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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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*Ex parte* HASAN KHATIB

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Appeal 2017-011299  
Application 14/074,685  
Technology Center 1600

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Before JEFFREY N. FREDMAN, DEBORAH KATZ, and JOHN G. NEW,  
*Administrative Patent Judges.*

FREDMAN, *Administrative Patent Judge.*

DECISION ON APPEAL

This is an appeal<sup>1,2</sup> under 35 U.S.C. § 134 involving claims to a method of genetically selecting cattle for increasing milk fat yield or milk fat percentage. The Examiner rejected the claims as indefinite, directed to non-statutory subject matter, and anticipated. We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

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<sup>1</sup> Appellant identifies the Real Party in Interest as the Wisconsin Alumni Research Foundation (*see* App. Br. 2).

<sup>2</sup> We have considered and herein refer to the Specification of Aug. 28, 2015 (“Spec.”); Final Office Action of Sept. 12, 2016 (“Final Act.”); Appeal Brief of Mar. 1, 2017 (“App. Br.”); Examiner’s Answer of July 6, 2017 (“Ans.”); and Reply Brief of Sept. 4, 2017 (“Reply Br.”)

*Statement of the Case*

*Background*

“Dairy cows are significant investments for dairy farmers, and . . . systematic animal breeding programs and artificial insemination, have been and continue to be invested in ensuring that the . . . milk produced is of high quality or has desired composition” (Spec. ¶ 4). “[S]election based purely on phenotypic characteristics does not efficiently take into account genetic variability caused by complex gene action and interactions, and the effect of environmental and developmental variants” (Spec. ¶ 6). “Marker-assisted selection can lower the high cost and reduce the extended time commitment . . . [t]herefore, there is [] a need for genetic markers for improved milk production traits” (Spec. ¶ 7).

*The Claims*

Claims 20–26, 29, and 30 are on appeal. The Examiner has withdrawn the rejections of claims 20–26 (Final Act. 2; Ans. 11). Claims 29 and 30 remain under review (Reply Br. 2).

Independent claim 29 is representative and reads as follows:

29. A method for increasing milk fat yield or milk fat percentage of dairy cattle, the method comprising determining the nucleotide identity of position 213 of the bovine signal transducer and activator of transcription (STAT1) gene of a cow, wherein the STAT1 gene comprises a nucleotide sequence of SEQ ID NO: 2, and using a cow which has cytosine at the position for milk production.

*The Issues*

A. The Examiner rejected claims 29 and 30 under 35 U.S.C. § 112 (pre-AIA), second paragraph as being indefinite (Final Act. 4–6; Ans. 2).

B. The Examiner rejected claim 29 under 35 U.S.C. § 102(e) as being anticipated by Raadsma<sup>3</sup> (Final Act. 14–17; Ans. 8–11).

C. The Examiner rejected claims 29 and 30 under 35 U.S.C. § 101, as being directed to non-statutory subject matter (Final Act. 8–13; Ans. 3–8).

A. *35 U.S.C. § 112, second paragraph*

The Examiner finds the recitation of “using a cow which has cytosine at the position for milk production” in claim 29 “vague and unclear” (Ans. 3). In particular, the Examiner finds that “[i]t is unclear if merely breeding [a] cow is considered using it for milk production or if it requires something in addition to breeding” (*id.*).

Appellant further contends that “claim 29 does not recite a breeding step” and that “there is simply nothing unclear to one of ordinary skill[] in the art in regard to using a cow for milk production” (App. Br. 8).

Appellant’s position is consistent with the claim language. Claim 29 is directed to a method for increasing milk fat yield or milk fat percentage of dairy cattle including the step of using a cow for milk production. The plain meaning of the claim requires the production of milk, i.e., milking, as would be recognized by one of ordinary skill in the art. While the scope of the claim allows for a broad range of activities, “breadth is not to be equated with indefiniteness.” *In re Miller*, 441 F.2d 689, 693 (CCPA 1971).

