



UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte BAXTER INTERNATIONAL, INC.,
Patent Owner and Appellant

Appeal 2009-006493
Reexamination Control 90/007,751
Patent 5,247,434¹
Technology Center 3900

Decided: March 18, 2010

Before MICHAEL R. FLEMING, *Chief Administrative Patent Judge*,
ALLEN R. MACDONALD, *Vice Chief Administrative Patent Judge*,
CAROL A. SPIEGEL, ROMULO H. DELMENDO, and
JEFFREY T. SMITH, *Administrative Patent Judges*.

DELMENDO, *Administrative Patent Judge*.

DECISION ON APPEAL

¹ The patent under reexamination (hereinafter the “434 Patent”) issued to Bruce A. Peterson, Michael E. Hogard, Harley D. Johnson, Thomas D. Kelly, Jean M. Long, and William G. Preston, Jr. on September 21, 1993 from Application 07/688,174 filed on April 19, 1991.

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Baxter International, Inc., the owner of the patent under reexamination, appeals under 35 U.S.C. §§ 134(b) and 306 from a final rejection of claims 12-19 and 26-34 (Appeal Brief filed June 12, 2008, hereinafter “App. Br.,” at 1; Final Office Action mailed December 14, 2007).² We have jurisdiction under 35 U.S.C. §§ 134(b) and 306.

We AFFIRM.

STATEMENT OF THE CASE

This reexamination proceeding arose from a third-party request for *ex parte* reexamination filed by John C. Phillips of Fish & Richardson, PC (San Diego, California) on October 18, 2005. We have been informed that the ‘434 Patent is one of several patents involved in a patent infringement action in which the United States Court of Appeals for the Federal Circuit recently issued a decision on appeal of the District Court’s rulings. *Fresenius USA, Inc. v. Baxter Int’l, Inc.*, 582 F.3d 1288 (Fed. Cir. 2009). Additionally, Appellant states that this appeal is related to an appeal in Reexamination Control 90/007,730 involving United States Patent 6,284,131 B1 (‘131 Patent) (Appeal No. 2009-006498) (App. Br. 1).

Judges Spiegel, Delmendo, and Smith heard oral arguments on June 17, 2009, a written transcript of which was entered into the record on July 10, 2009. Subsequent to the oral arguments, the merits panel was expanded

² See Patent Assignment Abstract of Title, Reel 006570, Frame 0001, which was entered into the record of this proceeding as “Title Report” on October 20, 2005.

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to include MICHAEL R. FLEMING, *Chief Administrative Patent Judge*,
and ALLEN R. MACDONALD, *Vice Chief Administrative Patent Judge*.

The '434 Patent states that the invention relates to an improved kidney dialysis machine including a touch screen user interface (col. 1, ll. 6-7; col. 8, ll. 19-20; appealed claims 12 and 26).

Claims 12, 26-28, and 30-34 on appeal read as follows:

12. In a method of operating a hemodialysis machine, an improvement in a user/machine interfacing process, the improvement comprising:

(a) providing a touch screen operably coupled to the machine, the touch screen adapted to display an indicium soliciting a user of the machine to touch a region on the screen so as to select a machine-operation parameter;

(b) touching the region to select the machine operation parameter;

(c) in response to said touching, invoking on the screen a data-entry display associated with the machine-operation parameter, the data entry display including a display of a permissibly settable range of the machine-operation parameter, so as to allow the user to select and enter a parametric value associated with the machine-operation parameter within said range; and

(d) touching the data-entry display to select and enter the parametric value so as to cause the machine to operate in conformance with the selected machine-operation parameter and the entered parametric value.

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.

27. The hemodialysis machine according to claim 26 wherein the touch screen further provides an indicium soliciting, from the user, programmed settings of a time-varying machine-operating parameter.

28. The hemodialysis machine according to claim 26 further comprising means for delivering blood at a prescribed flow rate from a patient, through a blood compartment of a hemodialyzer, and back to the patient, wherein the touch screen further provides a visual display of a parameter associated with said means for delivering blood.

30. The hemodialysis machine according to claim 26 further comprising means for delivering an anticoagulant to a patient. wherein the touch screen further provides an indicium soliciting input from the user corresponding to a rate of anticoagulant delivery.

31. The hemodialysis machine according to claim 26 wherein the touch screen further provides an indicium soliciting, from the user, a programmed setting of an alarm limit about the machine operating parameter.

32. In a method of operating a hemodialysis machine, an improvement in a man/machine interfacing process used in

changing and setting a treatment parameter, the improvement comprising:

(a) providing a touch screen interface with a parameter-select indicium thereon;

(b) touching the parameter-select indicium;

(c) in response to said touching, invoking on the touch screen a value-select indicium and a value-enter indicium;

(d) touching the value-select indicium to select a parametric value corresponding to the treatment parameter;

(e) touching the value-enter indicium to enter the parametric value; and

(f) in response to steps (b)-(e), comparing the entered parametric value against present limits corresponding to a permissible operational range for said parametric value and, if the entered parametric value is within said limits, causing the treatment parameter to operate in accordance with the entered parametric value.

33. In a method of operating a hemodialysis machine, an improvement in a man/machine interfacing process used in changing and setting a treatment parameter, the improvement comprising:

(a) providing a touch screen interface with a parameter-select indicium thereon;

(b) touching the parameter-select indicium;

(c) in response to said touching, invoking on the touch screen a value-select indicium and a value-enter indicium;

(d) touching the value-select indicium to select a parametric value corresponding to the treatment parameter;

(e) touching the value-enter indicium to enter the parametric value; and

(f) in response to steps (b)-(e), invoking an alarm limit to be set at a preset increment relative to the entered parametric

value so as to enable an alarm signal to be triggered whenever, during subsequent operation of the hemodialysis machine, the parametric value passes outside the alarm limit.

