United States Court of Appeals for the Federal Circuit

00-1166, -1167

RESEARCH CORPORATION TECHNOLOGIES, INC.,

Plaintiff-Appellant,

and

BRISTOL-MYERS SQUIBB COMPANY,

Plaintiff-Appellant,

v.

GENSIA LABORATORIES, INC.,

Defendant-Appellee,

and

PHARMACHEMIE BV,

Defendant-Appellee,

and

AMERICAN PHARMACEUTICAL PARTNERS, INC.,

Defendant-Appellee.

DECIDED: March 23, 2001

Before LOURIE, RADER, and GAJARSA, Circuit Judges.

LOURIE, Circuit Judge.

DECISION

Research Corporation Technologies, Inc. ("Research Corp.") and Bristol-Myers Squibb Company appeal from the decision of the United States District Court for the District of New Jersey holding that claims 1, 2, and 5 of Research Corp.'s U.S. Patent 5,562,925 are invalid for obviousness-type double patenting. In re Research Corp. Techs. Patent Litig., No. 97-2836 (D.N.J. Oct. 21, 1999) (order). Because the district court did not err in holding the claims invalid, we affirm.

BACKGROUND

Bristol-Myers Squibb is the exclusive licensee of Research Corp.'s '925 patent, which claims a composition for treating cancer with cisplatin, cis-Pt(II)$(NH_3)_2Cl_2$. Claims 1, 2, and 5 of the '925 patent are reproduced below:

> 1. A therapeutic composition comprising a therapeutically effective amount of an inorganic planar dsp^2 platinum (II) coordination complex, which complex is protected from light, and which is suitable for therapeutic administration by injection in solution therefor, wherein the donor ligands are Cl, Br, CN, NH_3, OS, NO_3, H_2O, hydroxy, ethylene diamine, or propylene diamine, and wherein the donor ligands of the complex form coordinate covalent bonds with the central platinum ion.
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> . . . .
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> 2. The therapeutic composition according to claim 1 wherein the platinum coordination complex is dissolved in a stabilizing effective amount of a saline or buffer solution.
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> . . . .
>
> 5. The therapeutic composition according to claim 4 which is cis-Pt(II)$(NH_3)_2Cl_2$.

'925 patent, col. 6, ll. 31-42, 48-49 (emphasis added).

The '925 patent issued in 1996 and claims priority from a parent application filed in 1970. Two method patents also issued from the 1970 application: U.S. Patent 4,177,263 (issued 1979) and U.S. Patent 4,339,437 (issued 1982). Both method patents expired in 1996. Claims 1 and 4 of the '263 patent are as follows:

> 1. A method of treating animal malignant tumor cells sensitive to cis-Pt(II)$(NH_3)_2Cl_2$ in animals which comprises parenterally administering to an animal afflicted with said tumor cells a solution containing cis-Pt(II)$(NH_3)_2Cl_2$ in an amount sufficient to cause regression of the animal tumor cells.

> . . . .
>
> 4. A method according to claim 1 wherein the chloroplatinumammine is administered in a saline salt-containing buffer solution.

'263 patent, col. 6, ll. 35-40, 45-47 (emphasis added).

Claims 1, 4, and 5 of the '437 patent are as follows:

> 1. A method of treating animal malignant tumor cells sensitive to a planar dsp^2 platinum(II) coordination compound or an ochtahedral [sic] d^2sp^3 platinum (IV) coordination compound wherein the donor ligands are Cl, Br, CN, NO_3, ethylene diamine, propylene diamine, pyridine, H_2O, OH, OS, in animals which comprises parenterally administering to an animal afflicted with said tumor cells a solution containing one of said compounds in an amount sufficient to cause regression of the animal tumor cells.
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> . . . .
>
> 4. A method according to claim 1 wherein the compound is administered in a saline or salt-containing buffer solution.
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> . . . .
>
> 5. A method according to claim 1 wherein the compound is a chloroplatinumammine.

'437 patent, col. 6, ll. 35-44, 49-53 (emphasis added).

