UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

CAREFUSION CORPORATION,

Petitioner,

v.

BAXTER INTERNATIONAL, INC.,

Patent Owner.

Patent No. 6,231,560

Issue Date: May 15, 2001

Title: METHOD AND APPARATUS FOR

AUTOMATICALLY CONTROLLING THE LEVEL OF MEDICATION

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 6,231,560

UNDER 35 U.S.C. §§ 311-319 AND 37 C.F.R. § 42.1-.80 & 42.100-.123

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Petitioner CareFusion Corporation ("CareFusion" or "Petitioner") respectfully petitions for *inter partes* review of claims 1-18 of U.S. Patent No. 6,231,560 ("the '560 patent") (Ex. 1001) in accordance with 35 U.S.C. §§ 311-319 and 37 C.F.R. § 42.100 *et seq*.

I. COMPLIANCE WITH REQUIREMENTS FOR A PETITION FOR *INTER PARTES* REVIEW

A. Grounds for Standing (37 CFR § 42.104 (a))

Petitioner certifies it is not barred or estopped from requesting *inter partes* review of the '560 patent. Neither Petitioner, nor any party in privity with Petitioner, has filed a civil action challenging the validity of any claim of the '560 patent. The '560 patent has not been the subject of a prior *inter partes* review by Petitioner or a privy of Petitioner.

Petitioner also certifies this petition for *inter partes* review is filed within one year of the date of service of a complaint alleging infringement of a patent. Petitioner was served with a complaint alleging infringement of the '560 patent on or about November 9, 2015, captioned No. 1:15-cv-9986 in the U.S. District Court for the Northern District of Illinois. A copy of Baxter's original Complaint is attached as Exhibit 1012.

Because the date of this petition is less than one year from November 9, 2015, this petition complies with 35 U.S.C. § 315(b).

B. Fee for *Inter Partes* Review (37 CFR § 42.15(a))

The Director is authorized to charge the fee specified by 37 CFR § 42.15(a) to Deposit Account No. 06-1910.

C. Mandatory Notices (37 CFR § 42.8(b))

i. Real Party in Interest (37 CFR § 42.8(b)(1))

The real parties in interest for this petition are Petitioner CareFusion Corporation, located at 3750 Torrey View Court, San Diego, California 92130, and/or its corporate parent, Becton, Dickinson and Company, located at 1 Becton Drive, Franklin Lakes, New Jersey 07417.

ii. Other Proceedings (37 CFR § 42.8(b)(2))

The '560 patent is the subject of a civil action in the U.S. District Court for the Northern District of Illinois, captioned *Baxter International, Inc. v. CareFusion Corporation and Becton, Dickinson and Company*, No. 1:15-cv-9986 ("the district court lawsuit").

iii. Designation of Counsel and Service Information (37 CFR §§ 42.8(b)(3)-(4))

Petitioner identifies the following counsel (a power of attorney accompanies this Petition):

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Service information for counsel is provided above. Counsel may also be served by fax at (612) 492-7077.

D. Proof of Service (37 CFR §§ 42.6(e) and 42.105(a))

Proof of service of this Petition is provided in **Attachment A**.

II. INTRODUCTION AND IDENTIFICATION OF THE CLAIMS BEING CHALLENGED (37 CFR § 42.104(B)(1))

This is a petition for *inter partes* review of claims 1-18 of U.S. Patent No. 6,231,560 ("the '560 patent"), titled "Method and Apparatus for Automatically Controlling the Level of Medication," issued on May 15, 2001, to Bui *et al.* and assigned to Baxter International, Inc. ("Baxter"). The '560 patent is attached as Exhibit 1001. The '560 patent is generally directed to a medical infusion pump that collects information regarding a patient's condition and modifies the amount of medication being delivered based on that patient information.

The ’560 patent has four independent claims, claims 1, 8, 9, and 16. Claims 1, 8, and 16 are method claims, and claim 9 is an apparatus claim. Claim 1 is representative of the alleged invention:

> 1. A method for automatically controlling the level of a patient’s medication administered from a programmable infusion pump, comprising:
>
> programming the infusion pump with a medication algorithm;
>
> initiating an evaluation of the patient’s medication;
>
> obtaining information pertaining to the patient’s condition;
>
> obtaining information pertaining to the patient’s current medication;
>
> evaluating the patient’s current medication and condition with the medication algorithm; and
>
> controlling administration of the patient’s medication based on the evaluation.

(Ex. 1001, Cl. 1.)

The prior art references cited and discussed in this petition for *inter partes* review are one U.S. patent and one published user manual, both belonging to CareFusion’s predecessors. The cited patent (“Bollish”) is based on the prototype of CareFusion’s accused Alaris system, and it is specifically directed to the “PCA

Pause"[1] features and functionality Baxter accuses of infringement in the district court lawsuit. CareFusion denies that these features fall within Baxter's claims, but if they do, the '560 patent is anticipated by CareFusion's prior invention of the accused features. In any event, even under the proper claim construction, the Bollish reference renders the '560 patent claims obvious.

The cited user manual ("TITRATOR") relates to a device called the TITRATOR that CareFusion's predecessor company IVAC Corporation sold in the late 1980s. The TITRATOR device attached to an existing infusion pump to provide automated control of sodium nitroprusside dosages in response to changes in a patient's blood pressure. It would have been obvious to combine the TITRATOR module with the infusion pump described in the Bollish patent, at least because the TITRATOR was designed to be connected with existing infusion pumps for the purpose of adding automated control in response to patient condition and because the Bollish pump and the TITRATOR were both developed by CareFusion's predecessors. Even if the Bollish patent by itself does not anticipate

[1] Patient-controlled analgesia, or "PCA," refers to a specialized category of medical infusion pumps that are designed to deliver narcotic pain medication to a conscious patient, who can request additional doses when needed by pushing a button. (*See* Ex. 1003 at ¶¶ 3, 9-10.)

or render obvious every claim of the ’560 patent, Bollish in combination with TITRATOR does.

Thus, the references relied on herein raise a reasonable likelihood that CareFusion will prevail with respect to at least one challenged claim, and CareFusion’s petition for *inter partes* review of the ’560 patent should be granted.

III. BACKGROUND OF THE ’560 PATENT

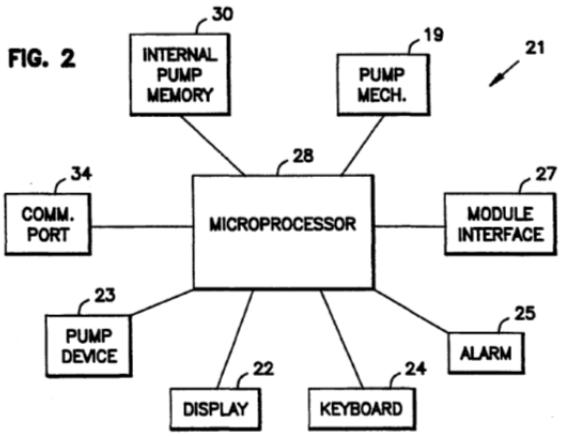
A. Effective Filing and Priority Dates of the ’560 Patent

The ’560 patent issued from U.S. Application No. 09/248,492 (“the ’492 application”), with a filing date of February 10, 1999. The ’560 patent does not claim priority to any earlier application. Furthermore, under the scheduling order in the district court lawsuit (Ex. 1013 at APP0538) and Northern District of Illinois Local Patent Rule 2.1(a)(2) (Ex. 1014 at APP0547), Baxter was required to produce “all documents concerning the conception, reduction to practice, design, and development of each claimed invention” in the ’560 patent by June 10, 2016. Baxter’s production does not include any document that could corroborate either conception or any efforts to reduce the ’560 claims to practice prior to the application’s February 10, 1999 filing date. *See generally, e.g.*, *Microsoft Corp. v. SurfCast, Inc.*, IPR2013-00292, Paper No. 93, at 15-21 (Oct. 14, 2014). Accordingly, CareFusion states that the priority date for the ’560 patent is February 10, 1999.

B. Relevant Prosecution History of the '560 Patent

The file history for the '560 patent is particularly helpful in understanding what Baxter claims it invented. The file history is attached as Exhibit 1002.

The examiner initially rejected Baxter's '492 application in light of prior art infusion pumps that disclosed all of the hardware recited in the claims, including U.S. Patent No. 5,368,562 ("Blomquist"). (Ex. 1002 at APP0108.) The Blomquist patent is attached as Exhibit 1011, and Figure 2 of Blomquist is reproduced below:



(Ex. 1011 at Fig. 2.)

In response, Baxter did not dispute that prior art infusion pumps contained all of the hardware components recited in the claims. Nor did it dispute that prior art pumps stored medication dosing instructions and other patient-specific information in electronic memory. Instead, Baxter argued that its invention was using the processor in the pump to "gather data on the patient," to "evaluate" that

data, and to change the patient's dosing level "within a preset range" based on the collected data:

> As shown above, unlike Blomquist, Applicants' independent claims generally recite **gathering data** on the patient, **evaluating the data** with preset ranges stored in memory, and then **automatically controlling administration of medication** through the pump based on the evaluation. … The patient-specific information [disclosed in Blomquist] is utilized merely for tying in certain information into the pump to create a medication log for subsequent reviewing. There is no disclosure or suggestion in Blomquist relating to evaluating obtained information in order to **change the administration of medicant to the patient within a preset range**. Accordingly, the approach disclosed in Blomquist provides a far more basic and different type of control system for statically setting initial pump settings, as opposed to the automatic and dynamic control system recited in Applicants' claims.

(Ex. 1002 at APP0130 (emphasis added).)

Following Baxter's response, the examiner issued an office action rejecting the '492 application over additional prior art. (*Id.* at APP0139.) Baxter again responded that "[n]one of the cited references anticipates or renders obvious such a system which conducts queries as to the patient's condition and subsequently controls the delivery of medication based on the condition of the patient." (*Id.* at

APP0152 (emphasis in original); *see also id.* at APP0153.) The examiner allowed the '560 patent to issue based on Baxter's arguments. (*See id.* at APP0158-59.)

C. Person of Ordinary Skill in the Art

A person of ordinary skill in the art in the field of the '560 patent in the 1999 time frame would have been someone with at least a bachelor's or graduate degree in pharmacy, medicine, biomedical engineering, or a related field, and at least 8 years of combined clinical and infusion pump design experience. (*See* Declaration of Stephen J. Bollish, Exhibit 1003, at ¶ 15.)

IV. CLAIM CONSTRUCTION (37 CFR § 42.104(B)(3))

In this proceeding, claims must be given their broadest reasonable construction in light of the specification. 37 CFR § 42.100(b); *Cuozzo Speed Techs. v. Lee*, slip op. at 20 (S. Ct. June 20, 2016).[2] The broadest reasonable construction should be determined, in part, by taking into account the subject

[2] CareFusion notes that the broadest reasonable construction is not the appropriate standard for claim construction in litigation. *See generally Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (en banc); *see also, e.g.*, *Cuozzo Speed*, slip. op. at 12. As noted, CareFusion disagrees with the claim construction positions taken by Baxter in its infringement contentions. Accordingly, CareFusion may propose a different claim construction in the district court lawsuit.

matter Baxter contends infringes the claims and the constructions Baxter has advanced in litigation. Also, if Baxter contends terms in the claims should be read to have a special meaning, those contentions should be disregarded unless Baxter also amends the claims consistent with 35 U.S.C. § 112 to make them expressly correspond to those contentions. *See* 77 Fed. Reg. 48764 at II.B.6 (August 14, 2012); *cf. In re Youman*, 679 F.3d 1335, 1343 (Fed. Cir. 2012). Unless stated otherwise below, CareFusion contends that each term in the claims should be given its plain and ordinary English meaning.