34. In a method of operating a hemodialysis machine, an improvement in a user/machine interfacing process, the improvement comprising:

(a) providing a touch screen operably coupled to the machine, the touch screen adapted to display an indicium soliciting a user of the machine to touch a region on the screen so as to cause the screen to display a machine-operation parameter;

(b) touching the region on the screen;

(c) in response to said touching, invoking on the screen an analog display associated with the machine-operation parameter, the analog display including a display of a previously set value of the machine-operation parameter and allowing the user [sic, user] to select and enter a desired value associated with the machine-operation parameter; and

(d) touching the data-entry display to select and enter the desired value of the machine-operation parameter so as to cause the machine to operate in conformance with the desired value.

(Claims App'x, App. Br. 95, 98-101.)

The Examiner relied upon the following as evidence of unpatentability (Examiner's Answer mailed September 26, 2008, hereinafter "Ans.," 4-22):

Lichtenstein	4,370,983	Feb. 1, 1983
Thompson	4,710,166	Dec. 1, 1987
Kerns	4,756,706	July 12, 1988
Rubalcaba	4,898,578	Feb. 6, 1990

CMS 08 – HANDBOOK F330311-F330379 (Fresenius AG 1988) (hereinafter "CMS 08 Handbook").

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SARNS[®] 9000 PERFUSION SYSTEM: OPERATORS MANUAL F298963-F299092 (3M 1989) (hereinafter “Sarns 9000 Manual”).

In rebuttal to the Examiner’s obviousness conclusion as to the combination of a touch screen user interface and a hemodialysis machine, Appellant relies on the following evidence appended to the Appeal Brief (Evidence App’x):

- Ex. A: Rebuttal Expert Report of J. Dennis Bruner, ¶ 40.
- Ex. B: Rebuttal Expert Report of Lee W. Henderson, ¶ 97.
- Ex. C: Dep. Tr. of Ben J. Lipps, 38-39, 65-66, 80, 190.
- Ex. D: Dep. Tr. of Martin Joseph Crnkovich, 10-11, 13-14.
- Ex. E: Dep. Tr. of Thomas D. Kelly, 63-66.
- Ex. F: Decl. of John Turner, ¶¶ 16, 18, 21-23.
- Ex. G: *Touch the Future*, DrakeWillock, cover page only (date unknown).
- Ex. H: *Drake Willock System 1000: The Future Generation* (partially illegible), The Althin Group (date unknown).
- Ex. I: *Tina – your new co-worker*, Althin (date unknown).
- Ex. J: Martin Crnkovich, *June-July Hemodialysis R&D* (publication status or date unknown).
- Ex. K: Christian Schlaeper and Michael Fasanella, *2008K Product Launch*, 3, 22 (2000).
- Ex. L: *The Highest Standards in Hemodialysis*, Fresenius USA (1998).
- Ex. M: *Step Up to the 2008K*, Fresenius Medical Care (publication date unknown).
- Ex. P: *Design and Development Plan: Phase One – Hemodialysis Equipment* (publication status and date unknown).
- Ex. Q: Dep. Tr. of Martin J. Crnkovich, 29.

The Examiner rejected the claims under 35 U.S.C. § 103(a) as follows:

- I. Claims 26-29 and 31 as unpatentable over the combined teachings of CMS 08 Handbook, Lichtenstein, Sarns 9000 Manual, Rubalcaba, and Kerns (Ans. 4-12);
- II. Claim 30 as unpatentable over the combined teachings of CMS 08 Handbook, Lichtenstein, Sarns 9000 Manual, Rubalcaba, Kerns, and Thompson (Ans. 12-14);
- III. Claims 12-18 as unpatentable over the combined teachings of CMS 08 Handbook, Lichtenstein, Sarns 9000 Manual, Rubalcaba, and Kerns (Ans. 14-16);
- IV. Claim 19 as unpatentable over the combined teachings of CMS 08 Handbook, Lichtenstein, Sarns 9000 Manual, Rubalcaba, and Kerns (Ans. 16-17);
- V. Claim 32 as unpatentable over the combined teachings of CMS 08 Handbook, Lichtenstein, Sarns 9000 Manual, Rubalcaba, and Kerns (Ans. 17-19);
- VI. Claim 33 as unpatentable over the combined teachings of CMS 08 Handbook, Lichtenstein, Sarns 9000 Manual, Rubalcaba, and Kerns (Ans. 19-20); and
- VII. Claim 34 as unpatentable over the combined teachings of CMS 08 Handbook, Lichtenstein, Sarns 9000 Manual, Rubalcaba, and Kerns (Ans. 20-22).

ISSUES

Obviousness of Combining a Touch Screen Interface with a Hemodialysis Machine

The Examiner found that the CMS 08 Handbook and Lichtenstein independently describe a computer-controlled hemodialysis machine that differs from the claimed machine only in terms of the touch screen user/machine interface limitation (Ans. 4-7; claim 26). To resolve this difference, the Examiner relied on the Sarns 9000 Manual, Rubalcaba, and Kerns, all of which disclose the use of a touch screen interface to control critical operational variables, including fluids delivered to a patient, in a medical device (Ans. 8-9). Relying on reasoning based on the same core prior art references against similar claims in *Ex parte Connell*, Appeal No. 2003-0235³ (BPAI Aug. 28, 2003), the Examiner concluded that the collective teachings of the prior art references would have prompted one of ordinary skill in the art to incorporate a touch screen user interface into a conventional hemodialysis machine (Ans. 10-12, 14-16, and 22-23). Furthermore, the Examiner found Appellant's rebuttal arguments and evidence unpersuasive (Ans. 22-61).

³ *Ex parte Connell* was an appeal from the rejected claims of application 09/711,240. Application 09/711,240, filed November 13, 2000 and now abandoned, is a continuation of application 09/067,922, filed April 28, 1998 and now abandoned, which is a continuation of application 08/479,688, filed June 7, 1995 and now U.S. Patent 5,744,027, which is a divisional of application 08/122,047, filed September 14, 1993 and now U.S. Patent 5,486,286, which is a divisional of application 07/688,174, filed April 14, 1991 and now U.S. Patent 5,247,434, which is the patent under reexamination in this appeal.

