678 F.3d 1357
United States Court of Appeals,
Federal Circuit.

In re BAXTER INTERNATIONAL, INC.

No. 2011–1073.
|
May 17, 2012.

Synopsis
Background: The Board of **Patent** Appeals and Interferences, 2010 WL 1048980, and 2010 WL 3032865,affirmed an examiner's rejections on reexamination, for obviousness, of claims of **patent** relating to hemodialysis machines that can functioned in place of a patient's kidney to cleanse the blood of toxins using a solution called a dialysate, and patentee appealed.

[Holding:] The Court of Appeals, Lourie, Circuit Judge, held that substantial evidence supported findings that claims of **patent** requiring that hemodialysis machines interface to prompt the user for entry of specific data were invalid for obviousness.

Affirmed.

Newman, Circuit Judge, filed dissenting opinion.

West Headnotes (8)

[1] **Patents** Judicial Review or Intervention

Patentee waived its arguments regarding the "means for delivering an anticoagulant" limitation in claim of **patent** relating to hemodialysis machines that can function in place of a patient's kidney to cleanse the blood of toxins by failing to timely raise them before the Board of **Patent** Appeals and Interferences.

3 Cases that cite this headnote

[2] **Patents** Degree of proof

A challenger that attacks the validity of **patent** claims in civil litigation has a statutory burden to prove invalidity by clear and convincing evidence; should the challenger fail to meet that burden, the court will not find the **patent** "valid," only that the **patent** challenger did not carry the burden of establishing invalidity in the particular case before the court. 35 U.S.C.A. § 282.

9 Cases that cite this headnote

[3] Patents Conduct of reexamination proceedings;scope of inquiry

Patents Conclusiveness and effect of administrative decisions

In Patent and Trademark Office (PTO) reexaminations, the standard of proof, a preponderance of the evidence, is substantially lower than in a civil case, and there is no presumption of validity in reexamination proceedings.

9 Cases that cite this headnote

[4] Patents Conduct of reexamination proceedings;scope of inquiry

When a party who has lost in a court proceeding challenging a patent, from which no additional appeal is possible, provokes a reexamination in the Patent and Trademark Office (PTO), using the same presentations and arguments, even with a more lenient standard of proof, the PTO ideally should not arrive at a different conclusion.

6 Cases that cite this headnote

[5] Patents Conduct of reexamination proceedings;scope of inquiry

Patent and Trademark Office (PTO) was not barred from conducting the reexamination of patent because of the final judgment in declaratory judgment action holding that competitor failed to establish patent's invalidity for obviousness.

3 Cases that cite this headnote

[6] Patents Particular products or processes

Substantial evidence supported findings that claims of patent requiring that hemodialysis machines interface to prompt the user for entry of specific data were invalid for obviousness; it would have been obvious to one of ordinary skill in the art to modify the user interface described in prior art to provide an indicium soliciting input from the user that corresponded to a rate of anticoagulant delivery.

7 Cases that cite this headnote

[7] Patents In general;utility

US Patent 4,370,983, US Patent 4,710,166. Cited as Prior Art.

13 Cases that cite this headnote

[8] Patents In general;utility

US Patent 5,247,434. Invalid.

Cases that cite this headnote

Attorneys and Law Firms

***1358** William F. Lee, Wilmer Cutler Pickering Hale and Dorr, LLP, of Boston, MA, argued for the appellant. With him on the brief were William G. McElwain, David L. Cavanaugh, Todd C. Zubler, Thomas G. Saunders and Heather M. Petruzzi, of Washington, DC.

Sydney O. Johnson, Jr., Associate Solicitor, Office of the Solicitor, United States **Patent** and Trademark Office, of Alexandria, VA, argued for appellee. With him on the brief were Raymond T. Chen, Solicitor, and Janet A. Gongola, Associate Solicitor. Of counsel was Scott C. Weidenfeller, Associate Solicitor.

Michael E. Florey, Fish & Richardson P.C., of Minneapolis, MN, for amici curiae, Fresenius USA, Inc., et al.

Before NEWMAN, LOURIE, and MOORE, Circuit Judges.

Opinion

Opinion for the court filed by Circuit Judge LOURIE. Dissenting opinion filed by Circuit Judge NEWMAN.

LOURIE, Circuit Judge.

Baxter International Inc. ("Baxter") appeals from the decision of the Board of **Patent** Appeals and Interferences ("the Board") affirming the examiner's rejections of claims 26–31 of U.S. **Patent** 5,247,434 ("the #434 **patent**") for obviousness under 35 U.S.C. § 103(a). *See Ex parte Baxter Int'l, Inc.,* No. 2009–006493, 2010 WL 1048980 (B.P.A.I. Mar. 18, 2010) ("*Board Decision* "); *Ex parte Baxter Int'l, Inc.,* No. 2009–006493, 2010 WL 3032865 (B.P.A.I. July 20, 2010) ("*Board Rehearing Decision* "). Because the Board did not err in determining that those claims would have been obvious to one of ordinary skill in the art, we *affirm.*

BACKGROUND

I.

This **patent** appeal relates to hemodialysis machines that can function in place of a patient's kidney to cleanse the blood of toxins using a solution called a dialysate. During hemodialysis, the patient's blood is pumped though the hemodialysis machine and the dialysate acts to absorb the toxins. To ensure that the process does not filter essential nutrients from the blood, a hemodialysis machine must facilitate the monitoring and control of a number of parameters.