*Conclusion of Law*

The evidence of record does not support the Examiner’s conclusion that claim 29 is indefinite.

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<sup>3</sup> Raadsma et al., WO 2007/050735 A2, published May 3, 2007.

*B. 35 U.S.C. § 102(e) over Raadsma*

The Examiner finds “Raadsma teaches the 200 nucleotide sequence of SEQ ID NO 14915 [page 8] which comprises a portion of the claimed SEQ ID NO 2 with a Y at position 213 which encompasses a T, U, or C” (Ans. 9). The Examiner further finds “Raadsma teaches selecting an animal for milk fat yield, which anticipates the breadth of the using step of the claim . . . [abstract, page 7]” (Ans. 11; *see also* Ans. 16, citing Raadsma abstract, pages 2, 7, 8).

The issue with respect to the rejection is: Does a preponderance of the evidence of record support the Examiner’s conclusion that Raadsma anticipates claim 29?

*Findings of Fact*

1. Raadsma teaches a method for managing an animal, wherein said animal is selected according to the method of any one of the first to twentieth aspects.

The management of the animal may comprise determining whether the animal is to be used for breeding purposes or production purposes . . . . This determination may be made in the context of any one of the traits selected from . . . milk fat yield

(Raadsma 7:4–10).

2. Raadsma teaches “[t]he methods of the invention are applicable to animals including but not limited to cattle” (Raadsma 7:32–33).

3. Raadsma teaches a “second aspect” as:

a method for selecting an animal for milk fat yield, wherein said method comprises:

(a) analyzing a nucleic acid sample from said animal for a polymorphism in at least one genetic marker selected from the group set out in Table 2; and

(b) selecting the animal based on the presence or absence of the polymorphism in the at least one genetic marker, wherein the polymorphism is predictive of milk fat yield.

(Raadsma 2:11–17).

4. Raadsma teaches: “a sequence listing of SEQ ID NOS: 1–15380 reflecting the identity of the genetic markers referred to herein, including details of relevant polymorphisms and flanking sequence of [the] same” (Raadsma 8:11–14).

5. Raadsma teaches SEQ ID NO. 14915 as a genetic marker having a positive value for fat yield in Table 2 (*see* Raadsma 16:2–11; 108:1; 118, col. 6).

#### *Principles of Law*

The Examiner bears the initial burden of establishing a prima facie case of anticipation. *In re King*, 801 F.2d 1324, 1326–27 (Fed. Cir. 1986). Anticipation under 35 U.S.C. § 102 requires that “each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999).

#### *Analysis*

We adopt the Examiner’s findings of fact and reasoning regarding the scope and content of the prior art (Ans. 8–11; FF 1–5) and agree that the claim is anticipated by the prior art. We address Appellant’s arguments below.

Appellant contends

[t]here is . . . no mention whatsoever in Raadsma that a particular SNP is correlated with desired high milk fat content . . . Raadsma does not in any way teach or suggest that the

sequence has any biological meaning, not to mention a milk production method based thereupon

(Reply Br. 9).

We find this argument unpersuasive because Raadsma teaches selecting cattle for milk fat yield (FF 1–3) wherein specific genetic markers, such as SEQ ID NO. 14915, which includes a cytosine at position 213 of the STAT1 gene, are correlated with a positive value for milk fat yield (FF 5).

Appellant contends that “the ‘using a cow for milk production’ recitation is not indefinite,” and is therefore, a required element of the claim. (App. Br. 12). As part of this discussion, Appellant argues that as long as the steps of claim 29 are performed, “the resultant cows will necessarily have the trait of improved or increased milk yield production” (App. Br. 7). As discussed above, we agree with Appellant that the recitation is not indefinite; however, we find that this element is taught in the prior art.

In particular, Raadsma teaches managing cattle by “determining whether the animal is to be used for breeding purposes or production purposes” based on genetic traits, including milk fat yield (FF 1, 2). Because Raadsma teaches using a cow for milk production based on genetic traits, including the cytosine substitution at position 213 of the STAT1 gene, any resulting increase in milk fat yield is an inherent result of the known use. “‘Newly discovered results of known processes directed to the same purpose are not patentable because such results are inherent.’” *In re Montgomery*, 677 F.3d 1375, 1381 (Fed. Cir. 2012).