Appellant contends that the Sarns 9000 Manual, Rubalcaba, and Kerns do not teach a centralized control (App. Br. 16-17). Appellant also asserts that the testimonies of certain witnesses demonstrate that the use of a touch screen interface in a hemodialysis machine would have been confronted with skepticism and is therefore unobvious (App. Br. 28-31). Appellant further urges that it has produced evidence of secondary considerations of nonobviousness including commercial success and copying (App. Br. 73-90).

Thus, the principal dispositive issues are:

- (1) Has the Examiner erred in concluding that a person of ordinary skill in the art would have been prompted to couple a touch screen user/machine interface with a hemodialysis machine in view of the collective teachings of the prior art references?
- (2) Has the Examiner erred in finding that the relied-upon evidence is insufficient to confer nonobviousness?

Claim 26

The Examiner found that the teachings of CMS 08 Handbook and/or Lichtenstein describe, or suggest, to one of ordinary skill in the art, element (a) of claim 26 (“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”) (Ans. 5-6, 25-27, 38-39). First, the Examiner found that the CMS 08 Handbook “provides all necessary equipment for hemodialysis including various motorized pumps (Na, K, HCO₃, and UFR), pump lines,

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dialyzer and computer control (microprocessor) devices for the delivery, setting and control of dialysate concentration and ultrafiltration rate . . . ” (Ans. 38). Second, the Examiner found that Lichtenstein, which discloses manual control of various flow rates, teaches temperature sensors, heaters, coolers, and microprocessor equipment, as well as motorized pumps, pump lines, and microprocessor control (Ans. 6, 39). Together with additional findings concerning the use of a touch screen user interface in other similar medical devices, the Examiner concluded that “it would have been prima facie obvious to one of ordinary skill in the art . . . to have modified the CMS08/A2008 dialysis machine or the dialysis machine of Lichtenstein, to utilize a touch screen . . . to control the central processing unit microcomputer and machine (including various pumps, lines etc.) for delivery of treated or treatment fluids to a patient” (Ans. 8-10).

Appellant contends that the means for controlling a dialysate temperature and means for controlling a dialysate concentration, both as specified in claim 26, require: a microprocessor, a heater, and a temperature-sensing device; and a microprocessor and concentrate pump, respectively (App. Br. 37). According to Appellant, the Examiner “no where identifies corresponding structures in the CMS08 Handbook that are necessary to meet” these limitations of element (a) (*id.*). With respect to Lichtenstein, Appellant argues that the reference does not suggest any particular input device for operational parameters and that, unlike the claimed invention, “control is preferably automatically controlled by the microcomputer” (App. Br. 41).

Thus, the issues are:

(3) Has the Examiner erred in finding that the CMS 08 Handbook or Lichtenstein describes element (a) of claim 26?

(4) Has the Examiner erred in finding that Lichtenstein teaches user-initiated control of operational parameters?

Claim 27

The Examiner found that the sodium, potassium, and bicarbonate concentrations and the ultrafiltration rate described in the CMS 08 Handbook are “programmed settings of time-varying machine-operating parameter[s],” as recited in claim 27 (Ans. 44-45). According to the Examiner, “the CMS08 [Handbook] explicitly exemplifies the same time variable parameters during hemodialysis, see particular settings for sodium, potassium and bicarbonate concentration[s] and ultrafiltration rate” (Ans. 45).

Appellant, on the other hand, contends that the CMS 08 Handbook does not describe the claim limitation because the prior art device “does not actively ‘solicit’ information related to the setting of a time-varying hemodialysis parameter by requesting an input” (App. Br. 49-50).

Thus, the issue is:

(5) Has the Examiner erred in finding that the CMS 08 Handbook describes a “time-varying machine-operating parameter,” as recited in claim 27?

Claims 28 and 29

The Examiner found that the CMS 08 Handbook describes a microcomputer control that operates in concert with components (e.g., blood pumps) of the A2008 hemodialysis machine, as required by the means-plus-function language “means for delivering blood at a prescribed flow rate” of claim 28 (Ans. 46). Additionally, the Examiner found that Lichtenstein also describes the disputed claim limitation (Ans. 46-49).

Appellant asserts “that the blood pump in the A2008 [hemodialysis machine] is initially set manually (CMS08 Handbook, F330337) and is not controlled by the user interface on the CMS08 unit” (App. Br. 52). As to Lichtenstein, Appellant argues that while Lichtenstein discloses computerized control of blood flow, it does not suggest a visual display for the automatic, computer-controlled operation of the function at a prescribed flow rate (App. Br. 53).

Thus, the issue is:

(6) Has the Examiner erred in finding that either the CMS 08 Handbook or Lichtenstein describes a “means for delivering blood at a prescribed flow rate,” as recited in claim 28?

Claim 30

The Examiner found that Thompson discloses the administration of a secondary fluid such as an anticoagulant in administration systems operating under the control of electronic instrumentation (Ans. 13). The Examiner then concluded that one of ordinary skill in the art would have found it obvious to deliver an anticoagulant to a patient undergoing hemodialysis

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with the CMS 08 unit for the purpose of preventing coagulation or blood clotting and to control the delivery of the anticoagulant with a touch screen user interface (Ans. 14).

Appellant contends that “Thompson does not contain any disclosure relevant to ‘an indicium soliciting from the user’ the anticoagulant delivery rate, though the rate can apparently be set using the device” (App. Br. 55).

Thus, the issue is:

(7) Has the Examiner erred in reaching the conclusion that a person having ordinary skill in the art would have found it obvious to control anticoagulant delivery rate with a touch screen user interface, as required by claim 30?

Claim 31

The Examiner found that the CMS 08 Handbook, Lichtenstein, and the Sarns 9000 Manual teach the use of an alarm when critical parameters (e.g., conductivity and blood ultrafiltration rate) fall outside preset limits and concluded that a person having ordinary skill in the art would have found it obvious to set these limits by using a touch screen user interface (Ans. 12, 50-51).

