

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte

NEBOJSA JANJIC, LARRY GOLD, PAUL SCHMIDT,
CHANDRA VARGESE, and MICHAEL WILLIS

Appeal 2008-2252
Application 10/832,941
Technology Center 1600

Decided: June 27, 2008

Before DEMETRA J. MILLS, RICHARD M. LEBOVITZ, and
FRANCISCO C. PRATS, *Administrative Patent Judges*.

PRATS, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to a composition for treating macular degeneration. The Examiner has rejected the claims under the doctrine of obviousness-type double patenting. We have jurisdiction under 35 U.S.C. § 6(b).

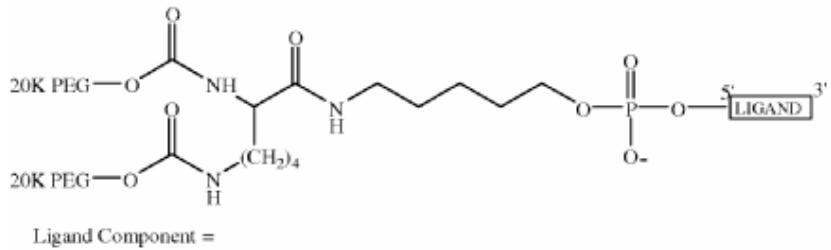
We agree with the Examiner that certain claims in the conflicting patent render the appealed claims obvious. However, because the Examiner's rejection is based on an improper rationale, we reverse the Examiner's rejection and enter a new ground of rejection for obviousness-type double patenting.

STATEMENT OF THE CASE

Claims 1-7 are pending and on appeal (App. Br. 2), and read as follows:

1. A pharmaceutically effective composition for treating macular degeneration comprising:
 - a RNA ligand to VEGF comprising the sequence fCmGmGrArAfUfCmAmGfUmGmAmAfUmGfCfUfUmAfUmAfCmAfUfCfCmG-3'3'-dT (SEQ ID NO:8; wherein f=2'-fluoro and m=2'-O-methyl and
 - a pharmaceutically acceptable carrier suitable for administration via intravitreal injection.
2. The composition of claim 1 wherein said RNA ligand is complexed with a Non-Immunogenic, High Molecular Weight Compound.
3. The composition of claim 2 wherein said Non-Immunogenic, High Molecular Weight Compound is Polyalkylene Glycol.
4. The composition of claim 3 wherein said Polyalkylene Glycol is polyethylene glycol.
5. The composition of claim 4 wherein said polyethylene glycol has a molecular weight of about between 10-80 K.
6. The composition of claim 5 wherein said polyethylene glycol has a molecular weight of about 20-45 K.

7. The composition of claim 6 wherein said complex has the structure:



fCmGmGrArAfUfCmAmGfUmGmAmAfUmGfCfUfUmAfUmAfCmAfUfCfCmG-3'3'-dT (SEQ ID NO:8), wherein f=2'-fluoro and m=2'-O-methyl.

The Examiner applies the following patent in rejecting the claims:

Janjic et al. US 6,168,778 B1 Jan. 2, 2001

THE APPEALED REJECTION

ISSUE

Claims 1-7 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 23 and 27-31 of Janjic (Ans. 3).

The Examiner states that, while the appealed claims are not identical to the patented claims, “they are not patentably distinct from each other because the claims of the patent are directed to methods of making complexes of VEGF ligands while the instant claims are directed to compositions comprising such a VEGF ligand and a pharmaceutically acceptable carrier” (*id.*). The Examiner contends that it would have been obvious to combine a pharmaceutically acceptable carrier with the VEGF ligands made by the patented process “because the disclosure of the patent provides support for such compositions for the purpose of treating macular degeneration at column 9, lines 38-45” (*id.*).

Appellants contend that the Examiner's rejection is improper because "only those portions of the specification which provide support for the patent claims may be considered when addressing the issue of whether a claim in the application defines an obvious variation of an invention claimed in the patent" (App. Br. 6).

The issue with respect to this rejection, then, is whether the Examiner's *prima facie* case of obviousness-type double patenting is improperly based on disclosure from the conflicting patent's specification.

PRINCIPLES OF LAW

"[T]he examiner bears the initial burden, on review of the prior art or on any other ground, of presenting a *prima facie* case of unpatentability." *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992). Thus, in obviousness-type double patenting rejections, the Examiner must establish, in an analysis comparable to that under 35 U.S.C. § 103, that one of ordinary skill would have considered the rejected claims obvious over the conflicting claims. *See In re Braat*, 937 F.2d 589, 592-93 (Fed. Cir. 1991).

To show that a claimed invention is "a mere variation . . . which would have been obvious to those of ordinary skill in the relevant art . . . there must be some clear evidence to establish why the variation would have been obvious which can properly qualify as 'prior art.'" *In re Kaplan*, 789 F.2d 1574, 1580 (Fed. Cir. 1986). Therefore, unless the conflicting patent qualifies as prior art, that patent's specification cannot be used as evidence that the claims under examination would have been obvious. *See id.*; *see also In re Vogel*, 422 F.2d 438, 441 (CCPA 1970) ("[T]he patent disclosure may not be used as prior art.")

