daily gain, or carcass lean (claim 5). Pet. 39–40.

Patent Owner does not address the limitations of claims 4 and 5 separately, relying instead on the contention that limitations of claim 1 are missing in Dekkers. *See generally* Prelim. Resp. 24–34.

On the record at the stage of the proceeding, Petitioner has made an adequate showing that Dekkers meets the limitations of claims 4 and 5. In particular, Dekkers discloses the use of marker-assisted selection (MAS). Ex. 1004, 407. Dekkers explains that “[o]nce markers associated with the trait have been identified and validated, they can be used for genetic improvement.” *Id.* at 408. “Most genetic improvement in pigs is based on selection within pure breeds or lines. Within-breed selection can be improved with availability of genotype on markers that are associated with the trait(s) of interest.” *Id.* at 410. Dekkers Table 16.6, shown above in

§ II.D.5.f, discloses a list of known genetic markers, identifying the gene *MC4R* (*melanocortin-4 receptor*) that has been associated with lean growth, fatness, and feed intake traits, and gene *HMGA 1* (*high mobility group AT hook 1*) that has been associated with the backfat thickness trait. *Id.* at 413 (Table 16.6). Dekkers teaches that single nuclear polymorphism (SNP) panels have become available, which allow for the detection of genetic markers that are associated with the trait based on population-wide linkage disequilibrium markers (LD) and with qualitative trait loci (QTLs). *Id.* at 408.

Accordingly, having considered the evidence and arguments presented at this stage of the proceeding, Petitioner shows a reasonable likelihood of prevailing on its assertion that claims 4 and 5 are anticipated by Dekkers.

E. Ground 1B: Obviousness of Claims 1–5 over Dekkers and either Maxwell, Garner, or Kim

Alternatively, Petitioner contends that claims 1–5 are unpatentable as obvious over the combination of Dekkers and either Maxwell, Garner, or Kim. Pet. 41–45. Patent Owner opposes. Prelim. Resp. 34–39. Based on the current record, Petitioner shows a reasonable likelihood that it would prevail in showing that at least one challenged claim is unpatentable as obvious over Dekkers and either Maxwell, Garner, or Kim.

a. Claims 1–3

Petitioner argues that Dekkers meets each and every element of the claims. Pet. 41–45; *see above* § II.D.5. Petitioner contends that “Dekkers expressly discloses that sex-sorting semen to produce ‘either male or female offspring for sire or dam lines’ is ‘very useful’ in the genetic nucleus.”

Pet. 42 (citing Ex. 1004, 396). According to Petitioner “[t]he only way to carry out either AI [(artificial insemination)] or sorting boar sperm by sex is to first collect it from the boar of interest.” Pet. 42 (citing Ex. 1002 ¶¶ 139, 149). To the extent that Dekkers does not teach sorting the sperm into two subpopulation having at least 80% of either subpopulation sorted, Petitioner relies on the disclosure of either Maxwell or Garner to establish that one of ordinary skill in the art at the time the invention was made would have known that in order to sex skew the offspring using sorted sperm would require a level purity of 85–95% for each subpopulation. Pet. 43 (citing Ex. 1005, 81; Ex. 1006, 944; Ex. 1002 ¶¶ 140–148).

Patent Owner contends that Dekkers does not disclose increasing genetic progress within the genetic nucleus and that neither Maxwell nor Garner make up for that deficiency. *See* Prelim. Resp. 26, 32–34. Specifically, Patent Owner contends that Dekkers does not disclose selecting one or more of said offspring as a parent in the genetic nucleus. *Id.* at 26, 30. Patent Owner contends that Dekkers merely describes “disseminating genetics from the genetic nucleus to others outside of the nucleus.” *Id.* at 27. According to Patent Owner, Dekkers disclosure that nucleus breeding farms typically maintain specific breeds or lines “says nothing about increasing genetic progress of a particular line or breed within the nucleus.” *Id.* at 28–29. According to Patent Owner, Dekkers generic statements that genetic improvement of specific characteristics is important to consumers says nothing about making improvements in the sire or dame lines. “This is merely a general statement that genetic improvement of specific characteristics is an aim of breeders of sire or dame lines.” *Id.* at 29. Patent

Owner contends that Dekkers is focused on breeding different lines outside the genetic nucleus. *Id.* (citing Ex. 2001 ¶¶ 26–29, 40–44, 50).

