UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte LEE-MING CHUANG and WEN-LING CHOU

Appeal 2008-5143
Application 11/147,849
Technology Center 1600

Decided: November 13, 2008

Before ERIC GRIMES, RICHARD M. LEBOVITZ, and JEFFREY N. FREDMAN, *Administrative Patent Judges*.

FREDMAN, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to an isolated polypeptide encoding a prostaglandin reductase which the Examiner has rejected as anticipated. We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

Background

"Peroxisome proliferator-activated receptors (PPARs) belong to a family of nuclear receptors that regulate lipid and glucose metabolism" (Spec. 1:10-11). The Specification notes that after "activation by either dietary fatty acids or their metabolic derivatives, PPARs trigger a cascade of transcriptional events leading to altered lipid and glucose metabolism" (Spec. 1:12-14). According to the Specification "PPARs are promising therapeutic targets of diseases, e.g., type II diabetes, obesity, dyslipidemia, coronary heart disease, inflammatory disease, and cancer" (Spec. 1:17-19).

Statement of the Case

The Claims

Claims 4 and 20-22 are on appeal.[1] We will focus on claims 4 and 20, which are representative and read as follows:

> 4. An isolated polypeptide, comprising the amino acid sequence of SEQ ID NO: 1.
>
> 20. An isolated polypeptide, comprising a sequence that has at least 95% sequence identity to SEQ ID NO: 1, wherein the polypeptide reduces 15-keto prostaglandin but does not reduce leukotriene B4.

The prior art

The Examiner relies on the following prior art references to show unpatentability:

Kawai et al., *Functional annotation of a full-length mouse cDNA collection*, 409 NATURE 685-690 (2001).

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[1] Claims 13-19 were withdrawn from consideration (*see* App. Br. 1).

Okazaki et al., *Analysis of the mouse transcriptome based on functional annotation of 60,770 full-length cDNAs*, 420 NATURE 563-573 (2002).

The issues

The rejections as presented by the Examiner are as follows:

A. Claims 4 and 20-22 stand rejected under 35 U.S.C. § 102(b), as being anticipated by Kawai (Ans. 4).

B. Claims 4 and 20-22 stand rejected under 35 U.S.C. § 102(b), as being anticipated by Okazaki (Ans. 5).

A. 35 U.S.C. § 102(b) rejection over Kawai

The Examiner contends that "Kawai . . . disclose the isolation of a polynucleotide and encoded polypeptide annotated as a zinc-containing alcohol dehydrogenase superfamily homolog having 100% homology to SEQ ID NO: 1" (Ans. 4). The Examiner argues that "the polypeptide sequence of the three [two?] cited references were used in the rejection and not the cDNA sequence. Thus, the examiner is not saying that a cDNA anticipates a protein but that a conception of an amino acid sequence in [the] prior art anticipates the claimed protein" (*id.* at 7).

Appellants begin by citing "*Wen-Hwa Lee v. Thaddeus P. Dryja*, 79 U.S.P.Q.2d 1614; 2005 WL 3121465, a decision made by the Board of Patent Appeals and Interferences" (App. Br. 2). Appellants rely upon *Wen-Hwa Lee* to argue that a "cDNA is **at most** an equivalent of its encoded protein but does not contain **every element** of the isolated protein encoded thereby" (*id.* at 3). Appellants quote from *Wen-Hwa Lee*:

> "assuming arguendo that it was well within ordinary skill in the art to prepare, isolate and purify the protein product of a given

> cDNA clone at the time the '163 application [the patent application at issue] was filed, the 4.7 kb cDNA described in the '163 specification would have made its encoded protein **obvious at best"**

(App. Br. 3).

Appellants also contend that "disclosure of the cDNA **at best** renders its encoded protein **obvious**. In other words, the fact that a novel product can be readily made does not render the product not novel" (*id.* at 3).

In view of these conflicting positions, we frame the anticipation issue before us as follows:

Does the teaching of the amino acid sequence of SEQ ID NO: 1 by Kawai without a teaching of the expressed protein product anticipate an isolated protein comprising SEQ ID NO: 1?

Findings of Fact (FF)

1. The Examiner states that both Kawai and Okazaki teach "the isolation of a polynucleotide and encoded polypeptide annotated as a zinc-containing alcohol dehydrogenase superfamily homolog having 100% homology to SEQ ID NO: 1" (Ans. 4, 5). This fact is not disputed by Appellants.

