

The opinion in support of the decision being entered today
is *not* binding precedent of the Board.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte THOMAS E. CAREY, THANKAM S. NAIR,
and JENNIFER GRAY BECKMAN

Appeal 2007-0746
Application 10/139,496
Technology Center 1600

Decided: May 30, 2007

Before TONI R. SCHEINER, ERIC GRIMES, and NANCY J. LINCK,
Administrative Patent Judges.

LINCK, *Administrative Patent Judge*.

DECISION ON APPEAL

This is a 35 U.S.C. § 134 appeal in the above-referenced case.¹

We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

¹ The application was filed May 6, 2002. The real party in interest is the assignee, The University of Michigan.

STATEMENT OF THE CASE

Sensorineural hearing loss (SNHL) “is the result of damage to either the sensory system within the inner ear or the nerves that carry information from the sensory system to the brain.” (Specification (“Spec.”) 1.)

“Autoimmunity is suspected to be a cause of some cases of sudden onset, rapidly progressive or fluctuating hearing loss, particularly when bilateral involvement occurs.” (Spec. 2.)

“Currently there is general consensus among researchers in the field that the target antigen of the hearing loss antibody is a 68 kDa protein found in the inner ear. It has been postulated that the 68 kDa protein is HSP-70,” but “the correlation between the Western blot [for HSP-70] and patient [response] to steroid treatment is low . . .” (Spec. 3.)

The claimed invention in this case “generally relates to a purified novel antigen, Inner Ear Supporting Cell Antigen (IESCA) reactive with an autoantibody associated with autoimmune sensorineural hearing loss (AISNHL), and to methods for predicting the response of AISNHL patients to therapeutic treatment.” (*Id.*) According to Appellants, the “present invention represents a major improvement over existing tests for AISNHL, which identify antibodies to a universally distributed substance [HSP-70] that is not unique to the inner ear and has never been linked to hearing loss.” (Spec. 4.) The specific autoantibody reactive to IESCA required by the claims is KHRI-3 monoclonal antibody.

Claims 1 and 10 are representative of the claimed subject matter:²

1. An immunopurified glycoprotein from the inner-ear organ of Corti reactive with a KHRI-3 monoclonal antibody.
 10. A kit for assaying for the presence of an antibody associated with autoimmune sensorineural hearing loss in a patient, where the kit comprises the glycoprotein of claim 1.

Claims 1, 4-8, and 10 are pending and on appeal. The Examiner has rejected claims 1, 4-8, and 10 under 35 U.S.C. § 112, ¶ 1 for lack of enablement; claims 1 and 4-8 under 35 U.S.C. § 102(b); and claim 10 under 35 U.S.C. § 103(a). The Examiner relies upon the following references:

Harris US 5,422,282 Jun. 6, 1995

Gary Zajic et al., *Monoclonal antibodies to inner ear antigens: I.*

Antigens expressed by supporting cells of the guinea pig cochlea, 52
Hearing Research 59-71 (1991) ("Zajic").

Thankam S. Nair et al., *Identification and Characterization of Choline Transporter-Like Protein 2, an Inner Ear Glycoprotein of 68 and 72 kDa That Is the Target of Antibody-Induced Hearing Loss*, 24 J. Neuroscience 1772-79 (2004) (“Nair”).

Bruce Alberts et al., Molecular Biology of the Cell 163-96, 258-71 (2nd ed. 1998) (“Alberts”).

² Appellants do not separately argue the claims. Thus, we address the § 112, ¶ 1 and § 102(b) issues with reference to claim 1; and we address the § 103(a) issue with reference to claim 10, the sole claim rejected under this section.

ENABLEMENT UNDER § 112, ¶ 1

The Enablement Issue

According to the Examiner:

The monoclonal antibody, KHRI-3 recited in claim 3 is essential to the claimed invention. The reproduction of monoclonal antibodies is an extremely unpredictable event. The monoclonal antibody KHRI-3 and hybridoma producing said monoclonal antibody, disclosed in the specification, must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. The instant specification does not disclose a repeatable process to obtain the hybridoma producing monoclonal antibody KHRI-3, and it is not apparent if the hybridoma is readily available to the public.

(Answer 3-4.)

The Examiner indicated this ground of rejection could be overcome by making a deposit pursuant to 37 C.F.R. §§ 1.801-.809. The Examiner emphasized that a deposit made after the filing date would require a statement that “the deposit is identical to the biological material described in the specification and in the applicant’s possession at the time the application was filed.” (Answer 5.) The Examiner’s position is based on Rule 804(b):

When the original deposit is made after the effective filing date of an application for patent, the applicant must promptly submit a statement from a person in a position to corroborate the fact, stating that the biological material which is deposited is a biological material specifically identified in the application as filed.

