

United States Court of Appeals for the Federal Circuit

01-1431
(Interference no. 104,199)

JAMES E. MANNING,

Appellant,

v.

NORMAN A. PARADIS,

Appellee.

Richard P. Vitek, Myers Bigel Sibley & Sajovec, P.A., of Raleigh, North Carolina, argued for appellant.

Roger L. Browdy, Browdy and Neimark, P.L.L.C., of Washington, DC, argued for appellee.

Appealed from: United States Patent and Trademark Office
Board of Patent Appeals and Interferences

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Appellant,

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Appellee.

DECIDED: July 12, 2002

Before MAYER, Chief Judge, RADER and DYK, Circuit Judges.

DYK, Circuit Judge.

James E. Manning (“Manning”) appeals from a decision of the Board of Patent Appeals and Interferences (“Board”) awarding judgment in an interference to the senior party, Norman A. Paradis (“Paradis”). Manning v. Paradis, Inter. No. 104,199 (Bd. Pat. App. & Inter. Feb. 27, 2001). Because the Board’s decision was supported by substantial evidence and was not contrary to law, we affirm.

BACKGROUND

The invention at issue in this interference concerns a method of treating a subject in cardiac arrest. The method includes inserting a catheter through the subject’s femoral artery

into the subject's aorta. A balloon on the catheter is then inflated to block arterial blood supply to the subject's abdomen and lower extremities. Once the aorta is closed off, an oxygen-carrying solution is injected through the catheter into the aortic arch to deliver oxygen to the heart. The count of the interference reads:

A method of treating a subject in cardiac arrest comprising:

blocking the descending aorta of said subject; and then

perfusing the aortic arch of said subject with an oxygen-carrying protective solution in an amount effective to deliver oxygen to the heart of said subject.

Paradis is the named inventor of U.S. Patent No. 5,334,142, the application for which was filed on September 9, 1991. Manning is the named inventor on U.S. application No. 08/452,527 (the "527 application"), which was filed on May 30, 1995, and which was accorded the benefit of U.S. application No. 07/769,132 (the "132 application"), filed September 30, 1991, now U.S. Patent No. 5,216,032. Accordingly, Paradis was the senior party by virtue of his earlier priority date. An interference was declared, and a hearing was held before the Board on February 27, 2001. By agreement of the parties, the sole issue presented for decision to the Board was whether Manning reduced to practice the subject matter of the count prior to Paradis's filing date of September 9, 1991.

To prove that he reduced the invention of the count to practice before September 9, 1991, Manning filed an affidavit concerning experiments he performed on dogs on October 2, 1990. In the October 1990 experiments, a catheter was inserted into a dog and a balloon on the catheter was inflated to occlude the descending aorta and isolate the aortic arch for perfusion. Then, the dog received an infusion into the aortic arch of about 500 mL of Oxypherol[®], a commercially available solution capable of carrying oxygen, and 2 mg of epinephrine over one minute. The Oxypherol[®] had been oxygenated in a separate container before infusion.

The effect of the experiment on the dog was monitored and recorded by sensors that measured the blood pressures in the mid-aortic arch, in the right atrium, and in the descending aorta; by a probe that measured carotid blood flow in the left common carotid artery; and by an electrocardiogram ("ECG") that measured the activity of the dog's heart. The data recorded by the pressure sensors during perfusion indicated a pressure gradient between the aortic arch and the right atrium of 6 - 64 mm Hg. Manning asserted in his affidavit that a pressure gradient of "15 mm Hg during CPR has been shown to be required in order to provide sufficient blood flow to the heart to allow for successful resuscitation."

Manning further asserted in his affidavit that the rising pressure in the right atrium during perfusion indicated that the oxygenated solution flowed from the arterial system through the heart to the venous system and that the ECG data recorded during perfusion correlated with greater success rates for restoring normal intrinsic heart contraction.