Baxter owns the #434 **patent**, entitled "Method and Apparatus for Kidney Dialysis," which discloses and claims a hemodialysis machine integrated with a touch screen user interface that allows an operator to monitor and control a number of parameters. Figure 8 of the **patent**, reproduced below, depicts an exemplary touch screen interface:

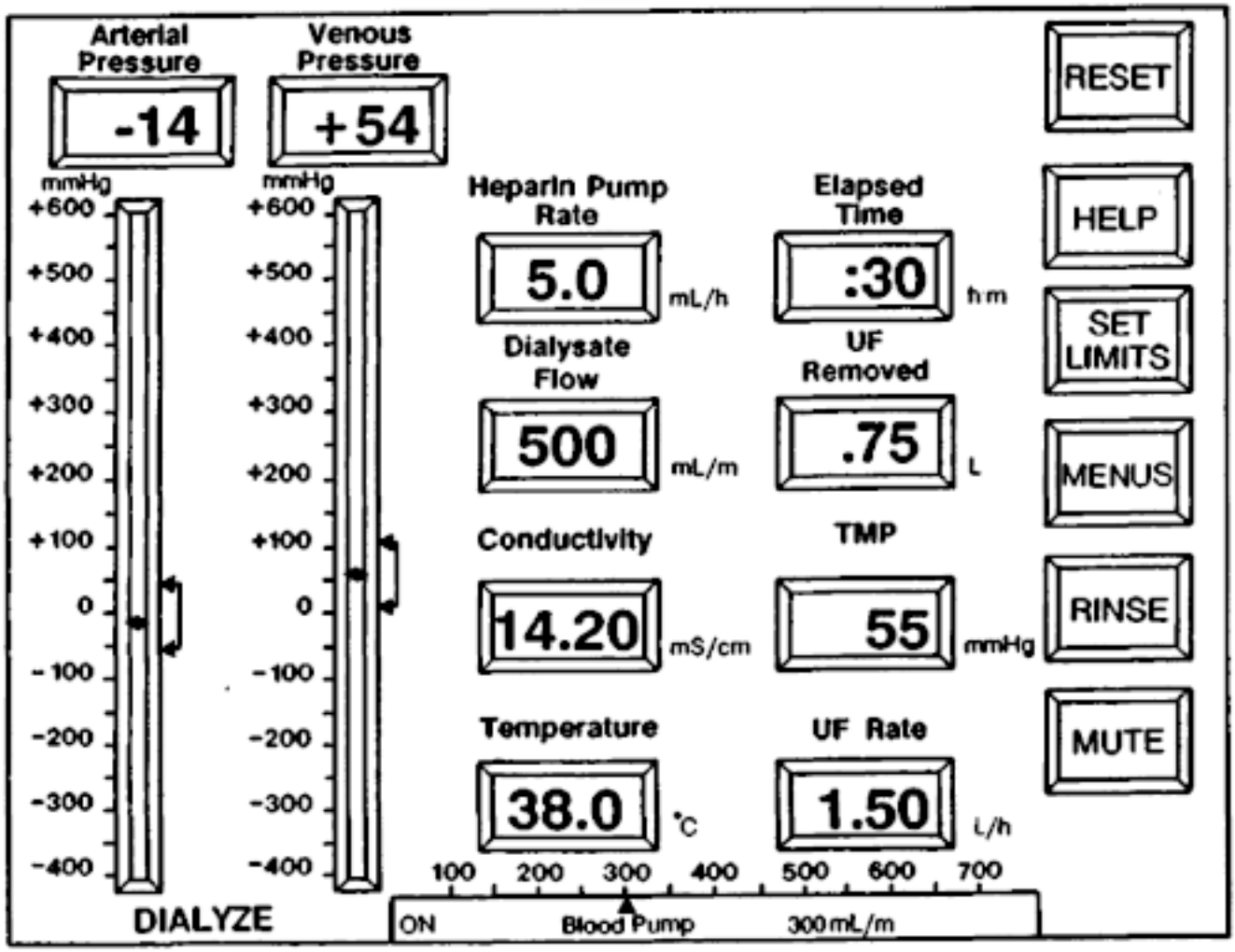

FIG. 8

***1359** As depicted above, the interface allows an operator to monitor and control a number of treatment parameters, such as the dialysate temperature, and the **patent** details the computer system that interfaces with the touch screen to control the delivery of the dialysate and other liquids. Claim 26 of the **patent**, reproduced below, recites the elements of the integrated hemodialysis machine:

> 26. A hemodialysis machine comprising:
>
> (a) *means for controlling a dialysate parameter* selected from a group consisting of dialysate temperature and dialysate concentration, and *means for delivering the dialysate to a dialysate compartment of a hemodialyzer;* and
>
> (b) a user/machine interface operably coupled to said dialysate-delivery means, the user/machine interface comprising a touch screen adapted to display an indicium corresponding to a parameter pertinent to operation of the hemodialysis machine for performing hemodialysis and to permit the user, by touching the indicium, to cause a change in the parameter.

#434 **patent**, col.40 ll.29–43 (emphases added). Dependent claim 30 includes an additional means plus function limitation, reciting that the hemodialysis machine further comprises a "means for delivering an anticoagulant to a patient." *Id.* col.40 ll.60–64. Finally, dependent claims 27, 30, and 31 recite that the touch screen provide "indicium soliciting" specific information from the machine's user: "programmed settings of a time-varying machine-operating parameter" (claim 27);

"input from the user corresponding to a rate of anticoagulant delivery" (claim 30); or "a programmed setting of an alarm limit about the machine-operating parameter" (claim 31). *Id.* col.40 ll.44–47, 60–68.

***1360** II.

The #434 **patent** has been subject to litigation. In 2003, one of Baxter's competitors, Fresenius, filed a declaratory judgment action in the United States District Court for the Northern District of California, seeking, among other claims, a declaration that the **patent's** claims were invalid. *Fresenius Med. Care Holdings, Inc. v. Baxter Int'l, Inc.,* No. C 03–1431 SBA, 2007 WL 518804, at *1 (N.D.Cal. Feb. 13, 2007). The parties tried Fresenius's invalidity claims to a jury, which found that Fresenius had proved by clear and convincing evidence that claims 26–31 of the **patent** would have been obvious at the time the invention was made. *Id.* at *2. After trial, Baxter moved for judgment as a matter of law, and the district court granted Baxter's motion. *Id.* at *2, *8–9. In particular, the district court concluded that Fresenius failed as a matter of law to show by clear and convincing evidence that Fresenius's proffered prior art, *viz.,* the CMS 08 Manual, the Cobe C3 Manual, or the Seratron System, contained the "means for controlling" and "means for delivering" limitations of claim 26. *Id.* at *8.

Upon the entry of a final judgment, Fresenius appealed. We affirmed the district court's grant of judgment as a matter of law, but for "somewhat different reasons than those articulated by the district court." *Fresenius USA, Inc. v. Baxter Int'l, Inc.,* 582 F.3d 1288, 1299 (Fed.Cir.2009). We concluded that "Fresenius failed to present any evidence—let alone substantial evidence—that the structure corresponding to the means for delivering dialysate limitation [in claim 26], or an equivalent thereof, existed in the prior art." *Id.* In particular, Fresenius failed to identify "the structure in the specification that corresponds to the means for delivering dialysate" and further failed to compare the identified structure to those structures present in the prior art. *Id.* at 1300. We thus held that the district court correctly granted Baxter's motion for judgment as a matter of law. *Id.*

III.

In 2006, in parallel with the *Fresenius* litigation, the United States **Patent** & Trademark Office ("PTO") began to reexamine the #434 **patent**, stimulated by Fresenius. In the course of those proceedings, the examiner found that a number of references rendered obvious claims 26–31 of the **patent**, including, among other references, the CMS 08 Manual, the Sarns 9000 Manual, U.S. **Patent** 4,370,983 ("Lichtenstein"), and U.S. **Patent** 4,710,166 ("Thompson"). Specifically, with regard to claims 26–29 and 31, the examiner concluded that those claims would have been obvious in light of the combined teachings of the CMS 08 Manual, Lichtenstein, the Sarns 9000 Manual, and two other references not at issue on appeal. *Board Decision,* 2010 WL 1048980, at *4. Regarding claim 30, the examiner concluded that it would not have been **patentable** over a combination of the same references in view of Thompson. *Id.*

Baxter appealed the examiner's final rejections to the Board. After briefing and oral argument before the Board but prior to issuance of the Board's decision, we decided the *Fresenius* case. Shortly thereafter, Baxter petitioned the Director of the PTO to remand the reexamination to the examiner to consider the rejections in light of our *Fresenius* decision. The Director denied the petition but ordered the Board to consider our decision in *Fresenius.*

The Board affirmed the examiner's rejections of claims 26–31. Regarding our *Fresenius* decision, the Board discussed the holding of the case and concluded that "[a]lthough claims 26–31 were not proven ***1361** invalid in court, a lower standard of proof and the broadest reasonable interpretation standard of claim construction apply at the PTO and therefore the agency is not bound by the court's determination." *Board Decision,* 2010 WL 1048980, at *12 (citing *Ethicon, Inc. v. Quigg,* 849 F.2d 1422, 1429 (Fed.Cir.1988); *In re Swanson,* 540 F.3d 1368, 1377 (Fed.Cir.2008)).

Turning to the merits of the examiner's rejections, the Board found that the CMS 08 Manual describes the "control of Na, K, and HCO3 flow rates using a control unit that may be programmed in ten minute intervals (i.e., a microprocessor) and a pump driven by a stepper motor," a disclosure that met the corresponding structure in the specification identified by Baxter and the examiner for the "means for controlling" limitation. *Board Decision,* 2010 WL 1048980, at *14. The Board also found that Baxter "did not assert that Lichtenstein lacks any structure corresponding to element (a) of claim 26" and thus declined to address the rejections based on Lichtenstein. *Id.*

The Board also affirmed the examiner's findings regarding the "soliciting" limitations in claims 27, 30, and 31. With respect to claim 27, the Board found that the CMS 08 Manual disclosed that a user can adjust or control time-dependent hemodialysis parameters such as the ultrafiltrate rate and the concentration of substances in the dialysate. *Board Decision,* 2010 WL 1048980, at *14. Regarding claim 30, the Board found that Thompson in combination with the CMS 08 Manual or the Sarns 9000 Manual rendered obvious the "indicium soliciting input from the user corresponding to a rate of anticoagulant delivery" limitation. *Id.* at *9–10, *15. Finally, the Board found that the Sarns 9000 Manual described the "indicium soliciting, from the user, a programmed setting of an alarm limit about the machine-operating parameter" limitation in claim 31. *Id.*

Following the Board decision, Baxter requested rehearing, which the Board denied. *Board Rehearing Decision,* 2010 WL 3032865, at *1. In particular, the Board rejected Baxter's argument that the Board had erroneously equated "soliciting" with "control" or "adjust," reiterating that the CMS 08 Manual disclosed that "the machine interface solicits the user for entry of data to control various parameters such as sodium concentration." *Id.*

Baxter timely appealed, and we have jurisdiction under 28 U.S.C. § 1295(a)(4)(A).

DISCUSSION

I.

The scope of our review in an appeal from a Board decision is limited. We review the Board's factual findings for substantial evidence and review the Board's legal conclusions *de novo. In re Kotzab,* 217 F.3d 1365, 1369 (Fed.Cir.2000). A finding is supported by substantial evidence if a reasonable mind might accept the evidence to support the finding. *Consol. Edison Co. v. NLRB,* 305 U.S. 197, 229, 59 S.Ct. 206, 83 L.Ed. 126 (1938).

Although the ultimate determination of obviousness under 35 U.S.C. § 103 is a question of law, it is based on several underlying factual findings, including the differences between the claimed invention and the prior art. *Graham v. John Deere Co.,* 383 U.S. 1, 17–18, 86 S.Ct. 684, 15 L.Ed.2d 545 (1966). Similarly, the determination of what a reference teaches is a question of fact. *Rapoport v. Dement,* 254 F.3d 1053, 1060–61 (Fed.Cir.2001); *see also In re Gartside,* 203 F.3d 1305, 1316 (Fed.Cir.2000). Thus, we review those factual determinations for substantial evidence. *Kotzab,* 217 F.3d at 1369.