Based on the current record, Patent Owner’s argument is weak. In particular, Dekkers emphasizes “that the breeding objective is actually implemented at the nucleus level.” Ex. 1004, 397. Illustrating this point, Dekkers teaches the selection of marker genotype of individuals for the purpose of creating commercial cross breeds and to provide feedback to the top of the pyramid as shown in Figure 16.4 of Dekkers, reproduced below:

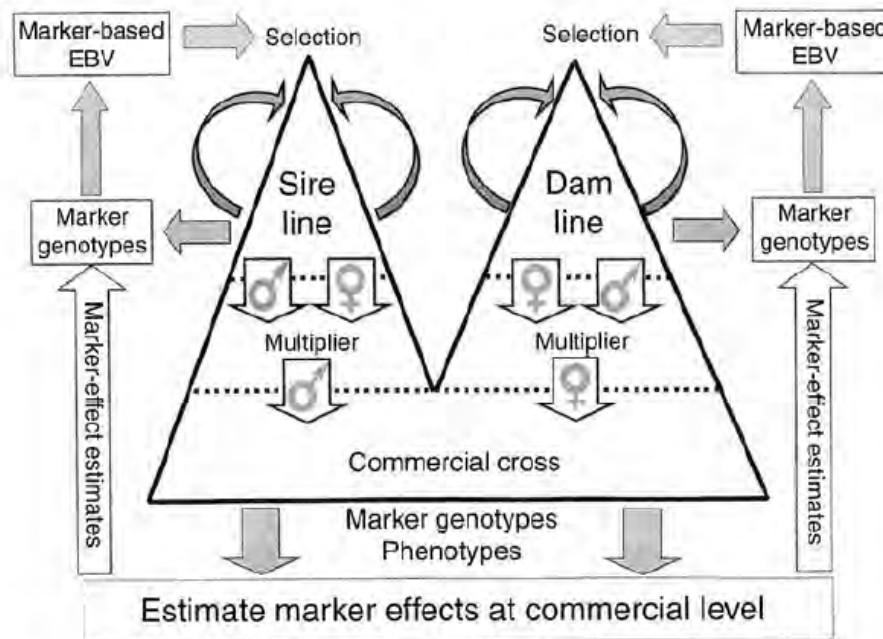


Figure 16.4 of Dekkers shows that marker genotypes are used for selection purposes in both the sire and dam lines. Ex. 1004, 417. “[G]enomic selection removes many of the limitations that exist in current phenotype-based programmes with regard to when and on which individuals phenotypes must be evaluated. . . . [G]enomic selection provides for selection within families.” *Id.* at 416. In other words, the use of genomic selection does not require that the animal has to be full-grown so that the phenotype may be

observed before an evaluation can be made of where to place an individual animal in a breeding program. Dekkers teaches that one of the benefits of marker selection is to “increase response to selection for a given rate of inbreeding by increasing selection intensities.” *Id.* Inbreeding reasonably suggest selecting individuals to be part of the genetic nucleus.

Marker data can also be used to address the problem associated with the genetic improvement of crossbred performance in commercial environments based on pure-line selection in nucleus environments by estimating effects on phenotypes and genotypes collected on crossbred individuals in the field, and using the resulting estimates to estimate breeding values of individuals in the purebred nucleus populations based on their marker genotypes. . . .

Ex. 1004, 411. Thus, Dekkers supports the position that marker data can be used not only for determining individuals in a pure-line, but also for evaluating markers for the benefit in the commercial environment.

Petitioner’s expert testifies that the primary objective of agricultural breeding is to maximize commercially desirable traits while minimizing undesirable traits within the population, including swine populations intended for food production. Ex. 1002 ¶ 37 (citing Ex. 1004, 391–392; Ex. 1008, 445; Ex. 1009, Abstract). Petitioner’s expert further explains that breeders maintain breeds within a genetic nucleus heard which would require some offspring to be used to perpetuate the line. “Breeds/lines used for the production of females are *dam lines*, and breeds/lines used for production of males are referred to as *sire lines*, respectively.” Ex. 1002 ¶ 40 (citing Ex. 1004, 393–394).

Hence, pure lines or breeds in the genetic nucleus must continually be maintained by mating boars and sows of the same line or breed in order to provide a source of animals with improved genetics for cross-breeding. While it may be theoretically possible to increase genetic progress in a population without the use of inbreeding, the rate of genetic gain would be prohibitively slow from a commercial standpoint. Accordingly, large-scale and commercial breeding programs routinely implement inbreeding in methods of increasing genetic process.

Ex. 1002 ¶ 42.

On the record before us, Petitioner shows sufficiently for the purpose institution that a person of ordinary skill in the art at the time the invention was made would have understood that Dekkers supports the position that the use of genetic markers can increase selection intensities for inbreeding.

Ex. 1004, 416, 417 (Fig. 16.4). The need to select offspring and use them for breeding purposes in the same line is further supported by Petitioner's expert testimony that the genetic nucleus must be continuously maintained by mating boars and sows within the same line or breed. In other words, one of ordinary skill in the art would have understood that if no offspring are selected as the parent for the next generation in the same line or breed, then a particular line or breed would become extinct because the animals at the top of the pyramid would end up getting too old to perpetuate the line. *See* Ex. 1002 ¶¶ 107 (“As known in the art, in order to maintain purebred lines or breeds, one must breed sows and boars from those lines or breeds. These lines and breeds are maintained in the genetic nucleus or nucleus herd.”), 108, 109, 110 (“breeding boars and sows within the same line is the industry practice for maintaining and improving a genetic nucleus that includes that line”).