A. "Controlling Administration of the Patient's Medication"; "Automatically Modifying Delivery of the Patient's Medication"; "Automatically Changing the Rate and Amount of the Liquid Medicant to be Administered to the Patient"

Claims 1 and 16 recite the step of "controlling administration of the patient's medication based on the evaluation." Claim 8 likewise recites the step of "automatically modifying delivery of the patient's medication based on the evaluation." Claim 9 recites the step of "automatically changing the rate and amount of the liquid medicant to be administered to the patient in accordance with the set of patient-specific, predetermined ranges of medication."

Baxter's infringement contentions in the district court lawsuit allege that this limitation can be met by *either* (a) not delivering a dose of pain medication in excess of the maximum allowed by the patient's physician *or* (b) "paus[ing] PCA infusion if an evaluation of the SPO2 or respiratory rate shows that either falls

below defined limits." (Ex. 1015 at APP0583; *see also id.* at APP0603-04.) CareFusion disagrees that Baxter's construction is proper.

The '560 patent specification describes "the patient's algorithm for automatically changing his PCA dose" as follows:

> The patient's algorithm defines the range of values for the basal dose, the bolus dose, [and] the maximum amount of drug to be administered. The patient algorithm can increase or reduce the amount or duration of any of the PCA elements, depending on the patient's pain level, side effects and any impairment of the patient's functionalities.

(Ex. 1001 at 11:32-42.) In contrast, the "Background" section of the '560 specification expressly admits that preventing PCA doses in excess of the maximum set by the physician is part of the well-known ***prior art***. (*See, e.g.*, *id.* at 1:49-52 ("However, if the patient exceeds the maximum number of boluses programmed, any additional requested boluses will not be successful and will not result in the delivery of medication."); *see also* Ex. 1003 at ¶¶ 9-11.)

Accordingly, the broadest reasonable interpretation of these claim elements, read in light of the specification, is "increasing or decreasing the amount or duration of the patient's ongoing delivery of medication." The plain language of the claims and the patent's description of its improvement over the prior art make it clear that this element requires *changing* the delivery rate, not stopping it.

B. "Modification of a Basal Delivery Rate, a Bolus Dose, and a Number of Bolus Allowed"

Claim 3 recites the limitation that "controlling administration of the patient's medication includes modification of a basal delivery rate, a bolus dose and a number of bolus allowed within a certain time frame." As with the "controlling administration" term itself, Baxter contends that this limitation may be met by simply shutting down or pausing the pump if a dosage limit is exceeded or the patient's oxygen saturation or respiration fall below safe levels. (*See* Ex. 1015 at APP0587-88.) For the reasons discussed in Section IV(A), above, Baxter's contention is not reasonable, and the broadest reasonable construction of this term is "increasing or decreasing the amount or duration of the ongoing basal delivery rate, increasing or decreasing the amount or duration of the available bolus doses, and increasing or decreasing the number of allowed future bolus doses."

C. "Obtaining Information…"

Claim 1 recites the steps of "obtaining information pertaining to the patient's condition" and "obtaining information pertaining to the patient's current medication." Likewise, claim 8 recites the elements "a procedure for obtaining information pertaining to the patient's pain level," "a procedure for obtaining information pertaining to the patient's side effects," "a procedure for obtaining information pertaining to the patient's impairment of functionalities," and "a procedure for obtaining information pertaining to the patient's current medication."

Claim 9 recites "a data acquiring routine for obtaining information pertaining to the patient's pain level, side effects and impairment of functionalities."

Baxter contends that "obtaining information pertaining to the patient's current medication" is satisfied by "keep[ing] track of the patient's current medication by *e.g.*, tracking when the last dose of medication was delivered." (Ex. 1015 at APP0578.) Baxter contends that "obtaining information pertaining to the patient's condition" and "obtaining information pertaining to the patient's pain level, side effects and impairment of functionalities" is satisfied by either registering the patient's PCA bolus dose requests or monitoring the patient's respiration or oxygen saturation. (*See id.* at APP0576-78, APP0598-APP0600.)

CareFusion disagrees that Baxter's constructions are correct. Regardless, for the purposes of evaluating the claims under their broadest reasonable interpretation, it is appropriate for the Board to consider Baxter's infringement positions when comparing these elements to the prior art. *See, e.g.*, *in re Icon Health & Fitness, Inc.*, 496 F.3d 1374, 1379 (Fed. Cir. 2007) ("[A]n infringement or invalidity analysis provides the context for claim construction."). CareFusion accordingly does not dispute Baxter's interpretation of these terms for the purpose of this Petition, though CareFusion may subsequently do so in the district court lawsuit.

V. IDENTIFICATION OF SPECIFIC STATUTORY GROUNDS FOR CHALLENGE (37 CFR § 42.104(B)(2))

CareFusion respectfully requests the cancellation of claims 1-18 of the '560 patent. The statutory grounds for the challenge are set forth below (all citations are to pre-AIA statues):

Ground	35 USC §	Claims	References
1	102(e)	1-3, 9-11	Bollish (Ex. 1004)
2	103(a)	1-18	Bollish (Ex. 1004)
3	103(a)	1-18	Bollish (Ex. 1004) in view of TITRATOR (Ex. 1005)

VI. DETAILED EXPLANATION AND EVIDENCE SUPPORTING GROUNDS FOR CHALLENGE (37 CFR §§ 42.104(B)(4)-(5))

A. Ground 1: Anticipation of Claims 1-3 and 9-11 Based on Bollish

Claims 1-3 and 9-11 are anticipated under 35 U.S.C. § 102 in view of Bollish as set forth below.

i. Disclosure of Bollish

The Bollish patent (U.S. Patent No. 5,957,885, attached as Ex. 1004) is directed to the "PCA Pause" features of CareFusion's modular Alaris infusion pump system – the same products and functionality that Baxter accuses of infringement in the district court lawsuit. (*See* Ex. 1003 at ¶¶ 4, 9-17; Ex. 1015 at APP0583, APP0603-04.) The Bollish patent issued from U.S. Patent Application No. 08/744,486, which was filed on November 6, 1996. (Ex. 1004 at APP0196.)

As discussed in Section III(A), above, Baxter has not produced any evidence supporting conception or efforts to reduce the claimed invention to practice prior to its February 10, 1999, filing date. Accordingly, the Bollish patent is prior art under at least pre-AIA 35 U.S.C. § 102(e).

Bollish teaches an infusion pump method and apparatus "for centrally interfacing and controlling administration of analgesics in a patient controlled analgesia methodology while monitoring the patient to prevent central nervous system and respiratory depression associated with administration of analgesics." (Ex. 1004 at 1:7-11.) Specifically, Bollish teaches a programmable infusion pump for use in patient controlled analgesia (PCA) applications that uses "pulse oximetry monitoring" to monitor and display both "the patient's percent blood oxygen saturation and pulse rate[.]" (*Id.* at 7:26-37.) The system includes an "auto shut-off option" to deactivate the pump (and therefore stop the flow of medication) if the patient's pulse or blood oxygen level indicate a potentially dangerous condition:

> Prior to starting pulse oximetry monitoring, the clinician may select the auto shut-off option for one or more other functional units, such as PCA unit 150A, so that central interface unit 100 shuts-off the selected functional unit(s) if the patient's blood oxygen saturation level or pulse rate falls outside of the specified maximum and minimum levels.

(*Id.*)

The Bollish patent also teaches that, because the system is designed for use in PCA applications, the analgesia doses controlled by the system include not only the "background continuous infusion" dose set by the clinician, but also bolus doses requested by the patient "by means of [a] patient dose request actuation device":

> PCA unit 150A is now operating with continuous monitoring by pulse oximetry unit 150B of the patient's percentage blood oxygen saturation and pulse rate. PCA unit 150A begins background continuous infusion, if one has been selected. In addition, the patient may now request a dose of narcotic analgesics at any time by means of patient dose request actuation device 135. Of course, whether the patient actually receives a requested dose depends upon the patient request dosing limits, if any, as well as the patient's current percent blood oxygen saturation and pulse rate relative to the minimum levels set by the clinician.

(*Id.* at 8:13-25.)

ii. Comparison of Claims 1-3 and 9-11 to Bollish

The claim chart below specifies where each element of claims 1-3 and 9-11 is found in Bollish.

'560 Claim Language	Citations to Bollish
1[a]. A method for automatically	Bollish states as follows: The present invention relates to a programmable

controlling the level of a patient's medication administered from a programmable infusion pump, comprising:	patient care system. Specifically, the present invention relates to a method and apparatus for centrally interfacing and controlling administration of analgesics in a patient controlled analgesia methodology while monitoring the patient to prevent central nervous system and respiratory depression associated with administration of analgesics. … Patient Controlled Analgesia (PCA) is a method for delivering parenteral narcotics wherein a patient controls the administration of the narcotic analgesics, since the patient is usually in the best position to determine the need for additional pain control. PCA is commonly administered via a stand-alone type of infusion device dedicated solely for PCA use. Examples of PCA devices are disclosed in U.S. Pat. No. 5,069,668, to Boydman, and U.S. Pat. No. 5,232,448, to Zdeb. (Ex. 1004 at 1:5-23.)
[1b.] programming the infusion pump with a medication algorithm;	Bollish states as follows: The clinician then selects PCA unit 150A and its corresponding channel by depressing SELECT key 156 on PCA unit 150A. By selecting PCA unit 150A, information display 102 is configured so as to act as the user interface and thus provides PCA function specific displays and softkeys, as shown in FIGS. 6-8. The clinician may first restore previous dosing units and analgesics concentration or select the dosing units from, for example, mcg, mg, or mL, and input the analgesics concentration, as shown in FIG. 6 and 7. Next, as shown in FIG. 8, the clinician may input or restore previous parameters for patient bolus dosage. For additional precaution to further prevent respiratory and central nervous system depression and as an alternative embodiment of the present invention, system 10 or PCA unit 150A may require the

	clinician to enter patient request dosing limits, such as maximum dose per hour or per 24-hour period. After entering the patient bolus dosage parameters, the clinician may choose to administer a background continuous infusion of narcotic analgesics by pressing softkey 106 adjacent to CONTINUOUS. Use of a background infusion in combination with patient requested doses provides a level of narcotic analgesia sufficient for periods of low activity such as when the patient is sleeping. Thus, when the patient wakes up and requires additional analgesia because of increased activity levels, the patient can self-administer additional narcotic analgesics to meet those needs. If a background continuous infusion is selected by pressing softkey 106 adjacent to CONTINUOUS, display 102 allows the clinician to input desired continuous infusion dose. FIG. 8 shows information display 102 after the clinician has entered values for both patient bolus dose and continuous dose. (Ex. 1004 at 7:46 – 8:10.)
[1c.] initiating an evaluation of the patient's medication;	Baxter's infringement contentions in the district court lawsuit equate "initiating an evaluation of the patient's medication" with determining whether to administer a medication dose "after a PCA Module patient request button is pressed[.]" (Ex. 1015 at APP0572-73.) Bollish discloses this element to the same extent that it can be found in the accused product. For example, Bollish states: [T]he patient may now request a dose of narcotic analgesics at any time by means of patient dose request actuation device 135. Of course, whether the patient actually receives a requested dose depends upon the patient request dosing limits, if