Appellant argues that neither the CMS 08 Handbook nor Lichtenstein discloses a touch screen user interface and that the touch screen in the Sarns 9000 Manual does not solicit the user to enter an alarm limit (App. Br. 56-57).

Thus, the issue is:

(8) Has the Examiner erred in reaching the conclusion that a person having ordinary skill in the art would have found it obvious to set an alarm in the CMS 08 hemodialysis machine of a critical parameter through a touch screen user interface, as required by claim 31?

Claim 32

The Examiner found that Rubalcaba teaches the concept of comparing values entered into a touch screen user interface with preset limits and if the values are within the preset limits, causing the parameter to be entered, and the machine to be operated in accordance with the set parameter (Ans. 18-19).

Appellant contends that Rubalcaba does not disclose element (f) of claim 32 because, unlike the claimed invention, Rubalcaba discloses automatic calculation of a fourth variable after three other variables are entered by the user (App. Br. 58).

Thus, the issue is:

(9) Has the Examiner erred in finding that Rubalcaba discloses element (f) of claim 32 because claim 32 excludes Rubalcaba's automatic calculation?

Claim 33

The Examiner found that the Sarns 9000 Manual teaches the concept of monitoring a parameter and sounding an alarm and stopping operation when the parameter falls outside preset limits and concluded that it would

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have been obvious for one of ordinary skill in the art to apply this concept to the hemodialysis machine described in the CMS 08 Handbook (Ans. 19-20).

Appellant argues that the prior art does not teach element (f) of claim 33, including the “preset increment” limitation (App. Br. 59-60).

Thus, the issue is:

(10) Has the Examiner erred in finding that the Sarns 9000 Manual teaches the concept of monitoring a parameter and sounding an alarm and stopping operation when the parameter falls outside preset limits?

Claim 34

The Examiner found that Rubalcaba teaches the concept of the use of “a memory function whereby the values may be stored for later recall, and the entered values may be displayed” (Ans. 21). According to the Examiner, Rubalcaba teaches that when the user returns to the titration calculator screen, the previously entered values are displayed (*id.*).

Appellant contends that Rubalcaba “is indefinite as to whether the touch screen *automatically* displays a previously set value or if the user must retrieve the previously set value from the memory storage” (App. Br. 61).

Thus, the issue is:

(11) Has the Examiner erred in finding that Rubalcaba discloses the automatic display of a previously entered value for user convenience, as required by element (c) of claim 34?

Claims 12-18

The Examiner concluded that the collective teachings of the CMS 08 Handbook, Lichtenstein, the Sarns 9000 Manual, Rubalcaba, and Kerns would have led a person having ordinary skill in the art to arrive at a method of operating a hemodialysis machine, as recited in claim 12 (Ans. 14-16).

Appellant contends that the Examiner's conclusion is in error because: (i) the Sarns 9000 Manual does not teach element (c) of claim 12 (App. Br. 64); (ii) "the cited reference fails to disclose a touch screen that centralizes controls in a single locations [sic]" (*id.* at 68); (iii) "[n]one of the references teach or suggest an apparatus that will minimize the display of the data-entry mechanism" (*id.* at 70); and (iv) Rubalcaba and Kerns teach a numeric keypad that is not "invoked" by touching the desired parameter (*id.* at 73).

Thus, the issues are:

(12) Has the Examiner erred in finding that the prior art teaches element (c) of claim 12?

(13) Has the Examiner erred in reaching the obviousness conclusion as to claim 12 because the claim requires a touch screen that centralizes controls in a single location and the prior art fails to disclose such a limitation?

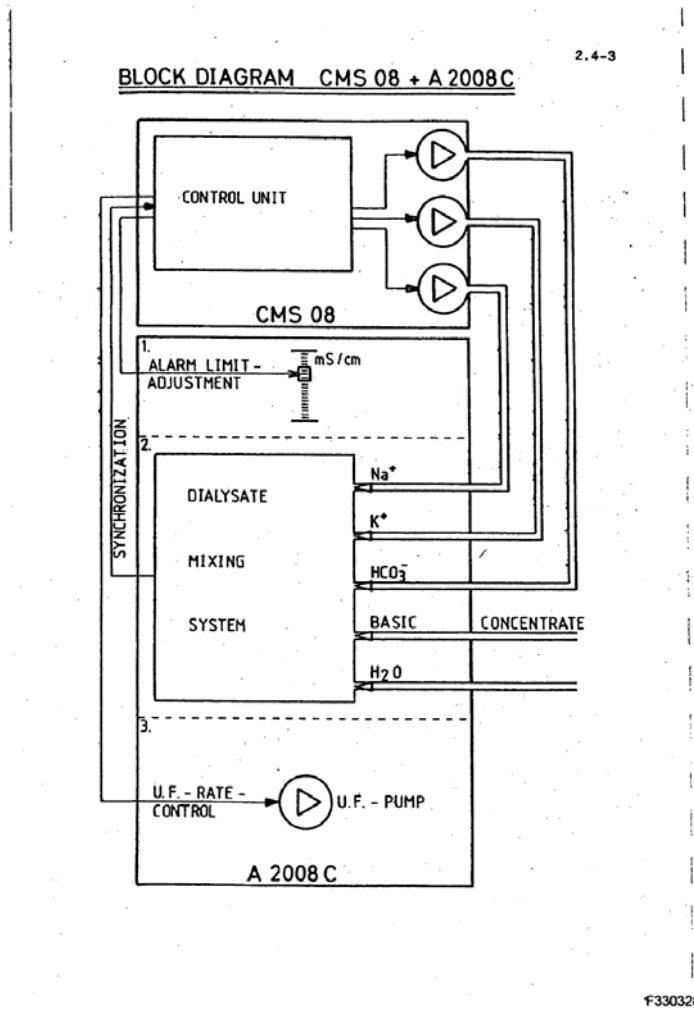
(14) Has the Examiner erred in reaching the obviousness conclusion as to claim 12 because the claim requires the minimization of the display of a data-entry mechanism and the prior art fails to disclose such a limitation?

(15) Has the Examiner erred in reaching the obviousness conclusion because Rubalcaba and Kerns do not teach a numeric keypad that is "invoked" by touching a desired parameter?

FINDINGS OF FACT (“FF”)

1. The CMS 08 Handbook describes an ancillary section of an A2008 dialysis treatment machine (F330324).
2. The CMS 08 Handbook states that the volumetric dosing of up to three (3) different electrolyte concentrations via stepper motor driven line pumps into the A2008 dialysate mixing system can be programmed (using a control unit) in ten minute time intervals (F330320, F330324, F330327, F330328).
3. In particular, the CMS 08 Handbook identifies the ultrafiltration rate, the Na concentration of the dialysate, the K concentration of the dialysate, and the bicarbonate concentration of the dialysate as “time depend[e]nt parameters” and that these parameters may be programmed by using a keyboard (F330324).

4. A figure in section 2.4 (F330328) of the CMS 08 Handbook is reproduced below:



The figure reproduced above is said to be a block diagram of the CMS 08 and A2008 combination.

5. Lichtenstein discloses a computer-controlled medical care system (e.g., hemodialysis) in which “[t]he adjustment of the various flow rates can be effected either manually by an operator or automatically where control means are provided” (col. 5, l. 34 to col. 6, l. 19; col. 6, ll. 54-56).

6. Lichtenstein teaches that the microcomputer can be any conventional computer suitable for the disclosed purposes and may include “a display means for indicating the sensed parameters and/or any needed adjustments in the operating conditions to maintain the procedure on schedule while keeping the physiological status of the patient within predetermined limits” (col. 8, ll. 1-34).
7. The ‘434 Patent Specification states:

Exemplary are parameters that are programmed to change over time (so-called profiled parameters). In this class are the sodium concentration of the dialysate solution, the bicarbonate concentration of the dialysate, kT/V , and the ultrafiltration rate.

(Col. 9, ll. 32-36.)
8. Thompson teaches that a secondary fluid, such as an anticoagulant, may be administered to a patient in administration systems operated under the control of electronic instrumentation either on a gravity delivery or a positive pressure basis (col. 1, ll. 9-25).
9. The Sarns 9000 Manual teaches the concept of using a touch screen interface to control various operational variables in a perfusion system (F298966-67, F298971-72, F298978, F298987-88, F299010-11, F299014, F299054-59).
10. The Sarns 9000 Manual further teaches the concept of using alarms to alert the operator of a perfusion system when certain monitored parameters (e.g., pressure for the arterial and cardioplegia pumps) fall outside preset limits and to stop the

pumps or display messages if pressures, temperatures, flow rates, or other alarm parameters exceed preset limits (F298987-88).

11. Rubalcaba teaches the use of a touch screen interface to control operational variables in a drug delivery system (Abstract; Figures 3 and 5-9; col. 1, ll. 20-38; col. 8, l. 52 to col. 12, l. 12).
12. Rubalcaba further teaches the concept of comparing an entered value of an operating parameter in a drug infusion system to preset values and, if outside the preset range, displaying the entered value along with an indication that the entered value is invalid (col. 6, ll. 1-24).
13. Rubalcaba also teaches (col. 6, ll. 25-32):

According to another aspect of the invention, there is provided means for storing the values that are assigned and calculated for the parameters. In the illustrated embodiment, the CPU circuitry 32 functions to serve this purpose. It includes suitable programming and sufficient memory to accomplish storage function so that the various values of the parameters need not be reentered.
14. Rubalcaba teaches that the system calculates “dosage, infusion rate, weight of drug, or volume of solution from the remaining ones of these parameters using one of two formulae” (col. 4, ll. 34-57).
15. The Sarns 9000 Manual discloses an indicium for a pulsatile screen that may be accessed through a “MAIN SCREEN” (F299053-54).

16. The Sarns 9000 Manual teaches that the pulsatile screen includes a “FLOW display” showing the average flow of an arterial pump and permitting an increase or decrease by touching up or down arrows (F299055).
17. Sarns 9000 teaches: “Touch the display area, use the increase/decrease switches to adjust the value, and touch the display area again” (F299055).
18. Kerns teaches the use of a touch screen interface to control operational parameters in an infusion pump system (Figures 7, 8, 11-18; col. 6, ll. 7-20; col. 11, ll. 39-51).
19. The Rau publication, discussed in *Fresenius*, 582 F.3d at 1301, was found by our reviewing court, the United States Court of Appeals of the Federal Circuit, to teach the use of a touch screen interface on a medical device such as an anesthesia delivery system.
20. The Rau publication was also found by the court to suggest the use of such a touch screen interface in a hemodialysis machine. *Fresenius*, 582 F.3d at 1301.
21. Dr. Rau, the author of the Rau publication, testified in court “that his publication ‘gave numerous examples of where you can use [touch screen technology] beneficially’ and stated that ‘one of the examples which [he] mentioned was hemodialysis and a hemodialysis machine.’” *Fresenius*, 582 F.3d at 1301.
22. Expert witness Dr. Robert C. Phares also testified in court as to “the ease and prevalence of ‘integrating a touch screen into

some kind of computer-controlled machine’ and opined that as of the relevant filing date, it would not have been difficult for one to [of ordinary skill in the art] to integrate a touch screen interface into a hemodialysis machine.” *Fresenius*, 582 F.3d at 1301.

23. Lipps testified that 20 years prior to the date of his testimony (September 26, 2005), touch screens were “highly unreliable” and not economical (Ex. C at 38).
24. Crnkovich testified that he “used a couple of touch screens during the early ‘80s, and . . . did not have a good experience with them” (Ex. D, 10:19-21).
25. Kelly testified that, in 1988, *he had heard from others* that touch screen interfaces posed cost and reliability concerns (Ex. E, 63-66).
26. Turner declares that in proposing the release of “2008K” hemodialysis machine, Fresenius listed the touch screen as the first among the “state-of-the art features” (Ex. F, ¶ 18).
27. Turner further testified that Fresenius sought to compete with Althin, another manufacturer of units with a touch screen interface (Ex. F, ¶¶ 21-23).