#### *Conclusions of Law*

A preponderance of the evidence of record supports the Examiner’s conclusion that claim 29 is anticipated.

C. 35 U.S.C. § 101, non-statutory subject matter

The Examiner finds that claim 29 is directed to “a naturally occurring correlation between a cytosine at a position corresponding to position 213 of SEQ ID NO 2 with improving milk fat yield or milk fat percentage” (Ans. 4). The Examiner finds “[w]hile this correlation was identified by applicants in the accompanying specification, the correlation existed in nature prior to the discovery of the claimed correlation or judicial exception by applicants” (Ans. 5). The Examiner further finds

the claim provides routine, conventional, well understood steps [in] addition to the natural correlation or judicial exception. These steps are generic as they provide no specific reagents, conditions, or guidance such [that] these additional steps fail to provide a further inventive concept.

...

Further, the claims do not recite any elements or steps that do more than describe the judicial exceptions with instructions for applying it.

(Ans. 6). The Examiner concludes “the claims are not considered to recite something significantly different than a judicial exception and thereby are not directed to patent eligible subject matter” (Ans. 8).

The issue with respect to this rejection is: Does the evidence of record support the Examiner’s conclusion that claim 29 is directed to non-statutory subject matter?

*Findings of Fact*

6. The Specification teaches “[t]he present invention relates to a method of cattle progeny testing using molecular genetic methods by assaying for the presence of at least one genetic marker which is indicative of . . . milk fat content” (Spec. ¶ 3).

7. The Specification teaches “[b]y direct sequencing of genomic DNA, a single nucleotide polymorphism (SNP) in the EST corresponding to *STAT1* (GenBank accession number AW289395) at position 213 was identified” (Spec. ¶ 80).

8. The Specification teaches that prior art data was used to conduct an analysis of milk properties, specifically “[d]aughter yield deviations (DYD) data for milk yield, milk protein and fat yields, milk protein and fat percentages, . . . were obtained from the Animal Improvement Programs Laboratory” and “[w]eighted least squares analysis was employed to study the effects of *STAT1* variants on production and function traits” (Spec. ¶¶ 80, 81).

9. The Specification teaches that “[t]he observed effects of the bovine *STAT1* on milk composition . . . was not surprising because” of prior art associations of STAT1 with the hormone prolactin (Spec. ¶¶ 83–85).

10. The Specification teaches “a significant association between different haplotypes of the protease inhibitor gene and several production traits in Holstein dairy cattle including milk yield, milk fat yield . . . was found (Khatib et al. 2005). Using this approach *STAT1* was chosen as a candidate gene affecting milk production traits” (Spec. ¶ 87).

### *Principles of Law*

[W]e set forth a framework for distinguishing patents that claim laws of nature, natural phenomena, and abstract ideas from those that claim patent-eligible applications of those concepts. First, we determine whether the claims at issue are directed to one of those patent-ineligible concepts. If so, we then ask, “[w]hat else is there in the claims before us?” To answer that question, we consider the elements of each claim both individually and “as an ordered combination” to determine whether the additional elements “transform the nature of the

claim” into a patent-eligible application. We have described step two of this analysis as a search for an “inventive concept” —*i.e.*, an element or combination of elements that is “sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the [ineligible concept] itself.”

*Alice Corp. Pty. Ltd. v. CLS Bank Int’l*, 134 S. Ct. 2347, 2355 (2014).

We agree with and adopt the Examiner’s findings of fact and reasoning regarding the conclusion that claim 29 is unpatentable as being directed to non-statutory subject matter consistent with binding precedent (Ans. 4–8; FF 1–10). We address Appellant’s arguments below.

