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The opinion in support of the decision being entered today
(1) was not written for publication in a law journal and
(2) is not binding precedent of the Board.

Paper No. 29

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte ELI YOUNG, DEBORAH DAVIS,
JAMES STOREY and GERALD BELTZ

Appeal No. 1995-1933
Application 07/661,370¹

ON BRIEF

Before WILLIAM F. SMITH, ELLIS and LORIN, **Administrative Patent Judges.**

ELLIS, **Administrative Patent Judge.**

DECISION ON APPEAL

This is an appeal under 35 USC § 134 from the final rejection of claims 2 through 5, 7 through 10, 22 through 28, 54 and 57. Claims 11 through 19, 21, 29 through 53 and 55 have been withdrawn from consideration by the examiner pursuant

¹ Application for patent filed February 28, 1991.

Appeal No. 1995-1993
Application 07/661,370

Modrow et al. (Modrow), "Computer-Assisted Analysis of Envelope Protein Sequences of Seven Human Immunodeficiency Virus Isolates: Prediction of Antigenic Epitopes in Conserved and Variable Regions," ***Journal of Virology***, Vol. 61, pp. 570-578 (1987).

Colasanti et al. (Colasanti), "The ***Escherichia coli rep*** Mutation. X. Consequences of Increased and Decreased Rep Protein Levels, ***Molecular and General Genetics***, Vol. 209, pp. 382-90 (1987).

The references relied on by the appellants are:

Olmsted et al. (Olmsted I), "Molecular Cloning of Feline Immunodeficiency Virus," ***Proceedings of the National Academy of Sciences, USA***, Vol. 86, pp. 2448-2458 (1989).

Olmsted et al. (Olmsted II), "Nucleotide Sequence Analysis of Feline Immunodeficiency Virus: Genome Organization and Relationship to Other Lentiviruses," ***Proceedings of the National Academy of Sciences, USA***, Vol. 86, pp. 8088-92 (1989).

The claims stand rejected as follows:

Claims 2 through 5, 7 through 10, 22 through 28 and 57 stand rejected under 35 USC § 103 as being unpatentable over Talbott, Pedersen and Kieny in view of Starcich, Pauletti, Modrow, Watanabe and Colasanti.

Claim 54 stands rejected under 35 USC § 103 as being unpatentable over Talbott, Pedersen, Kieny, Starcich, Pauletti, Modrow, Watanabe and Colasanti in view of O'Connor.

We have carefully considered the entire record which includes, ***inter alia***, the specification, the appellants' brief (Paper No. 27), the examiner's Answer (Paper No. 28), and the declaration of Dr. Young (Paper No. 17), and we find ourselves in substantial

Appeal No. 1995-1993
Application 07/661,370

agreement with the appellants' position. Accordingly, we **reverse** both rejections.

The present invention is directed to the 0.4 kb envelope protein of feline immunodeficiency virus (FIV),³ a plasmid which comprises a DNA sequence encoding said protein, an eukaryotic host cell transformed with said plasmid, a method of producing said protein, a process for making a pharmaceutical composition comprising the amino acid sequence of said protein and a pharmacologically acceptable carrier, a pharmaceutical composition comprising said protein, the use of said pharmaceutical composition for immunizing a cat against FIV, and a kit for detecting FIV antibodies in a biological sample.

Rejection I

The examiner has premised his conclusion of obviousness on the teachings of Talbott, Pedersen, and Kieny in view of Starcich, Pauletti, Modrow, Watanabe and Colasanti. As we understand it, the examiner is proposing two theories by which he believes the claimed subject matter would have been obvious to one of ordinary skill in the art. Theory I is primarily based on the combined teachings of Talbott, Pedersen and Kieny and, Theory II, on the combination of Talbott, Starcich, Pauletti and Modrow. Both theories hinge on the examiner's finding that the FIV 0.4 envelope protein and the

³ According to the specification, FIV is a member of the family **Retroviridae** which includes human and simian immunodeficiency viruses. Specification, p. 1, lines 24-29.