	any, as well as the patient's current <u>percent blood oxygen saturation and pulse rate</u> relative to the minimum levels set by the clinician. (Ex. 1004 at 8:19-25 (emphasis added).)
[1d.] obtaining information pertaining to the patient's condition;	For example, Bollish states as follows: FIG. 5 shows information display 102 after the clinician has entered or recalled previous values. Prior to starting pulse oximetry monitoring, the clinician may select the auto shut-off option for one or more other functional units, such as PCA unit 150A, so that central interface unit 100 shuts-off the selected functional unit(s) if the patient's blood oxygen saturation level or pulse rate falls outside of the specified maximum and minimum levels. Once pulse oximetry monitoring starts, the patient's percent blood oxygen saturation and pulse rate are displayed in Sp02% display 180 and Pulse display 182, respectively, as previously described and shown in FIG. 1. Although the preferred embodiment patient care system 10 automatically initiates both audio and visual alarms as well as notifies medical personnel, such as triggering a nurse call, if the patient's percent blood oxygen saturation or pulse rate falls above or below specified maximum or minimum levels, system 10 can be configured such that the clinician can also select specific alarms and notification to medical personnel in such an event. (Ex. 1004 at 7:26-45.) Accordingly, Bollish teaches this element at least to the same extent it can be found in the accused products. (*See* §IV(C), *supra*; Ex. 1015 at APP0576-78.)
[1e.] obtaining information pertaining to the patient's current medication;	As indicated above, Bollish teaches a clinician programming a patient's medication dosage into the PCA system. Bollish goes on to state: Once the above steps have been completed, the clinician attaches [a] PCA administration set to the

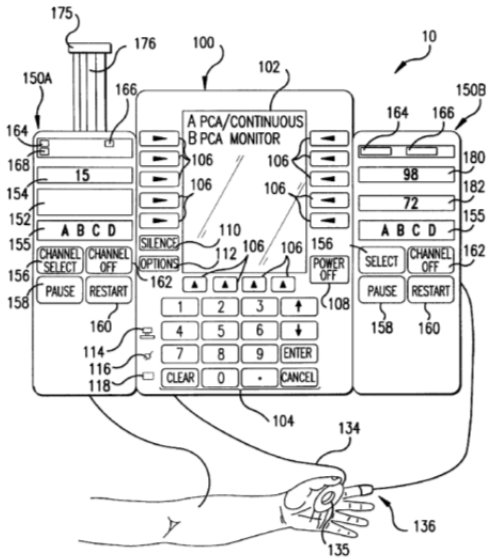
	patient's indwelling vascular access device (not shown) and presses softkey 106 adjacent to START on central interface unit 100. PCA unit 150A is now operating with continuous monitoring by pulse oximetry unit 150B of the patient's percentage blood oxygen saturation and pulse rate. PCA unit 150A begins background continuous infusion, if one has been selected. In addition, the patient may now request a dose of narcotic analgesics at any time by means of patient dose request actuation device 135. Of course, whether the patient actually receives a requested dose depends upon the patient request dosing limits, if any, as well as the patient's current percent blood oxygen saturation and pulse rate relative to the minimum levels set by the clinician. (Ex. 1004 at 8:11-25 (emphasis added).) Comparing the requested PCA dose of narcotics to the "patient request dosing limits" inherently teaches that the device has stored and retrieved information regarding the patient's current medication level, at least as this term is being construed by Baxter. (*See* §IV(C), *supra*; Ex. 1015 at APP0578-581; Ex. 1003 at ¶ 18.)
[1f.] evaluating the patient's current medication and condition with the medication algorithm; and	As discussed, Bollish states: Once the above steps have been completed, the clinician attaches PCA administration set to the patient's indwelling vascular access device (not shown) and presses softkey 106 adjacent to START on central interface unit 100. PCA unit 150A is now operating with continuous monitoring by pulse oximetry unit 150B of the patient's percentage blood oxygen saturation and pulse rate. PCA unit 150A begins background continuous infusion, if one has been selected. In addition, the patient may now request a dose of narcotic analgesics at any time by means of patient dose request actuation device 135. Of course, whether the patient actually receives a requested dose

	depends upon the patient request dosing limits, if any, as well as the patient's current percent blood oxygen saturation and pulse rate relative to the minimum levels set by the clinician. (Ex. 1004 at 8:11-25 (emphasis added).) The unit thus evaluates both the patient's current medication level and the patient's physical condition (as indicated by the pulse oximetry data). (*See* Ex. 1003 at ¶ 19.)
[1g.] controlling administration of the patient's medication based on the evaluation.	As discussed, Bollish states: Once the above steps have been completed, the clinician attaches [a] PCA administration set to the patient's indwelling vascular access device (not shown) and presses softkey 106 adjacent to START on central interface unit 100. PCA unit 150A is now operating with continuous monitoring by pulse oximetry unit 150B of the patient's percentage blood oxygen saturation and pulse rate. PCA unit 150A begins background continuous infusion, if one has been selected. In addition, the patient may now request a dose of narcotic analgesics at any time by means of patient dose request actuation device 135. Of course, whether the patient actually receives a requested dose depends upon the patient request dosing limits, if any, as well as the patient's current percent blood oxygen saturation and pulse rate relative to the minimum levels set by the clinician. (Ex. 1004 at 8:11-25 (emphasis added).) Likewise, Bollish states that In the event that the patient's percent blood oxygen saturation and pulse rate is outside of the maximum and minimum levels set by the clinician, **central interface unit 100 immediately shuts-off PCA unit 150A, and thereby stops further administration of any background infusion and bolus doses**. As illustrated in FIG. 10, position A of display 102 indicates ANALGESIA ALARM SHUTOFF status for PCA unit 150A. In addition,

	central interface unit 100 activates audio alarm 260, displays visual alarm on information display 102, flashes ALARM indicator 164 on PCA unit 150A and/or pulse oximetry unit 150B, and sends an emergency signal via interface ports 122 and external communications controller 274 in order to alert appropriate medical personnel. (*Id.* at 8:42-55 (emphasis added).) Thus, to the extent that shutting off the infusion pump can be considered "controlling administration of the patient's medication," as Baxter contends, Bollish teaches this limitation. (*See* §IV(A), *supra*; Ex. 1015 at APP0583-85; Ex. 1003 at ¶¶ 11-13, 16-17.)
2[a]. The method of claim 1,	Bollish discloses all the limitations of **claim 1**, as detailed above.
[2b.] wherein the step of obtaining information pertaining to the patient's current medication comprises storing information pertaining to the amount of medication administered to the patient over a predetermined period of time.	As discussed above in connection with **claim 1**, Bollish states: Once the above steps have been completed, the clinician attaches PCA administration set to the patient's indwelling vascular access device (not shown) and presses softkey 106 adjacent to START on central interface unit 100. PCA unit 150A is now operating with continuous monitoring by pulse oximetry unit 150B of the patient's percentage blood oxygen saturation and pulse rate. PCA unit 150A begins background continuous infusion, if one has been selected. In addition, the patient may now request a dose of narcotic analgesics at any time by means of patient dose request actuation device 135. Of course, <u>whether the patient actually receives a requested dose depends upon the patient request dosing limits, if any</u>, as well as the patient's current percent blood oxygen saturation and pulse rate relative to the minimum levels set by the clinician. (Ex. 1004 at 8:11-25 (emphasis added).) Comparing the requested PCA dose of narcotics to the "patient request

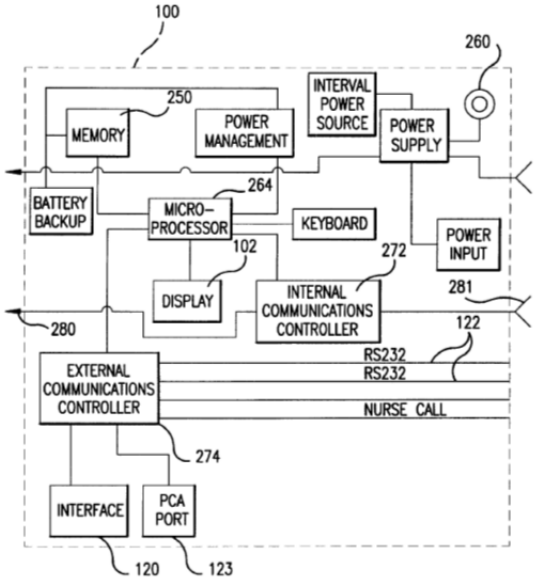
	dosing limits" inherently teaches that the device has stored and retrieved information regarding the amount of narcotic administered to the patient over the relevant period of time. (*See* Ex. 1003 at ¶ 18, 20.)
3[a]. The method of claim 1,	Bollish discloses all the limitations of **claim 1**, as detailed above.
[3b.] wherein the controlling administration of the patient's medication includes modification of a basal delivery rate, a bolus dose and a number of bolus allowed within a certain time frame.	As discussed above in connection with **claim 1**, Bollish states: Once the above steps have been completed, the clinician attaches PCA administration set to the patient's indwelling vascular access device (not shown) and presses softkey 106 adjacent to START on central interface unit 100. PCA unit 150A is now operating with continuous monitoring by pulse oximetry unit 150B of the patient's percentage blood oxygen saturation and pulse rate. PCA unit 150A begins background continuous infusion, if one has been selected. In addition, the patient may now request a dose of narcotic analgesics at any time by means of patient dose request actuation device 135. Of course, whether the patient actually receives a requested dose depends upon the patient request dosing limits, if any, as well as the patient's current percent blood oxygen saturation and pulse rate relative to the minimum levels set by the clinician. (Ex. 1004 at 8:11-25 (emphasis added).) Likewise, Bollish states that In the event that the patient's percent blood oxygen saturation and pulse rate is outside of the maximum and minimum levels set by the clinician, **central interface unit 100 immediately shuts-off PCA unit 150A, and thereby stops further administration of any background infusion and bolus doses**. As illustrated in FIG. 10, position A of display 102 indicates ANALGESIA ALARM SHUTOFF status for PCA unit 150A. In addition,

	central interface unit 100 activates audio alarm 260, displays visual alarm on information display 102, flashes ALARM indicator 164 on PCA unit 150A and/or pulse oximetry unit 150B, and sends an emergency signal via interface ports 122 and external communications controller 274 in order to alert appropriate medical personnel. (*Id.* at 8:42-55 (emphasis added).) Thus, to the extent that shutting off the infusion pump can be considered "modification of a basal delivery rate, a bolus dose and a number of bolus allowed," as Baxter contends, Bollish teaches this limitation. (*See* §IV(B), *supra*; Ex. 1015 at APP0587-88; Ex. 1003 at ¶¶ 9-13, 16-17.)
9[a]. An infusion pump for administering a liquid medicant to a patients [sic] comprising:	*See discussion of* ***element 1a.***
[9b.] a liquid injection device adapted to be connected to the patient;	For example, Bollish states as follows: Once the above steps have been completed, the clinician attaches PCA administration set to the patient's indwelling vascular access device (not shown) and presses softkey 106 adjacent to START on central interface unit 100. (Ex. 1004 at 8:11-14.) See also, *e.g.*, Figure 1:

	 FIG.1
[9c.] a conduit connected to the liquid injection device;	For example, Bollish states as follows: PCA unit 150A contains channel message display 152, which may be used to display informational, advisory, alarm, or malfunction messages, and rate display 154 which may be used to display, for example, the infusion rate at which the PCA unit is operating or the lockout interval. PCA unit 150A may also include a door lock (not shown) for providing security for enclosed narcotics or other medication to be infused. For electromechanical fluid infusion, PCA unit 150A also contains syringe pusher 175 and syringe 176. PCA unit 150A further includes an infusion pumping device within its housing which infuses bolus doses of narcotic analgesics in response to commands from central interface unit 100. As known in the prior art, PCA unit 150A can be either a syringe based pumping system, a large volume parenteral type of pumping system, or other appropriate configurations as can be readily determined by one skilled in the art. PCA unit 150A includes standard pumping and safety mechanisms to control various functions performed by the pumping device such

	as control of fluid delivery to the patient and monitoring of fluid path for occlusion or air-in-line. (Ex. 1004 at 7:26-45 (emphasis added); *see also, e.g.*, Fig. 1 (reproduced above).) A person of ordinary skill in the art would have understood this disclosure as referring to a conduit for delivering fluid from the PCA pump to the patient. (*See, e.g.*, Ex. 1003 at ¶¶ 5, 9-10.)
[9d.] a pumping mechanism for pumping the liquid medicant through the conduit and into the patient via the liquid injection device;	For example, Bollish states as follows: PCA unit 150A contains channel message display 152, which may be used to display informational, advisory, alarm, or malfunction messages, and rate display 154 which may be used to display, for example, the infusion rate at which the PCA unit is operating or the lockout interval. PCA unit 150A may also include a door lock (not shown) for providing security for enclosed narcotics or other medication to be infused. For electromechanical fluid infusion, PCA unit 150A also contains syringe pusher 175 and syringe 176. PCA unit 150A further includes an infusion pumping device within its housing which infuses bolus doses of narcotic analgesics in response to commands from central interface unit 100. As known in the prior art, PCA unit 150A can be either a syringe based pumping system, a large volume parenteral type of pumping system, or other appropriate configurations as can be readily determined by one skilled in the art. PCA unit 150A includes standard pumping and safety mechanisms to control various functions performed by the pumping device such as control of fluid delivery to the patient and monitoring of fluid path for occlusion or air-in-line. (Ex. 1004 at 7:26-45 (emphasis added).)
[9e.] a controller for controlling the	For example, Bollish states as follows: Patient care systems providing for central control

pumping mechanism, wherein the controller controls the amount of liquid medicant administered to the patient;	of multiple pump units, potentially including PCA units, are known in the medical field. Examples of such systems are disclosed in U.S. Pat. No. 4,756,706 to Kerns et al., U.S. Pat. No. 4,898,578, to Rubalcabe, Jr., and U.S. Pat. No. 5,256,157, to Samiotes et al. Each of these prior art systems generally provides a **controller** which interfaces with a plurality of individual pumps to provide various control functions. An improved patient care system is disclosed in U.S. patent application Ser. No. 08/403,503 (U.S. Pat. No. 5,713,856) of Eggers et al. The central management unit of the Eggers et al. system can, for example, obtain infusion parameters for a particular infusion unit from the clinician and **serve as an interface to establish the infusion rate and control infusion accordingly**, individually control the internal setup and programming of each functional unit, and receive and display information from each functional unit. The Eggers et al. patient care system also provides for central control of various monitoring apparatus, such as pulse oximeters and heart monitors. … The following preferred embodiments of the present invention are described generally in the context of the programmable modular patient care system disclosed in U.S. patent application Ser. No. 08/403,503, filed Mar. 13, 1995, and still pending, entitled Modular Patient Care System, filed by the assignee of the present application, and incorporated herein in its entirety by reference. However, a person skilled in the art will recognize that the disclosed methods and apparatus are readily adaptable for broader application, including but not limited to other patient care systems as described in the above referenced U.S. Patents to Kerns et al., to Rubalcabe, Jr., and to Samiotes et al.

	(Ex. 1004 at 2:5-24, 3:66-4:10 (emphasis added).) See also, *e.g.*, Figure 3:  FIG.3
[9f.] a memory storing a set of patient-specific, predetermined rates and amounts of liquid medicant to be administered to the patient;	Bollish states as follows: The clinician then selects PCA unit 150A and its corresponding channel by depressing SELECT key 156 on PCA unit 150A. By selecting PCA unit 150A, information display 102 is configured so as to act as the user interface and thus provides PCA function specific displays and softkeys, as 50 shown in FIGS. 6-8. The clinician may first restore previous dosing units and analgesics concentration or select the dosing units from, for example, meg, mg, or mL, and input the analgesics concentration, as shown in FIG. 6 and 7. Next, as shown in FIG. 8, the clinician may input or restore previous parameters for patient bolus dosage. For additional precaution to further prevent respiratory and central nervous system depression and as an alternative embodiment of the present invention, system 10 or PCA unit 150A may require the clinician to enter patient request dosing limits, such as maximum dose per hour or per 24-hour

	period. After entering the patient bolus dosage parameters, the clinician may choose to administer a background continuous infusion of narcotic analgesics by pressing softkey 106 adjacent to CONTINUOUS. Use of a background infusion 65 in combination with patient requested doses provides a level of narcotic analgesia sufficient for periods of low activity such as when the patient is sleeping. Thus, when the patient wakes up and requires additional analgesia because of increased activity levels, the patient can self-administer additional narcotic analgesics to meet those needs. If a background continuous infusion is selected by pressing softkey 106 adjacent to CONTINUOUS, display 102 allows the clinician to input desired continuous infusion dose. FIG. 8 shows information display 102 after the clinician has entered values for both patient bolus dose and continuous dose. (Ex. 1004 at 7:46-8:10.) A person of ordinary skill in the art would have understood that these parameters are inherently stored in memory. (*See* Ex. 1003 at ¶¶ 18, 20; *see also, e.g.*, "MEMORY" 250 depicted in Fig. 3.)
[9g.] a data acquiring routine for obtaining information pertaining to the patient's pain level, side effects and impairment of functionalities; and	For example, Bollish states as follows: FIG. 5 shows information display 102 after the clinician has entered or recalled previous values. Prior to starting pulse oximetry monitoring, the clinician may select the auto shut-off option for one or more other functional units, such as PCA unit 150A, so that central interface unit 100 shuts-off the selected functional unit(s) if the patient's blood oxygen saturation level or pulse rate falls outside of the specified maximum and minimum levels. <u>Once pulse oximetry monitoring starts, the patient's percent blood oxygen saturation and pulse rate are displayed in Sp02% display 180 and Pulse display 182, respectively, as previously</u>

	described and shown in FIG. 1. Although the preferred embodiment patient care system 10 automatically initiates both audio and visual alarms as well as notifies medical personnel, such as triggering a nurse call, if the patient's percent blood oxygen saturation or pulse rate falls above or below specified maximum or minimum levels, system 10 can be configured such that the clinician can also select specific alarms and notification to medical personnel in such an event. (Ex. 1004 at 7:26-45 (emphasis added).) Bollish further states that Once the above steps have been completed, the clinician attaches PCA administration set to the patient's indwelling vascular access device (not shown) and presses softkey 106 adjacent to START on central interface unit 100. PCA unit 150A is now operating with continuous monitoring by pulse oximetry unit 150B of the patient's percentage blood oxygen saturation and pulse rate. PCA unit 150A begins background continuous infusion, if one has been selected. In addition, the patient may now request a dose of narcotic analgesics at any time by means of patient dose request actuation device 135. Of course, whether the patient actually receives a requested dose depends upon the patient request dosing limits, if any, as well as the patient's current percent blood oxygen saturation and pulse rate relative to the minimum levels set by the clinician. (*Id.* at 8:11-25 (emphasis added).) Likewise, Bollish states that In the event that the patient's percent blood oxygen saturation and pulse rate is outside of the maximum and minimum levels set by the clinician, central interface unit 100 immediately shuts-off PCA unit 150A, and thereby stops further administration of any background infusion and

	bolus doses. As illustrated in FIG. 10, position A of display 102 indicates ANALGESIA ALARM SHUTOFF status for PCA unit 150A. In addition, central interface unit 100 activates audio alarm 260, displays visual alarm on information display 102, flashes ALARM indicator 164 on PCA unit 150A and/or pulse oximetry unit 150B, and sends an emergency signal via interface ports 122 and external communications controller 274 in order to alert appropriate medical personnel. (*Id.* at 8:42-55 (emphasis added).) Thus, to the extent that monitoring a patient's bolus requests, pulse, and/or oxygen saturation can be considered "obtaining information pertaining to the patient's pain level, side effects and impairment of functionalities," as Baxter contends, Bollish teaches this limitation. (*See* §IV(C), *supra*; Ex. 1015 at APP0598-APP0600; Ex. 1003 at ¶¶ 12-13, 18-19.)
[9h.] a control routine for processing the data pertaining to the patient's pain level, the patient's side effects, the patient's impairment of functionalities, and a current rate and amount of liquid medicant being administered to the patient and for automatically changing the rate and amount of the liquid medicant to be administered to the patient in accordance with the set of patient-	As discussed above in connection with **claim 1**, Bollish states: Once the above steps have been completed, the clinician attaches PCA administration set to the patient's indwelling vascular access device (not shown) and presses softkey 106 adjacent to START on central interface unit 100. PCA unit 150A is now operating with continuous monitoring by pulse oximetry unit 150B of the patient's percentage blood oxygen saturation and pulse rate. PCA unit 150A begins background continuous infusion, if one has been selected. In addition, the patient may now request a dose of narcotic analgesics at any time by means of patient dose request actuation device 135. Of course, whether the patient actually receives a requested dose depends upon the patient request dosing limits, if any, as well as the patient's current percent blood oxygen saturation and pulse rate relative to the minimum levels set by the clinician.

specific, predetermined ranges of medication.	(Ex. 1004 at 8:11-25 (emphasis added).) Likewise, Bollish states that In the event that the patient's percent blood oxygen saturation and pulse rate is outside of the maximum and minimum levels set by the clinician, **central interface unit 100 immediately shuts-off PCA unit 150A, and thereby stops further administration of any background infusion and bolus doses**. As illustrated in FIG. 10, position A of display 102 indicates ANALGESIA ALARM SHUTOFF status for PCA unit 150A. In addition, central interface unit 100 activates audio alarm 260, displays visual alarm on information display 102, flashes ALARM indicator 164 on PCA unit 150A and/or pulse oximetry unit 150B, and sends an emergency signal via interface ports 122 and external communications controller 274 in order to alert appropriate medical personnel. (*Id.* at 8:42-55 (emphasis added).) Thus, to the extent that shutting off the infusion pump can be considered "changing the rate and amount of the liquid medicant to be administered to the patient in accordance with the set of patient-specific, predetermined ranges of medication," as Baxter contends, Bollish teaches this limitation. (*See* §IV(A), *supra*; Ex. 1015 at APP0603-04; Ex. 1003 at ¶¶ 12-13, 16-17.)
10[a]. The infusion pump of claim 9	Bollish discloses all the limitations of **claim 9**, as detailed above.
[10b.] further wherein the memory stores data regarding the liquid medicant administered to the patient over a predetermined period of time and wherein the modification routine processes the data	*See discussion of **elements 2b** & **3b**.*

regarding liquid medicant administered to the patient.	
11[a]. An infusion pump of claim 10	Bollish discloses all the limitations of **claim 10**, as detailed above.
[11b.] wherein the current rate and amount of liquid medicant being administered to the patient comprises a basal delivery rate, a bolus dose and a number of bolus allowed within a certain time frame.	*See discussion of **element 3b.***

B. Ground 2: Obviousness of Claims 1-18 Based on Bollish

Claims 1-18 would have been obvious to a person of ordinary skill in the art under 35 U.S.C. § 103(a) in view of Bollish as set forth below.

i. Disclosure of Bollish

The disclosure of Bollish is discussed in Section VI(A)(i), above.

ii. Obviousness of Claims 1-3 and 9-11 Based on Bollish

Claims 1-3 and 9-11 are anticipated by Bollish for the reasons stated in Section VI(A) – at least as Baxter would have the claims construed. Accordingly, claims 1-3 and 9-11 would also have been obvious to a person of ordinary skill in the art, because "anticipation is the epitome of obviousness." *In re McDaniel, 293*

F3d. 1379, 1385 (Fed. Cir. 2002). Furthermore, to the extent that the Board believes any differences exist between the claims (as Baxter would construe them) and Bollish, such differences are inconsequential.

For example, as noted in Section VI(A)(ii), Bollish inherently teaches storing and retrieving information regarding the patient's medication dosage levels (*see* elements 1e, 2b, and 9f). Should the Board conclude that Bollish does not inherently require this information to be stored in the device, however, it certainly would have been obvious to a person of ordinary skill in the art to store the patient's medication information in order to perform the calculations taught by Bollish. (*See* Ex. 1003 at ¶¶ 18-21.)

iii. Comparison of Claims 1-18 to Bollish

The claim chart below specifies where each element of claims 1-18 is found in Bollish.

'560 Claim Language	Citations to Bollish
1. …	Bollish discloses the elements of **claim 1** for the reasons discussed in Section VI(A)(ii), above.
2. …	Bollish discloses the elements of **claim 2** for the reasons discussed in Section VI(A)(ii), above.
3. …	Bollish discloses the elements of **claim 3** for the reasons discussed in Section VI(A)(ii), above.
4[a]. The method of claim 1,	Bollish discloses the elements of **claim 1** for the reasons discussed in Section VI(A)(ii), above.
[4b.] wherein the step of obtaining	As discussed above in connection with **claim 1**, Bollish states:

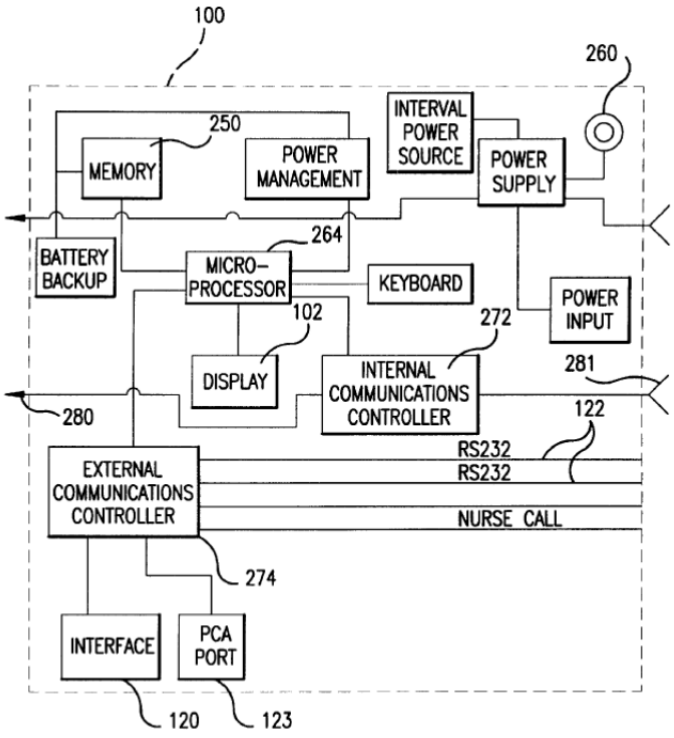
information pertaining to the patient's condition further comprises storing the number of bolus requests made by the patient which exceed the maximum number of permitted boluses.	Once the above steps have been completed, the clinician attaches PCA administration set to the patient's indwelling vascular access device (not shown) and presses softkey 106 adjacent to START on central interface unit 100. PCA unit 150A is now operating with continuous monitoring by pulse oximetry unit 150B of the patient's percentage blood oxygen saturation and pulse rate. PCA unit 150A begins background continuous infusion, if one has been selected. In addition, the patient may now request a dose of narcotic analgesics at any time by means of patient dose request actuation device 135. Of course, <u>whether the patient actually receives a requested dose depends upon the patient request dosing limits, if any</u>, as well as the patient's current percent blood oxygen saturation and pulse rate relative to the minimum levels set by the clinician. (Ex. 1004 at 8:11-25 (emphasis added).) A person of ordinary skill in the art would thus have understood that Bollish inherently teaches storing the number of bolus requests made by the patient, the maximum number of allowed boluses, and comparing the two numbers. (*See* Ex. 1003 at ¶ 22.) It would have been obvious to a person of ordinary skill in the art for the pump to also store the number of bolus requests in excess of the permitted maximum. (*See id*.)
5[a]. The method of claim 1,	Bollish discloses the elements of **claim 1** for the reasons discussed in Section VI(A)(ii), above.
[5b.] wherein the obtaining information pertaining to the patient's condition further comprise the steps of querying the patient regarding the patient's pain level,	Baxter's infringement contentions in the district court lawsuit equate a patient's "dosage button" medication requests with "information pertaining to the patient's pain level." (Ex. 1015 at APP0599.) Baxter's infringement contentions likewise equate monitoring the patient's blood oxygen saturation with "obtain[ing] information pertaining to the patient's side effects and/or impairment of functionalities." (*Id.* at APP0600.)

side effects and impairment of functionalities.	Bollish discloses this element to the same extent that it can be found in the accused product. As discussed above in connection with **claim 1**, Bollish states: [T]he patient may now request a dose of narcotic analgesics at any time by means of patient dose request actuation device 135. Of course, whether the patient actually receives a requested dose depends upon the patient request dosing limits, if any, as well as the patient's current percent blood oxygen saturation and pulse rate relative to the minimum levels set by the clinician. (Ex. 1004 at 8:19-25 (emphasis added).) Likewise, Bollish states that In the event that the patient's percent blood oxygen saturation and pulse rate is outside of the maximum and minimum levels set by the clinician, central interface unit 100 immediately shuts-off PCA unit 150A, and thereby stops further administration of any background infusion and bolus doses. (*Id.* at 8:42-47.) A person of ordinary skill in the art would thus have understood that the number of bolus requests, the patient's blood oxygen saturation, and the patient's pulse rate would have been indicative of the patient's pain level, side effects and impairment of functionalities, at least as Baxter would construe the terms. (*See* Ex. 1003 at ¶¶ 18-19.)
6[a]. The method of claim 1,	Bollish discloses the elements of **claim 1** for the reasons discussed in Section VI(A)(ii), above.
[6b.] wherein the step of obtaining information pertaining to the patient's condition further comprises the step of	Baxter's infringement contentions in the district court lawsuit equate monitoring the patient's blood oxygen saturation with "obtain[ing] information pertaining to the patient's side effects and/or impairment of functionalities." (Ex. 1015 at APP0600.) Baxter's infringement contentions likewise equate "determin[ing] whether or not to automatically deliver an additional

providing an evaluation of the patient's side effects.	dose of medication" based on the patient's blood oxygen saturation with "evaluat[ing] the patient's… side effects[.]" (*Id.* at APP0573.) Bollish discloses this element to the same extent that it can be found in the accused product. As discussed above in connection with **claim 1**, Bollish states: [T]he patient may now request a dose of narcotic analgesics at any time by means of patient dose request actuation device 135. Of course, whether the patient actually receives a requested dose depends upon the patient request dosing limits, if any, as well as the patient's current percent blood oxygen saturation and pulse rate relative to the minimum levels set by the clinician. (Ex. 1004 at 8:19-25 (emphasis added).) Likewise, Bollish states that In the event that the patient's percent blood oxygen saturation and pulse rate is outside of the maximum and minimum levels set by the clinician, central interface unit 100 immediately shuts-off PCA unit 150A, and thereby stops further administration of any background infusion and bolus doses. (*Id.* at 8:42-47.) A person of ordinary skill in the art would thus have understood that shutting off the PCA pump in response to an out-of-limit blood oxygen saturation involves "providing an evaluation of the patient's side effects," at least as Baxter would construe the term. (*See* Ex. 1003 at ¶¶ 18-19.)
7[a]. The method of claim 1,	Bollish discloses the elements of **claim 1** for the reasons discussed in Section VI(A)(ii), above.
[7b.] wherein the step of obtaining information pertaining to the patient's	Baxter's infringement contentions in the district court lawsuit equate monitoring the patient's blood oxygen saturation with "obtain[ing] information pertaining to the patient's side effects and/or impairment of

condition further comprises the step of providing an evaluation of the patient's impairment of functionalities.	functionalities." (Ex. 1015 at APP0600.) Baxter's infringement contentions likewise equate "determin[ing] whether or not to automatically deliver an additional dose of medication" based on the patient's blood oxygen saturation with "evaluat[ing] the patient's … impairment of functionalities[.]" (*Id.* at APP0573.) Bollish discloses this element to the same extent that it can be found in the accused product. As discussed above in connection with **claim 1**, Bollish states: [T]he patient may now request a dose of narcotic analgesics at any time by means of patient dose request actuation device 135. Of course, whether the patient actually receives a requested dose depends upon the patient request dosing limits, if any, as well as the patient's current percent blood oxygen saturation and pulse rate relative to the minimum levels set by the clinician. (Ex. 1004 at 8:19-25 (emphasis added).) Likewise, Bollish states that In the event that the patient's percent blood oxygen saturation and pulse rate is outside of the maximum and minimum levels set by the clinician, central interface unit 100 immediately shuts-off PCA unit 150A, and thereby stops further administration of any background infusion and bolus doses. (*Id.* at 8:42-47.) A person of ordinary skill in the art would thus have understood that shutting off the PCA pump in response to an out-of-limit blood oxygen saturation involves "providing an evaluation of the patient's impairment of functionalities," at least as Baxter would construe the term. (*See* Ex. 1003 at ¶¶ 18-19.)
8[a]. A routine for operating an infusion	*See discussion of* ***element 1a.***