Appellant contends

even though the two claims under review recite a naturally occurring phenomenon (a correlation between a particular SNP and the milk production ability of the dairy cow having such a SNP), they also recite additional elements or steps, which, *when viewed as a whole*, add meaningful limits on the use of the correlation. The totality of these steps integrates the correlation into the claimed methods, and amounts to more than merely detecting the SNP, and instructing a breeder or a dairy farmer to “apply it.”

(Reply Br. 7).

We do not find this argument persuasive because Appellant fails to identify how the additional steps, when viewed as a whole, add meaningful limits on the use of the correlation. Applying the first step of the two step test in *Mayo* and *Alice*, we agree with the Examiner that the correlation between cytosine at position 213 of the STAT1 gene and increased milk fat yield/percentage is directed to a patent ineligible concept, specifically natural laws regarding genetic information that controls milk production in cows. The method of increasing (*i.e.*, optimizing) milk fat yield/percentage by identifying a natural correlation is factually similar to *Mayo*, where the

“method of optimizing therapeutic efficacy” was based on identifying naturally occurring levels of thioguanine. *See Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 74 (2012). Like *Mayo*, the relation between the naturally occurring SNP and increased milk production “exists in principle apart from any human action” and is a consequence of “entirely natural processes.” *Id.* at 77.

Appellant contends that “the combination of steps, *when viewed as a whole*, is not routine and conventional, and ensures that the selected dairy cattle [] possess unexpected, inventive characteristics, as opposed to dairy cattle not subjected to such selection” (Reply Br. 7–8).

We do not find Appellant’s argument persuasive. “*Mayo* demanded that, when a claim involves . . . a law of nature . . . eligibility under section 101 requires that the claim involve ‘enough’ else—applying the idea in the realm of tangible . . . physical actions (for process claims)—that is beyond ‘well-understood, routine, conventional activity.’” *SmartGene, Inc. v. Advanced Biological Laboratories, SA*, 555 F. App’x 950, 955 (Fed. Cir. 2014).

Under the second step of the two-step test, we find that claim 29 does not add “significantly more” to the natural law of milk production in dairy cattle. Each step of claim 29 is a routine, prior art, conventional activity as acknowledged by Appellant’s own Specification and evidenced by Raadsma. For example, the step of determining the nucleotide identify uses known sequencing techniques (FF 3, 7). The step of correlating the effects of STAT1 variants relies on known statistical techniques and a prior art dataset (FF 3–5, 8). The “selecting” step of using a cow which has cytosine at the position for milk production simply refers to the conventional process of

using cattle based on phenotypes that had already been catalogued in the prior art dataset (FF 3–5, 8). Thus, Appellant does not identify an inventive concept that is more than applying routine, conventional steps to a natural phenomenon specified at a high level of generality. *See Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1378 (Fed. Cir. 2015).

Appellant contends that “[c]laim 29 recites a milk production method, and *is only one of the many possible aspects of how the correlation can be applied*, thus does not preempt its application. Claim 30 further limits the use [to] homozygous cows” (Reply Br. 8).

We find this argument unpersuasive because “[w]hile preemption may signal patent ineligible subject matter, the absence of complete preemption does not demonstrate patent eligibility.” *Ariosa*, 788 F.3d at 1379.

Importantly, the preemption concern is addressed by the two-part test considered above. *See id.* After all, every patent “forecloses . . . future invention” to some extent, *Mayo*, 566 U.S. at 86, and, conversely, every claim limitation beyond those that recite the abstract idea limits the scope of the preemption.

#### *Conclusion of Law*

The evidence of record supports the Examiner’s conclusion that claim 29 is directed to non-statutory subject matter.

### SUMMARY

In summary, we reverse the rejection of claims 29 and 30 under 35 U.S.C. § 112, second paragraph.

We affirm the rejection of claim 29 under 35 U.S.C. § 102(e) as anticipated by Raadsma.

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We affirm the rejection of claim 29 under 35 U.S.C. § 101, as being directed to non-statutory subject matter. Claim 30 falls with claim 29.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED