

For Opinion See 2012 WL 5275335 , 678 F.3d 1357

United States Court of Appeals,
Federal Circuit.

In Re BAXTER INTERNATIONAL INC.
No. 2011-1073.
September 10, 2012.

Appeal from the United States Patent and Trademark Office, Board of Patent Appeals and Interferences.
(Reexamination No. 90/007,751)

Response of Appellee - Director of the United States Patent and Trademark Office Opposing Rehearing and Rehearing
En Banc

Raymond T. Chen, Solicitor.Sydney O. Johnson, Jr., Scott C. Weidenfeller, Associate Solicitors, Mail Stop 8, U.S.
Patent and Trademark Office, P.O. Box 1450, Alexandria, Virginia 22313-1450, 571-272-9035, Attorneys for the
Director of the United States Patent and Trademark Office.

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I. INTRODUCTION

Baxter seeks review of the Panel's decision concerning a means-plus-function ("MPF") limitation. Baxter makes a fact-bound argument that the pumps and pump lines in the prior art identified by the Examiner do not satisfy the "means for delivering dialysate" limitation of claim 26. Both the Board and this Court squarely rejected that argument in light of the evidence of record. Baxter now attempts to recast the Panel's review of this fact question as an announcement of a new legal standard for MPF analysis that conflicts with the Patent Statute and precedent from this Court. Baxter asserts that the Panel decision "deviated" from the MPF analysis standards established by this Court, when in fact the Panel expressly noted the USPTO's MPF analysis and this Court's pertinent *en banc* precedent, and simply affirmed the agency's factual findings with which Baxter disagrees. In affirming the USPTO's decision, the Panel did not overlook any fact or rule of law.

Baxter also insists that the Panel's decision conflicts with this Court's *Fresenius* decision because the reexamination proceeding and the district court litigation reached different outcomes while involving the same limitation and the same prior art - the CMS08 Manual. However, the Panel noted that the different outcomes were justified because the two proceedings applied different burdens of proof and relied on different records. Indeed, different outcomes are particularly appropriate here because *Fresenius* failed to satisfy its burden of proof in the district court, and the Examiner relied on a prior art reference in the reexamination proceeding that was *not* discussed by the district court judge in overturning the jury's obviousness determination. Given the significant differences between the two proceedings, Baxter's conflict theory is untenable, and its petition should be denied.

II. BACKGROUND AND SUMMARY OF PANEL DECISION

Baxter International Inc., ("Baxter") owns U.S. Patent No. 5,247,434 ("the '434 patent"). In 2003, *Fresenius, Inc.*, ("Fresenius") filed a suit against Baxter seeking a declaratory judgment of invalidity and non-infringement of the '434 patent. *Fresenius U.S.A., Inc. v. Baxter Int'l Inc.*, 2007 WL 518804 (N.D. Cal. 2007). The jury found claim 26 invalid

as obvious over the prior art. However, the district court granted Baxter's motion for judgment as a matter of law because Fresenius had failed to provide the jury with substantial evidence to support its verdict. *Fresenius*, 2007 WL 518804 *9, 14. In affirming the district court's decision, the Court held that Fresenius failed to present to the jury "any evidence ***that the structure corresponding to the means for delivering dialysate limitation, or an equivalent thereof, existed in the prior art." *Fresenius*, 582 F.3d at 1299.

In 2005, while the district court litigation was pending, Fresenius filed a request for ex parte reexamination of the '434 patent, which was subsequently granted. With respect to element (a) of claim 26, the Examiner (A9284; A9292) and the Board (A34) found that the CMS08 Manual and Lichtenstein describe element (a) of claim 26.

