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UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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*Ex parte* PREETI G. LAL, JENNIFER L. JACKSON, NEIL C. CORLEY,  
KARL J. GUEGLER, MARIAH R. BAUGHN,  
SUSAN K. SATHER, and PURVI SHAH

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Appeal 2015-008196  
Application 14/177,534  
Technology Center 1600

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Before DEMETRA J. MILLS, JOHN G. NEW, and DAVID COTTA,  
*Administrative Patent Judges.*

MILLS, *Administrative Patent Judge.*

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134. The Examiner has rejected the claims for lack of utility, lack of enablement, anticipation and obviousness. We have jurisdiction under 35 U.S.C. § 6(b).

We affirm.

STATEMENT OF CASE

The following claim is representative.

27. An isolated antibody or fragment thereof which specifically binds to a human signal peptide-containing protein (SIGP) consisting of the amino acid sequence of SEQ ID NO:9.

App. Br. 13 (Claims Appendix).

*Cited References*

Young                      6,620,912 B2                      Sept. 16, 2003

Grounds of Rejection

1. Claims 27–34 and 36 are rejected under 35 U.S.C. § 101 because the claimed invention is not supported by either a specific or substantial asserted utility or a well-established utility.
2. Claims 27–34 and 36 are also rejected under 35 U.S.C. §112, first paragraph, as failing to adequately teach how to use the instant invention for those reasons given above with regard to the rejection of these claims under 35 U.S.C. §101.
3. Claims 27–34 are rejected under pre-AIA 35 U.S.C. § 102(b) as being anticipated by Young.
4. Claim 36 is rejected under pre-AIA 35 U.S.C. § 103(a) as being unpatentable over Young.

## FINDINGS OF FACT

The Examiner's findings of fact are set forth in the Answer at pages 3–15.

## PRINCIPLES OF LAW

In making our determination, we apply the preponderance of the evidence standard. *See, e.g., Ethicon, Inc. v. Quigg*, 849 F.2d 1422, 1427 (Fed. Cir. 1988) (explaining the general evidentiary standard for proceedings before the Office).

Section 101 requires a utility that is both substantial and specific. A substantial utility requires

show[ing] that an invention is useful to the public as disclosed in its current form, not that it may prove useful at some future date after further research. Simply put, to satisfy the “substantial” utility requirement, an asserted use must show that that claimed invention has a significant and presently available benefit to the public.

*In re Fisher*, 421 F.3d 1365, 1371 (Fed. Cir. 2005). A specific utility is “a use which is not so vague as to be meaningless.” *Id.* In other words, “in addition to providing a ‘substantial’ utility, an asserted use must also show that that claimed invention can be used to provide a well-defined and particular benefit to the public.” *Id.*

The uses asserted in *Fisher* were neither substantial nor specific. They were not substantial because “all of Fisher’s asserted uses represent merely hypothetical possibilities, objectives which the claimed ESTs, or any EST for that matter, *could* possibly achieve, but none for which they have been used in the real world.” *Id.* at 1373. “Consequently, because Fisher failed to prove that its claimed ESTs can be

successfully used in the seven ways disclosed in the ‘643 application, we have no choice but to conclude that the claimed ESTs do not have a ‘substantial’ utility under § 101.” *Id.* at 1374.

The uses disclosed in Fisher were also found not to be “specific.” The Court explained:

Fisher’s seven asserted uses are plainly not “specific.” Any EST transcribed from any gene in the maize genome has the potential to perform any one of the alleged uses. . . . Nothing about Fisher’s seven alleged uses set the five claimed ESTs apart from the more than 32,000 ESTs disclosed in the ‘643 application or indeed from any EST derived from any organism. Accordingly, we conclude that Fisher has only disclosed general uses for its claimed ESTs, not specific ones that satisfy § 101.

*Id.*

## ANALYSIS

### I

The pending application is a divisional of application no. 13/620,526 which is a division of application no. 11/386,937 (“the ‘937 Application”). The ‘937 Application was ultimately appealed to the Board. *See*, Appeal No. 2011-005611, decided Aug. 29, 2012. Where the present application includes claims to antibodies that bind a peptide having the amino acid sequence of SEQ ID NO:9, the ‘937 Application included very similar claims drawn to a polynucleotide encoding a polypeptide having the amino acid sequence of SEQ ID NO:9. The Examiner similarly found in the ‘937 Application that, “the claimed invention is not supported by either a specific or substantial asserted utility or a well-established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed

Appeal 2015-008196  
Application 14/177,534

invention so that it would operate as intended without undue experimentation.” ‘937 Ans. 8. In the ‘937 Application, the Board affirmed the Examiner’s 35 U.S.C. § 101 and 35 U.S.C. § 112, first paragraph rejections as well as prior art rejections over Young.

## II

In the present case, we agree with the rejections and responses to Appellants’ arguments that are set out in the Final Action and Examiner’s Answer, and therefore adopt the Examiner’s findings and reasoning as our own. We provide the following additional comment to the Examiner’s argument set forth in the Final Rejection and Answer.

We agree with the Examiner that the

asserted utilities related to the protein, and therefore to the antibody which binds the protein, are not considered to be specific and substantial because the specification fails to disclose any particular function or biological significance for the signal peptide-containing protein (SEQ ID N0:9) and therefore the claimed antibody also lacks utility. The instant specification fails to make any assertions regarding biological activity for the polypeptide of SEQ ID N0:9 or provide for an asserted use in a method of treating cancer based on this statement of structural similarity or for the antibody which binds it.

Final Act. 3.

Appellants allege that

The present application provides numerous utilities for the claimed antibody against the polypeptide of SEQ ID N0:9, among which is its ability to identify the polypeptide of SEQ ID N0:9 as a marker for reproductive, gastrointestinal, hematopoietic and immune tissues. The specification discloses that northern analysis was used to

determine the expression of SIGPs in 17 different types of tissue: reproductive, gastrointestinal, cardiovascular, bladder, breast, brain, dermal, developmental, endocrine, hematopoietic, immune, muscle, musculoskeletal, neural, spleen, thyroid and urologic tissues. See specification at pages 30-77.

Br. 7. We are not persuaded.

Just as in *Fisher*, cited above, Appellants' alleged uses are plainly not "substantial." A substantial utility requires "show[ing] that an invention is useful to the public as disclosed in its current form, not that it may prove useful at some future date after further research." Simply put, to satisfy the "substantial" utility requirement, an asserted use must show that that claimed invention has a significant and presently available benefit to the public. *In re Fisher*, 421 F.3d 1365, 1371 (Fed. Cir. 2005). Here, we find that the claims are drawn to an antibody which binds a protein of as yet undetermined significance. Accordingly we find that the claimed antibody does not provide a significant and presently available benefit to the public.

Appellants' alleged uses are also not "specific." A specific utility is "a use which is not so vague as to be meaningless." *Id.* In other words, "in addition to providing a 'substantial' utility, an asserted use must also show that that claimed invention can be used to provide a well-defined and particular benefit to the public." *Id.* Similar to the EST's disclosed in *Fisher*, we find that Appellants have only disclosed general uses for its claimed antibody, not specific ones that satisfy § 101.

Each of the Examiner's rejections is affirmed for the reasons of record. We note that our affirmance of the Examiner's rejection for lack of utility dictates that we also affirm the Examiner's rejection for lack of enablement. *See, Fisher*, 421 F.3d at 1378 ("It is well established that the enablement requirement of § 112 incorporates the utility requirement of §

Appeal 2015-008196  
Application 14/177,534

101.”). We further note that Appellants challenge to the Examiner’s obviousness and anticipation rejections requires that they claim priority to their original application, which they cannot do since their application does not meet the requirements of 35 U.S.C. § 112.

#### CONCLUSION OF LAW

The cited references support the Examiner’s lack of utility, lack of enablement, anticipation and obviousness rejections, which are affirmed for the reasons of record. All pending, rejected claims fall.

#### TIME PERIOD FOR RESPONSE

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