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BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte HARUO SUGIYAMA and YUSUKE OJI

Appeal 2017-010332
Application 13/143,492[1]
Technology Center 1600

Before ERIC B. GRIMES, ELIZABETH A. LAVIER, and RYAN H. FLAX, *Administrative Patent Judges*.

LAVIER, *Administrative Patent Judge*.

DECISION ON APPEAL

Pursuant to 35 U.S.C. § 134(a), Appellants seek review of the Examiner's rejection of claims 20, 22, 24, and 26. We have jurisdiction under 35 U.S.C. § 6(b). For the reasons set forth below, we REVERSE.

BACKGROUND

The Specification relates to methods for detecting cancer and compositions for prevention and treatment of cancer. Spec. ¶ 1. Claim 20 is illustrative:

> 20. A method for the treatment of a cancer in an HLA-A*0201-positive subject, comprising administering to said subject an

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[1] Appellants identify the real party in interest as International Institute of Cancer Immunology. Br. 2.

> effective amount of an eEF2 peptide consisting of an amino acid sequence composed of contiguous amino acids of an eEF2 protein, wherein the amino acid sequence is selected from the group consisting of:
>
> (a) Leu Ile Leu Asp Pro Ile Phe Lys Val (SEQ ID NO:14); and
>
> (b) an amino acid sequence of SEQ ID NO: 14 having a substitution or substitutions of the amino acid Ile at position 2 with Leu or Met and/or a substitution of the amino acid Val at position 9 with Leu, wherein the eEF2 peptide retains a binding ability to the HLA-A*0201 molecule.

Claims Appendix 3.[2]

REJECTION MAINTAINED ON APPEAL

Claims 20, 22, 24, and 26 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. Ans. 3.

DISCUSSION

The appealed claims are directed to a method of treating cancer, but the Specification's supporting data are derived from *in vitro*, not *in vivo*, studies. In the Examiner's view, the Specification's *in vitro* data are not sufficient to enable the appealed claims:

> applicant provides a multitude of examples. Some of the example[s] show the use of SEQ ID NO. 14 and show its binding to HLA-A*0201 and the peptide[']s ability to increase cytotoxic activity in vitro and increase IFN-gamma activity in vitro. Additionally, Table 21 shows that the peptides having the substitutions of L or M for position 2 and L for position 9 also retain the same activity. The data provided is limited to in vitro use yet the claims are directed to in vivo use. There is no

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[2] The Claims Appendix is appended to the Appeal Brief, and is separately paginated.

> objective evidence to show the correlation of the in vitro data to use in vivo.

Non-Final Action 3;[3] *see also* Ans. 10.

As Appellants point out, the Examiner does not challenge the Specification's enablement of how to make the recited peptides, or how to administer them. *See* Br. 6. "Rather the focus of the enablement rejection is on whether the recited peptides would be reasonably expected to be effective in treating cancer in an HLA-A*0201-positive subject." *Id.* As such, the present appeal presents the same basic question addressed by the Federal Circuit in *In re Brana*, 51 F.3d 1560, 1564 (Fed. Cir. 1995): "what must the applicant prove regarding the practical utility or usefulness of the invention for which patent protection is sought"? For the *Brana* court and the present appeal, this issue of utility is an aspect of the enablement requirement under § 112,[4] because "[o]bviously, if a claimed invention does not have utility, the specification cannot enable one to use it." *Id.* The *Brana* court made it clear that evidence of clinical efficacy is *not* a prerequisite:

> Usefulness in patent law, and in particular in the context of pharmaceutical inventions, necessarily includes the expectation of further research and development. The stage at which an invention in this field becomes useful is well before it is ready to be administered to humans. Were we to require Phase II testing in order to prove utility, the associated costs would prevent many companies from obtaining patent protection on promising new inventions, thereby eliminating an incentive to

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[3] Non-Final Action dated Oct. 24, 2016.
[4] The rejection on appeal in *Brana* was based on 35 U.S.C. § 112, first paragraph, not 35 U.S.C. § 101. *See Brana*, 51 F.3d at 1362.

> pursue, through research and development, potential cures in many crucial areas such as the treatment of cancer.

Id. at 1568.

The burden of establishing a prima facie case of non-enablement rests with the Examiner. *See In re Wright*, 999 F.2d 1557, 1561–62 (Fed. Cir. 1993). Where the asserted lack of enablement is premised on lack of utility,

> the PTO has the initial burden of challenging a presumptively correct assertion of utility in the disclosure. Only after the PTO provides evidence showing that one of ordinary skill in the art would reasonably doubt the asserted utility does the burden shift to the applicant to provide rebuttal evidence sufficient to convince such a person of the invention's asserted utility.

Brana, 51 F.3d at 1566 (citations omitted).

The evidence cited by the Examiner in support of the present rejection (*see generally* Non-Final Action 4–6) might suffice if absolute predictability were the standard for enablement. But it is not sufficient to undermine the reasonable correlation Appellants draw between their *in vitro* results and *in vivo* efficacy, as evinced by the data in the Specification[5] as well as the pre-filing supporting references offered in support of the August 20, 2015 Declaration of Dr. Sugiyama. Put differently, by requiring Appellants to support their treatment claims with *in vivo* evidence specific to the claimed peptides, or possibly through some sure-fire correspondence between an *in vitro* assay and *in vivo* efficacy (*see, e.g.,* Ans. 10 ("For a true correlation, the in vitro assay used by appellant should be correlated to in vivo use either by appellant (who shows that the peptide can be effective in vivo) or by a

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[5] Indeed, referring to Appellants' *in vitro* data, the Examiner acknowledges the "multitude of examples" provided in the Specification. Non-Final Action 3.

showing that the compound (any compound that is used in the same in vitro assay as appellant's) can be effective in vivo for the treatment of cancer."), the rejection appears to rely on the erroneous premise that absolute predictability is required to satisfy the enablement requirement of § 112.

Accordingly, on this record, we cannot conclude that the Examiner has established a prima facie case of non-enablement, and we cannot sustain the rejection.

CONCLUSION

The rejection of claims 20, 22, 24, and 26 is reversed.

REVERSED