Cisplatin may undergo at least two relevant degradation reactions. In one reaction, aquation, a water molecule (H_2O) replaces a chloride (Cl) ligand, resulting in $Pt(II)(NH_3)_2Cl(H_2O)$. In re Research Corp. Techs. Patent Litig., No. 97-2836, slip op. at 18 (D.N.J. Oct. 25, 1999) (memorandum opinion deciding double patenting issue) ("Research III"). Perumareddi teaches that this reaction is light-sensitive, although the parties dispute its sensitivity to light in the visible spectrum. Id. In another reaction, the addition of a chloride ion to cisplatin in saline solution replaces an amine group (NH_3), thereby forming trichloroammineplatinate[II] ($Pt(II)(NH_3)Cl_3$), or "TCAP." Bristol asserts that the inventors of the '925 patent discovered that light accelerates the irreversible formation of TCAP when cisplatin is in a saline solution.

During prosecution of the '925 patent, the examiner rejected the claims on the ground of obviousness-type double patenting in view of the previously issued '263 and '437 method patents. Id. at 6. In response, the applicants amended the independent claim to recite "which complex is protected from light" in place of the original language, "stored in the dark." The applicant then argued that:

> Thus, as the specification points out at page 4, the compounds per se must be protected from light. This consideration is not recited in connection with the methods claimed in the ['263 and '437] patents. The claims of the present

> application are thus patentably distinguished from the claims in the patents, and therefore the rejections of the present invention for obviousness-type double patenting over the claims in the ’437 and the ’263 patents are overcome.

Id. at 7. The examiner apparently found this argument persuasive and the ’925 patent issued shortly thereafter. Id.

Research Corp. and Bristol-Myers Squibb (hereinafter collectively, "Bristol") sued Gensia Laboratories, Inc., Pharmachemie BV, and American Pharmaceutical Partners, Inc. (collectively, "the defendants") for infringement of claims 2 and 5 of the ’925 patent under 35 U.S.C. § 271(e)(2) based on the defendants’ Abbreviated New Drug Applications (ANDAs), which sought approval to sell generic forms of cisplatin-based anticancer drugs. Research III at 2. The Judicial Panel on Multidistrict Litigation transferred the cases to the United States District Court for the District of New Jersey. Id.

First, the court determined that the relevant field of art was cancer research and excluded extrinsic evidence from other disciplines to construe the claims. In re Research Corp. Techs., No. 97-2836, slip op. at 9 (D.N.J. Aug. 11, 1998) (memorandum opinion construing "protected from light" claim limitation) ("Research I"). The court then construed the phrase in claim 1 of the ’925 patent, "protected from light," as meaning "maintained in the absence of light from preparation until use." Research I at 13. The court interpreted the phrase "suitable for therapeutic administration by injection in solution therefor" as meaning "a tumor reducing platinum complex that is capable of being placed into solution or other nonharmful media for parenteral administration." In re Research Corp. Techs., No. 97-2836, slip op. at 19 (D.N.J. Oct. 20, 1998) (memorandum opinion construing "therapeutic administration" claim limitation) ("Research II"). The court also interpreted the phrase in claim 2 of the ’925 patent, "stabilizing effective amount of a saline or buffer solution," as meaning "that the solution contains sufficient chloride or other ions so as to effect some stabilization of the platinum complex against hydrolysis in aqueous solutions." Id. at 19.

The court then invalidated claims 1, 2, and 5 for obviousness-type double patenting over the method claims of the ’263 and ’437 patents (collectively, "the method patents") in combination with other pertinent references, primarily Perumareddi. Research III at 19-20. The court found that Perumareddi taught that light caused the degradation of cisplatin by promoting aquation. Id. at 18. The court concluded that the prior art taught that "it was well known [at the time of invention] that the platinum complexes were light-sensitive, and that exposure to light could cause a chemical change in the compound." Id. at 19. The court found that the only material distinction between the claimed invention and the claims in the method patents was the limitation that the platinum complexes be protected from light. Id. at 21. The court then concluded that the claims were invalid for obviousness-type double patenting.