Manning had described the results of the October 1990 experiment in an article submitted for publication on September 6, 1991, to the peer-reviewed medical journal, *Annals of Emergency Medicine*. The article was eventually published in the September 1992 volume of the journal. In the journal article, Manning stated that the flow of oxygenated fluid to the heart was not actually measured and that, although a pressure gradient between the aortic arch and the right atrium was measured and an increase of right atrium pressure was observed during perfusion, he was not certain that the aortic arch of the dog was perfused with an oxygen-carrying protective solution in an amount effective to deliver a measureable amount of oxygen to the dog's heart. He stated:

Despite flow rates and pressure gradients that strongly suggest good perfusion [of the heart], myocardial and cerebral flows were not quantitated. . . . All the hemodynamic effects observed in this study may be due solely to the epinephrine administered. The value of perfluorochemicals cannot be addressed. These experiments were not undertaken to prove the efficacy of selective aortic arch perfusion but rather to demonstrate this new technique and provide preliminary data that may be helpful in designing controlled outcome studies.

(emphases added). Manning also indicated in the journal article that the increase in right atrium pressure during perfusion may have indicated retrograde blood flow from the aortic arch through the heart to the venous system of the right heart, and also may have indicated merely a pressure build-up due to antegrade flow in the systemic circulation while the aortic arch was occluded. In other words, Manning cautioned that the measured increase in the aortic arch - right atrium pressure gradient may have been the result of blocking off the descending aorta and a pressure build-up in the aortic arch due to the heart's normal pumping function rather than the cause of retrograde fluid flow from the aortic arch, through the heart, to the venous system. Specifically, Manning stated:

The consistent increases in infusion midaortic arch pressure seen in all [subjects] . . . during selective aortic arch perfusion demonstrate the ability to pressurize the aortic arch. The observed increases in infusion right atrial pressure during infusion indicated flow from the aortic arch to the venous system and right heart. This right atrial pressure rise probably represents both antegrade flow through the systemic circulation and retrograde flow through the pulmonary vasculature with the relative importance of each being unclear.

(emphasis added).

In the interference proceeding the Board adopted Manning's proposed construction of the count and treated the count as merely requiring the delivery of oxygen to the heart, though the Board stated that "this construction is not necessarily the correct one" Manning, Inter. No. 104,199, slip op. at 6. Under this construction the Board held that Manning had not demonstrated a reduction to practice of the invention in the October 2, 1990, experiment because he had not demonstrated that he appreciated that

oxygen actually was delivered to the heart during the experiments. *Id.* at 11. The Board noted that Manning's affidavit did not explicitly state that oxygen was delivered to the heart of the dog; that during the experiments the amount of pre-oxygenation of the Oxypherol[®] was not quantified; that there was no indication of the amount of oxygen carried by the Oxypherol[®]; and that there was no indirect evidence that oxygen was provided to the heart of the subjects during the experiments. *Id.* at 7. The Board reasoned that Manning's affidavit that the measured pressure gradient indicated "substantial myocardial perfusion" was contradicted by statements in his journal article that the pressure gradient only "suggest [ed]" perfusion but that myocardial flow was not actually measured. *Id.* at 8. The Board concluded that Manning "failed to definitively establish substantial myocardial perfusion, not to mention delivery of oxygen to the heart." *Id.* at 6.

Alternatively, the Board found that during prosecution of his patent application, Manning had amended his claims such that the count corresponding to Manning's claim "requires [that] an effective amount of oxygen be delivered to the heart." *Id.* at 10 (emphasis in original). While the Board's opinion was less than clear, apparently the Board alternatively construed the count to require that an amount of oxygen effective for treatment be delivered to the heart. Because the Board found that Manning had not proved that he delivered an effective amount of oxygen to the heart but only that he had supplied oxygenated fluid to the aortic arch, the Board held that Manning had not reduced the count to practice.

Manning filed this timely appeal. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(4).