A divided panel of this Court found that substantial evidence supported the Board's findings on claim 26. Op. 11. After noting the *In re Donaldson Co.*, 16 F.3d 1189 (Fed. Cir. 1994) (*en banc*), decision, the Panel found that the Examiner properly analyzed the claimed function, and that she "identified a pump, the same type of structure that Baxter contends is the corresponding structure for the 'means for delivering the dialysate' limitation." Op. 12. The Panel noted that "on their face, the pumps identified by the Examiner in the CMS08 Manual appear similar in structure and functionality to the 'concentrate' pumps and pump lines" that Baxter identified as the corresponding structure for the means for delivering dialysate limitation. Op. 13. And like the Examiner and the Board, the Panel found that Lichtenstein discloses a pump that delivers dialysate into the dialysate compartment of a hemodialyzer. *Id.*

The Panel rejected Baxter's argument that the Board erred in failing to provide a detailed explanation of why it reached a different outcome than the one issued by the *Fresenius* Court. The Panel held that there was no error because the reexamination proceeding and the district court litigation applied different burdens of proof and relied on different records. Op. 13.

Judge Newman dissented, stating that the Panel decision violates the Constitution because "for the issue of validity, the evidence, and the parties in interest are the same in the agency reexamination as in the finally resolved litigation." Dissent 1.

III. ARGUMENT

A. Neither Rehearing Nor Rehearing En Banc Is Warranted Because The Panel's Analysis Of The Means-Plus-Function Limitation Does Not Conflict With The Patent Statute Or Precedent From This Court

The parties agree that a MPF limitation "shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof." 35 U.S.C. § 112, ¶ 6; *Donaldson*, 16 F.3d at 1193. When the MPF limitation is construed as part of a patentability determination, a three-step analysis is required. The first step is to define the particular function of the claim limitation. *In re Aoyama*, 656 F.3d 1293, 1297 (Fed. Cir. 2011). The next step is to identify the corresponding structure for the function disclosed in the specification. *Id.* The final step is to determine whether the disclosed and prior art structures are the same or equivalent. *Donaldson*, 16 F.3d at 1193; *Odetics, Inc. v. Storage Tech. Corp.*, 185 F.3d 1259, 1267 (Fed. Cir. 1999).

Baxter contends that the Panel deviated from these well-established principles when it stated that the disclosed and the prior art structures "appear similar in structure and functionality." Pet. 7-8. However, the Panel clearly demonstrated that it was affirming the USPTO's conclusions, which were based on *5 the Examiner's proper three-step MPF analysis of the means for delivering dialysate limitation. First, the Examiner found that the function is supplying dialysate to the hemodialyzer. A9284. Second, the Examiner found that structure for the function disclosed in the specification includes pumps and pump lines (A9284) - the same structure Baxter identified as corresponding to this limitation. A7883:10a (explaining that the corresponding structure is pump 22 and associated structure). Finally, the Examiner found that the CMS08 Manual's pumps and pump lines deliver dialysate to the hemodialyzer. The Board agreed with the Examiner's factual findings that the CMS08 Manual describes claim 26. A34. The Panel properly applied this

Court's precedent, noted the Examiner's MPF analysis of the means for delivering dialysate limitation (Op. 12), and affirmed the Board's finding that the prior art discloses the structure corresponding to the means for delivering dialysate in claim 26. Op. 13. The Panel's statement that the structures "appear similar in structure and functionality" does not alter its application of the correct standard.

Nor did the Panel break new legal ground when it used the word "similar" in its MPF analysis. Pet. 7. According to Baxter, the Panel's emphasis on "similarity" is inappropriate because it "fundamentally alters the standard for analyzing means-plus-function limitations." *Id.* Baxter is wrong on that score. Neither the statute nor decisions from this Court require "magic words" when *6 analyzing MPF limitations. All that is required is a finding that the claimed and prior art structures are the same or equivalent, and that is exactly what happened here - the Panel found that the structures are equivalent, although it used the word "similar" rather than "equivalent" in its analysis. After noting that the structure of the means for controlling is a microprocessor and concentration pumps, the Panel found that the CMS08 Manual discloses a processor and stepper motor driven line pumps that can be programmed, and that Lichtenstein discloses a microcomputer that is programmable to permit hemodialysis. Op. 12. As the Panel correctly found, the "description in both references are similar to the microcontroller and concentrate pumps identified for the 'means for controlling' limitation" in the specification. *Id.* Therefore, while the Panel used the word "similar," its analysis demonstrates that it found the disclosed and prior art structures equivalent. Accordingly, the Panel's use of the word "similar" instead of "equivalence" in its analysis was a distinction without a difference, and it did not conflict with the statute or this Court's prior decisions.