PRINCIPLES OF LAW

On appeal to this Board,

An appellant may attempt to overcome an examiner’s obviousness rejection on appeal to the Board by submitting arguments and/or evidence to show that the Examiner made an

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error in either (1) an underlying finding of fact upon which the final conclusion of obviousness was based, or (2) the reasoning used to reach the legal conclusion of obviousness. Similarly, the applicant may submit evidence of secondary considerations of non-obviousness. *See Kahn*, 441 F.3d at 985-86 (“On appeal to the Board, an applicant can overcome a rejection by showing insufficient evidence of prima facie obviousness or by rebutting the prima facie case with evidence of secondary indicia of nonobviousness.”) (quoting *In re Rouffet*, 149 F.3d 1350, 1355 (Fed. Cir. 1998), *overruled in part on other grounds*, *KSR*, 550 U.S. at 422).

Ex parte Frye, ___ USPQ2d ___ (BPAI March 1, 2010) (precedential)
<http://des.uspto.gov/Foia/ReterivePdf?system=BPAI&fINm=fd2009006013-02-26-2010-1>. *See also* 37 C.F.R. § 41.37(c)(1)(vii).

“During reexamination, as with original examination, the PTO must give claims their broadest reasonable construction consistent with the specification Therefore, we look to the specification to see if it provides a definition for claim terms, but otherwise apply a broad interpretation.” *In re ICON Health and Fitness, Inc.*, 496 F.3d 1374, 1379 (Fed. Cir. 2007).

This longstanding principle is based on the notion that “during patent prosecution when claims can be amended, ambiguities should be recognized, scope and breadth of language explored, and clarification imposed.” *In re Zletz*, 893 F.2d 319, 321 (Fed. Cir. 1989). That is, a patent applicant has the opportunity and responsibility to remove any ambiguity in claim term meaning by amending the application. “Only in this way can uncertainties of claim scope be removed, as much as possible, during the administrative process.” *Id.* at 322. “[A]s applicants may amend claims to narrow their scope, a broad construction during prosecution creates no unfairness to the applicant or patentee.” *ICON Health*, 496 F.3d at 1379.

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The Supreme Court of the United States explained that “[w]hen a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one.” *KSR Int’l Co. v. Teleflex, Inc.*, 550 U.S. 398, 417 (2007). According to the Court, “if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill.” *Id.*

ANALYSIS

Concurrent Court Proceedings

In *Fresenius*, our reviewing court reversed the district court’s decision to overturn a jury’s verdict of obviousness as to claims 1-3 and 13-16 of the ‘131 Patent and held that substantial evidence supported a conclusion that the subject matter “directed to a hemodialysis machine integrated with a touch screen user interface” would have been obvious to a person having ordinary skill in the art. *Fresenius*, 582 F.3d at 1300-1302. As to secondary considerations (e.g., commercial success of an embodiment of the patents in suit), our reviewing court stated that substantial evidence supported the jury’s finding that Appellant’s evidence was insufficient. *Fresenius*, 582 F.3d at 1302.

The court found, however, that *Fresenius* (the alleged infringer) failed to prove invalidity by clear and convincing evidence with respect to the asserted ‘434 Patent claims (i.e., claims 26-31). *Fresenius*, 582 F.3d at 1299. Specifically, the court stated that “*Fresenius* neither identified the

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structure in the specification that corresponds to the means for delivering dialysate nor compared it to the structures present in the prior art.” *Id.* at 1299. In addition, the court held that “Fresenius failed to present any evidence that the required stepper motor structure [in claim 30] existed in the prior art.” *Id.* at 1300.

Although claims 26-31 were not proven 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. *Ethicon v. Quigg*, 849 F.2d 1422, 1429 (Fed. Cir. 1988) (“[T]he Board and the courts take different approaches in determining invalidity and on the same evidence could quite correctly come to different conclusions.”); *In re Swanson*, 540 F.3d 1368, 1377 (Fed. Cir. 2008) (explaining the different standards of proof and claim construction used in reexamination relative to civil litigation in district court).

*Obviousness of Combining a Touch Screen Interface
with a Hemodialysis Machine*

We share the Examiner’s well-stated position that the collective teachings of the applied prior art references would have prompted a person of ordinary skill in the art to couple a touch screen interface with a hemodialysis machine. Both CMS 08 Handbook and Lichtenstein identify a need to control certain parameters pertinent to the operation of a hemodialysis machine (FF 1-6). The Sarns 9000 Manual, Kerns, and Rubalcaba all disclose the concept of controlling critical operational parameters in medical devices, which are similar to those disclosed in either the CMS 08 Handbook or Lichstenstein in terms of requiring the precise

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delivery of fluids into a human body, by a touch screen user/machine interface (FF 9-18). The interrelatedness of the prior art teachings, coupled with the expectation that a technique used to improve one device would also improve other similar devices, amply support the Examiner's obviousness conclusion. *KSR*, 550 U.S. at 417-18.

While Appellant urges that the Sarns 9000 Manual, Kerns, and Rubalcaba do not teach centralized control, we have not been directed to any language in the appealed claims that require centralized control. *In re Self*, 671 F.2d 1344, 1348 (CCPA 1982) ("Many of appellant's arguments fail from the outset because, as the solicitor has pointed out, they are not based on limitations appearing in the claims.").

We also find no error in the Examiner's refusal to credit the testimonies of certain experts as supporting Appellant's skepticism or lack of a reasonable expectation of success argument. As pointed out by the Examiner (Ans. 35-36), these experts testified on the knowledge of a person of ordinary skill in the art at a time period significantly before the relevant filing date (FF 23-25). We have not been directed to any evidence indicating that further advances in touch screen technology did not occur up to the relevant filing date. Moreover, we have not been directed to any evidence that these witnesses, before giving their testimonies, considered the teachings of the applied prior art references, which plainly disclose the successful incorporation of touch screen interfaces into critical medical systems. Indeed, Appellant has admitted that "not a single witness from either Baxter or Fresenius had even heard of the Sarns machine" (App. Br.