Patent Owner contends that “the petition does not identify any disclosure in the cited references that explains or suggests why sex skewing the swine sex ratio *within* a genetic nucleus would lead to increased prevalence of any desired trait, such as feed efficiency, average daily gain or carcass lean.” Prelim. Resp. 35.

Based on the current record, Patent Owner’s argument is weak. In particular, Dekkers marks as “important . . . that the breeding objective is actually implemented at the nucleus level, but it is targeted to the production level and to future markets.” Ex. 1004, 397. Petitioner’s expert explains that one of ordinary skill in the art at the time the invention was made in light of the teachings of Dekkers, specifically Figure 16.4 shown above, would have known that in order “to produce females for a gilt line or males for a boar line by selecting a subpopulation of sorted sperm cells containing predominantly X-chromosomes to increase the likelihood of producing female offspring or containing predominantly Y-chromosomes to increase the likelihood of producing male offspring, respectively.” Ex. 1002 ¶ 131 (citing Ex. 1004, 396). Dekkers further teaches that the

breeding goals are defined separately for sire and dam lines. The sire lines are mainly selected for genetic improvement in production traits such as growth rate, carcass quality, meat quality, feed conversion and conformation. The breeding goal for dam lines typically includes the same production traits, but in addition female reproductive traits, such as litter size, piglet survival, age at puberty, conception rate, number weaned and weaning to oestrus interval.

Ex. 1004, 397. Petitioner shows sufficiently for institution that breeding goals are defined separately for sire and dam lines having the ability to preselect progeny for sex reduces cost. *See* Ex. 1002 ¶ 48 (“Preselecting for

sex in a swine dam or sire line in the genetic nucleus was recognized as one of the main applications of sexing technology. . . . The use of sex sorted sperm permits breeders to reduce cost associated with the production of progeny of the undesired sex.”); *see also* Ex. 1055, 80 (“The main application by pig producers is for the use of sex-sorting technology in nucleus herds, particularly for producing female lines.”).

Patent Owner contends that a person of ordinary skill in the art at the time the invention was made would not have had the requisite “reasonable expectation of success” in the combination because the references “teachaway” from using sex sorted sperm for breeding purposes. Prelim. Resp. 36 (citing Ex. 2001 ¶¶ 25–28, 39–43, 50, 55–70). Specifically, Patent Owner contends that the low fertility rate of using sexed semen would lead one of ordinary skill in the art away from making the combination. *Id.* at 38.

Based on the current record, Patent Owner’s argument is weak. Absolute predictability is not necessary to reach an obviousness determination; only a reasonable expectation of success is needed. *Pharma Stem Therapeutic, Inc. v. ViaCell, Inc.*, 491 F.3d 1342, 1360 (2007); *In re Kubin*, 561 F.3d 1351, 1360 (Fed. Cir. 2009); *In re O’Farrell*, 853 F.2d 894, 903–904 (Fed. Cir. 1988) (“Obviousness does not require absolute predictability of success For obviousness under § 103, all that is required is a reasonable expectation of success.”). In particular, Dekkers teaches that sorted sperm can be used for artificial insemination. Specifically, acknowledging that “new developments in sperm sexing technology allow for the production of either male or female offspring for sire or dam lines, and this can be very useful for the nucleus and multiplication tiers.” Ex. 1004, 396; Ex. 1002 ¶ 48; *see also* Ex. 1055, 80

(“The main application by pig producers is for the use of sex-sorting technology in nucleus herds, particularly for producing female lines.”). Petitioner shows sufficiently for the purpose institution that given the teachings of Dekkers one of ordinary skill in the art would have appreciated that the use of sex sorted semen when breeding in a dam line, would increase the number of female offspring, and by increasing the population of females the likelihood of finding a desirable trait in a particular line is also increased. The same would apply for using the same type of selection in a sire line.

Dekkers further suggests using markers to improve within-breed selection. “Once markers associated with the trait have been identified and validated, they can be used for genetic improvement. . . . [and] to enhance within-breed selection.” Ex. 1004, 408, *see also id.* at 416 (“genomic selection removes many of the limitations that exist in current phenotype-based programmes with regard to when and on which individuals phenotypes must be evaluated”). It is not inventive to confirm something that was already suggested in the art. “Scientific confirmation of what was already believed to be true may be a valuable contribution, but it does not give rise to a patentable invention.” *Pharma Stem*, 491 F.3d at 1363–1364.

As for Patent Owner’s contention that Dekkers taught away from the claimed invention (or, somehow taught away from the prior art combination), we disagree based on the record before us. A “teaching away” requires a reference to actually criticize, discredit, or otherwise discourage the claimed solution. *See In re Fulton*, 391 F.3d 1195, 1201 (Fed. Cir. 2004). “[T]he question is whether there is something in the prior art as a whole to suggest the desirability, and thus the obviousness, of making the combination, not whether there is something in the prior art as a whole to

suggest that the combination is the most desirable combination available.” *Id.* at 1200 (citation and emphasis omitted) (alteration in original). “The prior art’s mere disclosure of more than one alternative does not constitute a teaching away from . . . alternatives because such disclosure does not criticize, discredit, or otherwise discourage the solution claimed.” *Id.* at 1201. Here, Dekkers does not criticize, discredit, or discourage the claimed invention or the prior art combination. Dekkers, at most, is silent with respect to the purity needed for the use of sexed semen when using artificial insemination, but both Maxwell and Garner support the required purity level for using sex sorted semen.