DISCUSSION

Reduction to practice is a legal determination that we review without deference. *Holmwood v. Sugavanan*, 948 F.2d 1236, 1238, 20 USPQ2d 1712, 1714 (Fed. Cir. 1991). However, this court reviews the Board's factual findings supporting its legal conclusions for substantial evidence. *In re Gartside*, 203 F.3d 1305, 1315, 53 USPQ2d 1769, 1775 (Fed. Cir. 2000).

I

"In order to establish an actual reduction to practice, the inventor must prove that: (1) he constructed an embodiment or performed a process that met all the limitations of the interference count; and (2) he determined that the invention would work for its intended purpose." *Cooper v. Goldfarb*, 154 F.3d 1321, 1327, 47 USPQ2d 1896, 1901 (Fed. Cir. 1998). An inventor must prove these elements by a preponderance of the evidence. *Id.* Here, because the senior party in his brief to the Board conceded that the first element of the *Cooper* test has been met, we are concerned only with the second element, namely, whether the junior party, Manning, knew that his invention would work for its intended purpose. In other words, in

the context of the count we must determine the intended purpose of the invention and whether Manning in fact appreciated that he had performed a process that worked for the intended purpose.

Where the count does not itself state the intended purpose of the invention, difficult questions concerning how to construe the intended purpose of the invention may be presented. Compare DSL Dynamic Sciences Ltd. v. Union Switch & Signal, Inc., 928 F.2d 1122, 1125, 18 USPQ2d 1152, 1154-55 (Fed. Cir. 1991) with Fujikawa v. Wattanasin, 93 F.3d 1559, 1564, 39 USPQ2d 1895, 1899 (Fed. Cir. 1996). But here we conclude that the count does state the intended purpose of the invention.

Patent interference count construction is a matter of law, and this court reviews the Board's count construction without deference. Adang v. Fischhoff, 286 F.3d 1346, 1352, 62 USPQ2d 1504, 1509 (Fed. Cir. 2002). The opinion of the Board is somewhat confusing as to whether the count should be construed to be satisfied by the delivery of any amount of oxygen to the heart of the subject or whether it requires something more.

If we construed the intended purpose of the count as the delivery of any amount of oxygen to the heart, we might have difficulty sustaining the Board's decision, because there is considerable evidence that Manning's process delivered at least some oxygen to the heart, and that Manning appreciated that it did so. However, while counts should be given the broadest possible interpretation, we think the count must be construed to require the delivery of an amount of oxygen sufficient to have a therapeutic effect on the subject's heart while the subject is in cardiac arrest.

The count claims, not just a method of delivering oxygen to the heart of a subject, but a method of "treating a subject in cardiac arrest" by "perfusing the aortic arch of said subject with an oxygen-carrying protective solution in an amount effective to deliver oxygen to the heart." (emphasis added). Manning urges that a subject in cardiac arrest is treated if any amount of oxygen is delivered to the heart, even when the amount of oxygen is one molecule of oxygen. In effect, Manning urges that the preamble of the count—that the method is directed to "treating a subject in cardiac arrest"—does not limit the count, and that the count is satisfied when the oxygen-carrying protective solution delivers even an infinitesimal amount of oxygen to the heart. However, we have recently held, also in the context of an interference dispute, that "[a] preamble to a claim has the import that the claim as a whole suggests for it." Griffin v. Bertina, 285 F.3d 1029, 1033, 62 USPQ2d 1431, 1434 (Fed. Cir. 2002) (internal citation omitted). In Griffin, the interference count claimed:

A method for diagnosing an increased risk for thrombosis or a genetic defect causing thrombosis comprising the steps of:

(A) obtaining, from a test subject, test nucleic acid comprising codon 506 within EXON 10 of the human Factor V gene; and

(B) assaying for the presence of a point mutation in the nucleotides of codon 506 within EXON 10 of the human Factor V gene, wherein said point mutation correlates to a decrease in the degree of inactivation of human Factor V and/or human Factor Va by activated protein C, wherein the presence of said point mutation in said test nucleic acid indicates an increased risk for thrombosis or a genetic defect causing thrombosis.

Id. at 1031, 62 USPQ2d at 1432 (emphases omitted). The junior party to the interference urged that the count should be construed to require only the manipulative steps and should not be limited by the preamble or wherein clauses. We disagreed and reasoned that:

Consideration of the preamble gives meaning and purpose to the manipulative steps in this case. The first step recites that the test nucleic acid should be obtained from a “test subject.” In the absence of the preamble’s stated objective to diagnose thrombosis, the term “test subject” is empty language. What is one testing for, and who is a suitable subject? Similarly, without the preamble, “assaying for the presence of a point mutation” has no purpose. Obtaining nucleic acid and assaying for a point mutation alone are merely academic exercises. The preamble is thus a necessary limitation.

Id. at 1033, 62 USPQ2d at 1434.

Just as the preamble of a count may define a limitation of the count, so too it may define the intended purpose of the invention. Here the preamble defines the intended purpose of the invention because unless oxygen were delivered to the heart of the subject in a therapeutic amount the invention would have no purpose. Thus, we conclude that the preamble is not superfluous.

The preamble of the count states that the purpose of the invention is to treat a subject in cardiac arrest. The plain meaning of the word “treat”^[1] requires that the invention of the count is used to seek or to achieve a therapeutic effect on the subject, rather than simply providing oxygen to the subject’s heart. Further, the parties agree that it is appropriate to look to the specification of Manning’s application to understand the meaning of “treat[ing] a subject in cardiac arrest” as used in the count. See Rapaport v. Dement, 254 F.3d 1053, 1059, 59 USPQ2d 1215, 1220 (Fed. Cir. 2001). In the “Background of the Invention” section of his application Manning stated that when a person suffers cardiac arrest, the blood flow to the heart and brain cannot sustain cellular survival, and that the invention is based on a means by which survival rates of a patient in cardiac arrest may be increased. Thus, one of the purposes of the invention of “treat[ing] a subject in cardiac arrest” was to sustain cellular survival of the subject’s heart tissue. This is confirmed by Manning’s statements to the Board and to this court. In his briefs to both the Board and this court, Manning stated that “[o]ne goal for treatment during cardiac arrest, therefore, is to provide oxygen to the most critical organs to prevent cellular damage until the subject’s spontaneous circulation is restored.” (Appellant’s Br. at 6.) Accordingly, we hold that the intended purpose of the invention as stated in the count is to deliver an amount of oxygen to the heart of a subject in cardiac arrest, where the amount of oxygen is sufficient to have the therapeutic effect of preventing cellular damage to the subject’s heart and brain.

Our construction of the count is confirmed by the prosecution history of Manning’s patent application. During prosecution, Manning initially filed an application claiming

[a] method of treating a subject in cardiac arrest, comprising . . . perfusing the aortic arch of said subject with a protective solution, which protective solution is capable of delivering oxygen to the heart of said subject, and administering said subject a vasoconstrictor concurrently with said perfusing step in an amount effective to enhance coronary perfusion with said protective solution.

(emphases added). The examiner rejected this claim as indefinite under 35 U.S.C. § 112 because it “encompass[ed] solutions which carry less oxygen than required to sustain the heart.” (emphasis added). In response to this rejection, Manning’s representative participated in an interview with the examiner. After the interview, to overcome the rejection, Manning amended his application to claim

a method of treating a subject in cardiac arrest comprising . . . perfusing the aortic arch of said subject with an oxygen-carrying protective solution in an amount effective to deliver oxygen to the heart of said subject, and concurrently administering said subject an alpha adrenergic receptor agonist in an amount effective to enhance coronary perfusion with said protective solution.