26). That admission reveals the lack of any substantial value in the relied-upon evidence vis-a-vis Appellant's argument.

Appellant relies primarily on the Turner Report as demonstrating commercial success or copying (FF 26-27). We, like the Examiner (Ans. 54-57), find the relied-upon evidence, including the Turner Report, unpersuasive. The evidence fails to conclusively establish that commercial success, if any, was directly attributable to the touch screen interface. *In re Huang*, 100 F.3d 135, 140 (Fed. Cir. 1996) (“Even assuming that Huang had sufficiently demonstrated commercial success, that success is relevant in the obviousness context only if there is proof that the sales were a direct result of the unique characteristics of the claimed invention – as opposed to other economic and commercial factors unrelated to the quality of the patented subject matter.”); *Asyst Technologies, Inc. v. Emtrak, Inc.*, 544 F.3d 1310, 1316 (Fed. Cir. 2008) (“While the evidence shows that the overall system drew praise as a solution to a felt need, there was no evidence that the success of the commercial embodiment . . . was attributable to the . . . only material difference between [the prior art] and the patented invention.”).

The obviousness of combining a touch screen interface with a hemodialysis machine is buttressed by *Fresenius*, which upheld a jury determination that the incorporation of a touch screen in a hemodialysis machine would have been obvious to a person of ordinary skill in the art over similar prior art. Here, Appellant has urged in the present appeal that we should defer to the district court's ruling because “[a]part from the Thompson reference, the evidence here is the same as that examined by the District Court” (App. Br. 11; Reply Br. 8; FF 19-22). Because Appellant has

repeatedly relied on the district court proceeding in support of nonobviousness, we discern no unfairness in subjecting Appellant to any adverse consequence that may arise from such reliance in the current reexamination, which is conducted under the preponderance of the evidence standard – a standard that is substantially lower than the clear and convincing standard used in district court.

Claim 26

It is undisputed that the structure corresponding to the recited “means for controlling . . . dialysate concentration” includes, at a minimum, a microprocessor and a concentrate pump (App. Br. 37; Ans. 5-6, 25-27, 38-39). Contrary to Appellant’s belief, the Examiner did identify the structures in the CMS 08 Handbook that correspond to the recited means-plus-function language (Ans. 5-6, 25-27, 38-39). Indeed, the CMS 08 Handbook 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 (FF 1-4). Thus, with respect to the CMS 08 Handbook, Appellant failed to demonstrate any reversible error on the part of the Examiner. Additionally, Appellant did not assert that Lichtenstein lacks any structure corresponding to element (a) of claim 26 (App. Br. 40-43). Thus, we cannot reverse the Examiner’s rejection of claim 26 on the basis of the recited means-plus-function language in claim 26, element (a).

We are not persuaded by Appellant’s contention that Lichtenstein lacks any teaching with respect to any particular input device for operational parameters, i.e., user-initiated control of an operational parameter (App. Br.

40-43). As pointed out by the Examiner (Ans. 6), Lichtenstein plainly teaches that the adjustment of the flow rates can be effected manually, which would necessarily require user input (FF 5).

In light of these factual findings, we affirm the rejection of claim 26.

Claim 27

Appellant's argument that the CMS 08 does not teach the setting of a time-varying hemodialysis parameter is factually incorrect (App. Br. 49-50). Like the '434 Patent Specification, the CMS 08 Handbook explicitly teaches that Na concentration of the dialysate, K concentration of the dialysate, bicarbonate concentration of the dialysate, and ultrafiltration rate are time-dependent hemodialysis parameters that can be adjusted or controlled by the user (FF 3 and 7).

Thus, we uphold the rejection of claim 27.

Claims 28 and 29

Appellant does not dispute that the CMS 08/A2008 combination discloses a blood pump, which together with the microprocessor, constitutes one of two components corresponding to the recited "means for delivering blood at a prescribed flow rate" (App. Br. 52). Rather, Appellant's position appears to be that the control unit described in the CMS 08 Handbook does not control the blood pump and therefore the rejection cannot stand (*id.*).

We cannot agree. The Examiner's view is that a person having ordinary skill in the art would have found it obvious to control the blood pump with the CMS 08 microcomputer control because the reference

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“makes clear that the computer control device is functional in concert with the A2008 device” (Ans. 46; FF 2 and 3). This position is reasonable. Appellant has not shown why the Examiner’s reasoning is flawed and therefore we discern no reversible error.

Turning to Lichtenstein, Appellant’s argument that Lichtenstein does not disclose “a visual display of a parameter associated with said means for delivering blood” (claim 28) is also unpersuasive (App. Br. 53). As noted by the Examiner (Ans. 6-7), Lichtenstein teaches the use of a microcomputer including a display means (FF 6). Appellant failed to address this teaching in any meaningful way and therefore we see no error in the Examiner’s reasoning.

Claim 30

We are not persuaded by Appellant’s argument that Thompson does not contain any disclosure relevant to “an indicium soliciting input from the user corresponding to a rate of anticoagulant delivery rate” (claim 30; App. Br. 55). Here, Appellant does not contest the Examiner’s finding that Thompson teaches that an anticoagulant may be administered to a patient undergoing medical treatment involving a system operated under the control of electronic instrumentation (FF 8). Given that it was known that operating parameters may be entered by soliciting input from a user (FF 2 and 3), we detect no error in the Examiner’s reasoning based on the collective teachings of the prior art references.

Claims 31 and 33

We agree with the Examiner that the Sarns 9000 Manual would have provided a reason for one of ordinary skill in the art to include an alarm/shutoff system for association with the CMS 08/A2008 operation parameters in order to improve safety (FF 10). While Appellant argues that the prior art does not solicit the user to enter an alarm limit (App. Br. 56-57), the Sarns 9000 Manual describes the setting of alarm limits and therefore the entry of such limits would have been obvious to a person having ordinary skill in the art.