Baxter argues that the Panel's decision cannot be sustained because the pumps the Examiner cited do not perform the identical function required by the claim. Pet. 8. But Baxter never asserted that the pumps relied on by the Examiner fail to perform the required function. Rather, in its appeal brief to the Board, as it relates to the means for delivering dialysate found in element (a), Baxter only *7 argued that "Element (a) is only met if the reference cited provides the *specific structure* disclosed in the specification of the '434 Patent that supports the means-plus-function claim under 35 U.S.C. § 112, paragraph 6." A7883:42a-45a (emphasis added). The Board rules explicitly warn that arguments not raised in the briefs are untimely. 37 C.F.R. § 41.37(c)(vii) ("Any arguments or authorities not included in the brief or a reply brief *** will be refused consideration"). Therefore, Baxter's arguments concerning the function of the pumps in the CMS08 Manual are waived. *See e.g., In re Watts*, 354 F.3d 1362, 1367-68 (Fed. Cir. 2004) (arguments not raised to the Board are waived).

In any event, contrary to Baxter's contention, the pumps that the Panel and the Examiner identified perform the identical claimed function, namely, delivering dialysate to the dialysate compartment of a hemodialyzer. As the Panel observed, the CMS08 Manual discloses a "dialysate mixing system" that must be connected to a hemodialyzer, which necessarily requires the dialysate to be pumped between the machines." Op. 13. Indeed, the CMS08 Manual describes using pumps and pump lines in its system. A305-306. As the Examiner found, the pumps and pump lines supply dialysate to a hemodialyzer. A9284.

Baxter contends that the Examiner, the Board, and the Panel failed to find that the CMS08 Manual discloses structure corresponding to supply pump 42 and flow equalizer 54 in the '434 patent, which Baxter asserts are also part of the MPF *8 limitation. Pet. 9. However, Baxter is presenting this specific issue for the first time in its petition. After the Examiner identified the pumps and pump lines in the CMS08 Manual as the corresponding structure for the means for delivering limitation, Baxter never alleged that the Examiner's finding was erroneous because she did not find supply pump 42 and flow equalizer 54 in the CMS08 Manual as well. Thus, Baxter waived its newly-minted argument about the supply pump and flow equalizer. *See 37 C.F.R. § 41.37(c)(vii); Watts*, 354 F.3d at 1367-68.

Moreover, Baxter's generic arguments about the "associated structure" in its briefs were entirely insufficient to inform the Examiner, the Board, and the Panel of the features in the corresponding structure that Baxter believed were missing from the Examiner's findings. In its brief to the Board, Baxter generally argued that the "corresponding structure is a pump 22" and "the associated structure described in Col. 1, line 58-Col. 2, line 12" (A7883:10a), not 5:30-32, which it now cites, Pet. 9. As Baxter correctly notes, the specification lists "at least 30 components" for the

associated structure. *Id.* Baxter's opening brief to this Court was even less specific. In that brief, Baxter simply argued that the corresponding structure includes "ultiple structures" (Baxter Br. at 32); it did not assert that the CMS08 Manual fails to disclose the supply pump and flow equalizer. The Examiner, the Board, and the Panel were not expected to respond to such skeletal arguments by hunting through the list of at least 30 components, comparing each *9 with the CMS08 Manual, and determining whether the component is disclosed by the CMS08 Manual. Indeed, this Court has treated this sort of argument as waived. See *SmithKline Beecham Corp. v. Apotex Corp.*, 439 F.3d 1312, 1320 (Fed. Cir. 2006) (citing *United States v. Dunkel*, 927 F.2d 955, 956 (7th Cir. 1991) ("A skeletal 'argument,' does not preserve a clam. ***Judges are not like pigs, hunting for truffles buried in briefs.")).