Bristol appeals from the court’s claim construction and subsequent invalidity judgment. We have jurisdiction of this appeal pursuant to 28 U.S.C. § 1295(a)(1) (1994).

DISCUSSION

Claim construction is an issue of law, Markman v. Westview Instruments, Inc., 52 F.3d 967, 970-71, 34 USPQ2d 1321, 1322 (Fed. Cir. 1995) (en banc), aff’d, 517 U.S. 370 (1996), that we review de novo. Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1456, 46 USPQ2d 1169, 1172 (Fed. Cir. 1998) (en banc). We interpret the claims in light of the specification, but it is

improper for a court to add extraneous limitations to a claim that are added wholly apart from any need to interpret what the patentee meant by particular words or phrases in the claim. Hoganas AB v. Dresser Indus., Inc., 9 F.3d 948, 950, 28 USPQ2d 1936, 1938 (Fed. Cir. 1993).

A defendant asserting a double patenting defense must prove facts supporting a conclusion of invalidity by clear and convincing evidence. Symbol Techs., Inc. v. Opticon, Inc., 935 F.2d 1569, 1580, 19 USPQ2d 1241, 1249 (Fed. Cir. 1991). The doctrine of double patenting is intended to prevent a time-wise extension of a patent for the same invention or an obvious modification thereof. In re Lonardo, 119 F.3d 960, 965, 43 USPQ2d 1262, 1266 (Fed. Cir. 1997). "Obviousness-type" double patenting is "judicially created and prohibits an inventor from obtaining a second patent for claims that are not patentably distinct from the claims of the first patent." Lonardo, 119 F.3d at 965, 43 USPQ2d at 1266. The proper question in an obviousness-type double patenting inquiry is whether the claims at issue would have been obvious to one of ordinary skill in the art over the subject matter of the claims in the first patent. See, e.g., In re Kaplan, 789 F.2d 1574, 1579-80, 229 USPQ 678, 682 (Fed. Cir. 1986); In re Longi, 759 F.2d 887, 893, 225 USPQ 645, 648 (Fed. Cir. 1985). "In considering the question, the patent disclosure may not be used as prior art." In re Vogel, 422 F.2d 438, 441, 164 USPQ 619, 622 (CCPA 1970). We review the factual underpinnings of the district court's double patenting conclusions for clear error and its ultimate legal conclusion de novo. Fed. R. Civ. P. 52(a); Longi, 759 F.2d at 893, 225 USPQ at 648.

A. Claim Construction

Bristol first argues that the court erred in its selection of the relevant field of art as cancer research, arguing that it should be "oncological pharmaceutics" and that the court improperly excluded expert testimony from this discipline for its claim construction. Next, Bristol asserts that the expression "protected from light" in the art of pharmaceutics means that the composition must be protected from harmful light, but not from all light, which it states would be a physical impossibility. Finally, Bristol argues that the "suitable for therapeutic administration by injection in solution therefor" language requires a solution free from harmful impurities that retains its therapeutic properties even after storage.

The defendants respond that the court did not err in determining the relevant art to be cancer research. They also argue that the district court correctly construed "protected from light" as "maintained in the absence of light from preparation until use." Finally, the defendants respond that we should uphold the district court's construction of "suitable for therapeutic administration by injection in solution therefor" as "a tumor reducing platinum complex that is capable of being placed into solution or other nonharmful media for parenteral administration," Research II at 19, because no claim language or other evidence supports Bristol's assertion that the solution must be sterile or that it must be as therapeutic after storage as it was at the time of manufacture.