Accordingly, having considered the arguments and evidence presented by the parties at this stage in the proceedings, we find that Petitioner has established a reasonable likelihood of prevailing on its assertion that claims 1–3 are obvious over Dekker in view of either Maxwell or Garner.

b. Claims 4 and 5

Petitioner argues that Dekkers expressly describes using SNPs as genetic markers for selection purposes. Pet. 45. Because Dekkers “discloses these [genetic] markers [associated with traits such as lean growth, fatness, feed intake, and backfat thickness] are for use in swine breeding to improve the listed traits, it would have been obvious to select SNPs in Table 16.6 [reproduced above in § II.D.5.f] relating to these traits as genetic markers, including *MC4R*” for selection purposes. Pet. 45. Kim cited by Dekkers teaches that *MCR4* is a SNP and is useful as a genetic marker. In particular, Kim teaches that

given the strong relationship of *MC4R* variants to leanness, growth, and feed intake, this mutation could be used

immediately for marker-assisted selection. . . . For instance, in sow lines where appetite is normally decreased after farrowing, selection for the *MC4R* allele 2 could help to improve feed intake. . . . Therefore, genotyping for the *MC4R* mutation in pig breeding lines will improve the selection efficiency of feed-related production traits including growth and leanness.

Ex. 1007, 134.

Patent Owner does not address the limitations of claims 4 and 5 separately, relying instead on the contention that there is no reasonable expectation of success in arriving at the limitations of claim 1 based on the combination of Dekkers, Maxwell, Garner, and Kim. Prelim. Resp. 34–39.

c. Summary

To summarize, based on the evidence and arguments presented by the parties at this stage in the proceeding, Petitioner has shown that there is a reasonable likelihood that claims 1–5 of the '734 patent would have been obvious over Dekkers in view of Maxwell, Garner, or Kim under Ground 1b.

F. Ground 2: Obviousness of Claims 1–5 over Dekkers and Okere

Petitioner contends that claims 1–5 are unpatentable as obvious over the combination of Dekkers and Okere. Pet. 46–48. Patent Owner opposes. Prelim. Resp. 39–41.

1. Overview of Okere (Ex. 1008)

Okere teaches increasing “reproductive efficiency and rates of genetic improvement” in pig reproduction. Ex. 1008, 445. Okere states that the “real impact on herd productivity will come from combining new reproductive techniques with powerful DNA technologies” and that the “new reproductive techniques will allow a rapid turnover of generations, whereas the DNA technology can provide selection, which does not need phenotypic

information when the selection decisions are made.” *Id.* Okere discloses that selection “involves identifying the best animals to be the parents of the next generation” and “relies on the desired traits being inherited.” *Id.* According to Okere, in 1991, the USDA produced the “first piglets with semen sorted for sex.” *Id.* at 446 (Table 1). Okere indicates that thereafter, the “shift in the sex ratio is usually from the standard 1:1 to about 8 or 9:1.” *Id.* at 447. Okere concludes that sperm sexing technology (SST) combined with powerful molecular techniques “offer possibilities for improving the rate of genetic progress.” *Id.* at 451.

2. Analysis

Petitioner contends that Dekkers discloses each and every element of claims 1–5. Pet. 46. Petitioner relies on Okere for teaching increasing genetic progress in swine including at the level of the nucleus heard. *Id.* (citing Ex. 1008, Abstract, 446; Ex. 1002 ¶ 77). “Because predetermination of the sex of offspring would not only improve the rate of genetic progress per Dekkers, but improve feed efficiency and carcass lean content (e.g., by selecting for females), a POSA would have been motivated to sort boar semen to the high levels of purity disclosed by Okere.” Pet. 47–48.

Patent Owner contends “neither Dekkers nor Okere teach the use of sexed semen in the genetic nucleus, and because the references teach away from and/or clearly express doubt about the success of using sexed semen in pig breeding.” Prelim. Resp. 39. Specifically, Patent Owner contends that Dekkers fails to disclose using sexed semen within a genetic nucleus to improve genetic progress and that Okere does not fill the gap. *Id.* Patent Owner contends that Okere speculates that sexed semen might be useful at a lower level tier of pig breeding and not at the genetic nucleus. *Id.* Patent

Owner contends that Okere is speculative and doubts that artificial insemination using sexed sorted sperm would work. *Id.* at 40 (citing Ex. 1008, 446–447; Ex. 2001, ¶¶ 37, 54, 71–73).

