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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte MICHAEL HAGEN

Appeal 2011-002413
Application 10/416,262
Technology Center 1600

Before FRANCISCO C. PRATS, STEPHEN WALSH, and
JACQUELINE WRIGHT BONILLA, *Administrative Patent Judges*.

WALSH, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal¹ under 35 U.S.C. § 134(a) from the rejection of claims directed to an antigenic composition. The Patent Examiner rejected the claims for obviousness. We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

¹ Appellant notes there is a related appeal in Application 11/544,056. (App. Br. 3.) That appeal, Appeal No. 2011-002779, is being decided concurrently.

STATEMENT OF THE CASE

Claims 1, 12-15, 20, and 26-28 are on appeal. Claim 1 is representative and reads as follows:

1. An antigenic composition comprising a selected antigen from a pathogenic virus, bacterium, fungus or parasite, or from a cancer cell or tumor cell, or from an allergen, or from a self molecule, and an effective adjuvanting amount of the combination of: (1) an aminoalkyl glucosamine phosphate compound (AGP), and (2) a cytokine or lymphokine selected from the group consisting of granulocyte macrophage colony stimulating factor (GM-CSF) and interleukin-12 (IL-12) wherein the combination of adjuvants enhances the immune response in a vertebrate host to said antigen.

The Examiner rejected claims 1, 12-15, 20, and 26-28 under 35 U.S.C. § 103(a) as unpatentable over Ahlers,² Johnson,³ and Staats.⁴

OBVIOUSNESS

The Issue

After making the required *Graham* findings, the rejection concluded:

It would have been prima facie obvious at the time the invention was made to combine the cytokine (e.g. GM-CSF) as taught by Ahlers et al, the adjuvants (e.g. aminoalkyl glucosamine phosphate compounds) as taught by Johnson et al to a composition comprising T1SP10 MN(A) (e.g. SEQ ID NO:1) to be used as a vaccine composition against HIV-1 because Ahlers et al have demonstrated that GM-CSF is the single most effective cytokine for enhancing both cellular and humoral immunity to two previously characterized HIV-1 MN vaccine constructs, Johnson et al teach that AGPs enhance the

² Jeffrey S. Ahlers et al., *Cytokine-in-Adjuvant Steering of the Immune Response Phenotype to HIV -1 Vaccine Constructs*, 158 J. IMMUNOLOGY 3947-3958 (1997).

³ David A. Johnson et al., WO 98/50399, published Nov. 12, 1998.

⁴ Herman F. Staats et al., *Mucosal Immunity to HIV-1*, 157 J. IMMUNOLOGY 462-472 (1996).

generation of antibody in immunized animals, stimulate the production of cytokines and stimulates cell-mediated response including a cytotoxic T-lymphocyte response and Staats et al teach that this peptide is a vaccine candidate to be used in vaccines against HIV. It would be expected barring evidence to the contrary, a composition comprising a GM-CSF (a cytokine), AGPs (adjuvants) and T1SP1 0 MN(A) (e.g. SEQ 10 NO:1) would be effective at treating patients with HIV-1.

(Rejection mailed Aug. 6, 2009; Ans. 4-5.)

Appellant contends that the rejection failed:

[a] “to articulate why it would have been motivating to one of ordinary skill in the art to combine the prior art elements to yield Appellant's claimed invention

[b] to articulate why someone skilled in the art would have predicted the utility of the combination of elements in Appellant's claimed invention

[c] to apply the PTO guidelines regarding the KSR decision
[and]

[d] to properly interpret the concept of art-recognized equivalents as described in *In re Kerkhoven* and in MPEP §2144.06.” (App. Br. 4.)

Findings of Fact

1. We adopt the Examiner's findings concerning the scope and content of the prior art. (*See* Ans. 3-5 and 11-16.)
2. The record contains a “Declaration Under 37 C.F.R. § 1.132” by Applicant-Inventor Michael Hagen, dated Sept. 17, 2008.
3. Declarant Hagen states:

Based on what was known prior to November 10, 2000, it is my opinion that a Ph.D. scientist in the field of immunology would not have been able to predict that the combination of an aminoalkyl glucosamine phosphate compound (AGP) with granulocyte macrophage colony stimulating factor (GM-CSF) or interleukin-12

(IL-12) and the HIV antigen of the claimed invention would have provided an effective immune response.

(Hagen Decl. ¶ 4.)