While the parties vigorously dispute the relevant field of art, we conclude that the disputed claim terms should be construed without reference to extrinsic evidence from any discipline, because such evidence is not necessary to assist in our understanding of those terms. See Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1584, 39 USPQ2d 1573, 1577 (Fed. Cir. 1996). The district court therefore did not err in excluding evidence relating to oncological pharmaceutics, as no extrinsic evidence is required to determine if the claims contain the disputed limitations relevant to the obviousness-type double patenting analysis. We will construe the claims only to that extent; any further construction would be advisory. Hester

Indus., Inc., v. Stein, Inc., 142 F.3d 1472, 1485, 46 USPQ2d 1641, 1651-52 (Fed. Cir. 1998) (declining to construe a claim term because the district court did not construe the term in conjunction with a final judgment and the issue was mooted by invalidity).

1. "Protected From Light"

We are not persuaded by the minor distinction between the parties' proposed constructions of the expression "protected from light." The specification indicates that the phrase "protected from light" is no more than a direction for care. It states that the inventors stored the platinum complex in the dark until testing. '925 patent, col. 2, ll. 20-23. No other reference is made to protecting cisplatin from light in the patent. Although the applicants asserted during prosecution that "the compounds per se must be protected from light" and that "the claims of the present application are thus patentably distinguished from the claims in the [method] patents," J.A. at 9490, we are not persuaded that this direction for care adds any limitation to the structure of the composition, which is the subject of the claim.

We are not construing a composition claim that contains a material that in fact protects it from light. No brown bottle appears as part of the claim, nor is there any ingredient in the composition that protects the composition from light. The only apparent distinction between the claimed composition protected from light and that not protected from light is how it is treated; that is not a structural or otherwise meaningful claim limitation. If anything, the inventors discovered only a property — light sensitivity in the context of TCAP formation — of the composition recited in the method patents. A direction for care that does no more than reflect the inventor's recognition of a newly discovered property does not itself impart patentability to that composition. See, e.g., In re Spada, 911 F.2d 705, 708, 15 USPQ2d 1655, 1657 (Fed. Cir. 1990) (holding that the discovery of a new property of an old product does not render the old product patentable); Ex parte Masham, 2 USPQ2d 1647, 1648 (Bd. Pat. App. & Int. 1987) (holding that a claimed apparatus was anticipated because it did not "undergo a metamorphosis to a new apparatus merely by affixing instructions thereto" that it be completely submerged, which the prior art device was also capable of). Thus, the "protected from light" language provides no distinguishing structure to the claim. There is simply "no there there." We therefore construe the expression "protected from light" to be non-limiting.

2. "Suitable for Therapeutic Administration by Injection in Solution Therefor"

Bristol argues that this limitation provides a patentable distinction over the method claims because it requires purity and maintenance of therapeutic properties after storage. We need not evaluate this argument because, even assuming its correctness, such a limitation would have been an obvious modification over the prior method claims, as we will discuss infra. We therefore proceed to address the double patenting arguments.

B. Double Patenting

Bristol argues that the grant of "therapeutic composition" claims in the '925 patent did not extend the term of its method claims and thus does not violate the "basic policy" served by the obviousness-type double patenting doctrine as a matter of law. Bristol cites cases such as General Foods and Symbol Technologies as supporting the proposition that there is no double patenting where one can practice the invention claimed in the earlier-issued patents without infringing the inventions claimed in the later-issued patent or vice-versa. Gen. Foods Corp. v. Studiengesellschaft Kohle mbH, 972 F.2d 1272, 1282-83, 23 USPQ2d 1839, 1847 (Fed. Cir.

1992); Symbol Techs., 935 F.2d at 1581, 19 USPQ2d at 1249. Bristol contends that because the claims in the prior method patents may be practiced without infringing the composition claims, we need not inquire further into obviousness-type double patenting. Alternatively, Bristol asserts that the defendants' double patenting defense should fail because the prior art does not suggest the need to protect a cisplatin-based therapeutic composition from light and stabilize it with saline to prevent the formation of TCAP. Bristol further argues that "protected from light" is not the only patentable distinction between the claims in the '925 patent and the claims in the prior method patents because saline in claim 2 of the '925 patent is used in a novel and different way to impart stability when the composition is protected from light. Bristol contends that saline in the claims in the prior method patents was used only for administration at levels isotonic with body fluids.