On the record at the stage of the proceeding, Petitioner has made an adequate showing for purposes of institution that the combination of Dekkers and Okere suggests using sex sorted sperm for driving genetic progress. The teachings of Dekkers are discussed above *See* § II.D.5.a–i. In particular, Dekkers in Figure 16.4, reproduced above, teaches a swine breeding schematic that shows the use of estimated markers effects at the commercial level to estimate breeding values of individuals at the purebred level. Ex. 1004, 417; *see also* Ex. 1002 ¶ 109 (“the curved arrows shown in connection with the sire and dam lines within the genetic nucleus illustrate that boars and sows from a line or breed within a genetic nucleus are selected for breeding within the genetic nucleus.”).

Okere teaches that the main objective of modern reproductive technologies is to increase reproductive efficiency and rates of genetic improvement. Ex. 1008, Abstract. “The real impact on herd productivity will come from combining new reproductive techniques with powerful DNA technologies. The new reproductive techniques will allow a rapid turnover of generations, whereas the DNA technology can provide selection, which does not need phenotypic information when the selection decisions are made.” *Id.* Okere teaches that in 1991, sex sorted semen was used for the production of piglets. Ex. 1008, 446 (Table 1). Okere explains that artificial insemination (AI) reached a level of practicality about 40 years ago.

By using AI, genetically superior boars can be used extensively, particularly *at the nucleus* and the multiplier levels of the pig

breeding pyramid. At the nucleus level, AI has made it possible to link several units to create a large ‘super nucleus’, thereby increasing genetic gain at the nucleus level and a decrease in genetic lag between nucleus herds and the commercial population.

Ex. 1008, 446 (emphasis added). Okere teaches benefits of sex selection noting that “that single sex production also avoids the need for split-sex feeding. If successful, the semen sexing technology will be an easy and inexpensive application to on-farm AI collection. . . . In the short term sex determination probably represents the greatest single potential step forward in pig production and is therefore well worth the effort.” Ex. 1008, 447; *see also* Ex. 1002 ¶ 48 (“Preselecting for sex in a swine dam or sire line in the genetic nucleus was recognized as one of the main applications of sexing technology. . . . The use of sex sorted sperm permits breeders to reduce cost associated with the production of progeny of the undesired sex.”); Ex. 1055, 80 (“The main application by pig producers is for the use of sex-sorting technology in nucleus herds, particularly for producing female lines.”). Here, Okere acknowledges that sex sorting sperm samples is still not at the level that it can be used on a commercial farm but it has great potential if it can be implemented at the production tier. Okere teaches that “[i]mprovements in the Beltsville technology⁶ in the last two years has lead [sic] to the development of a commercial high speed cell sorter which can produce 5 to 6×10^6 sperm/hour at 85 to 90% purity for X (female producing) or Y (male

⁶ The Beltsville sperm sexing technology is a flow cytometry method developed by Dr. Larry Johnson of the USDA at Beltsville. *See* Ex. 1008, 447.

producing) sperm cells in most livestock species.” Ex. 1008, 447 (footnote added).

The speed at which genetic improvements can be achieved by traditional methods is slow. Many of the new reproductive technologies offer possibilities for improving the rate of genetic progress. These include *in vitro* embryo production (IVEP), nonsurgical embryo transfer (ET), sperm sexing technology (SST), and molecular biology techniques. The real impact on genetic progress will come from combining new reproductive techniques with powerful molecular techniques. The new reproductive techniques will allow a rapid turnover of generations, whereas the molecular techniques can provide selection, which does not need phenotypic information when the selection decisions are made.

Ex. 1008, 451–52. Okere teaches that artificial insemination “[e]nables dissemination of superior genetics[, a]ffords more controlled breeding and mate selection and potentially decreases inbreeding.” Ex. 1008, 451 (Table 4). Okere acknowledges that challenges remain, especially at the level of collecting and processing the semen. *Id.* Okere explains that genetic improvement requires selection, which “involves identifying the best animals to be the parents of the next generation” and relies on the “desired traits being inherited.” Ex. 1008, 445.

Based on the current record, we consider Patent Owner’s argument that Okere is speculative to be weak. Prelim. Resp. 40 (citing Ex. 1008, 446–447; Ex. 2001 ¶¶ 37, 54, 71–73). Absolute predictability is not necessary to reach an obviousness determination; only a reasonable expectation of success is needed. *Pharma Stem*, 491 F.3d at 1360. In particular, Okere teaches that sex sorted semen was used as early as 1991 to produce the first piglets. Ex. 1008, 446 (Table 1). Okere, therefore, expressly teaches that sex

sorted sperm has successfully resulted in piglet production. Okere recognizes that the sorting technology has not yet advanced to the point that it is economically feasible to apply sex sorted semen at the commercial production level, but recognizes that there are many benefits to being able to select the particular sex of offspring to make it worthwhile to keep trying. *See* Ex. 1008, 447 (“that the main benefits of semen sexing lies in improved feed efficiency and carcass lean content . . . single sex production also avoids the need for split-sex feeding”); *see also* Ex. 1002 ¶ 48 (“The use of sex sorted sperm permits breeders to reduce cost associated with the production of progeny of the undesired sex.”); Ex. 1055, 80 (“The main application by pig producers is for the use of sex-sorting technology in nucleus herds, particularly for producing female lines.”).