***1362** In contrast, claim construction is a legal issue that we review *de novo. Cybor Corp. v. FAS Techs., Inc.,* 138 F.3d 1448, 1454–55 (Fed.Cir.1998) (en banc). To ascertain the scope and meaning of the asserted claims, we look to the words of the claims themselves, the specification, the prosecution history, and, lastly, any relevant extrinsic evidence. *Phillips v. AWH Corp.,* 415 F.3d 1303, 1315–17 (Fed.Cir.2005) (en banc).

II.

A.

As an initial matter, the PTO argues that Baxter waived its arguments regarding the "means plus function" limitations in claims 26 and 30 because it failed to timely present those arguments to the Board. Baxter responds that it presented those issues to the Board in its opening brief, its reply brief, and at oral argument. Baxter also argues that the Director allowed Baxter to pursue those arguments in its order denying Baxter's petition to remand the case from the Board to the examiner.

[1] We agree with the PTO that Baxter waived its arguments regarding the "means for delivering an anticoagulant" limitation in claim 30 by failing to timely raise them before the Board. Absent exceptional circumstances, *see In re DBC,* 545 F.3d 1373, 1379–80 (Fed.Cir.2008), we generally do not consider arguments that the applicant failed to present to the Board, *In re Watts,* 354 F.3d 1362, 1367–68 (Fed.Cir.2004). Although Baxter recited the "means for delivering anticoagulant" claim language in the background of its opening brief before the Board, Baxter did not raise that limitation in the arguments section, instead arguing that "Claim 30 Is **Patentable** Because the Prior Art, Including the Thompson **Patent**, Fails To Teach or Suggest Touch–Screen Control." J.A. 7883:11a, 7883:59a. In its reply brief before the Board, Baxter did not address the examiner's rejection of claim 30 in any respect. *See* J.A. 9358–59. Unsurprisingly, the Board did not provide an analysis of the "means for delivering an anticoagulant limitation," but only addressed Baxter's arguments regarding the "indicium soliciting from the user" limitation of claim 30. *Board Decision,* 2010 WL 1048980, at *9–10, *15.

Ultimately, Baxter failed to raise the "means for delivering an anticoagulant" limitation before the Board, and, contrary to Baxter's arguments, the Director's order denying Baxter's petition did not preserve for appeal arguments relating to a claim limitation that Baxter never put at issue before the Board. Finally, Baxter has not presented an exceptional circumstance that would allow us to consider arguments that it failed to present to the Board. We accordingly decline to address them.

The record does indicate, however, that Baxter timely raised its arguments regarding the examiner's analysis of limitation (a) of claim 26 as well as the substantive merit of those rejections, at least regarding the rejections based on the CMS 08 Manual. J.A. 7883:42a–45a. While those arguments did not specifically name the cases that Baxter primarily relies upon on appeal, we do not require such case specificity to preserve a point of error for appeal. *See Nelson v. Adams USA, Inc.,* 529 U.S. 460, 469–70, 120 S.Ct. 1579, 146 L.Ed.2d 530 (2000) (explaining that the general rule of error preservation "does not demand the incantation of particular words" but simply requires that the lower tribunal "be fairly put on notice as to the substance of the issue"). Thus, we will address Baxter's arguments on those issues.

B.

Regarding claim 26, Baxter raises a number of arguments on appeal. First, ***1363** Baxter argues that the PTO failed to perform the structural analysis required by *In re Donaldson Co.,* 16 F.3d 1189 (Fed.Cir.1994). Baxter also argues that the Board's findings that the prior art discloses the "means for controlling" and "means for delivering the dialysate" limitations are not supported by substantial evidence and contradict the findings of the district court and this court in the *Fresenius* litigation, to both of which the PTO failed to give serious consideration. Regarding the "means for controlling" limitation, Baxter argues that none of the pages of the prior art references cited by the examiner and the Board actually disclose a microprocessor. With respect to the "means for delivering" limitation, Baxter argues that the prior art "pumps and pump lines" identified by the examiner do not deliver dialysate to a dialysate compartment of a hemodialyzer but instead deliver fluids to other destinations.

The PTO responds that a structural analysis was performed for the "means for controlling" and "means for delivering" limitations. It also argues that substantial evidence shows that the CMS 08 Manual and Lichtenstein disclose the structure corresponding to the challenged means plus function limitations. Finally, the PTO argues that the lower court's decision and this court's decision in *Fresenius* do not control the reexamination proceeding because the PTO and the court system apply different approaches to determine invalidity and **patentability**.

We agree with the PTO that substantial evidence supported the Board's findings on claim 26. Regarding Baxter's arguments that the examiner did not specifically determine the corresponding structure for the "means plus function" limitations in limitation (a), the record indicates that both the examiner and Baxter agreed that the corresponding structure disclosed in the specification for the "means for controlling" limitation included a microprocessor and a concentrate pump. *Board Decision,* 2010 WL 1048980, at *14; J.A. 9283–84. Similarly, rather than engage in a purely functional analysis of the "means for delivering the dialysate" limitation, the examiner identified a pump, the same type of structure that Baxter contends is the corresponding structure for the "means for delivering the dialysate" limitation. *See* J.A. 7883:10a, 9284.

Turning to Baxter's specific arguments regarding the teachings disclosed in the references, we conclude that substantial evidence supports the Board's finding that the prior art discloses limitation (a) of claim 26. Regarding the "means for controlling" limitation, the CMS 08 Manual discloses a "computer modeling system" with a "[p]rocessor" and describes that "electrolyte concentrations" are delivered via "stepper motor driven line pumps" that can be "programmed in ten minute intervals." J.A. 284, 288, 290. Even if Baxter could overcome the Board's express finding that Baxter "did not assert that Lichtenstein lacks any structure corresponding" to limitation (a) of claim 26, *Board Decision,* 2010 WL 1048980, at *14, that reference, in any event, discloses a "microcomputer" that is programmable to carry out specific procedures, including hemodialysis. Lichtenstein, col.3 ll.64–65, col.8 ll.23–25; *see also id.* col.20 ll.9–15 ("Computer systems such as the ... Intel 'Multibus' for its SBC 80 Microcomputer System, can be purchased as assembled units to provide the microcomputer functions, when appropriately programmed."). The descriptions in both references are similar to the microcontroller and concentrate pumps identified by Baxter as the corresponding structure for the "means for controlling" limitation. #434 **patent**, col.16 ll.45–48, col.17 ll.29–33 (explaining that the microprocessor is "built using an Intel 8040 microcontroller" and that the concentrate ***1364** pumps "are stepper motor driven ... diaphragm pumps which deliver a calibrated volume of concentrate per stepper motor revolution").

Substantial evidence also supports the Board's finding that the prior art disclosed structure corresponding to the "means for delivering the dialysate" limitation. While Baxter argues that the specific pumps in the CMS 08 Manual do not deliver dialysate to a dialysate compartment of a hemodialyzer but instead perform other functions, the reference discloses a "dialysate mixing system" that must be connected to a hemodialyzer, which necessarily requires the dialysate to be pumped between the machines. J.A. 292–99. In addition, on their face, the pumps identified by the examiner in the CMS 08 Manual appear similar in structure and functionality to the "concentrate" pumps and pump lines that Baxter identified as corresponding structure in the #434 **patent** for this "means plus function" limitation. J.A. 7883:10a (identifying concentrate pump 22 and "the associated structure"). Further, even if Baxter's arguments regarding Lichtenstein are properly before us, that reference also teaches that a pump delivers dialysate through a flow meter into the dialysate side of a dialysis container used in connection with hemodialysis equipment. Lichtenstein, col.12 ll.60–61, col.13 ll.41–47.

[2] **[3]** We also reject Baxter's argument that the Board erred because it "ignored" our decision in *Fresenius* and failed to "give serious consideration" to the district court's *Fresenius* decision. Opening Br., Baxter Int'l Inc. at 36, 41, 2011 WL 5997217. First, as recounted above, the Board expressly considered our decision in *Fresenius.* More fundamentally, the PTO in reexamination proceedings and the court system in **patent** infringement actions "take different approaches in determining validity and on the same evidence could quite correctly come to different conclusions." *Swanson,* 540 F.3d at 1377 (quoting *Ethicon,* 849 F.2d at 1428). In particular, a challenger that attacks the validity of **patent** claims in civil litigation has a statutory burden to prove invalidity by clear and convincing evidence. *Id.* (citing 35 U.S.C. § 282); *see also Microsoft Corp. v. i4i Ltd.,* —— U.S. ——, 131 S.Ct. 2238, 2242, 180 L.Ed.2d 131 (2011). Should the challenger fail

to meet that burden, the court will not find the **patent** "valid," only that "the **patent** challenger did not carry the 'burden of establishing invalidity in the *particular case* before the court.' " *Swanson,* 540 F.3d at 1377 (quoting *Ethicon,* 849 F.2d at 1429 n. 3 (internal citations omitted)). In contrast, in PTO reexaminations "the standard of proof—a preponderance of the evidence—is substantially lower than in a civil case" and there is no presumption of validity in reexamination proceedings. *Id.* at 1378.

This case thus illustrates the distinction between a reexamination and a district court proceeding. In *Fresenius,* we upheld the district court's grant of judgment as a matter of law because the **patent** challenger failed to meet its burden to prove invalidity by clear and convincing evidence—it "failed to present any evidence ... that the structure corresponding to the means for delivering dialysate limitation [in claim 26], or an equivalent thereof, existed in the prior art" and did not identify "the structure in the specification that corresponds to the means for delivering dialysate" or compare the identified structure to those structures present in the prior art. *Fresenius,* 582 F.3d at 1299. Ultimately, we concluded that the clear and convincing burden of proof in the "means plus function" context "cannot be carried without clearly identifying the corresponding structure in the prior art." *Id.* at 1300.

***1365** In contrast, during the reexamination, the examiner sufficiently identified the corresponding structure recited in the #434 **patent** and identified the structures in the prior art such that a reasonable person might accept that evidence to support a finding that claim 26 is not **patentable** under a preponderance of the evidence standard of proof. Moreover, in addition to relying on the CMS 08 Manual, the examiner based those rejections on prior art references that were not squarely at issue during the trial on the invalidity issues, such as Lichtenstein and Thompson. *See Fresenius,* 2007 WL 518804, at *7–8 (discussing the Cobe C3 Manual, the CMS 08 Manual, the Sarns 9000, and the Seratron System). Thus, because the two proceedings necessarily applied different burdens of proof and relied on different records, the PTO did not err in failing to provide the detailed explanation now sought by Baxter as to why the PTO came to a different determination than the court system in the *Fresenius* litigation.

[4] Lest it be feared that we are erroneously elevating a decision by the PTO over a decision by a federal district court, which decision has been affirmed by this court, the following additional comments must be made. When a party who has lost in a court proceeding challenging a **patent**, from which no additional appeal is possible, provokes a reexamination in the PTO, using the same presentations and arguments, even with a more lenient standard of proof, the PTO ideally should not arrive at a different conclusion.

[5] However, the fact is that Congress has provided for a reexamination system that permits challenges to **patents** by third parties, even those who have lost in prior judicial proceedings. Usually one would expect that any such reexamination, such as the one before us, would raise new issues. In this case, the **patent** examiner relied on new prior art that had not been raised in the prior district court proceeding. Why Fresenius did not present that prior art before the district court we do not know. But the Director apparently found that a substantial new question of **patentability** had been raised and the examiner was then entitled to conduct a reexamination on the basis of the new art presented and her search of the prior art. Thus, this case is not about the relative primacy of the courts and the PTO, about which there can be no dispute. Finally, we could not conclude that the PTO was barred from conducting the reexamination of the #434 **patent** because of the final judgment in *Fresenius* without overruling *Ethicon* and *Swanson,* which we cannot do. *See Hometown Fin., Inc. v. United States,* 409 F.3d 1360, 1365 (Fed.Cir.2005) ("[W]e are bound to follow our own precedent as set forth by prior panels....").

