

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 JOSEPH K. BELANOFF

Appeal 2007-1155¹
Application 10/230,575
Technology Center 1600

Decided: June 29, 2007

Before TONI R. SCHEINER, DONALD E. ADAMS, and
RICHARD M. LEBOVITZ, *Administrative Patent Judges*.

ADAMS, *Administrative Patent Judge*.

DECISION ON APPEAL

This appeal under 35 U.S.C. § 134 involves claims 1-15, the only claims pending in this application. We have jurisdiction under 35 U.S.C. § 6(b).

¹ Heard May 17, 2007.

INTRODUCTION

The claims are directed to a method of inhibiting cognitive deterioration in an adult patient with Down's syndrome but without dementia. Claim 1 is illustrative:

1. A method of inhibiting cognitive deterioration in an adult patient with Down's syndrome but without dementia, the method comprising the step of administering to the patient an amount of a glucocorticoid receptor antagonist effective to inhibit cognitive deterioration, with the proviso that the patient be not otherwise in need of treatment with a glucocorticoid receptor antagonist.

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

Schatzberg ('596)	WO 9959596	Nov. 25, 1999.
Schatzberg ('046)	US 6,369,046 B1	Apr. 9, 2002.
Schatzberg ('802)	US 6,620,802 B1	Sep. 16, 2003.

Yoshiki Sekijima et al., "Prevalence of Dementia of Alzheimer Type and Apolipoprotein E Phenotypes in Aged Patients with Down's Syndrome," European Neurology, Vol. 39, No. 4, pp. 234-237 (1998).

The rejections as presented by the Examiner are as follows:

1. Claims 1-15 stand rejected under 35 U.S.C § 103(a) as unpatentable over the combination of Schatzberg '596 and Sekijima.
2. Claims 1-15 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of Schatzberg '802.

3. Claims 1-15 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 of Schatzberg‘046.

We reverse.

DISCUSSION

Down’s syndrome (DS) is a genetic trait that “arises from one of three chromosomal abnormalities” (Specification 1: ¶ 03). In most cases “DS is the result of trisomy 21, or the presence of an extra chromosome 21 in otherwise diploid cells” (*id.*). However, about 2-4% of DS cases are the result of a translocation event, “occurring when a fragment of chromosome 21 becomes attached to another chromosome, most typically chromosome 14” (*id.*). “The rarest form of DS[](about 1-4% of cases) results from nondisjunction of chromosome 21 during early embryogenesis. Such individuals are mosaic, with both normal and trisomic cells being present” (*id.*).¹

“DS individuals are almost invariably cognitively impaired . . .” (Specification 1: ¶ 04). “Generally, significant developmental delays are apparent in DS child[ren] in infancy and early childhood. . .” (*id.*). “Superimposed on this early cognitive impairment, however, is a more serious deterioration of cognition that begins to appear as individuals with DS age” (Specification 1: ¶ 05). “No effective treatment for the cognitive impairment and decline of DS individuals is known” (*id.* at 2: ¶ 06). Appellant asserts that “[t]he present invention therefore fulfills the need for an effective preventive measure for cognitive deterioration in DS patients by

providing methods of administering glucocorticoid receptor antagonists to improve cognitive function in DS patients” (Specification 4: ¶ 10).

OBVIOUSNESS:

Claims 1-15 stand rejected under 35 U.S.C § 103(a) as unpatentable over the combination of Schatzberg ‘596 and Sekijima. Claim 1 is directed to a method of inhibiting cognitive deterioration in an adult patient with Down’s syndrome but without dementia. Claims 2-15 ultimately depend from claim 1. The claimed method comprises the single step of administering a glucocorticoid receptor antagonist to an adult patient with Down’s syndrome, but without dementia, in an amount that is effective to inhibit cognitive deterioration. According to Appellant’s Specification, “dementia was previously known to be treated by glucocorticoid antagonists” (Specification 12: ¶ 43). Therefore, “Down syndrome patients with dementia are outside the scope of this invention” (*id.*). In this regard, we recognize that the claim method requires that the patient must not otherwise be in need of treatment with a glucocorticoid receptor antagonist.