Accordingly, having considered the evidence and arguments presented at this stage of the proceeding, Petitioner shows a reasonable likelihood of prevailing on its assertion that claim 1 is obvious over Dekkers in view of Okere.

3. Summary

To summarize, based on the evidence presented at this stage in the proceeding, Petitioner has sufficiently shown that there is a reasonable likelihood that claim 1 of the '734 patent would have been obvious over Dekkers and Okere. We have reviewed Petitioner's contentions with respect to claims 2–5, and determine that the Petition provides the requisite showing, at this stage of the proceeding, that the combination of Dekker and Okere teaches or suggests the subject matter of these claims. *See* Pet. 46–48. Patent Owner does not offer, at this stage, any arguments addressing Petitioner's substantive showing. *See* Prelim. Resp. 39–41.

G. Ground 3: Obviousness of Claims 1–5 over Buttram and Maxwell

Petitioner contends that claims 1–5 are rendered obvious based on the combination of Buttram and Maxwell. Pet. 48–58. Patent Owner opposes. Prelim. Resp. 41–46.

1. Overview of Buttram (Ex. 1009)

Buttram teaches methods of “improving porcine (pig) genetics, at both the individual animals and herds levels.” Ex. 1009, ¶ 3. As background, Buttram states that the means of using newly available genotypic information to improve the development of commercial swine products “must allow for the rapid genetic improvement in desirable traits in a swine population (e.g., target herd) without jeopardizing the potential for long-term genetic improvement.” *Id.* ¶ 9. Buttram purports to further this need “by providing a method for the rapid genetic change of a target herd, based on phenotypic and genotypic information about both the target herd and the GN [(genetic nucleus)] herd, while maintaining a more balanced approach to selection in the GN herd.” *Id.* Buttram’s method includes “allocating a small purebred GN herd (~200 sows) for the purpose of maximizing rate of genetic progress over the long term and, simultaneously, creating a second purebred sow herd (target herd) of the same genetic line that will be mated to a small number of elite sires (e.g., ~1 to 3 sires/generation) produced from the GN.” *Id.* ¶ 10.

Buttram indicates that in general, “inbreeding will accumulate in a ‘genetic nucleus’ (GN) herd as a result of intra-herd selection.” *Id.* ¶ 38. The genetic nucleus is a population that “serves as the source of genetic improvement over time” in which top ranking young males and females “are identified from this population each generation and used back in the GN

herd to replace older, lower ranking animals thereby creating genetic improvement that accumulates from one generation to the next.” *Id.* ¶ 56. A “target herd” is “a non-GN herd of female swine to which elite boars from the GN herd are mated for the purpose of transferring desirable genes/traits from the GN to the target herd.” *Id.* ¶ 74. Buttram’s method results in “the eventual genetic improvement of commercial swine products” because “the commercial swine products may be direct progeny of animals in the target herd or may be descendents [sic] of animals in the target herd” while the “target herd may be made up of purebred females from the same genetic line as that of the GN herd or may be made up of any swine females for which it would be desirable to include genes/traits from the GN herd.” *Id.* ¶ 88. “Typically, production nucleus herd is a purebred herd that is of the same genetic line as the GN herd and is mated to elite sires from the GN herd for the purpose of transferring genes/traits to the terminal boar product.” *Id.* ¶ 89. Further, the target herd can be a “target herd for producing crossbred terminal boars,” also referred to as a “crossbred boar multiplier herd” in which “the target herd is not the same genetic line as the GN herd.” *Id.* ¶ 90.

Buttram’s method includes using semen aliquots “to inseminate a sufficient number of females.” *Id.* ¶ 94. Further, boars from resulting litters may be “genotyped and/or phenotyped to determine which received the desired genetic traits from the parents.” *Id.* ¶ 96. Animals possessing the desirable traits/markers are then used “to improve the herd.” *Id.* ¶ 117.

Figure 13 of Buttram is reproduced below.

