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(1) was not written for publication in a law journal and
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Paper No. 37

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte MANAMI MOROZUMI, MASAO KUMAGAI, and
TOYOFUMI YAMAGUCHI

Appeal No. 95-3056
Application 07/833,718¹

HEARING: December 10, 1998

Before KIMLIN, GRON, and WARREN, Administrative Patent Judges.
GRON, Administrative Patent Judge.

DECISION ON APPEAL UNDER 35 U.S.C. § 134

This is an appeal under 35 U.S.C. § 134 from an
examiner's rejections of Claims 1-3, 7-13, and 15-28, all
claims pending in this application.

¹ Application for patent filed February 11, 1992.

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1. Introduction

Claims 1-3, 7-13, and 15-28 stand rejected under 35 U.S.C. § 103 as being unpatentable over the teaching of either Miyasaka et al. (Miyasaka), U.S. Patent 4,956,345, patented September 11, 1990, or Matsuda et al. (Matsuda), "Introduction of Carbon Substituents at C-2 Position of Purine Nucleosides," Nucleic Acids Research, Symposium Series No. 12, pp. 5-8 (1983), in view of the teaching of Weygand et al. (Weygand), Preparative Organic Chemistry (Hilgetag et al., eds., John Wiley & Sons, New York, pp. 1096-98, 1111-21, and 1127 (1972)). The examiner's rejection of Claim 23 under 35 U.S.C. § 112, fourth paragraph, has been withdrawn (Supplemental Examiner's Answer (Supp. Ans.), p. 3, l. 19-21). The examiner appears also to have withdrawn the appealed rejections of appellants' claims under 35 U.S.C. § 103 in view of the teaching of Miyasaka or Matsuda alone and in view of appellants' admissions in combination with Weygand's teaching (Examiner's Answer (Ans.), p. 5, l. 15, to p. 6, l. 20).

All claims stand or fall together with Claim 1. See 37 CFR

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§ 1.192(c)(5)(October 22, 1993). Claim 1 reads:

1. Solid 2-octynyl adenosine having a water content of not more than 3%.

2. Examiner's findings

A. The examiner finds that each of Miyasaka and Matsuda describe 2-octynyl adenosine (Ans., p. 5, l. 19-20).

B. The examiner finds that Weygand describes "processes commonly used by the practitioner to produce and isolate compounds which are free from impurities, i.e., recrystallization from anhydrous solvents, drying under vacuum at temperatures above ambient, etc." (Ans., p. 5, l. 21-24).

C. The examiner finds that Miyasaka and Matsuda isolated 2-octynyl adenosine as a "hydrate" (Ans., p. 5, l. 27-28).

D. The examiner finds that 2-octynyl adenosine hydrates are not patentably distinct from anhydrous 2-octynyl adenosine (Ans., pp. 5-6, bridging sentence).

E. Based on Morozumi's Declarations Under 37 CFR 1.132, filed July 6, 1993 (Paper No. 14) and April 13, 1994 (Paper No. 21^{1/2}) and accompanying remarks, the examiner finds that persons having ordinary skill in the art would have known that "practical production of 2-octynyladenosine on large scale was

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rendered commercially impractical because [of] the instability of hydrated 2-octynyladenosine when stored" (Ans., pp. 6-7, bridging para.).

F. The examiner finds that "it does not defy logic . . . that a compound of known chemical structure, initially isolated in hydrated form, should not be patentably distinguishable from the identical compound rendered anhydrous by one or more conventional purification steps" (Ans., p. 6, l. 9-13).

G. The examiner finds that applicants have solved "a very simple problem quickly understood by any ordinary practitioner using commonly available analytical techniques . . . and quickly soluble [sic] using routine purification techniques" (Ans., p. 7, l. 6-10).

H. The examiner finds that "pharmaceuticals are routinely tested for activity as a function of storage conditions to determine how they must be processed in preparation for storage" (Ans., p. 7, l. 13-15).