C.

[6] Lastly, Baxter argues that the Board erroneously construed the term "soliciting" in claims 27, 30, and 31 and, under a correct construction of that term, the rejections of those claims were not supported by substantial evidence. In particular, Baxter argues that the Board implicitly construed "soliciting" in an overbroad manner to encompass a touch screen user

interface that allows a user to adjust or control the machine, a construction that is not supported by the specification. Baxter argues that the term should have been construed to require the machine to actively seek an action by a user.

We disagree. The PTO does not dispute Baxter's construction of "soliciting" as requiring the touch screen user interface to actively seek an action by the user, and the Board applied a construction identical in scope, requiring the machine interface to prompt the user for entry of specific data. J.A. 40. That requirement finds support ***1366** in the written description. *E.g.,* # 434 **patent**, col.10 ll.1–6 (describing that the machine "solicits" a sodium value "by means of a pop-up keypad").

Under that construction, substantial evidence supports the rejections of claims 27, 30, and 31. In particular, the CMS 08 Manual discloses the "soliciting" limitation in claim 27 because the reference depicts a user interface that prompts the user to input a variety of time-varying operating parameters, such as the ultrafiltration rate and the sodium electrolyte profile. J.A. 307–08. Similarly, substantial evidence supports the PTO's finding that the Sarns 9000 Manual teaches the "soliciting" limitation in claim 31 because that reference discloses a user interface that prompts the user to input a pressure alarm limit. J.A. 450.

Finally, substantial evidence supports the Board's finding that the CMS 08 Manual or the Sarns 9000 Manual, when combined with Thompson, renders obvious the "indicium soliciting input from the user corresponding to a rate of anticoagulant delivery" limitation in claim 30. As explained above, the CMS 08 Manual and the Sarns 9000 Manual disclose providing an "indicium soliciting" input from a user. Baxter does not contest that Thompson teaches delivering anticoagulants to a patient. *See* Thompson, col.1 ll.9–25. Nor does Baxter contest on appeal that, in view of Thompson's disclosure, it would have been obvious to one of ordinary skill in the art to modify the user interface described in the CMS 08 Manual or the Sarns 9000 Manual to provide an indicium soliciting input from the user that corresponds to a rate of anticoagulant delivery.

CONCLUSION

We have considered Baxter's remaining arguments and conclude that they are without merit. For the foregoing reasons, the Board's determination that claims 26–31 were not **patentable** is

AFFIRMED

NEWMAN, Circuit Judge, dissenting.

The **Patent** and Trademark Office's Board of **Patent** Appeals and Interferences, on reexamination of a **patent** that had previously been litigated to final judgment in the district court and on appeal to the Federal Circuit, states that "the agency is not bound by the court's determination." BPAI Op. at 26. My colleagues appear unperturbed by the agency's nullification of this court's final decision. Instead, the court itself ignores our own prior final decision, although it is the law of this case. Thus the court violates not only the constitutional plan, but also violates the rules of litigation repose as well as the rules of estoppel and preclusion—for the issue of validity, the evidence, and the parties in interest are the same in this agency reexamination as in the finally resolved litigation.

No authority, no theory, no law or history, permits administrative nullification of a final judicial decision. No concept of government authorizes an administrative agency to override or disregard the final judgment of a court. Judicial rulings are not advisory; they are obligatory. In *San Remo Hotel, L.P. v. City & County of San Francisco,* 545 U.S. 323, 125 S.Ct. 2491, 162 L.Ed.2d 315 (2005) the Court explained:

> The general rule implemented by the full faith and credit statute—that parties should not be permitted to relitigate issues that have been resolved by courts of competent jurisdiction—predates the Republic. It "has found its way into every system of jurisprudence, not only from its obvious fitness and propriety, but because without it, an end could never be put to litigation."

***1367** *Id.* at 336–37, 125 S.Ct. 2491 (quoting *Hopkins v. Lee,* 19 U.S. (6 Wheat.) 109, 114, 5 L.Ed. 218 (1821)).

Finality is fundamental to the Rule of Law. In *Southern Pacific Railroad v. United States,* 168 U.S. 1, 18 S.Ct. 18, 42 L.Ed. 355 (1897) the Court stressed the importance of repose and conclusiveness following upon judicial decision:

> This general rule is demanded by the very object for which civil courts have been established, which is to secure the peace and repose of society by the settlement of matters capable of judicial determination. Its enforcement is essential to the maintenance of social order; for the aid of judicial tribunals would not be invoked for the vindication of rights of person and property if, as between parties and their privies, conclusiveness did not attend the judgments of such tribunals in respect of all matters properly put in issue, and actually determined by them.

Id. at 49, 18 S.Ct. 18. All departments of government are bound by the finality of the judicial ruling. "Judgments, within the powers vested in courts by the Judiciary Article of the Constitution, may not lawfully be revised, overturned or refused faith and credit by another Department of Government." *Chi. & S. Air Lines, Inc. v. Waterman S.S. Corp.,* 333 U.S. 103, 114, 68 S.Ct. 431, 92 L.Ed. 568(1948).