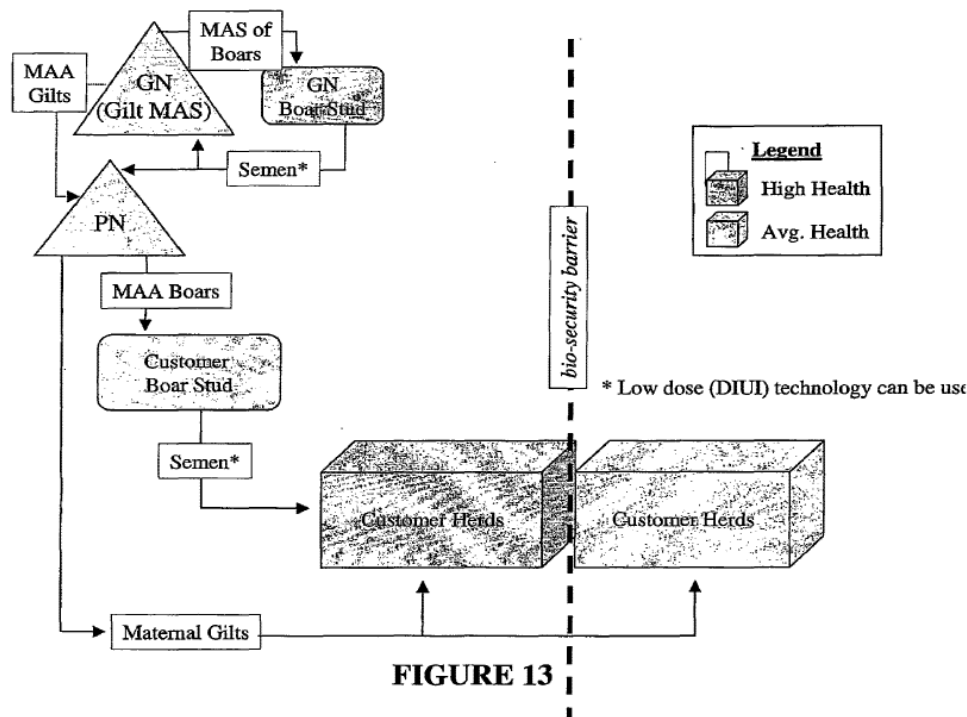


FIGURE 13

Figure 13 is a schematic representation of “the use of marker-assisted selection (MAS) and marker-assisted allocation (MAA).” *Id.* ¶ 31. A top pyramid represents the genetic nucleus that includes MAS gilt and a pyramid below represents a production nucleus. *Id.* ¶¶ 163, 167. Accordingly, this depicted breeding technique involves breeding of members within the genetic nucleus as seen via the arrows extending to and from the “GN (Gilt MAS)” pyramid. *Id.*

2. Analysis

Petitioner contends that Buttram teaches that the genetic nucleus is a population that serves “as the source of genetic improvement over time” in which “top ranking young males and females are identified from this population each generation and used back in the *GN herd* to replace older, lower ranking animals thereby creating *genetic improvement* that

accumulates from one generation to the next.” Pet. 48 (citing Ex. 1009 ¶ 56); Ex. 1009 ¶¶ 83 (“a method for producing terminal swine parents (i.e. terminal sires and terminal dams) and/or replacement animals (for the genetic nucleus and/or target herds). . . . selecting the offspring exhibiting improved germplasm for use as terminal parents or replacement animals.”), 67 (“‘marker-assisted selection’ (MAS) is the use of phenotypic and genotypic information to identify animals with superior estimated breeding values (EBVs) for selection and use as breeding animals for the genetic nucleus GN herd.”).

According to Petitioner,

Buttram’s use of sire lines is dictated by the objective of improving terminal boars, and the use of sire lines is required to achieve that objective. A POSA would have understood that the selection of either a dam line or a sire line in methods for genetic improvement will depend on the breeding objective. A POSA would have understood that the general methods of Buttram could be used with a dam line or a sire line.

Pet. 56 (citing Ex. 1002 ¶ 188). Petitioner acknowledges that “Buttram discloses the use of artificial insemination . . . , [but] it does not teach the use of sex sorted semen.” Pet. 54 (citing Ex. 1009 ¶¶ 51, 102).

Petitioner relies on the teachings of Maxwell for teaching the use of sex sorting semen to achieve “faster genetic progress.” *Id.*; Ex. 1005, 80 (“Livestock production can benefit from sex pre-selection because inseminations can be planned to produce a specific sex. In addition to faster genetic progress there are other advantages for the management and efficiency of livestock production.”).

Based on these disclosures, Petitioner concludes that one of ordinary skill in the art would have been motivated to combine the teachings of Buttram and Maxwell, because

Buttram is directed to methods for increasing genetic progress in a porcine genetic nucleus herd comprising the use of artificial insemination and the selection of desirable traits. EX1009, ¶¶ [0009], [00013], [0016]. Maxwell is directed to the use of sorted porcine semen, including for purposes of increasing genetic progress faster. EX1005, p. 80, 81. As one of Buttram's objectives is "maximizing [the] rate of genetic progress over the long term" in the genetic nucleus (¶[0010]), and Maxwell teaches that that faster genetic progress may be made using sexed-semen, a POSA would therefore have applied Maxwell's sex-sorting methods to produce sex-sorted semen for use in the methods of Buttram. EX1002, ¶¶195, 196.

Pet. 57–58 (alteration in original).

Patent Owner contends that Buttram is not directed to improving genetic progress within a genetic nucleus. Prelim. Resp. 41–46. Patent Owner contends that nothing in Buttram is directed to within-genetic nucleus breeding methods or techniques. *Id.* at 44 (citing Ex. 1009 (Fig. 13)). Patent Owner contends that neither Buttram nor Maxwell "provides any disclosure of using at least 80% sex-selected semen to increase genetic progress within a genetic nucleus." *Id.* at 45 (emphasis omitted). According to Patent Owner, Maxwell speculates that sex selected semen can be used for faster genetic progress. *Id.* at 46.