4. Declarant Hagen states:

Furthermore, one skilled in the field would not have been able to predict the nature of the interaction of the individual components of the claimed invention as asserted by the Examiner when citing particular references, particularly Ahlers et al. ... Johnson et al. ... and Staats et al.

(*Id.*)

5. Declarant Hagen states: “Adjuvants and cytokines have inherently different mechanisms of action and, in my opinion, would not be considered as equivalents.” (*Id.* at ¶ 8.)

Principles of Law

“[T]he ‘evidence’ of motive will likely consist of an explanation of the well-known principle or problem-solving strategy to be applied.” *DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co.*, 464 F.3d 1356, 1366 (Fed. Cir. 2006).

Analysis

Upon consideration of the evidence on this record, and each of Appellant’s contentions, we find that the preponderance of evidence on this record supports the Examiner’s conclusion that the subject matter of Appellant’s claims is unpatentable. Accordingly, we sustain the Examiner’s rejections for the reasons set forth in the Answer, which we incorporate

herein by reference, including the Examiner's responses to Appellant's arguments. We add the following comments for emphasis.

We find the Examiner provided a thorough explanation showing how the prior art motivated the rejection's proposed combination of HIV peptide, AGP, and GM-CSF or IL-12. *See, e.g., DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co.*, 464 F.3d 1356, 1366 (Fed. Cir. 2006) ("the 'evidence' of motive will likely consist of an explanation of the well-known principle or problem-solving strategy to be applied").

We agree with the Examiner that, given three references disclosing effective adjuvanting amounts of AGP, GM-CSF, and IL-12, there would have been a reasonable expectation of success for the rejection's proposed combination. The presence of a reasonable expectation of success is measured from the perspective of a person of ordinary skill in the art at the time the invention was made. *Life Techs., Inc. v. Clontech Labs., Inc.*, 224 F.3d 1320, 1326 (Fed. Cir. 2000). Judging that perspective from the evidence in the prior art references, we agree with the Examiner. We have reviewed Declarant Hagen's opinion (FF 3), but find it entitled to little weight because it dismisses the references without establishing that their disclosures are erroneous or inapplicable.

Contrary to Declarant Hagen's contention, the Examiner did not "predict the nature of the interaction of the individual components of the claimed invention" (FF 4), and the rejection was not premised on a prediction of component interaction. Declarant Hagen states that "[a]djuvants and cytokines have inherently different mechanisms of action" (FF 5), but the point does not rebut the case for obviousness. Different mechanisms may favor combining AGP and cytokine to gain the advantage

of different mechanisms of achieving the same result. *See, e.g., In re Diamond*, 360 F.2d 214, 217 (CCPA 1966) (where the evidence showed that synergy was expected because combined drugs targeted different cellular mechanisms, and no evidence to the contrary was produced, “[w]e are not convinced of the non-obviousness of the combination of two drugs, A5MP and a glucocorticoid . . . particularly since the record supports the [PTO’s] contention that the drugs selected are two of the commonly used drugs in the treatment of such collagen diseases”).

Appellant argues that the Examiner erred by mis-applying the “concept of art-recognized equivalents as described in *In re Kerkhoven*.” (App. Br. 4.) We disagree. First, it is undisputed that Ahlers had already taught using both an adjuvant and GM-CSF in a peptide vaccine comprising an HIV peptide, an adjuvant, and GM-CSF. This is not a situation where the art had not earlier used both adjuvant and a cytokine in a peptide vaccine. Second, the *Kerkhoven* opinion does not explain the decision by using the term “equivalents,” and does not set out a “concept of art-recognized equivalents” as Appellant argues (*see id*). Instead, the opinion states that “[i]t is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition which is to be used for the very same purpose.” *In re Kerkhoven*, 626 F.2d 846, 850 (CCPA 1980). To the extent *Kerkhoven* bears on this case, it supports the conclusion that combining AGP and GM-CSF in an HIV peptide vaccine would have been obvious, because AGP and GM-CSF are each taught in the prior art “to be useful for the same purpose” of acting as an adjuvant in a vaccine.

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Claims 12-15, 20, and 26-28 have not been argued separately and therefore fall with claim 1. 37 C.F.R. § 41.37(c)(1)(vii).

SUMMARY

We affirm the rejection of claims 1, 12-15, 20, and 26-28 under 35 U.S.C. § 103(a) as unpatentable over Ahlers, Johnson, and Staats.

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

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