The defendants respond that Bristol's proposed cross-infringement test applies only to "same invention-type" double patenting, and that it has been rejected for determining "obviousness-type" double patenting in Lonardo, 119 F.3d at 967, 43 USPQ2d at 1267. They assert that under the appropriate "obvious modification" inquiry, the only new limitation of the composition claim, "protected from light," is an obvious modification of the claims in the method patents in light of prior art references such as Perumareddi that teach the light sensitivity of platinum complexes. The defendants argue that the recitation of saline in claim 2 of the '925 patent does not distinguish it over the recitation of saline in the claims in the method patents because, if present for administration purposes, the saline would necessarily also stabilize cisplatin for the asserted storage purposes of the '925 patent.

We agree with the defendants that the district court did not err in concluding that double patenting existed here. General Foods and Symbol Technologies do not entitle Bristol to a threshold cross-infringement test or patent term extension test. In General Foods, we first stated that the two patents at issue did not claim the same invention and then found that "[u]nder an obviousness-type double patenting analysis, neither claimed process is a mere obvious variation of the other. No other kind of 'double patenting' is recognized, so there is no double patenting." 972 F.2d at 1278, 23 USPQ2d at 1843. Thus, we made the "obvious modification" inquiry that is required by precedent to resolve obviousness-type double patenting issues. See, e.g., Lonardo, 119 F.3d at 967, 43 USPQ2d at 1267; Vogel, 422 F.2d at 441, 164 USPQ at 622.

In Symbol Technologies, we first dismissed the double patenting challenge on the ground that 35 U.S.C. § 121 precluded the defense. Symbol Techs. at 1580, 19 USPQ2d at 1249. We then decided, in the event that the safeguard of § 121 did not apply, that the differences between the claims at issue would not have been obvious. Id. at 1581, 19 USPQ2d at 1250. Finally, we stated as a matter of policy that the decision did not allow the unlawful extension of the patent grant. Id. However, the policy rationale upon which Bristol relies does not supplant the case law requirement that a court determine whether or not the claims at issue would have been obvious variations over the prior claims, an inquiry that we conducted in both General Foods and Symbol Technologies.

Our decision in Lonardo illustrates application of the proper obviousness-type double patenting test. Lonardo, 119 F.3d at 967, 43 USPQ2d at 1267. In that case, the United States Patent and Trademark Office had held the claims invalid because one could not practice the invention of the prior claims without infringing the later claims. Id. We affirmed the rejection, but on the ground that each additional limitation led only to an obvious modification of the device in the prior claims. Id. Likewise, in this case, the proper obviousness-type double patenting test

inquiry is whether each additional limitation leads to an obvious modification of the invention of the prior claims. Accordingly, the district court did not err in rejecting Bristol's proffered double patenting threshold tests.

Furthermore, we discern no error in the court's conclusion that claims 1, 2, and 5 of the '925 patent are invalid for obviousness-type double patenting. The composition of the '925 claims, when there are two chloride and two ammonia ligands in a platinum (II) complex, is the same as the composition used in the claims in the method patents. Bristol is correct that the composition claims in the '925 patent do not define the same invention as the claims in the method patents because they are drawn to different statutory classes of subject matter. See Studiengesellschaft Kohle mbH v. Northern Petrochem. Co., 784 F.2d 351, 354, 228 USPQ 837, 840 (Fed. Cir. 1986) (holding that "because the two patents claim different statutory classes of subject matter, composition and process, they are not the same invention"). Nevertheless, even though the claims do not define the same invention, there is no per se nonobvious distinction between a method of using a device and the device itself. Lonardo, 119 F.3d at 968, 43 USPQ2d at 1268 (holding that method claims were invalid for obviousness-type double patenting over claims to the structure, which suggested the obvious method of using the device). In this case, as in Lonardo, the same invention is not claimed twice, but there is no nonobvious variation between the claimed composition and the composition to be used in the claimed methods.