37 C.F.R. § 1.804(b).

In their Appeal Brief, Appellants do not argue their Specification is enabling. (*See Br. passim.*³) Rather, they rely on a biological deposit:

Appellants deposited murine hybridom[a]-mouse (BalbC) spleen cells/SP-2.0 myeloma: KHRI-3 to the ATCC, Manassas, VA, on October 18, 2005. The deposit was accepted and assigned Patent Deposit Designation PRA-7169, February 18, 2006.

It is respectfully submitted that Appellants' agreement to deposit hybridoma cells that produce KHRI-3 monoclonal antibodies renders the Examiner's arguments moot.

Appellants respectfully request that the rejection be withdrawn.

(Br. 6-7.)

Given these conflicting positions of the Examiner and Appellants, we frame the enablement issue as follows: Have the Appellants satisfied the enablement requirement of § 112, ¶ 1, by meeting the biological deposit requirements of 37 C.F.R. §§ 1.801-.809?

Findings of Fact Relating to the Deposit Issue

1. “Appellants deposited murine hybridom[a]-mouse (BalbC) spleen cells/SP-2.0 myeloma: KHRI-3 to the ATCC, Manassas, VA, on October 18, 2005.” (Br. 6. *See also ATCC International Form.*)
2. “The deposit was accepted and assigned Patent Deposit Designation PRA-7169, February 18, 2006.” (Br. 7. *See also ATCC International Form.*)

³ In their Reply Brief, Appellants state, without citation to the record: “[T]he specification clearly describes reproducible methods to make KHRI-3 antibody. Thus, one of skill in the art, utilizing teachings of the present invention, is able to reproducibly generate KHRI-3 antibody.” (Reply Br. 8.) We disagree with this statement but otherwise do not address the merits of the enablement rejection.

3. Appellants have not identified any submission containing “a statement from a person in a position to corroborate the fact, stating that the biological material which is deposited is a biological material specifically identified in the application as filed.” 37 C.F.R. § 1.804(b). (*See Br. passim & Reply Br. passim.*)

4. In spite of making their deposit on October 18, 2005, Appellants have not yet submitted an amendment to their Specification to satisfy the requirements of 37 C.F.R. § 1.809(d) (2006).

Discussion of the Deposit Issue

We affirm the Examiner’s rejection under § 112, ¶ 1, based on Appellants’ failure to perfect their deposit. See Findings 3 and 4 above. If Appellants submit the appropriate documents and thereby satisfy requirements of 37 C.F.R. §§ 1.801-.809, this ground of rejection should be withdrawn.

PATENTABILITY UNDER §§ 102(b) AND 103(a)

The §§ 102(b) and 103(a) Issue

Our determination of both patentability issues turns on whether Zajic isolated and identified the same glycoprotein as the “immunopurified glycoprotein” claimed by Appellants (See Br. 7-12; Reply Br. 4-7.)

According to the Examiner: Zajic “teaches the immunoprecipitation and Western blotting of guinea pig-inner ear organ of corti tissue, wherein KHRI-3 binds a glycoprotein that is about 65,000 to 68,000 daltons (about broadens the claim to include other proteins of similar size) under non-reducing conditions (see pages 62-64 and Fig. 4). . . .” (Answer 5.) As

noted in the Nair paper, when Zajic's "antigen that is 65-68kDA in size . . . was sequenced the sequence was homologous to CTL2." (Answer 5-6.)

Appellants respond:

Zajic et al. teaches use of KHRI-3 antibody in a Western blotting procedure to identify the presence or absence of protein on a membrane. Specifically, Zajic et al.'s teaching of gel purification (i.e., separating by electrophoresis on a gel matrix by size) of the total population of proteins present within inner-ear organ of Corti tissue, followed by Western blotting (i.e., transferring the total population of size separated proteins present within the gel matrix onto a membrane and using sequential hybridization of primary antibody specific for a protein on the gel (e.g., KHRI-3) followed by a detectable secondary antibody specific for the primary antibody to detect the presence or absence of a protein on the membrane) does not provide an immunopurified protein of the present invention.

(Reply Br. 4-5.)

In view of these positions, we frame this decisive issue: Has the Examiner made a *prima facie* case that the glycoprotein isolated and identified by Zajic is the same glycoprotein as that claimed by Appellants, when the claim language is given its broadest reasonable interpretation, as we are required to do during examination?