However, while the conflicting patent's specification cannot be used as prior art, it can nonetheless be used in certain circumstances "as a dictionary to learn the meaning of terms in a claim." *Vogel*, 422 F.2d at 441. The conflicting patent's disclosure may also be consulted to clarify the patented claims' scope, by referring to tangible embodiments of the patented claims that are disclosed in the specification. *See id.* at 442. Nonetheless, "only the disclosure of the invention claimed in the patent may be examined." *Id.*

FINDINGS OF FACT ("FF")

1. Claims 23 and 27-31 of Janjic reads as follows:

23. A method for the preparation of a Complex comprised of a VEGF Nucleic Acid Ligand comprising 2'-F-modified nucleotides and a Non-Immunogenic, High Molecular Weight Com-pound [sic] of Lipophilic Compound, said method comprising:

- a) identifying a VEGF Nucleic Acid Ligand from a Candidate Mixture of Nucleic Acids by the method comprising:
 - (i) contacting the Candidate Mixture with VEGF, wherein Nucleic Acids having increased affinity to VEGF relative to the Candidate Mixture may be partitioned from the remainder of the Candidate Mixture;
 - (ii) partitioning the increased affinity VEGF Nucleic Acids from the remainder of the Candidate Mixture;
 - (iii) amplifying the increased affinity VEGF Nucleic Acids to yield a ligand-enriched mixture of Nucleic Acids; and
- b) forming a covalent bond between said identified VEGF Nucleic Acid Ligand and a Non-Immunogenic, High Molecular Weight Compound of Lipophilic Compound.

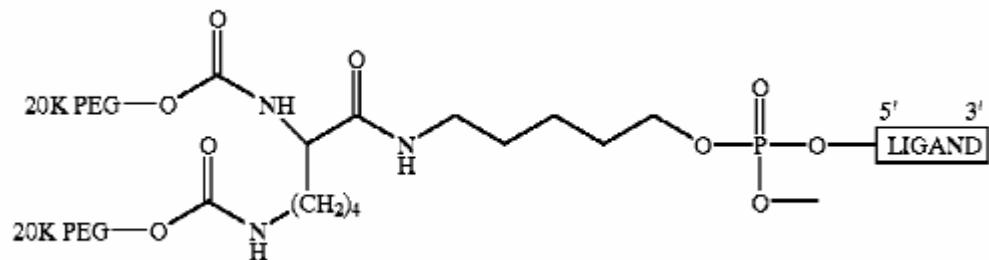
27. The method of claim 23 wherein said Non-Immunogenic, High Molecular Weight Compound is Polyalkylene Glycol.

28. The method of claim 27 wherein said Polyalkylene Glycol is polyethylene glycol.

29. The method of claim 28 wherein said polyethylene glycol has a molecular weight of about between 10-80 K.

30. The method of claim 29 wherein said polyethylene glycol has a molecular weight of about 20-45 K.

31. The method of claim 30 wherein said Complex has the structure



Ligand Component=
fCmGmGrArAfUfCmAmGfUmGmAmAfUmGfCfUfUmAfU
mAfCmAfUfCfCmG-3'3'-dT (VEGF ligand) (SEQ ID NO: 8).

(Janjic, col. 99, l. 24 through col. 100, l. 56.)

2. Thus, Janjic's claim 31 recites a process of producing a complex having a VEGF ligand encoded by SEQ ID NO: 8, the same VEGF ligand present in the composition recited in appealed claims 1-7. Moreover, the complex recited in Janjic's claim 31 has the same structure as the complex in the composition recited in appealed claim 7.

3. None of Janjic's claims 23 and 27-31 recites combining the VEGF ligand with "a pharmaceutically acceptable carrier suitable for administration via intravitreal injection," as recited in the appealed claims.

4. Janjic discloses that it is one "object of the invention to provide a method for inhibiting macular degeneration by the administration of a VEGF Nucleic Acid Ligand or Complex comprising a VEGF Nucleic Acid Ligand and Non-Immunogenic, High Molecular Weight Compound or Lipophilic Compound or a Lipid Construct comprising a Complex of the present invention" (Janjic, col. 9, ll. 39-45).

ANALYSIS

We agree with Appellants that the Examiner improperly relied on Janjic's disclosure as evidence of what one of ordinary skill would have considered obvious at the time the claimed invention was made.

We note that Janjic discloses that its VEGF ligands are suitable for treating macular degeneration (FF 4). However, in an obviousness-type double patenting analysis, one may only consult those portions of the conflicting patent's disclosure that support the subject matter recited in the conflicting claims. *See In re Vogel*, 422 F.2d at 442.

In the instant case, the claims in Janjic cited by the Examiner as conflicting with the appealed claims are all directed to methods of making a VEGF ligand complex. In contrast, the cited portion of Janjic explains how the VEGF ligand can be used (*see* FF 4).