2. The Examiner states that the RIKEN/FANTOM database disclosed "the polypeptide sequence having 100% sequence homology to SEQ ID NO:1 . . . Accession # IPR002085, Hit number 18 ID=B83006H24 and the polypeptide sequence with date stamp May 18, 2001" (Ans. 4, 5). This fact is not disputed by Appellants

A. Discussion of 35 U.S.C. § 102(b) over Kawai

We agree with the Examiner that the prior art teaches polypeptide sequences which are 100% identical to those claimed by Appellants (FF 1-2). Appellants have provided no evidence to rebut the teachings identified by the Examiner. Appellants also acknowledge that, in the prior art, "[o]ne of the myriad cDNAs encodes an amino acid sequence identical to SEQ ID NO: 1" (App. Br. 2). While we recognize that the prior art did not physically create the claimed proteins, the Federal Circuit in *Donohue* addressed this issue, noting "[i]t is not, however, necessary that an invention disclosed in a publication shall have actually been made in order to satisfy the enablement requirement." *In re Donohue*, 766 F.2d 531, 533 (Fed. Cir. 1985). *See Bristol-Myers Squibb Co. v. Ben Venue Laboratories, Inc.*, 246 F.3d 1368, 1379 (Fed. Cir. 2001) ("[A]nticipation does not require actual performance of suggestions in a disclosure. Rather, anticipation only requires that those suggestions be enabling to one of skill in the art").

Appellants did not dispute that the prior art of Kawai, in concert with the knowledge of the skilled artisan, was enabling for expression of the isolated polypeptide of claim 4 (*see* App. Br. 3). A reference is presumed to be enabled for the purpose of an anticipation rejection. The burden rests with the Appellants to establish that the prior art is not enabling.

> [P]roof of efficacy is not required for a prior art reference to be enabling for purposes of anticipation. . . . [T]he proper issue is whether the [prior art] is enabling in the sense that it describes the claimed invention sufficiently to enable a person of ordinary skill in the art to carry out the invention.

Impax Labs. v. Aventis Pharms., 468 F.3d 1366, 1383 (Fed. Cir. 2006). "Anticipation does not require the actual creation or reduction to practice of the prior art subject matter; anticipation requires only an enabling disclosure." *Schering Corp. v. Geneva Pharms., Inc.*, 339 F.3d 1373, 1380 (Fed. Cir. 2003) (citing *In re Donohue*, 766 F.2d 531, 533 (Fed. Cir. 1985)). Consequently, we find that the Kawai reference was enabled for the expression of SEQ ID NO: 1 and under *Donohue*, properly anticipates claim 4.

In our opinion, *Wen-Hwa Lee*, cited by Appellants, differs from the facts in this case in several ways. First, *Wen-Hwa Lee* was an interference proceeding in which the issue was whether Dryja had sufficient evidence to establish that it had possession of a single enabled embodiment within the scope of the count. Thus, the standard was not the same anticipation standard as in this case. Secondly, there was no evidence in the record that Dryja had disclosed a complete coding sequence for a protein. Instead, there was evidence that the plasmids containing a mutation where "*in vivo* analysis confirmed that the Dryja plasmids were unable to express the retinoblastoma protein." *Wen-Hwa Lee v. Thaddeus P. Dryja*, 79 USPQ2d 1614, 1627-28 (BPAI 2005). Thus, the reason that the cDNA did not anticipate was because the disclosed cDNAs had a stop codon and were not enabled to express the protein. *Id.* The reason was not because the Board applied a generic rule that cDNAs cannot anticipate proteins.

We affirm the rejection of claim 4 as anticipated by Kawai. Pursuant to 37 C.F.R. § 41.37(c)(1)(vii)(2006), we also affirm the rejections of claims 20-22, as these claims were not argued separately.

B. 35 U.S.C. § 102(b) rejection over Okazaki

Appellants rely upon the arguments discussed above regarding the Kawai reference in order to overcome the Okazaki reference. We have already addressed these arguments in our discussion of claim 4 above, and we found them to be unavailing. It therefore follows that Appellants have not shown that the Examiner erred in concluding that the Okazaki reference anticipates claim 4.

We affirm the rejection of claim 4 as anticipated by Okazaki. Pursuant to 37 C.F.R. § 41.37(c)(1)(vii)(2006), we also affirm the rejections of claims 20-22, as these claims were not argued separately.

CONCLUSION

In summary, we affirm the rejection of claim 4 as anticipated by Kawai. Pursuant to 37 C.F.R. § 41.37(c)(1)(vii)(2006), we also affirm the rejections of claims 20-22, as these claims were not argued separately. We affirm the rejection of claim 4 as anticipated by Okazaki. Pursuant to 37 C.F.R. § 41.37(c)(1)(vii)(2006), we also affirm the rejections of claims 20-22, 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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