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EXAMINER

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte JERE W. McBRIDE and CHRISTOPHER KUYLER DOYLE¹

Appeal 2015-006282
Application 12/377,926
Technology Center 1600

Before DONALD E. ADAMS, RYAN H. FLAX, and DAVID COTTA,
Administrative Patent Judges.

FLAX, *Administrative Patent Judge.*

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134(a) involving claims directed to a composition, isolated antibody, or kit. Claims 1, 8, 36, 37, 55, 58–60, and 64–68 are on appeal as rejected under 35 U.S.C. § 101. We have jurisdiction under 35 U.S.C. § 6(b).

We reverse.

¹ We understand the Real Party in Interest to be Research Development Foundation. App. Br. 3.

STATEMENT OF THE CASE

The appealed claims can be found in the Claims Appendix of the Appeal Brief. Claims 1, 36, and 55 are the independent claims. Claims 1 and 36 are representative and read as follows:

1. A composition comprising an isolated polypeptide that is from 24 to 75 amino acids in length, said polypeptide being selected from the group consisting of:

(a) an isolated polypeptide comprising SEQ ID NO:13; and

(b) an isolated polypeptide that is at least 95% identical to SEQ ID NO:13;

wherein the isolated polypeptide is bound to a solid support or a detectable label.

36. An isolated antibody that recognizes and binds immunologically to a polypeptide that consists of SEQ ID NO:13 or a polypeptide that is at least 95% identical to such a polypeptide, wherein the antibody is either bound to a solid support or a detectable label.

App. Br. 11 (Claims App'x).

The following rejections are on appeal:

Claims 1, 8, 55, 58–60, and 64 stand rejected under 35 U.S.C § 101 as directed to patent eligible subject matter. Final Action 4.

Claims 36, 37, 55, and 65–68 stand rejected under 35 U.S.C § 101 as directed to patent eligible subject matter. Final Action 5.

DISCUSSION

We address both patent eligibility rejections together because they turn largely on the same facts and determinations by the Examiner.

The Examiner determined that the claims are directed to patent ineligible subject matter as natural phenomena, i.e., law of nature/natural principles, and do not recite additional elements so as to confer patent eligibility. Final Action 4–5. The Examiner determined that the recited polypeptide, e.g., a naturally occurring *E. canis* polypeptide, and the recited antibody, e.g., an antibody naturally occurring in body fluids of a patient with *E. canis* infection, are mere products of nature. *Id.* Further, the Examiner determined that the recited “solid support” and “detectable label” are also directed to naturally occurring things, e.g., a stone or rock, and colored elements, respectfully, and so, fail to make the claimed subject matter “markedly different” from what occurs in nature. *Id.*

In analyzing patent eligibility questions under 35 U.S.C. § 101, the Supreme Court instructs us to “first determine whether the claims at issue are directed to a patent-ineligible concept.” *Alice Corp. Pty. Ltd. v. CLS Bank Int’l*, 134 S. Ct. 2347, 2355 (2014). If this threshold is met, we move to a second step of the inquiry and “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.” *Id.* (quoting *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1297 (2012)).

Here, the claims are directed to a combination of a polynucleotide and either a solid structure or a detectable label, but not merely as components packaged together, they are “bound” together to form a unit. The question under *Alice*’s first step turns on this claim term and is whether these *bound* components are mere products of nature. We note, “[a]t some level, ‘all

inventions . . . embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas,” and whether one takes a macroscopic or microscopic view of a claim may be determinative on the issue. *Alice*, 134 S. Ct. at 2354 (quoting *Mayo*, 132 S. Ct. at 1293); and *see Amdocs (Israel) Ltd. v. Openet Telecom, Inc.*, --- F.3d ---, 2016 WL 6440387 *9 (Fed. Cir. Nov. 1, 2016).

Although, as the Examiner determined, the individual components recited by the claims, arguably, can be naturally occurring things, the Examiner has not provided evidence that these things would be found naturally-bound to one another. Looking to the Specification to ascertain the meaning of “bound” as used in the claims, we find it retains its plain meaning, which is, e.g., attached to, linked to and/or immobilized with respect to one another. *See, e.g.*, Spec. ¶¶ 94 (“label may be attached”), 224, 262, (“antibody is linked to a detectable label”), 271 (“imaging moieties are bound to the antibody using linkers”), 276, 288 (“immobilized onto the well surface”), and 303. The Examiner identifies examples of natural solid surfaces, such as charcoal, sand, rock, and glass, in asserting that this claimed component is, individually, merely a product of nature. *See, e.g.*, Ans. 10–11. Also, the Examiner points to “naturally fluorescent elements, natural stains, dyes, enzymes naturally occurring,” as examples of natural detectable labels. *See, e.g.*, Ans. 15.

While it may be reasonably argued that these things identified by the Examiner may fall within the broadest reasonable interpretation of the respective claim terms’ scope when the terms are considered in isolation, the Examiner has not expressly identified how a bound unit comprising either of

these additional components and the recited polynucleotide or antibody is found in nature. The Examiner cites to several references (Ans. 10–15)² as support for the proposition that proteins may be naturally affixed to solid supports or labels by non-covalent adsorption, but in each case the affixing is the result of human intervention and is not a natural occurrence.

The Examiner points to the Supreme Court’s decision in *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 131 (1948), as support for the proposition that “[t]he combination of natural products or judicial exceptions does not make the resulting combination patent eligible.” Ans. 13. The facts distinguish the present case from *Funk Brothers*, where the claims were directed to the mere packaging of a plurality of selected, naturally occurring strains of different bacteria that were mutually non-inhibitive. Here, the individual components are *bound* together to form an immunogenic unit that is not naturally occurring. Here, the “discovery is not nature’s handiwork” and “accordingly it is patentable subject matter under § 101.” *Diamond v. Chakrabarty*, 447 U.S. 303, 310 (1980). Here, the polynucleotide (or antibody) and either the solid support or the detectable label are bound together; whether they are bound by a chemical bond where atoms share electrons or by non-covalent attractions, they are nevertheless

² The Examiner cites, e.g., U.S. Patent Application Pub. No. US 2009/0081708 A1 (published Mar. 26, 2009); U.S. Patent No. US 7,427,659 B2 (issued Sept. 23, 2008); U.S. Patent Application Pub. No. US 2005/0010059 A1 (published Jan. 13, 2005); U.S. Patent Application Pub. No. US 2015/0044705 A1 (published Feb. 12, 2015); and U.S. Patent No. 5,302,715 (issued Apr. 12, 1994).

bound together to form a new and non-natural composition and the Examiner provides no persuasive evidence to the contrary.

The first threshold under *Alice* is not met, that is, the claimed subject matter is not directed to a natural product. *See Alice*, 134 S. Ct. at 2355. The Examiner has not identified where in nature one might find a polynucleotide of SEQ ID NO:13 (or 95% thereof), or an antibody to such a polynucleotide, bound to a solid surface or to a detectable label; therefore, we find the claimed invention, considered as an ordered combination, is not merely the routine or conventional use of technology and is patent eligible. *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013).

SUMMARY

The rejection of claims 1, 8, 55, 58–60, and 64 under 35 U.S.C § 101 is reversed.

The rejection of claims 36, 37, 55, and 65–68 under 35 U.S.C § 101 is reversed.

REVERSED