Findings of Fact Relating to Patentability Under §§ 102(b) and 103(a)

The Examiner found Zajic discloses the same glycoprotein as is claimed in claim 1 (*see* Answer 5-6).

Appellants dispute this finding. (Br. 7-12; Reply Br. 4-7.)

Claims 1 and 10 are directed to a product, a "glycoprotein" that is "reactive with a KHRI-3 monoclonal antibody," and not a process for immunopurifying the protein.

Giving claim 1 its broadest reasonable interpretation, it does not require any particular level of purification for the glycoprotein, or the separation of any particular protein or other compound from the glycoprotein.

Appellants isolated and purified their claimed glycoprotein, IESCA, “with anti-IESCA monoclonal antibody (MAb) KHRI-3 both by immunoprecipitation and antibody affinity chromatography.” (Spec. 8.)

To the extent Zajic obtained the identical protein, regardless of how purified, it would anticipate the glycoprotein of Appellants’ claims.

Zajic’s “teaching of gel *purification* . . . of the total population of proteins present within inner-ear organ of Corti tissue, followed by Western blotting . . . using sequential hybridization of primary antibody specific for a protein on the gel (e.g., KHRI-3) followed by a detectable secondary antibody specific for the primary antibody to detect the presence or absence of a protein on the membrane,” (Reply Br. 4-5 (emphasis added)), *prima facie* provides Appellants’ claimed glycoprotein, separated from a mixture of other proteins.

With respect to the § 103(a) rejection of claim 10, Appellants do not dispute any claim limitation other than that disputed with respect to the § 102(b) rejection, i.e., the “immunopurified glycoprotein.” (See Br. 11-12; Reply Br. 6-7.)

Discussion of the §§ 102(b) and 103(a) Issues

During examination proceedings, “claims are given their broadest reasonable interpretation consistent with the specification. [This] proposition ‘serves the public interest by reducing the possibility that claims, finally allowed, will be given broader scope than is justified,’ . . . and it is

not unfair to applicants, because ‘before a patent is granted the claims are readily amended as part of the examination process’’ *In re Hyatt*, 211 F.3d 1367, 1372, 54 USPQ2d 1664, 1667 (Fed. Cir. 2000) (internal citations omitted). Upon doing so, we find the claim term “immunopurified glycoprotein” does not exclude a glycoprotein purified by a different process than that used by Appellants, if the resulting protein is the same. Thus, we further find the Examiner has made a *prima facie* case that Zajic’s glycoprotein (which is “reactive with” KHRI-3) is the same glycoprotein as that claimed by Appellants. Appellants have not provided evidence to the contrary.

Appellants argue: “Zajic et al. does not provide for the separation of HSP-70 from the claimed protein, both of which would co-exist in the same or similar location on a Western blot gel.” (Br. 11.) To support this argument, Appellants merely state that HSP-70 and their claimed glycoprotein “would co-exist in the same or similar location on a Western blot gel.” (*Id.*) They have not demonstrated Zajic’s glycoprotein would yield more than one protein when treated according to their procedures. In any case, as presently written, claim 1 does not exclude HSP-70. To the extent Appellants wish to do so, they may by amendment. *See Hyatt*, 211 F.3d at 1372, 54 USPQ2d at 1667.

In effect, Appellants appear to be arguing their claims should be treated as product-by-process claims and thus limited to a glycoprotein that has been purified by a particular process. However, during examination we do not so limit the claims. *See, e.g., In re Thorpe*, 777 F.2d 695, 697, 227 USPQ 964, 966 (Fed. Cir. 1985) (“patentability of a product does not depend on its method of production”). Once the Examiner has identified a prior art

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product appearing to be the same as that claimed, even though made by a different process, the burden shifts to the applicant to prove otherwise. *See id.* at 697, 227 USPQ at 966.

Based upon the above, we affirm the § 102(b) rejection of claim 1.

Appellants' arguments with respect to the § 103(a) rejection of claim 10 mirror those made with respect to the § 102(b) rejection. Thus, we also affirm the rejection of claim 10 under § 103(a).

CONCLUSION

In summary, we affirm the rejection of claim 1 under § 112, ¶ 1, and § 102(b). We also affirm the rejection of claim 10 under § 103(a).

Pursuant to § 41.37(c)(1)(vii)(2006), we also affirm the rejection of claims 4-8, and 10 under § 112, ¶ 1; and claims 4-8 under § 102(b), as these claims were not argued separately.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv)(2006).

AFFIRMED

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