pump to automatically control the level of a patient's medication,	
[8b.] the infusion pump comprising a controller for executing the routine and a memory for storing the routine, responsive to a request for an evaluation of the patient's current medication; comprising:	*See discussion of* ***element 1c.*** Bollish further states as follows: The clinician then selects PCA unit 150A and its corresponding channel by depressing SELECT key 156 on PCA unit 150A. By selecting PCA unit 150A, information display 102 is configured so as to act as the user interface and thus provides PCA function specific displays and softkeys, as 50 shown in FIGS. 6-8. The clinician may first restore previous dosing units and analgesics concentration or select the dosing units from, for example, meg, mg, or mL, and input the analgesics concentration, as shown in FIG. 6 and 7. Next, as shown in FIG. 8, the clinician may input or restore previous parameters for patient bolus dosage. For additional precaution to further prevent respiratory and central nervous system depression and as an alternative embodiment of the present invention, system 10 or PCA unit 150A may require the clinician to enter patient request dosing limits, such as maximum dose per hour or per 24-hour period. After entering the patient bolus dosage parameters, the clinician may choose to administer a background continuous infusion of narcotic analgesics by pressing softkey 106 adjacent to CONTINUOUS. Use of a background infusion 65 in combination with patient requested doses provides a level of narcotic analgesia sufficient for periods of low activity such as when the patient is sleeping. Thus, when the patient wakes up and requires additional analgesia because of increased activity levels, the patient can self-administer additional narcotic analgesics to meet those needs. If a background continuous infusion is selected by

	pressing softkey 106 adjacent to CONTINUOUS, display 102 allows the clinician to input desired continuous infusion dose. FIG. 8 shows information display 102 after the clinician has entered values for both patient bolus dose and continuous dose. (Ex. 1004 at 7:46-8:10.) A person of ordinary skill in the art would have understood that these parameters are inherently stored in memory – or at a bare minimum, that it would have been obvious to do so. (*See* Ex. 1003 at ¶¶ 18-21; *see also, e.g.*, "MEMORY" 250 in Fig. 3.)  FIG.3
[8c.] a set of patient-specific, predetermined ranges of medication stored in the memory;	Bollish states as follows: The clinician then selects PCA unit 150A and its corresponding channel by depressing SELECT key 156 on PCA unit 150A. By selecting PCA unit 150A, information display 102 is configured so as to act as the user interface and thus provides PCA function specific displays and softkeys, as 50

	shown in FIGS. 6-8. The clinician may first restore previous dosing units and analgesics concentration or select the dosing units from, for example, meg, mg, or mL, and input the analgesics concentration, as shown in FIG. 6 and 7. Next, as shown in FIG. 8, the clinician may input or restore previous parameters for patient bolus dosage. For additional precaution to further prevent respiratory and central nervous system depression and as an alternative embodiment of the present invention, system 10 or PCA unit 150A may require the clinician to enter patient request dosing limits, such as maximum dose per hour or per 24-hour period. After entering the patient bolus dosage parameters, the clinician may choose to administer a background continuous infusion of narcotic analgesics by pressing softkey 106 adjacent to CONTINUOUS. Use of a background infusion 65 in combination with patient requested doses provides a level of narcotic analgesia sufficient for periods of low activity such as when the patient is sleeping. Thus, when the patient wakes up and requires additional analgesia because of increased activity levels, the patient can self-administer additional narcotic analgesics to meet those needs. If a background continuous infusion is selected by pressing softkey 106 adjacent to CONTINUOUS, display 102 allows the clinician to input desired continuous infusion dose. FIG. 8 shows information display 102 after the clinician has entered values for both patient bolus dose and continuous dose. (Ex. 1004 at 7:46-8:10.)
[8d.] a procedure for obtaining information pertaining to the patient's pain level and	*See discussion of* ***element 5b.***

storing the patient's pain level information automatically;	
[8e.] a procedure for obtaining information pertaining to the patient's side effects and storing the patient's side effect information automatically;	*See discussion of* ***element 5b.***
[8f.] a procedure for obtaining information pertaining to the patient's impairment of functionalities and storing the patient's impairment of functionalities information automatically;	*See discussion of* ***element 5b.***
[8g.] a procedure for obtaining information pertaining to the patient's current medication;	*See discussion of* ***element 1e.***
[8h.] a procedure for evaluating stored information of the patient's current medication, pain level, side effects and impaired functionalities with the stored set of	*See discussion of* ***element 5b.***

patient-specific, predetermined ranges of medication; and	
[8i.] a procedure for automatically modifying delivery of the patient's medication based on the evaluation.	*See discussion of* ***element 1g.***
9. …	Bollish discloses the elements of **claim 9** for the reasons discussed in Section VI(A)(ii), above.
10. …	Bollish discloses the elements of **claim 10** for the reasons discussed in Section VI(A)(ii), above.
11. …	Bollish discloses the elements of **claim 11** for the reasons discussed in Section VI(A)(ii), above.
12[a]. The infusion pump of claim 11	Bollish discloses the elements of **claim 11** for the reasons discussed in Section VI(A)(ii), above.
[12b.] wherein data pertaining to the patient's pain level comprises the number of bolus requests made by the patient which exceed the maximum number of boluses.	*See discussion of* ***element 4b.***
13[a]. The infusion pump of claim 11	Bollish discloses the elements of **claim 11** for the reasons discussed in Section VI(A)(ii), above.
[13b.] wherein data pertaining to the patient's pain level, side effects and impairment of functionalities	*See discussion of* ***element 5b.***

comprises data stored in response to querying the patient regarding the patient's pain level, side effects and impairment of functionalities.	
14[a]. The infusion pump of claim 11	Bollish discloses the elements of **claim 11** for the reasons discussed in Section VI(A)(ii), above.
[14b.] wherein data pertaining to the patient's side effects comprises data stored from an independent evaluation of the patient's side effects.	*See discussion of* ***element 5b.***
15[a]. The infusion pump of claim 11	Bollish discloses the elements of **claim 11** for the reasons discussed in Section VI(A)(ii), above.
[15b.] wherein data pertaining to the patient's impairment of functionalities comprises data stored from an independent evaluation of the patient's impairment of functionalities.	*See discussion of* ***element 5b.***
16[a]. A method for automatically controlling the level of a patient's medication administered from a programmable infusion pump, comprising:	*See discussion of* ***element 1a.***

[16b.] programming the infusion pump with a set of patient specific, predetermined ranges of medication;	*See discussion of* ***elements 8b*** *&* ***8c.***
[16c.] evaluating the patient's current medication and recording the patient's current medication in the infusion pump;	*See discussion of* ***element 1f.***
[16d.] evaluating the patient's physiological conditions and recording the patient's physiological conditions in the infusion pump; and	*See discussion of* ***element 1f.***
[16e.] controlling administration of the patient's medication based on the evaluation of the patient's current medication and physiological conditions as compared with the programmed predetermined ranges of medication.	*See discussion of* ***elements 1g, 5b, 8c, 8h*** *&* ***8i.***
17[a]. The infusion pump of claim 16,	Bollish discloses or renders obvious all the limitations of **claim 16**, as detailed above.
[17b.] wherein the evaluating the patient's physiological	***See claim 5.***

conditions step includes evaluating the patient's pain level, the patient's side effects and the patient's impairment of functionalities.	
18[a]. The infusion pump of claim 16,	Bollish discloses or renders obvious all the limitations of **claim 16**, as detailed above.
[18b.] further comprising querying the patient about his physiological conditions; and storing the patient's responses.	***See claim 5.***

C. Ground 3: Obviousness of Claims 1-18 Based on Bollish in Combination with TITRATOR

Claims 1-18 would have been obvious to a person of ordinary skill in the art under 35 U.S.C. § 103(a) in view of Bollish and TITRATOR as set forth below.

i. Disclosure of Bollish

The disclosure of Bollish is discussed in Section VI(A)(i), above.

ii. Disclosure of TITRATOR

The *TITRATOR™ Sodium Nitroprusside Closed Loop Module Model 10K Directions for Use*, Copyright 1990 by IVAC Corporation ("TITRATOR"), attached as Exhibit 1005, discloses a closed loop system for regulating a patient's mean arterial pressure through controlled infusions of a drug. The closed loop

system is described as having three main components: a TITRATOR device, an infusion pump, and an arterial pressure transducer. (Ex. 1005 at APP0215.) For example, TITRATOR states, "In the AUTO mode, the TITRATOR device will automatically adjust the infusion rate as necessary when the infusion is being delivered." (*Id.* at APP0233.) The TITRATOR device does so by sending a newly computed infusion rate to the pump every ten seconds. (*Id.* at APP0230.)

In addition, TITRATOR states that a feature of the TITRATOR device is to limit drug "dosage rate and total dosage delivered through a toxicity limiting feature when solution concentration, total drug dose, and patient weight values are entered into the Closed Loop System." (*Id.* at APP0218.) This user entry of drug concentration, any previously delivered drug dose, and patient weight enables the TITRATOR device to automatically calculate and observe drug dosage rate and total drug dosage delivered limits. (*Id.* at APP0234-35.)

A copy of the TITRATOR manual was provided with every TITRATOR device sold by IVAC following the device's FDA approval in 1987. (Ex. 1009 at ¶¶ 3-7.) The particular copy of the manual submitted in support of this Petition bears a copyright date of 1990. (Ex. 1005 at APP0213, APP0263.) A published IEEE article from 1988 further corroborating the release of the TITRATOR is attached as Exhibit 1010. (*See also* Ex. 1009 at ¶¶ 4-5 (identifying further corroboration of the approval and use of the TITRATOR product).)

iii. Rationale for Combining the Teachings of Bollish and TITRATOR

A person of ordinary skill in the art of infusion pump design in 1999 would have readily understood the motivation to combine the automatic dosage modification features of the TITRATOR module with the PCA infusion pump disclosed by Bollish. First, TITRATOR itself includes an express motivation to apply its teachings to infusion pumps – it discloses an expansion module designed for connection to an off-the-shelf infusion pump, specifically an IVAC model 560i. (*See, e.g.*, Ex. 1005 at APP0215.) Second, Bollish describes the prototype of CareFusion's accused Alaris product, which was originally made by CareFusion's predecessor Alaris Medical Systems, Inc. (*See, e.g.*, Ex. 1004 at APP0196.) Alaris Medical Systems, Inc., was itself formed by the 1996 merger of two infusion pump manufacturers – IVAC Corporation and IMED Corporation. (*See* Ex. 1003 at ¶¶ 7-8; Ex. 1007 at APP0273; Ex. 1008 at APP0393.) One fundamental purpose of IVAC's merger with IMED was to merge the two companies' infusion pump technologies. (*See* Ex. 1003 at ¶¶ 7-8; Ex. 1007 at APP0289-90.) The accused Alaris pump system is the direct result of that corporate and technological merger. (*See* Ex. 1003 at ¶¶ 6-8.) Thus, the motivation to combine prior art IMED, IVAC, and Alaris infusion pump technologies in the late 1990s is not hypothetical – it is what the Alaris engineers actually did. (*See id*.) Nor was the motivation to combine pump technologies kept secret. The merger of IVAC and IMED was

disclosed publicly, as were its plans for continued research and development leveraging the IMED and IVAC technology. (*See* Ex. 1007 at APP0273, APP0289-90.)