In *Plaut v. Spendthrift Farm, Inc.,* 514 U.S. 211, 115 S.Ct. 1447, 131 L.Ed.2d 328 (1995) the Court traced the finality of judicial rulings in relation to the executive branch to *Hayburn's Case,* 2 U.S. (2 Dall.) 409, 1 L.Ed. 436 (1792), which "stands for the principle that Congress cannot vest review of the decisions of Article III courts in officials of the Executive Branch." *Plaut,* 514 U.S. at 218, 115 S.Ct. 1447. The Court explained:

> The record of history shows that the Framers crafted this charter of the judicial department with an expressed understanding that it gives the Federal Judiciary the power, not merely to rule on cases, but to *decide* them, subject to review only by superior courts in the Article III hierarchy—with an understanding, in short, that "a judgment conclusively resolves the case" because "a 'Judicial Power' is one to render dispositive judgments."

Id. at 218–19, 115 S.Ct. 1447 (quoting Frank H. Easterbrook, *Presidential Review,* 40 Case W. Res. L.Rev. 905, 926 (1990)) (emphasis in original). In *Town of Deerfield v. Federal Communications Commission,* 992 F.2d 420, 428 (2d Cir.1993), the court elaborated that revision by the FCC of the court's order would render the court's previous judgment merely advisory, and thus in violation of the Constitution.

Yet this court continues to authorize the **Patent** and Trademark Office to "revise, overturn, and refuse full faith and credit" to final judgments of the courts, in the words of *Chicago & Southern Air Lines,* 333 U.S. at 114. Such agency action has not been authorized by any other court. To the contrary, when the judicial decision is final as to the issue before the agency, the decision is binding on the agency. Finality is reflected in the law of the case doctrine, which "promotes the finality and efficiency of the judicial process by protecting against the agitation of settled issues." *Christianson v. Colt Industries Operating Corp.,* 486 U.S. 800, 815–16, 108 S.Ct. 2166, 100 L.Ed.2d 811 (1988). This universal doctrine in not new to the Federal Circuit, *see, e.g., Suel v. Secretary of Health & Human Services,* 192 F.3d 981, 984–85 (Fed.Cir.1999) (The law of the case doctrine "ensures judicial efficiency and prevents endless litigation. Its elementary logic is matched by elementary fairness—a litigant given one good bite at the apple should not have a second."); ***1368** *Perkin–Elmer Corp. v. Computervision Corp.,* 732 F.2d 888, 900 (Fed.Cir.1984) (the law of the case doctrine is designed to put an end to issues that have been fully litigated and resolved).

The theories of preclusion implement the fundamentals of judicial finality, for a final judicial determination controls the issue in all forums. *See Federated Dep't Stores, Inc. v. Moitie,* 452 U.S. 394, 401, 101 S.Ct. 2424, 69 L.Ed.2d 103 (1981) ("This Court has long recognized that '[p]ublic policy dictates that there be an end of litigation; that those who have contested an issue shall be bound by the result of the contest, and that matters once tried shall be considered forever settled as between the parties.' ") (quoting *Baldwin v. Traveling Men's Ass'n,* 283 U.S. 522, 525, 51 S.Ct. 517, 75 L.Ed. 1244 (1931)). In *Allen v. McCurry,* 449 U.S. 90, 94, 101 S.Ct. 411, 66 L.Ed.2d 308 (1980) the Court explained that "res judicata and collateral estoppel relieve parties of the cost and vexation of multiple lawsuits, conserve judicial resources, and, by preventing inconsistent decisions, encourage reliance on adjudication." Applying these principles to **patent** reexamination of the same issues of fact and law as were decided in judicial proceedings, the principles of preclusion apply. A **patent** that has been adjudicated to be valid cannot be invalidated by administrative action, any more than a **patent** adjudicated to be invalid can be restored to life by administrative action.

In enacting the various reexamination statutes, Congress did not purport to violate the constitutional strictures governing finality of judicial process. The possibilities for vexation and abuse were perceived from the initiation of reexamination; when the first reexamination statute was proposed, **Patent** Commissioner Diamond testified that the statute contained various safeguards and "carefully protects **patent** owners from reexamination proceedings brought for harassment or spite. The possibility of harassing **patent** owners is a classic criticism of some foreign reexamination systems and we made sure it would not happen here." Hearings on H.R. 6933, 6934, 3806 & 215, *Industrial Innovation & **Patent** & Copyright Law Amendments,* House Comm. on the Judiciary, 96th Cong., 2d Sess. 594 (1980). Nonetheless, commentators were skeptical; for example, Anthony H. Handal, *Re-examination: Some Tactical Considerations—A Private Practitioner's Viewpoint,* 9 AIPLA Q.J. 249 (1981), explained that

> a party threatened with litigation has the opportunity to file reexamination requests on the **patents** concerned, or without doing anything, has the threat of such action to use in any negotiation which may be in progress. Likewise, a threatened party also has the opportunity of putting a number of **patents** into reexamination which are not even related to the subject matter of the threat. Thus, even where the party threatened with litigation is in a relatively weak position with respect to the asserted **patents**, he can very viably threaten to retaliate against the **patent** owner by counter-attacking where the **patent** owner is in a relatively weak position.

Id. at 251. When reexamination was later enlarged, an article by William J. Speranza and Michael L. Goldman, *Reexamination—The **Patent** Challenger's View,* 69 J. Pat. & Trademark Off. Soc'y 295 (1987) remarked that reexamination "has potential for misuse by the **patent** challenger to achieve less-than-noble aims, such as delay or harassment, in an effort to escape liability where no legitimate defense exists." *Id.* at 296. [1]

***1369** Today, reexamination is part of the tactical armory of litigators. However, throughout this history, including the current legislative proposals to make reexamination more useful as a less costly alternative to litigation, we have uncovered no suggestion that reexamination is intended to deprive a final judgment of the full faith and credit attendant upon final judgments. We have found no hint that reexamination of the question of **patentability** is intended to override judicial resolution of the question of **patentability**. Nor would such legislation be contemplated, for "Article III, § 1 safeguards the role of the Judicial Branch in our tripartite system by barring congressional attempts 'to transfer jurisdiction [to non-Article III tribunals] for the purpose of emasculating' constitutional courts, and thereby preventing 'the encroachment or aggrandizement of one branch at the expense of the other.' " *Commodity Futures Trading Comm'n v. Schor,* 478 U.S. 833, 850, 106 S.Ct. 3245, 92 L.Ed.2d 675 (1986) (brackets in original, citations omitted). The Court stressed that "Article III, § 1, not only preserves to litigants their interest in an impartial and independent federal adjudication of claims within the judicial power of the United States, but also serves as 'an inseparable element of the constitutional system of checks and balances.' " *Id.* (quoting *N. Pipeline Constr. Co. v. Marathon Pipe Line Co.,* 458 U.S. 50, 58, 102 S.Ct. 2858, 73 L.Ed.2d 598 (1982)).