Thus, the cited portion Janjic is not directed to the patented claims' methods of making the VEGF ligand complex, nor does that portion of Janjic explain terms in the patented claims, or provide an illustrative tangible embodiment of the patented claims' method. We therefore do not agree with

the Examiner that the cited portion of Janjic was properly used as evidence to show that it would have been obvious to combine the VEGF ligand in the patented claims with “a pharmaceutically acceptable carrier suitable for administration via intravitreal injection,” as recited in appealed claim 1.

The Examiner argues that the pharmaceutical composition recited in the appealed claims is “an obvious species of the genus of compounds” prepared in the patented claims (Ans. 5), as evidenced by Janjic’s specification, which the Examiner cited “in lieu of using a secondary reference in order to demonstrate why one of ordinary skill in the art would conclude that the formulation of a complex into a pharmaceutical composition is an obvious variation of the patented invention” (*id.* at 6).

We are not persuaded by this argument. Claims 23 and 27-31 of Janjic are directed to methods of preparing VEGF ligands by the steps of (a) identifying a VEGF-binding nucleic acid ligand from a mixture of candidate nucleic acids, and (b) covalently binding the ligand to a non-immunogenic, high molecular weight compound (*see FF 1*). Thus, Janjic’s disclosure may be consulted only to the extent that it relates to *the process recited in the patented claims*. *See Vogel*, 422 F.2d at 442. Because claims 23 and 27-31 do not recite any step of using the produced compounds, the Examiner’s reliance on Janjic’s specification for that teaching was clearly improper.

Therefore, because the Examiner improperly applied the disclosure of the conflicting patent as evidence of obviousness, we reverse the Examiner’s obviousness-type double patenting rejection of claims 1-7 over claims 23 and 27-31 of Janjic.

NEW GROUND OF REJECTION

Under the provisions of 37 C.F.R. § 41.50(b), we enter the following new ground of rejection:

Claims 1-7 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 23-25 and 27-31 of Janjic (Ans. 3).

As discussed above, Janjic's claim 31, which depends on claims 23 and 27-30, recites a process of producing a complex having the same VEGF ligand present in the composition of all of appealed claims 1-7 (*see FF 1, 2*). None of Janjic's claims 23 and 27-31, however, recites combining the VEGF ligand-containing complex with "a pharmaceutically acceptable carrier suitable for administration via intravitreal injection," as recited in the appealed claims (*see FF 3*).

However, claims 24 and 25 of Janjic read as follows:

24. The method of claim 23 wherein said Complex is further associated with a Lipid Construct.

25. The method of claim 24 wherein said Lipid Construct is a Liposome.

Thus, taken together, Janjic's claims 24 and 25 recite a process of making a VEGF ligand-containing complex associated with a lipid carrier which can be a liposome. One of ordinary skill in the art viewing claims 23-25 and 27-31 of Janjic as a whole would therefore have reasoned that it would be desirable to formulate the complex of claim 31 with the lipid construct of claim 24, or the liposome carrier recited in claim 25.

As admitted in Appellants' Specification, liposomes were known as useful for systemic delivery of therapeutic drugs (*see, e.g., Spec. 32*), and

lipid constructs were suitable carriers for delivering the claimed complexes in methods of treating eye disorders including macular degeneration and diabetic retinopathy (*id.* at 15-16). Thus, proper reference to Appellants' Specification to determine which carriers were "suitable for administration via intravitreal injection" would have led one of ordinary skill to conclude that the lipid construct of claim 24 and liposome of claim 25 would be carriers suitable for intravitreal delivery.

Because Janjic's claims 24 and 25 would have prompted one of ordinary skill in the art to combine the complex of Janjic's claim 31 with lipid carriers suitable for intravitreal administration, appealed claims 1-7 would therefore have been obvious to a person of ordinary skill in the art in view of the cited claims of Janjic.

SUMMARY

We reverse the Examiner's obviousness-type double patenting rejection of claims 1-7 over claims 23 and 27-31 of Janjic.

We enter a new ground of rejection of claims 1-7 for obviousness-type double patenting over claims 23-25 and 27-31 of Janjic.
See 37 C.F.R. § 41.50(b).

TIME PERIOD FOR RESPONSE

This decision contains a new ground of rejection pursuant to 37 C.F.R. § 41.50(b) (effective September 13, 2004, 69 Fed. Reg. 49960 (August 12, 2004), 1286 Off. Gaz. Pat. Office 21 (September 7, 2004)). 37 C.F.R. § 41.50(b) provides "[a] new ground of rejection pursuant to this paragraph shall not be considered final for judicial review.

37 C.F.R. § 41.50(b) also provides that the Appellant, WITHIN TWO

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MONTHS FROM THE DATE OF THE DECISION, must exercise one of the following two options with respect to the new ground of rejection to avoid termination of the appeal as to the rejected claims:

- (1) *Reopen prosecution.* Submit an appropriate amendment of the claims so rejected or new evidence relating to the claims so rejected, or both, and have the matter reconsidered by the Examiner, in which event the proceeding will be remanded to the Examiner
- (2) *Request rehearing.* Request that the proceeding be reheard under § 41.52 by the Board upon the same record

REVERSED, 37 C.F.R. § 41.50(b)

cdc

SWANSON & BRATSCHUN, L.L.C.
8210 SOUTHPARK TERRACE
LITTLETON CO 80120