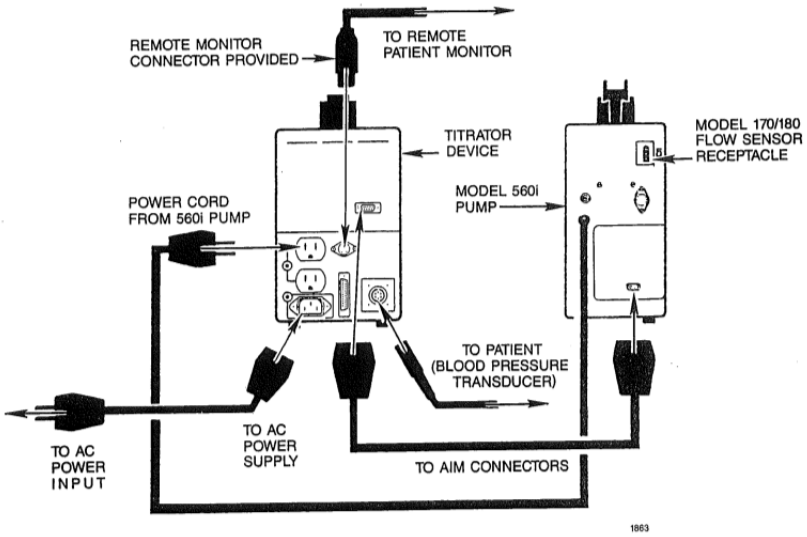
Thus, it would have been obvious to one of ordinary skill in the art at the time of Baxter's alleged invention in 1999 to modify TITRATOR's control module for connection to the Bollish PCA infusion pump. Such a modification is merely a combination of prior art elements according to known methods to yield predictable results. *See, e.g.*, M.P.E.P. § 2143; (Ex. 1003 at ¶¶ 23-26).

iv. Comparison of Claims 1-18 to Bollish and TITRATOR

The claim chart below specifies where each element of claims 1-18 is met by the Bollish and TITRATOR combination.

'560 Claim Language	Citations to Bollish and TITRATOR
1[a]. A method for automatically controlling the level of a patient's medication administered from a programmable infusion pump, comprising:	Bollish discloses **element 1a** for the reasons discussed in Section VI(A)(ii), at least as Baxter would construe the claim. TITRATOR teaches a closed loop system for regulating a patient's mean arterial pressure through controlled infusions of a drug. The closed loop system is described as having three main components: a TITRATOR device, an infusion pump, and an arterial pressure transducer. (Ex. 1005 at APP0215.) For example, TITRATOR states, "In the AUTO mode, the TITRATOR device will automatically adjust the infusion rate as necessary when the infusion is being delivered." (*Id.* at APP0233.) The TITRATOR device does so by sending a newly computed infusion rate to the pump every ten seconds. (*Id.* at APP0230.)

	Thus, the combination of Bollish and TITRATOR satisfies this claim element, regardless of what construction is applied.
[1b.] programming the infusion pump with a medication algorithm;	Bollish discloses **element 1b** for the reasons discussed in Section VI(A)(ii). TITRATOR likewise states that a feature of the TITRATOR device is to limit drug "dosage rate and total dosage delivered through a toxicity limiting feature when solution concentration, total drug dose, and patient weight values are entered into the Closed Loop System." (Ex. 1005 at APP0218.) This user entry of drug concentration, any previously delivered drug dose, and patient weight into the TITRATOR module enables the device to automatically calculate and observe drug dosage rate and total drug dosage delivered limits. (*Id.* at APP0234-35.)
[1c.] initiating an evaluation of the patient's medication;	Bollish discloses **element 1c** for the reasons discussed in Section VI(A)(ii). As discussed, TITRATOR likewise teaches that entry of drug concentration, previously delivered drug dose, and patient weight enables the device to automatically calculate and observe drug dosage rate and total drug dosage delivered limits. (Ex. 1005 at APP0234-35.) Thus, TITRATOR discloses initiating an evaluation of the patient's medication.
[1d.] obtaining information pertaining to the patient's condition;	Bollish discloses **element 1d** for the reasons discussed in Section VI(A)(ii). TITRATOR likewise teaches that a component of the closed loop system is a transducer for measuring arterial pressure. (Ex. 1005 at APP0215, APP0218.) FIG. 2 of TITRATOR illustrates that the transducer is an input to the device.

	 Figure 2. Cabling Diagram (*Id.* at APP0240; *see also id.* at APP0241.) In addition, TITRATOR states that the device displays the patient's measured arterial pressure. (*Id.* at APP0248.)
[1e.] obtaining information pertaining to the patient's current medication;	Bollish discloses **element 1e** for the reasons discussed in Section VI(A)(ii). TITRATOR discloses that the infusion pump monitors and displays total volume infused and retains in memory the current volume infused. (Ex. 1005 at APP0222.) TITRATOR also states that "[s]etting the concentration and patient weight enables the limits for SNP dosage infusion rate (dosage rate limit) and the total dosage delivered (toxicity limit). Limits are automatically calculated and observed." (*Id.* at APP0234-35; *see also id.* at APP0218.)
[1f.] evaluating the patient's current medication and condition with the medication algorithm;	Bollish discloses **element 1f** for the reasons discussed in Section VI(A)(ii), at least as Baxter would construe the claim. TITRATOR teaches that the device operates in an automatic mode where a patient's current arterial

and	pressure is measured and used to adjust the drug infusion rate so as to automatically maintain a desired arterial pressure level. (Ex. 1005 at APP0218.) As discussed, TITRATOR also teaches calculation of and compliance with a total drug dosage limit. (*Id.* at APP0234-35.) Thus, the combination of Bollish and TITRATOR satisfies this claim element, regardless of what construction is applied.
[1g.] controlling administration of the patient's medication based on the evaluation.	Bollish discloses **element 1g** for the reasons discussed in Section VI(A)(ii), at least as Baxter would construe the claim. As discussed, TITRATOR teaches that the device automatically maintains a desired mean arterial pressure by automatically adjusting the drug infusion rate and sending a newly computed rate to the pump every ten seconds. (Ex. 1005 at APP0215, APP0218, APP0230.) TITRATOR also teaches automatic calculation of and compliance with a total drug dosage limit. (*Id.* at APP0234-35.) Thus, the combination of Bollish and TITRATOR satisfies this claim element, regardless of what construction is applied.
2[a]. The method of claim 1,	The combination of Bollish and TITRATOR discloses all the limitations of **claim 1**, as detailed above.
[2b.] wherein the step of obtaining information pertaining to the patient's current medication comprises storing information pertaining to the amount of medication administered to the	Bollish discloses **element 2b** for the reasons discussed in Section VI(A)(ii). As discussed in connection with claim 1, TITRATOR likewise states that the infusion pump monitors and displays total volume infused and retains in memory the current volume infused. (Ex. 1005 at APP0222.) TITRATOR also states that the device includes memory for storing delivered drug dose. (*Id.* at APP0220.)

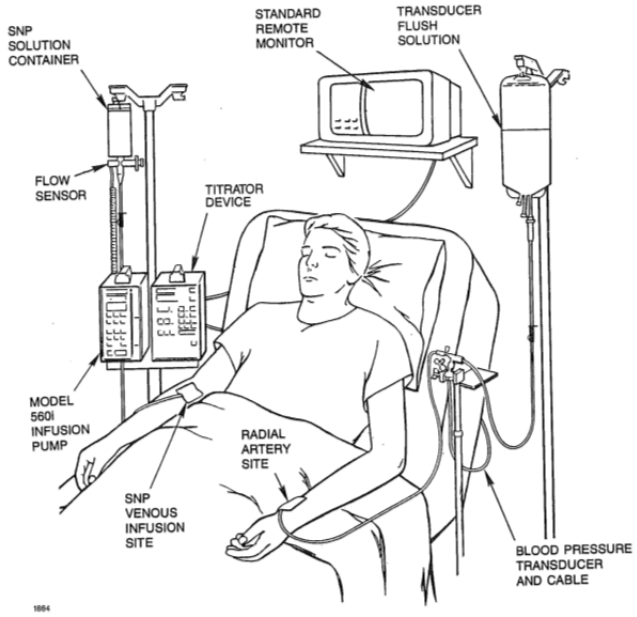
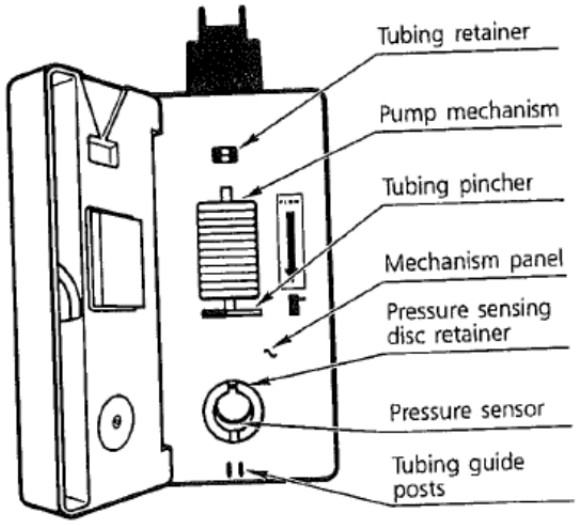
patient over a predetermined period of time.	
3[a]. The method of claim 1,	The combination of Bollish and TITRATOR discloses all the limitations of **claim 1**, as detailed above.
[3b.] wherein the controlling administration of the patient's medication includes modification of a basal delivery rate, a bolus dose and a number of bolus allowed within a certain time frame.	Bollish discloses **element 3b** for the reasons discussed in Section VI(A)(ii), at least as Baxter would construe the claim. As discussed in connection with claim 1, TITRATOR teaches automatically adjusting the drug infusion rate, within a limited range, to maintain desired arterial pressure. (Ex. 1005 at APP0218.) Thus, TITRATOR expressly discloses automatically controlling administration of the patient's medication by modification of a basal delivery rate. It would have been obvious to a person of ordinary skill in the art to use the teachings of TITRATOR to modify the patient-controlled analgesia (PCA) infusion pump taught by Bollish. (*See* 1003 at ¶¶ 23-26.) In such a combination, it would have been obvious to a person of ordinary skill in the art to modify the bolus dose and allowed number of boluses in the same manner that TITRATOR teaches modifying the basal dose. (*See id*.) Thus, the combination of Bollish and TITRATOR satisfies this claim element, regardless of what construction is applied.
4[a]. The method of claim 1,	The combination of Bollish and TITRATOR discloses all the limitations of **claim 1**, as detailed above.
[4b.] wherein the step of obtaining information pertaining to the patient's condition further comprises storing the	Bollish renders **element 4b** obvious for the reasons discussed in Section VI(B)(iii). As discussed in connection with claim 1, TITRATOR likewise teaches automatic calculation of and compliance with a total drug dosage limit. (*See* Ex. 1005 at APP0234-35.) In combining TITRATOR with a PCA

number of bolus requests made by the patient which exceed the maximum number of permitted boluses.	pump, such as that taught by Bollish, it would have been obvious for the pump to store the number of disallowed bolus requests in addition to the total volume of medication infused and the total dosage limit. (*See* Ex. 1003 at ¶ 22.)
5[a]. The method of claim 1,	The combination of Bollish and TITRATOR discloses all the limitations of **claim 1**, as detailed above.
[5b.] wherein the obtaining information pertaining to the patient's condition further comprise the steps of querying the patient regarding the patient's pain level, side effects and impairment of functionalities.	Bollish renders **element 5b** obvious for the reasons discussed in Section VI(B)(iii). As discussed in connection with claim 1, TITRATOR discloses obtaining information pertaining to the patient's condition, including measuring and displaying the patient's arterial pressure. (Ex. 1005 at APP0215, APP0218, APP0248.) A person of ordinary skill in the art would have understood that the patient's arterial pressure would have been indicative of potential side effects and impairment of functionalities resulting from the infusion. (*See* Ex. 1003 at ¶¶ 18-19.) TITRATOR further teaches that the patient should be monitored for signs and symptoms of toxicity. (*See* Ex. 1005 at APP0225, APP0252.)
6[a]. The method of claim 1,	The combination of Bollish and TITRATOR discloses all the limitations of **claim 1**, as detailed above.
[6b.] wherein the step of obtaining information pertaining to the patient's condition further comprises the step of providing an evaluation of the patient's side effects.	*See discussion of **element 5b.***
7[a]. The method of claim 1,	The combination of Bollish and TITRATOR discloses all the limitations of **claim 1**, as detailed above.