Appellant’s Specification defines the term “dementia” according to the “American Psychiatric Association: Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition [(DSM-IV)] . . . as characterized by multiple cognitive deficits that include impairments in memory . . .” (Specification 6: ¶ 22). In contrast, “[t]he term ‘cognitive deterioration’ refers to a loss of ability to remember concrete facts (names or objects) or to solve logical problems” (Specification 6: ¶ 21). According to Appellant’s Specification, “[w]here cognitive deterioration in adults with DS is severe, patients may meet the criteria for clinical dementia, as set forth in the DSM-

IV-TR” (Specification 12: ¶ 43). Therefore, as we understand it, while cognitive deterioration may lead to dementia, cognitive deterioration and dementia (including dementia of the Alzheimer’s type) represent two separately definable ailments. Accordingly, the claimed method intends to treat a DS patient exhibiting cognitive deterioration before the deterioration reaches the dementia stage.

The Examiner relies on Schatzber ‘596 to teach a method for treating dementia or Alzheimer’s disease in an adult patient by administering an effective amount of a glucocorticoid receptor antagonist (Answer 3-4). The Examiner recognizes, however, that Schatzberg ‘596 does not teach the treatment of “cognitive deterioration in an adult patient with Down’s syndrome” (Answer 4). To make up for this deficiency in Schatzberg ‘596, the Examiner relies on Sekijima to teach the prevalence of dementia of the Alzheimer’s type in DS patients (Answer 4).

Based on this evidence, the Examiner finds that “[i]t would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ the same active compounds in the same effective amount in a method of inhibiting cognitive deterioration in an adult [p]atient with Down’s syndrome” (Answer 4-5).

In response, Appellant asserts that both Schatzberg ‘596 and Sekijima address “dementia, such as dementia of [the] Alzheimer type (DAT)” and therefore provide no motivation or reasonable expectation of success in treating cognitive deterioration in DS patients (Br. 7). We agree.

Schatzberg ‘596 is directed to “a method of treating dementia in an individual diagnosed as having symptoms of dementia. . .” (Schatzberg ‘596 3). In addition, Schatzber ‘596 states that “[d]ementia associated with

Alzheimer's disease is treated by the methods of the invention" (Schatzberg '596 11). Schatzberg '596's definition of dementia is the same as Appellants (Schatzberg '596; Specification 6: ¶ 22). However, Appellant's expert Dr. Ranga Ram Krishnan explains, "cognitive deterioration from Down's syndrome, dementia of the Alzheimer's type, and mild cognitive impairment are regarded as distinct conditions in the medical community, even though some overlapping may exist in the symptoms" (Krishnan Declaration 4: ¶ 10). Accordingly, Dr. Krishnan declares that "a person of skill in the art would not reasonably expect one common treatment method . . . for cognitive deterioration in Down's syndrome, for dementia of the Alzheimer's type, and for mild cognitive impairment" (*id.*).

In response, the Examiner asserts that Schatzberg '596 uses descriptive terms that apply to both dementia and cognitive deterioration (Answer 8). We agree and note that there does not appear to be any dispute on this record that dementia and cognitive deterioration from Down's syndrome have overlapping symptoms (*see, e.g.*, Krishnan Declaration 4: ¶ 10). However, without evidence to the contrary, an overlap in symptoms does not lead to a conclusion that the impairments are equivalent or that the treatment of one condition will work for another (*id.*).