We have already determined that "protected from light" is a non-limiting direction for care and therefore cannot be a basis for distinguishing the composition claims over the prior method claims. We also conclude that "suitable for therapeutic administration by injection in solution therefor" is not a patentable distinction over those claims. Bristol asserts that the "invention" of the '925 patent is a pure and stable composition that degrades minimally to TCAP. We do not agree that a complex "suitable for therapeutic administration" requires a degree of purity greater than that already required by the claims of the method patents. Those claims are directed to treating malignant animal tumor cells by parenteral administration in an amount sufficient to cause regression of the tumor. '263 patent, col. 1, ll. 35-40; '437 patent, col. 6, ll. 35-44. Those method claims are also necessarily directed to the administration of therapeutic compositions because they are intended to cause regression of tumor cells. One of ordinary skill in the art would have employed the same purity standards for both the earlier claimed method and the instantly claimed composition.

Similarly, we are not persuaded by Bristol's argument that the limitation in claim 2 of the '925 patent, "dissolved in a stabilizing effective amount of a saline or buffer solution," patentably distinguishes that claim over the claims in the method patents reciting that the platinum compound is "administered in a saline salt-containing buffer solution." '263 patent, claim 4, col. 6, ll. 45-47; '437 patent, claim 4, col. 6, ll. 49-51. Although we may not use the disclosure of the prior patent as prior art in a double patenting analysis, it may be used to interpret the meaning of the claim. Vogel, 422 F.2d at 441, 164 USPQ at 622. Here, where Bristol asserts that the saline in the composition claims has a unique significance — maintenance of therapeutic properties after storage — that is lacking in the method claims, and the significance of saline is not evident from the claims themselves, we may look to the specification to construe how saline is used in each claim. The patents share the same written description, which indicates that saline was used to stabilize the solutions for the brief period of time between preparation and administration in the inventions of the various patents. '263 patent, col. 2, ll. 16-22; '437 patent, col. 2, ll. 21-27; '925 patent, col. 2, ll. 21-26. No other reason is given for the use of saline solution. We are thus not persuaded by Bristol's argument that the use of saline in the

method claims merely facilitated administration of the solution at levels isotonic with body fluids and that the use of saline in claim 2 of the '925 patent means something patentably different. We therefore conclude that there is no nonobvious distinction between the use of saline in the claims of the method patents and the use of the saline in "a stabilizing effective amount" in claim 2 of the '925 patent.

CONCLUSION

Because the district court did not err in determining that the composition claims at issue are invalid for obviousness-type double patenting over the claims in the prior method patents, we affirm.

FOOTNOTES:

[1] The defendants do not dispute that this patent covers cisplatin, despite the absence of ordinary amine groups among the recited donor ligands in the independent claim. Although claim 5 specifically recites chloroplatinumammine, it should not include subject matter not covered by the independent claim from which it depends. In any event, the failure to include NH_3 among the recited donor ligands appears to have been an inadvertent prosecution error. Indeed, NH_3 and OS ligands were added at the last minute by an examiner's amendment to the '925 patent. J.A. at 9503. For purposes of this appeal only, we will assume, without deciding, that the '437 patent covers a method of administering cisplatin. In any event, the '263 patent clearly covers such a method.

[2] J.R. Perumareddi and A.W. Adamson, Photochemistry of Complex Ions v. The Photochemistry of Some Square-Planar Platinum(II) Complexes, J. Phys. Chem., Vol. 72, No. 2, 414-420 (1968).

[3] Another defendant, Ben Venue, was involved in the consolidated proceeding. Because Ben Venue's interests stand apart from the other three defendants, the court's final order did not apply to it.

[4] Gertrude Stein, Everybody's Autobiography, ch. 4, in Chambers, Dictionary of Quotations 965 (Alison Jones ed., 1998).

[5] 35 U.S.C.A. § 121 (West Supp. 2000) provides that a patent issuing on an application in which a restriction requirement to one of two or more independent and distinct inventions was made will not be used as a reference against a divisional application directed to the other invention if the divisional application is filed before the issuance of the patent on the other application.