HIV gp40 envelope protein are “equivalent” or “strikingly similar.” Answer, pp. 6 and 11.

Turning first to the references used to support Theory I, we find that Talbott teaches the entire nucleotide sequence (9472 base pairs) and genomic organization of the Petaluma strain of FIV. Pedersen discloses compositions comprising whole FIV, or portions thereof. Pedersen further discloses that “Portions of the FTLV [FIV] of particular interest include the structural and regulatory proteins encoded by the FTLV genome including the envelope and core proteins, and fragments thereof.” Pedersen, col. 4, lines 24-27. Kieny discloses that the envelope protein of *human* immunodeficiency virus (HIV, a.k.a., LAV or HTLV-III) is a promising candidate for developing a vaccine strategy. Kieny, col. 1, lines 58-61. In Example 17, the portion of the patent relied on by the examiner, Kieny states that “it *may* be useful to generate a recombinant vaccinia virus which expresses the [human] gp40 alone” [emphasis added]. Kieny, col. 17, line 67- col. 18, line 2.

With respect to Theory I the examiner concludes that the DNA sequence encoding the entire FIV envelope protein, or any fragments thereof, would have been obvious to one of ordinary skill in the art in view of the combined teachings of Talbott, Pedersen and Kieny because the claimed sequence is “equivalent to the HIV *env* polypeptide fragments taught by Kieny et al., including the carboxyl-proximal gp40, produced by Kieny et al. for vaccine production, ... [and] ... because Pedersen et al. (‘753) specifically teach that such products are immunogenic and useful for preparing vaccines... and because Talbott et al. indicate

precisely where in an FIV genome the **env** coding sequence may be found.” Answer, p. 6.

As to Theory II, the examiner’s conclusion of obviousness is based on his finding that Starcich demonstrates that the env protein of HIV and FIV “share striking similarities.” Answer, p. 11. The examiner argues that Starcich teaches “the nucleotide and deduced amino acid sequences of the **env** gene from five independent HIV isolates, characterizing hypervariable regions on the basis of deduced polypeptide secondary structure and observed genetic variation as well as less variable regions and conserved regions on the same bases [sic, basis].” Answer, p. 8. The examiner further argues that four N-linked glycosylation sites adjacent to the cysteine pairs are conserved. *Id.*, p. 10. According to the examiner, “**Mere visual comparisons** of the deduced amino acid sequences of the FIV **env** gene taught by Talbott et al. and of the HIV **env** gene taught by Starcich et al. would readily indicate to one of ordinary skill in the art that two mutually conserved cysteine residues are present in the regions carboxyl-proximal to the mutually conserved proteolytic processing sites of FIV and HIV, since both pairs of cysteines are approximately 86 amino acids distant from the conserved cleavage sites and separated by five amino acids in the HIV isolates and by six in the FIV strain” [emphasis added]. Answer, p. 9. Having made this finding, the examiner then urges that Pauletti and Modrow demonstrate that antigenic epitopes present in a region of the HIV env protein correspond to the FIV 0.4 envelope protein.

Appeal No. 1995-1993
Application 07/661,370

Answer, para. bridging pp. 10-11.

We find both theories unpersuasive.

Here, we find that the examiner has overlooked the fact that the appropriate legal standard for determining obviousness is whether the applied prior art would have suggested the claimed invention to one of ordinary skill in the art. With respect to Theory I, in our review of the Talbott and Pedersen references, the only two references cited in the rejection which are directed to FIV, we do not find any teaching or suggestion of the FIV 0.4 envelope protein or a DNA sequence which encodes said protein. Nor do we find any teaching in Kieny, and none has been pointed out by the examiner, that the HIV gp40 peptide is equivalent to the FIV 0.4 envelope protein. As to Theory II and the examiner's attempt to relate the teachings of Starcich and Talbott to each other, we find that Starcich compares different *human* variants with one another, but that the reference is silent with respect to the relationship between FIV and HIV. We find that Talbott, on the other hand, appears to contradict each of the examiner's theories. That is, Figure 4 of Talbott suggests that HIV and FIV are phylogenically distinct. Talbott, p. 5746. Thus, in our view, Talbott suggests that one of ordinary skill in the art would not have expected to find that the envelope proteins of HIV and FIV are "strikingly similar."