There is no merit to Baxter's assertion that the Panel's alternative holding that Lichtenstein teaches the means for delivering dialysate limitation is a new ground. Pet. 10. Both the Examiner and the Board expressly found that Lichtenstein teaches this limitation. Lichtenstein teaches that pump P2 delivers dialysate through lines to the dialysate compartment 44 of hemodialyzer 42. See A202, Fig. 3; A220, col. 13,11. 40-47. The Examiner found that the "CMS08/A2008 and Lichtenstein hemodialysis devices note particular means for delivering, via pumps and pump lines, treated fluids to a patient." A9292. Thus, the Board observed that "the Examiner found that the teachings of CMS08 [Manual] and/or Lichtenstein describe, or suggest, to one of ordinary skill in the art, element (a) of claims 26 ("*means for delivering the dialysate to a dialysate compartment of a hemodialyzer*")." A10 (emphasis added). The Board found that Baxter "did not assert that Lichtenstein lacks any structure corresponding to element (a) of claim 26," and properly concluded that the CMS08 Manual or *10 Lichtenstein describe element (a) of claim 26. A34.

Baxter's related argument - that the Panel ignored structural elements that Lichtenstein does not disclose, such as the flow equalizer - also fails. Pet. 10. Although the Examiner and the Board found that Lichtenstein teaches each of the means limitations of element (a), Baxter did not contest these findings. Significantly, in its opening brief to this Court, Baxter failed to assert that Lichtenstein does not disclose a flow equalizer, even after the Board pointed out that Baxter "did not assert that Lichtenstein lacks any structure corresponding to element (a) of claim 26." A34. Because Baxter chose not to alert the Court to the structure that it perceived to be missing from Lichtenstein, the argument was waived, and the Panel was not required to address it. Watts, 354 F.3d at 1367-68.

B. The Panel Decision Does Not Conflict With This Court's Fresenius Decision

Besides not conflicting with the Patent Statute and cases involving MPF analysis, such as *Donaldson*, the Panel's decision also does not conflict with this Court's decision in *Fresenius*. Baxter argues that the Panel decision is in "tension" with the *Fresenius* decision because "[b]oth decisions reviewed the same limitation of the same claim of the same patent in light of the CMS08 Manual" and yet reached different holdings as to whether the CMS08 Manual disclosed the limitation. Pet. 12. However, the supposed "tension" is illusory. As the Panel correctly explained, the outcomes diverged because the two proceedings applied *11 different burdens of proof and relied on different records. Op. 15. Those differences account for the different findings and conclusions.

First, as the Panel explained at the outset, it is well settled that the burden of proof in a civil litigation is different than in a USPTO reexamination proceeding. Significantly, a party challenging the validity of patent claims in an infringement action has a statutory burden to prove invalidity by clear and convincing evidence, 35 U.S.C. § 282, whereas in a reexamination proceeding, "the standard of proof - a preponderance of the evidence - is substantially lower than in a civil case." In re Swanson, 540 F.3d 1368, 1378 (Fed. Cir. 2008).

Regarding claim 26, Fresenius' primary downfall was its failure to meet its burden of proof because it failed to present essential evidence to the jury. In fact, the Fresenius Court found that "Fresenius failed to present any evidence - let alone substantial evidence -that the structure corresponding to the means for delivering dialysate limitation, or an equivalent thereof, existed in the prior art." Fresenius, 582 F.3d at 1299. In the reexamination proceeding, the Examiner did not make the same mistake as Fresenius. The Examiner expressly stated that the prior art provides "pumps and pump lines" that deliver dialysate to the hemodialyzer (A9284)," which is precisely the same structure that Baxter argued to the Board performs the function for the means for delivering dialysate limitation. A7883:10a. As the Panel

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