Administrative agency override of judicial final decisions has no counterpart in any other field of subject matter. From the inception of judicial process in the nation, it was established that decisions of Article III courts are not subject to negation by proceedings in the other branches. The validity of the Baxter **patent** was resolved upon litigation in the district court and on appeal to the Federal Circuit. This judgment cannot be "revised, overturned or refused full faith and credit by another Department of Government." *Chi. & S. Air Lines,* 333 U.S. at 114, 68 S.Ct. 431. Nonetheless, the court again departs from this principle, trivializes our prior final judgment, and simply defers to the conflicting agency ruling. This is improper.

I support the concept of reexamination as an efficient and economical alternative to litigation in appropriate cases. My concern is with the distortion of this purpose, which was designed to provide a path to relief not available through the existing examination process. It was not intended to undermine the finality of judicial process; it was not intended to negate the repose provided by adjudication.

The only **patents** that are reexamined, like the only **patents** that are litigated, are **patents** on inventions that are of value. Most reexamination requests are granted by the PTO.[2] Reexamination of the Baxter **patent** was requested by Fresenius in 2005, two years into the litigation of Fresenius' declaratory judgment action against Baxter. The reexamination request presented to the PTO the same references that Fresenius had presented in ***1370** the litigation. Judgment in the district court was adverse to Fresenius, and the Federal Circuit's final judgment was issued in 2009, a year before the reexamination decision of the PTO Board. The Board stated that "the agency is not bound by the court's determination." BPAI Op. at 26. However, when there has been full litigation and final adjudication under Article III, the judicial resolution controls. Instead, my colleagues ignore this court's prior decision, which is the law of this case, and simply defer to the PTO, stating that its reexamination ruling is "supported by substantial evidence." Op. at 11–13 & 16. The nature of the burden of proof does not overcome the strictures of judicial finality.

The reexamination of Baxter's **patent** claims 26–29 and 31 was based solely on the same references on which Fresenius relied in the litigation. In response to the panel's request during oral argument, Baxter's counsel wrote that "all of the art relied upon by the Examiner to reject claims 26–29 and 31 of the # 434 **patent** (*i.e.,* Lichtenstein #983, the Fresenius CMS08 Handbook, the Sarns 9000 Perfusion System Operators Manual, Rubalcaba #578, and Kerns #706, *see* A9283) had been presented by Fresenius to the district court," Letter from William F. Lee (February 22, 2012). The PTO Deputy Solicitor wrote that "The Examiner only found Thompson," Letter from Sydney O. Johnson, Jr. (February 17, 2012); the Thompson reference was cited only against claim 30, for showing the inclusion of an anticoagulant in the dialysis. This aspect does not appear to be significant to the reexamination, but if it were, the failure of Fresenius to present such issue does not negate the finality of the decision upon full adjudication. *See* Charles Alan Wright, Arthur R. Miller & Edward H. Cooper, *Federal Practice and Procedure: Jurisdiction,* § 4426 at 141 (1981) ("Preclusion cannot be avoided simply by offering evidence in the second proceeding that could have been admitted, but was not, in the first."). Reexamination of the Baxter **patent** lasted from 2005 to 2010, continuing for a year after final decision in the Federal Circuit.

My colleagues justify the PTO's authority to overrule judicial decisions on the argument that the standard of proof is different in the PTO than in the courts. That theory is flawed, for obviousness is a question of law, and the PTO, like the court, is required to reach the correct conclusion on correct law. Any distinction between judicial and agency procedures cannot authorize the agency to overrule a final judicial decision. Even if the Federal Circuit were believed to have erred in its prior decision, the mechanism for correcting an unjust decision is by judicial reopening, not by administrative disregard. *See Christianson,* 486 U.S. at 817, 108 S.Ct. 2166 ("A court has the power to revisit prior decisions of its own or of a coordinate court in any circumstance, although as a rule courts should be loath to do so in the absence of extraordinary circumstances such as where the initial decision was clearly erroneous and would work a manifest injustice."). This procedure did not occur in this case.

The court's final judgment cannot be overridden by administrative proceeding. I respectfully dissent.

All Citations

678 F.3d 1357, 102 U.S.P.Q.2d 1925

Footnotes

1 A significant number of **patents** in litigation are also subject to reexamination. USPTO Reexamination Filing Data—September 30, 2011, http://www.uspto.gov/**patents**/stats/index.jsp (70% of **patents** undergoing inter partes reexamination and 33% of **patents** undergoing ex partes reexaminations are known to be in litigation). It is reported that 11% of **patents** accepted for reexamination by the USPTO are reexamined more than once, one as many as six times. Robert G. Sterne *et al., Reexamination Practice with Concurrent District Court Litigation or Section 337 USITC Investigations,* 11 Sedona Conf. J. 14 (Sept.2010).

2 The PTO reports that in 2007 through 2011 the percentage of reexamination requests granted was 97.1% in FY2007; 94.0% in FY2008; 93.5% in FY2009; 91.7% in FY2010; and 89.3% in FY2011. *USPTO Performance and Accountability Report for Fiscal Year 2011,* Table 14A at 171, http:// www.uspto.gov/about/stratplan/ar/index.jsp. The report does not distinguish whether the requests were filed by the patentee or by a third party.