We recognize the Examiner's assertions regarding Sekijima (Answer 8-9). We note, however, that the Examiner uses the terms Alzheimer's disease, cognitive decline, cognitive deterioration, and dementia as if they all relate to the same impairment. While cognitive decline may be a symptom of Alzheimer's disease, cognitive deterioration, and dementia, the evidence on this record supports the finding that these impairments represent distinct medical conditions. Accordingly, we disagree with the Examiner's assertion

that “it would be obvious to use a known compound for the treatment of dementia (and cognitive decline), specifically for use with Alzheimer’s disease, in patients with Down’s syndrome as there is a known increase in cognitive impairment and specifically of Alzheimer’s disease pathogenesis in Down’s syndrome patients” (Answer 9). To the contrary, the evidence of record points the other way. Specifically, Krishnan declares that

[i]t is particularly true that therapeutic regiments suitable for normal patients are not predictably effective or necessarily recommended for patients with genetic abnormalities, such as a patient with Down’s syndrome. This is because patients with genetic defects (e.g., Down’s syndrome) differ from genetically normal patients in multiple physiological/biochemical parameters, which can be immediately relevant to the effectiveness and possible side effects of any given treatment modality.

(Krishnan Declaration 5: ¶ 11.)

We remind the Examiner that a claim “composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art. Although common sense directs one to look with care at a patent application that claims as innovation the combination of two known devices according to their established functions, it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does.” *KSR Int’l v. Teleflex Inc.*, 127 S. Ct. 1727, 1741, 82 USPQ2d 1385, 1396 (2007).

On reflection, we find that Schatzber ‘596 fails to teach or suggest a method of inhibiting cognitive deterioration in an adult patient with Down’s syndrome, but without dementia. In our opinion, Sekijima fails to make up

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for the deficiency in Schatzber ‘596. Accordingly, we reverse the rejection of claims 1-15 under 35 U.S.C § 103(a) as unpatentable over the combination of Schatzber ‘596 and Sekijima.

OBVIOUSNESS-TYPE DOUBLE PATENTING:

Claims 1-15 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of Schatzberg ‘802. The claims in Schatzberg ‘802 are directed to a method of treating mild cognitive impairment. In the Examiner’s opinion, since the same active agent is administered the method of Schatzberg ‘802 and Appellants’ claimed methods overlap. We disagree. As discussed above, mild cognitive impairment and cognitive deterioration in Down’s syndrome are distinct impairments. For the reasons set forth above, we find no evidence on this record to suggest that a method of treating mild cognitive impairment would be effective to inhibit cognitive deterioration in an adult patient with Down’s syndrome but without dementia. Accordingly, we reverse the rejection of claims 1-15 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of Schatzberg ‘802.

Claims 1-15 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 of Schatzberg ‘046. The Examiner finds that Schatzberg ‘046 is “drawn to a method of inhibiting progression toward dementia in a patient therein administering the same glucocorticoid receptor antagonist as the instantly claimed” (Answer 7-8). According to the Examiner, the patient population

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in Schatzberg ‘046 overlaps the patient population in Appellant’s claimed method.

There can be no doubt that Schatzberg ‘046’s invention is directed to a method of inhibiting progression toward dementia by administering a glucocorticoid receptor antagonist in an amount that is effective to treat dementia. However, Schatzberg ‘046 requires that the patient being treated is determined to have a score of between 21 and 29 on the Folstein Mini Mental Status Exam. The Examiner makes no findings on this record to establish a nexus between the patient treated in Schatzberg ‘046 and the patient treated in Appellant’s claims. Instead, the Examiner simply asserts that the patient population is the same. In our opinion, the factual evidence before us is insufficient to sustain the rejection. Conclusions of obviousness must be based upon facts, not generality. *In re Warner*, 379 F.2d 1011, 1017, 154 USPQ 173, 178 (CCPA 1967); *In re Freed*, 425 F.2d 785, 787, 165 USPQ 570, 571 (CCPA 1970).

Accordingly, we reverse the rejection of claims 1-15 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 of Schatzberg ‘046.

CONCLUSION

In summary, we reverse all rejections of record.

REVERSED

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