I. The examiner finds that "[i]nstability in the presence of retained solvent, i.e. herein water of hydration, is not unheard of and . . . readily soluble [sic] in several different ways without undue expense" (Ans., p. 7, l. 16-18).

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J. The examiner finds that the claimed "purified" product would have been within the ordinary skill of the practitioner "seeking to optimize storage conditions for 2-octynyladenosine" (Ans., p. 7, l. 19-21).

3. Examiner's conclusions

Based on the aforementioned findings, the examiner holds that appellants' claimed "[s]olid 2-octynyl adenosine having a water content of not more than 3%" would have been obvious to a person having ordinary skill in the art in view of the combined teachings of Miyasaka and Weygand and/or Matsuda and Weygand. Accordingly, the subject matter of Claims 1-3, 7-13, and 15-28 on appeal stands rejected as unpatentable under 35 U.S.C. § 103.

Discussion

We hold that the examiner's case for unpatentability is based on clearly erroneous findings and improper criterion for obviousness under 35 U.S.C. § 103. Accordingly, we reverse the examiner's holding that the subject matter appellants claim is unpatentable under 35 U.S.C. § 103 in view of the combined prior art teachings.

First, we hold that the examiner's finding that 2-octynyl adenosine hydrates are not patentably distinct from anhydrous

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2-octynyl adenosine is clearly erroneous. See the examples in the specification and Morozumi's Declaration Under 37 CFR 1.132 filed July 6, 1993 (Paper No. 14), which establish by elemental and stability analysis that 2-octynyl adenosine monohydrate

(4.6% water) has markedly different properties from 2-octynyl adenosines with a water content ranging from 3.14 to 0.93%.

Compare In re Papesch, 315 F.2d 381, 391, 137 USPQ 43, 51

(CCPA 1963):

From the standpoint of patent law, a compound and all of its properties are inseparable; they are one and the same thing.

Based on the comparative properties of the compounds, we find that solid 2-octynyl adenosine monohydrate (4.6% water) is patentably distinct from solid 2-octynyl adenosines with a water content of not more than 3%. While it may "not defy logic . . . that a compound of known chemical structure, initially isolated in hydrate form, should not be patentably distinguishable from the identical compound rendered anhydrous" (Ans., p. 6, l. 9-12), the greater weight of evidence of record in this case reasonably suggests the contrary.

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Second, whether or not applicants solved "a very simple problem" (Ans., p. 7, l. 6-7) "is not inimical to patentability." In re Oetiker, 977 F.2d 1443, 1447, 24 USPQ2d 1443, 1446 (Fed. Cir. 1992). Oetiker also instructs at 1447, 25 USPQ2d at 1446:

See Goodyear Tire & Rubber Co. v. Ray-O-Vac Co., 321 U.S. 275, 279, [60 USPQ 386, 388] (1944)(simplicity of itself does not negate invention); *Panduit Corp. v. Dennison Mfg Co.*, 810 F.2d 1561, 1572, 1 USPQ2d 1593, 1600 (Fed. Cir.)(the patent system is not foreclosed to those who make simple inventions), *cert. denied*, 481 U.S. 1052 (1987).

Third, In re Spinnoble, 405 F.2d 578, 160 USPQ 237 (CCPA 1969), teaches at 585, 160 USPQ at 243:

. . . [A] patentable invention may lie in the discovery of the source of a problem even though the remedy may be obvious once the source of the problem is identified. This is *part* of the "subject matter as a whole" which should always be considered in determining the obviousness of an invention under 35 U.S.C. § 103.

Here, the examiner finds, based on applicants' own disclosure and declaratory evidence, that (1) the 2-octynyl adenosines which Miyasaka and Matsuda isolated are both hydrates (Ans., p. 5, l. 27-28), and (2) practical production of 2-octynyl adenosine

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on large scale was commercially impractical because [of] the instability of hydrated 2-octynyl adenosine when stored (Supp. Ans., p. 2, l. 15-18). We agree with the examiner that the evidence of record, as a whole, strongly suggests that Miyasaka and Matsuda both isolated a hydrate of 2-octynyl adenosine.