(emphases added). Thus, it appears that the examiner required Manning's claim to cover the delivery of oxygen in a sufficient amount to sustain the heart and that Manning amended his claim to require that the subject in cardiac arrest be treated by the actual delivery of oxygen to the heart. This supports a construction of the count that requires a treatment that has a physiological effect on the subject's heart because of the delivery of oxygen.

II

We turn then to the question whether Manning presented evidence that he appreciated that the invention would work for its intended purpose. In Estee Lauder, Inc. v. L'Oreal, S.A., 129 F.3d 588, 593, 44 USPQ2d 1610, 1614 (Fed. Cir. 1997), and Cooper, 154 F.3d at 1327, 47 USPQ2d at 1901, we made clear that when testing is required to establish that the invention works for its intended purpose, the inventor must at the time appreciate that such testing is successful. The record is undisputed that Manning did not know that his experiments established that the invention worked for the intended purpose required by our construction of the count.^[2] First, at oral argument Manning's counsel virtually conceded that if the count were construed as requiring the delivery of an amount of oxygen effective to prevent cell damage to the heart, Manning probably would not be entitled to priority.^[3] Second, the Board was not persuaded by Manning's declaration asserting that a pressure gradient between the aorta and the right atrium observed while the subject's aortic arch was perfused during the 1990 experiment was sufficient to produce "substantial" myocardial perfusion, and that the physiological effect of the perfusion on the subject's heart was indicated by an increase in ventricular fibrillation waveform deflections noted during the perfusion.

While the Manning declaration may show that Manning now appreciates that the 1990 experiments demonstrated that the invention provided a therapeutic effect, the declaration does not show that Manning appreciated this at the time. The Board found that statements made in Manning's 1992 journal article showed that Manning did not, in fact, appreciate this effect. Manning, slip op. at 8. In the journal article Manning stated that fluid flow from the aortic arch to the heart was not quantitated, and that "[a]ll the hemodynamic effects observed in this study may be due solely to the epinephrine administered. The value of the perfluorochemicals cannot be addressed." Thus, Manning's article recognized that oxygen may not have caused any of the observed hemodynamic effects. Manning's article also recognized that hemodynamic effects due to the epinephrine perfusion may have been achieved even though the fluid carrying the epinephrine did not enter the heart because "[e]pinephrine is given primarily to enhance CPR blood flow by increasing peripheral arterial resistance, which leads to greater aortic pressure and coronary perfusion pressure . . ." (emphasis added). Most significantly, Manning's article specifically admitted that the "experiments were not undertaken to prove the efficacy of selective aortic arch perfusion . . ." Accordingly, the Board found that Manning failed to appreciate that he had achieved "substantial myocardial perfusion, not to mention delivery of oxygen to the heart." Manning, slip op. at 8. Manning's statements in the 1992 journal article provide substantial evidence to support the Board's finding that Manning did not then appreciate that a substantial amount of oxygen, or even a quantifiable amount of oxygen, was delivered to the heart of the subjects in the 1990 experiments.

Under these circumstances, the Board's decision that there was no reduction to practice before the senior party's filing date is supported by substantial evidence, and the Board's decision must be affirmed.

COSTS

No costs.

[1] Dictionary definitions of "treat" include: ". . . **5 a** : to care for (as a patient or part of the body) medically or surgically : deal with by medical or surgical means : give a medical treatment to . . . **b** : to seek cure or relief of (as a disease)" Webster's Third New Int'l Dict., 2435 (1966).

[2] Manning urges that statements made in Paradis's patent amount to a concession that Manning's experiments worked for their intended purpose. However, Manning misconstrues the law concerning reduction to practice which requires that the inventor determine that his invention works for its intended purpose. Thus, statements by Paradis are irrelevant to the question whether Manning understood that his invention worked for its intended purpose.

[3] At oral argument the following exchange occurred:

THE COURT: If the count were properly interpreted as requiring the delivery of an effective amount of oxygen—that is, to prevent cell damage—would you lose?

COUNSEL FOR MANNING: Probably.