Based on the current record, Patent Owner's argument is weak. Absolute predictability is not necessary to reach an obviousness determination; only a reasonable expectation of success is needed. *Pharma Stem.*, 491 F.3d at 1360. In particular, Buttram teaches "a method for the

rapid genetic change of a target herd, based on phenotypic and genotypic information about both the target herd and the GN [(genetic nucleus)] herd, while maintaining a more balanced approach to selection in the GN herd.” Ex. 1009 ¶ 9. Buttram teaches that genetic improvement using marker-assisted selection (MAS) can apply to all levels of swine production including the genetic nucleus (GN). *Id.* ¶¶ 16, 31, 67, 83. Buttram explains that the use of a small purebred genetic (GN) herd allows “for the purpose of maximizing rate of genetic progress over the long term.” *Id.* ¶ 10. Buttram explains that by the “use of a target herd which is separate from the GN herd it is possible to separately improve the genetics of these two herds. . . . allowing for a relatively intense selection pressure to be placed on desired traits in the target herd while concomitantly allowing for selection practices in the GN herd which minimize inbreeding (an[d] maximize genetic variation) insofar as possible.” *Id.* ¶ 141. Buttram teaches the use of artificial insemination (AI), intrauterine insemination (IUI), and deep intrauterine insemination (DIUI). *See id.* ¶¶ 103–113.

Petitioner’s expert testifies that one of ordinary skill in the art at the time the invention was made would have understood that from the “commercial pig production perspective, using semen with less than 80% sex skew (i.e., purity for X or Y chromosomes) would not be efficient or economical, and consumers (e.g., pig producers) would not purchase such poorly enriched samples.” Ex. 1002 ¶ 113; *see also* Ex. 1055, 80 (“The main application by pig producers is for the use of sex-sorting technology in nucleus herds, particularly for producing female lines.”); Ex. 1054, 287 (“the successful preselection of sex after intrauterine AI with sex-sorted boar sperm. . . . sexing sperm may well hold the greatest promise for advancing

the reproductive efficiency of swine. Genetic progress, market flexibility and herd management will all be impacted positively by the use of AI and will in turn have a large-scale impact on the genomic character of swine production.”); Ex. 1048, 1606 (“Pre-selecting the sex of the offspring will have a significant impact on pig production. The application of sex pre-selection to genetic programs in pig production will accelerate genetic progress.”).

Here, Maxwell teaches that “[l]ivestock production can benefit from sex pre-selection because inseminations can be planned to produce a specific sex. In addition to faster genetic progress there are other advantages for the management and efficiency of livestock production.” Ex. 1005, 80; Ex. 1002 ¶ 144. Maxwell explains that the only way that sex-preselection before conception can be achieved is by sorting the sperm. Ex. 1005, 80; Ex. 1002 ¶¶ 145, 148. Maxwell teaches achieving sorting purity of more than 85% as well as the successful production of offspring using sex sorted sperm. *See* Ex. 1005, 81, 88.

Based on the evidence and arguments presented by the parties at this stage in the proceeding, Petitioner shows that there is a reasonable likelihood that claim 1 of the ’734 patent would have been obvious over Buttram and Maxwell under Ground 3.

3. Summary

To summarize, based on the evidence presented at this stage in the proceedings, Petitioner has shown that there is a reasonable likelihood that claim 1 of the ’734 patent would have been obvious over Buttram and Maxwell. We have reviewed Petitioner’s contentions with respect to claims 2–5, and determine that the Petition provides the requisite showing, at this

stage of the proceeding, that the combination of Buttram and Maxwell teaches or suggests the subject matter of these claims. *See* Pet. 48–59. Patent Owner does not offer, at this stage, any arguments addressing Petitioner’s substantive showing. *See* Prelim. Resp. 41–46.

III. CONCLUSION

On the preliminary record before us, Petitioner demonstrates a reasonable likelihood of prevailing at trial in showing that at least one claim of the ’734 patent would have been anticipated or obvious over the cited prior art. In accordance with the Court’s decision in *SAS Institute, Inc.*, 138 S. Ct. at 1359–60, and Office Guidance, we institute an *inter partes* review of all challenged claims (1–5) of the ’734 patent on all grounds (Grounds 1–3) asserted by Petitioner.

At this stage of the proceeding, the Board has not made a final determination as to the patentability of any challenged claim or the construction of any claim term.

IV. ORDER

It is hereby:

ORDERED that pursuant to 35 U.S.C. § 314(a), an *inter partes* review of claims 1–5 of the ’734 patent is instituted with respect to all grounds set forth in the Petition; and

FURTHER ORDERED that, pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4(b), *inter partes* review of the ’734 patent shall commence on the entry date of this Order, and notice is hereby given of the institution of a trial.

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