We also agree with the examiner that the evidence of record, as a whole, suggests that large scale commercial production of the 2-octynyl adenosine isolated by Miyasaka and Matsuda would have been impractical because of its storage instability. However, aside from the teaching in this specification and declarations of record, we find no evidence of record that persons having ordinary skill in the art would have known that Miyasaka and Matsuda isolated a hydrate of 2-octynyl adenosine rather than its anhydrous form. Moreover, even if persons having ordinary skill in the art reasonably would have known that Miyasaka and Matsuda isolated an unstable hydrate of 2-octynyl adenosine, there is no evidence in this record other than that found in applicants' own specification which reasonably would have suggested to persons having ordinary skill in the art that the water content of the 2-octynyl

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adenosine hydrate was responsible for the agent's storage
instability.

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The examiner argues (Supp. Ans., p. 2, l. 27, to p. 3, l. 9):

. . . [P]harmaceuticals are routinely tested for activity as a function of storage conditions to determine how they must be processed in preparation for storage (shelf-life determination). Instability in the presence of retained solvent, i.e. herein water of hydration, is not unheard of and as noted in Weygand, readily soluble in several different ways without undue expense. Therefore, the instant "purified" product is deemed to have been well within the perview [sic] of the ordinary practitioner seeking to optimize storage conditions for 2-octynyladenosine.

We certainly agree that it would have been well within the ordinary skill of the artisan to optimize a result effective variable. In re Boesch, 617 F.2d 272, 276, 205 USPQ 215, 219 (CCPA 1980). Moreover, we see no clear error in the examiner's finding that purity is considered a result effective variable for most drugs. However, we do not see that persons skilled in the art would have necessarily considered water of hydration to be an impurity. To the contrary, persons having ordinary skill in the art reasonably would have been justified in presuming that Miyasaka and Matsuda had purified their 2-octynyl adenosine sufficiently for effective use as an antihypertensive agent and optimum pharmaceutical activity. Furthermore, the evidence presented in Morozumi's Declaration

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Under 37 CFR 1.132 filed April 13, 1994 (Paper No. 21^{1/2}), evidence which contradicts the examiner's optimization theory with water as the result effective impurity for 2-octynyl adenosine, indicates that the 2-octynyl adenosine prepared by Miyasaka and Matsuda becomes more stable as its water content increases.

In re Dow Chemical Co., 837 F.2d 469, 5 USPQ2d 1529 (Fed. Cir. 1988), teaches at 473, 5 USPQ2d at 1531:

The consistent criterion for determination of obviousness is whether the prior art would have suggested to one of ordinary skill in the art that this process should be carried out and would have a reasonable likelihood of success, viewed in light of the prior art. . . . Both the suggestion and the expectation of success must be founded in the prior art, not in applicant's disclosure.

The prior art here cited against the claims on appeal would not have suggested to persons having ordinary skill in the art to reduce the water content of 2-octynyl adenosine to 3% or less to improve the storage stability of the known antihypertensive agent or for any other apparent reason. The examiner here, as did the PTO in Dow Chemical Co., at 473, 5 USPQ2d at 1532:

. . . presents an "obvious to experiment" standard for obviousness. However, selective hindsight is no more applicable to the design of experiments than it is to the

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combination of prior art teachings. There must be a reason or suggestion in the art for selecting the procedure used, other than the knowledge learned from the applicant's disclosure.

Accordingly, we reverse the examiner's holding of unpatentability under 35 U.S.C. § 103.

Conclusion

We reverse the examiner's rejection of Claims 1-3, 7-13, and 15-28 under 35 U.S.C. § 103 as being unpatentable over the teaching of either Miyasaka or Matsuda in view the teaching of Weygand.

REVERSED

EDWARD C. KIMLIN)
Administrative Patent Judge)
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TEDDY S. GRON)	BOARD OF PATENT
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