Claim 32

Again, we find ourselves in agreement with the Examiner (Ans. 18-19). In this case, Rubalcaba plainly teaches that if the entered value is not within preset limits, the value will be displayed along with an indication that it is invalid, together with an indication of the valid range (FF 12). While Appellant argues that Rubalcaba teaches automatic calculation of a fourth variable after entry of three other variables (FF 14), that fact does not demonstrate error because claim 32 does not exclude automatic calculation. Thus, the invention recited in appealed claim 32 cannot be distinguished over the prior art on this basis. *In re Self*, 671 F.2d at 1348.

Claim 34

Appellant contends that Rubalcaba is unclear “whether the touch screen automatically displays a previously set value or if the user must retrieve the previously set value from memory storage” (App. Br. 61). This

argument is unpersuasive. As found by the Examiner (Ans. 21, 52), Rubalcaba teaches “storage function so that various values of the parameters need not be reentered” (FF 13). That teaching would have led a person having ordinary skill in the art to incorporate the memory function for each parameter.

Claims 12-18

Appellant has not offered any additional argument in support of the separate patentability of any claim (App. Br. 72-73). Accordingly, we confine our discussion to claim 12. *See* 37 C.F.R. § 41.37(c)(1)(vii).

Regarding element (c) of claim 12, Appellant urges that the up and down arrows in the Sarns 9000 Manual “are not invoked when the user seeks to enter a value for the flow rate; they are already on the pulsatile screen” (App. Br. 64). A similar argument is advanced against Rubalcaba and Kerns (App. Br. 73).

Appellant’s arguments are unpersuasive because, as pointed out by the Examiner (Ans. 52), it “fails to recognize that the user [of the Sarns 9000 Manual] must first enter the pulsatile screen from the Main Screen by touching the Pulse indicium” (*Id.*; FF 15-17). Moreover, Appellant has not explained how the difference in graphical indicia on a computer display, if any, constitutes a nonobvious advance over the prior art.

We also find no merit in Appellant’s contention that “the cited reference fails to disclose a touch screen that centralizes controls in a single locations [sic]” or “minimize the display of the data-entry mechanism”

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(App. Br. 68, 70). Appellant has failed to direct us to any language in claim 12 that recites such limitations. *In re Self*, 671 F.2d at 1348.

Moreover, with respect to centralized control, a person having ordinary skill in the art is presumed to have some common sense and thus would have found it obvious to consolidate the control into a single system for ease and convenience. *KSR*, 550 U.S. at 421 (“A person of ordinary skill is also a person of ordinary creativity, not an automaton.”); *Perfect Web Techs., Inc. v InfoUSA, Inc.*, 587 F.3d 1324, 1329 (Fed. Cir. 2009) (“*KSR* expanded the sources of information for a properly flexible obviousness inquiry to include . . . the background knowledge, creativity, and common sense of the person of ordinary skill.”).

CONCLUSION

On this record, we conclude that there is no error in the Examiner’s factual findings and conclusions that:

a person of ordinary skill in the art would have been prompted to couple a touch screen user/machine interface with a hemodialysis machine in view of the collective teachings of the prior art references;

Appellant’s relied-upon evidence is insufficient to confer nonobviousness;

the CMS 08 Handbook or Lichtenstein describes element (a) of claim 26;

Lichtenstein teaches user-initiated control of operational parameters;
the CMS 08 Handbook describes a “time-varying machine-operating parameter,” as recited in claim 27;

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either the CMS 08 Handbook or Lichtenstein describes a “means for delivering blood at a prescribed flow rate,” as recited in claim 28;

a person having ordinary skill in the art would have found it obvious to control anticoagulant delivery rate with a touch screen user interface, as required by claim 30;

a person having ordinary skill in the art would have found it obvious to set an alarm in the CMS 08 hemodialysis machine of a critical parameter through a touch screen user interface, as required by claim 31;

Rubalcaba discloses element (f) of claim 32;

the Sarns 9000 Manual teaches the concept of monitoring a parameter and sounding an alarm and stopping operation when the parameter falls outside preset limits;

Rubalcaba discloses the automatic display of a previously entered value for user convenience, as required by element (c) of claim 34;

the Sarns 9000 Manual teaches or would have suggested element (c) of claim 12; and

one of ordinary skill in the art would have found the subject matter of claim 12 obvious over the applied prior art references.

DECISION

The Examiner’s decision to reject:

- I. Claims 26-29 and 31 as unpatentable over the combined teachings of CMS 08 Handbook, Lichtenstein, Sarns 9000 Manual, Rubalcaba, and Kerns;

- II. Claim 30 as unpatentable over the combined teachings of CMS 08 Handbook, Lichtenstein, Sarns 9000 Manual, Rubalcaba, Kerns, and Thompson;
- III. Claims 12-18 as unpatentable over the combined teachings of CMS 08 Handbook, Lichtenstein, Sarns 9000 Manual, Rubalcaba, and Kerns;
- IV. Claim 19 as unpatentable over the combined teachings of CMS 08 Handbook, Lichtenstein, Sarns 9000 Manual, Rubalcaba, and Kerns;
- V. Claim 32 as unpatentable over the combined teachings of CMS 08 Handbook, Lichtenstein, Sarns 9000 Manual, Rubalcaba, and Kerns;
- VI. Claim 33 as unpatentable over the combined teachings of CMS 08 Handbook, Lichtenstein, Sarns 9000 Manual, Rubalcaba, and Kerns; and
- VII. Claim 34 as unpatentable over the combined teachings of CMS 08 Handbook, Lichtenstein, Sarns 9000 Manual, Rubalcaba, and Kerns,

is affirmed.

Requests for extensions of time in this *ex parte* reexamination proceeding are governed by 37 C.F.R. § 1.550(c). *See* 37 C.F.R. § 41.50(f).

AFFIRMED

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