In fact, overall, we find that the evidence of record overwhelmingly supports a conclusion which is contrary to the examiner's unsupported allegation that "mere visual

inspection” of the HIV and FIV envelope proteins shows that they are “analogous” or “strikingly similar.” As pointed out by the appellants, the record demonstrates that persons of ordinary skill in the art would have understood that HIV and FIV are both phylogenically and antigenically distinct. Brief, pp. 10-13. For example, Pedersen and Olmsted I⁴ unequivocally state that FIV is not antigenically related to HIV. Pedersen, col. 3, lines 5-8; Olmsted I, p. 2452, lines, 3-5. In addition, as we discussed above, Talbott suggests that FIV and HIV are phylogenically distinct. Talbott, p. 5746, Figure 4. Finally, the most compelling evidence of record which provides a direct comparison of nucleotide and deduced amino acid sequences of FIV with other lentiviruses, including HIV, has been ignored by the examiner. We direct attention to Olmsted II⁵ wherein it is reported that significant sequence identities exist **only** in the **gag** and **pol** genes of FIV and other lentiviruses. Olmsted II, the abstract. Olmsted II concludes that “In each of the four analyses, the horizontal distances and branch orders indicate that FIV is more closely related to the nonprimate lentiviruses (EAIV and visna virus) than to the primate lentiviruses [HIV and SAIDS].” Olmsted II, p. 8091, col. 2, last para.

Cutting to the chase, the only location on this record, where we find a suggestion that the FIV 0.4 envelope protein is antigenic, is in the appellants’ specification. Thus, in

⁴ A reference provided by the appellants (Paper No. 6; attachment to the Information Disclosure Statement) and cited in their Brief. Brief, p. 12.

⁵ A reference provided by the appellants in Paper No. 23 and cited in their Brief. Brief, p. 11.

Appeal No. 1995-1993
Application 07/661,370

our view, the examiner has relied on impermissible hindsight in making his determination of obviousness. *In re Fritch*, 972 F.2d 1260, 1266, 23 USPQ2d 1780, 1784 (Fed. Cir. 1992) (“It is impermissible to engage in hindsight reconstruction of the claimed invention, using the applicant’s structure as a template and selecting elements from references to fill the gaps”); *Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1138, 227 USPQ 543, 547 (Fed. Cir. 1985); *W.L. Gore & Assocs. v. Garlock, Inc.*, 721 F.2d 1540, 1553, 220 USPQ 303, 312-313 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984) (“To imbue one of ordinary skill in the art with knowledge of the invention in suit, when no prior art reference or references of record convey or suggest that knowledge, is to fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher”). Accordingly, the rejection is reversed.

Rejection II

For the reasons explained above, we do not find that the subject matter of claim 54 would have been obvious to one of ordinary skill in the art over applied prior art. Although the examiner has additionally applied O'Connor in the second rejection, we do not find that the reference makes up for the shortcomings previously discussed. O'Connor discloses a kit for detecting the presence of FIV antibodies in a biological sample; however, he fails to suggest the use of the FIV 0.4 envelope protein in said kit. Accordingly, rejection II is reversed.

REVERSED

William F. Smith)	
Administrative Patent Judge)	
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)	BOARD OF PATENT
Joan Ellis)	
Administrative Patent Judge)	APPEALS AND
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)	INTERFERENCES
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Hubert C. Lorin)	
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Appeal No. 1995-1993
Application 07/661,370

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