[7b.] wherein the step of obtaining information pertaining to the patient's condition further comprises the step of providing an evaluation of the patient's impairment of functionalities.	*See discussion of* ***element 5b.***
8[a]. A routine for operating an infusion pump to automatically control the level of a patient's medication,	*See discussion of* ***element 1a.***
[8b.] the infusion pump comprising a controller for executing the routine and a memory for storing the routine, responsive to a request for an evaluation of the patient's current medication; comprising:	Bollish discloses **element 8b** for the reasons discussed in Section VI(B)(iii). TITRATOR likewise discloses that the system computes infusion rates and sends control signals to an infusion pump. (*See* Ex. 1005 at APP0215.) TITRATOR further discloses that the device includes memory for storing various parameters, which the device uses to calculate the dosage rate. (*See id.* at APP0220, APP0233.)
[8c.] a set of patient-specific, predetermined ranges of medication stored in the memory;	Bollish discloses **element 8c** for the reasons discussed in Section VI(B)(iii). TITRATOR likewise discloses that a feature of the system is to limit drug "dosage rate and total dosage delivered through a toxicity limiting feature when solution concentration, total drug dose, and patient weight values are entered into the Closed Loop System." (Ex. 1005 at APP0218; *see also, e.g.*, *id.* at APP0234-35.)

[8d.] a procedure for obtaining information pertaining to the patient's pain level and storing the patient's pain level information automatically;	*See discussion of* ***element 5b.***
[8e.] a procedure for obtaining information pertaining to the patient's side effects and storing the patient's side effect information automatically;	*See discussion of* ***element 5b.***
[8f.] a procedure for obtaining information pertaining to the patient's impairment of functionalities and storing the patient's impairment of functionalities information automatically;	*See discussion of* ***element 5b.***
[8g.] a procedure for obtaining information pertaining to the patient's current medication;	*See discussion of* ***element 1e.***
[8h.] a procedure for evaluating stored information of the patient's current	*See discussion of* ***element 5b.***

medication, pain level, side effects and impaired functionalities with the stored set of patient-specific, predetermined ranges of medication; and	
[8i.] a procedure for automatically modifying delivery of the patient's medication based on the evaluation.	*See discussion of* ***element 1g.***
9[a]. An infusion pump for administering a liquid medicant to a patients [sic] comprising:	*See discussion of* ***element 1a.***
[9b.] a liquid injection device adapted to be connected to the patient;	Bollish discloses **element 9b** for the reasons discussed in Section VI(A)(ii). TITRATOR likewise states that the closed loop system includes an infusion pump, which delivers the drug to the patient. (Ex. 1005 at APP0215; *see also* Fig. 3, reproduced below in connection with **element 9c**.)
[9c.] a conduit connected to the liquid injection device;	Bollish discloses **element 9c** for the reasons discussed in Section VI(A)(ii). For example, TITRATOR illustrates the infusion pump conduit in Figure 3 (*see* "SNP Venous Infusion Site" label below):

	 Figure 3. Closed Loop System Setup (Ex. 1005 at APP0242.)
[9d.] a pumping mechanism for pumping the liquid medicant through the conduit and into the patient via the liquid injection device;	Bollish discloses **element 9d** for the reasons discussed in Section VI(A)(ii). For example, TITRATOR illustrates and labels the pumping mechanism in the figure below: 

	(Ex. 1005 at APP0223.)
[9e.] a controller for controlling the pumping mechanism, wherein the controller controls the amount of liquid medicant administered to the patient;	Bollish discloses **element 9e** for the reasons discussed in Section VI(A)(ii). TITRATOR likewise discloses that the system computes infusion rates and sends control signals to an infusion pump. (*See*, *e.g.*, Ex. 1005 at APP0215, APP0230.)
[9f.] a memory storing a set of patient-specific, predetermined rates and amounts of liquid medicant to be administered to the patient;	Bollish discloses **element 9f** for the reasons discussed in Section VI(A)(ii). TITRATOR likewise discloses or renders obvious **element 9f** for the reasons discussed in connection with **elements 8b** and **8c**, above.
[9g.] a data acquiring routine for obtaining information pertaining to the patient's pain level, side effects and impairment of functionalities; and	Bollish discloses **element 9g** for the reasons discussed in Section VI(A)(ii). TITRATOR likewise discloses or renders obvious **element 9g** for the reasons discussed in connection with **element 5b**, above.
[9h.] a control routine for processing the data pertaining to the patient's pain level, the patient's side effects, the patient's impairment of functionalities, and a current rate and amount of liquid medicant being	Bollish discloses **element 9h** for the reasons discussed in Section VI(A)(ii). TITRATOR likewise discloses or renders obvious **element 9h** for the reasons discussed in connection with **elements 2b, 3b,** and **5b**, above.

administered to the patient and for automatically changing the rate and amount of the liquid medicant to be administered to the patient in accordance with the set of patient-specific, predetermined ranges of medication.	
10[a]. The infusion pump of claim 9	The combination of Bollish and TITRATOR discloses, or at least renders obvious, all the limitations of **claim 9**, as detailed above.
[10b.] further wherein the memory stores data regarding the liquid medicant administered to the patient over a predetermined period of time and wherein the modification routine processes the data regarding liquid medicant administered to the patient.	*See discussion of **elements 2b** & **3b**.*
11[a]. An infusion pump of claim 10	The combination of Bollish and TITRATOR discloses, or at least renders obvious, all the limitations of **claim 10**, as detailed above.
[11b.] wherein the current rate and amount of liquid medicant being administered to the patient comprises a	*See discussion of **element 3b**.*

basal delivery rate, a bolus dose and a number of bolus allowed within a certain time frame.	
12[a]. The infusion pump of claim 11	The combination of Bollish and TITRATOR discloses, or at least renders obvious, all the limitations of **claim 11**, as detailed above.
[12b.] wherein data pertaining to the patient's pain level comprises the number of bolus requests made by the patient which exceed the maximum number of boluses.	*See discussion of* ***element 4b.***
13[a]. The infusion pump of claim 11	The combination of Bollish and TITRATOR discloses, or at least renders obvious, all the limitations of **claim 11**, as detailed above.
[13b.] wherein data pertaining to the patient's pain level, side effects and impairment of functionalities comprises data stored in response to querying the patient regarding the patient's pain level, side effects and impairment of functionalities.	*See discussion of* ***element 5b.***
14[a]. The infusion pump of claim 11	The combination of Bollish and TITRATOR discloses, or at least renders obvious, all the limitations of **claim 11**,

	as detailed above.
[14b.] wherein data pertaining to the patient's side effects comprises data stored from an independent evaluation of the patient's side effects.	*See discussion of* ***element 5b.***
15[a]. The infusion pump of claim 11	The combination of Bollish and TITRATOR discloses, or at least renders obvious, all the limitations of **claim 11**, as detailed above.
[15b.] wherein data pertaining to the patient's impairment of functionalities comprises data stored from an independent evaluation of the patient's impairment of functionalities.	*See discussion of* ***element 5b.***
16[a]. A method for automatically controlling the level of a patient's medication administered from a programmable infusion pump, comprising:	*See discussion of* ***element 1a.***
[16b.] programming the infusion pump with a set of patient specific, predetermined ranges of medication;	*See discussion of* ***elements 8b*** *&* ***8c.***
[16c.] evaluating the patient's current	*See discussion of* ***element 1f.***

medication and recording the patient's current medication in the infusion pump;	
[16d.] evaluating the patient's physiological conditions and recording the patient's physiological conditions in the infusion pump; and	*See discussion of* ***element 1f.***
[16e.] controlling administration of the patient's medication based on the evaluation of the patient's current medication and physiological conditions as compared with the programmed predetermined ranges of medication.	*See discussion of* ***elements 1g, 5b, 8c, 8h*** & ***8i.***
17[a]. The infusion pump of claim 16,	The combination of Bollish and TITRATOR discloses, or at least renders obvious, all the limitations of **claim 16**, as detailed above.
[17b.] wherein the evaluating the patient's physiological conditions step includes evaluating the patient's pain level, the patient's side effects and the patient's impairment of	*See discussion of* ***element 5b.***

functionalities.	
18[a]. The infusion pump of claim 16,	The combination of Bollish and TITRATOR discloses, or at least renders obvious, all the limitations of **claim 16**, as detailed above.
[18b.] further comprising querying the patient about his physiological conditions; and storing the patient's responses.	*See discussion of **element 5b.***

VII. CONCLUSION

Because the information presented in this petition shows that there is a reasonable likelihood that Petitioner CareFusion will prevail with respect to at least one of the claims challenged in the petition, CareFusion respectfully requests that a Trial be instituted and that claims 1-18 be canceled as unpatentable.

Respectfully submitted,

Dated: July 19, 2016

/s/ Kurt J. Niederluecke

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PETITION FOR INTER PARTES REVIEW

OF U.S. PATENT NO. 6,231,560

Attachment A:

Proof of Service of the Petition

CERTIFICATE OF SERVICE

I hereby certify that on this 19th day of July, 2016, I caused a copy of this Petition, including all attachments, appendices and exhibits 1001 – 1015, to be served in their entirety by electronic mail and Federal Express on the following counsel of record for patent owner:

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Dated: July 19, 2016

PETITION FOR INTER PARTES REVIEW

OF U.S. PATENT NO. 6,231,560

Attachment B:

List of Evidence and Exhibits Relied Upon in Petition

Exhibit #	Reference Name	Exhibit Page #
1001	U.S. Patent No. 6,231,560	APP0001
1002	File History of U.S. Patent No. 6,231,560	APP0019
1003	Declaration of Stephen J. Bollish Regarding '560 Patent	APP0181
1004	U.S. Patent No. 5,957,885 to Bollish et al.	APP0195
1005	IVAC Corporation, *TITRATOR™ Sodium Nitroprusside Closed Loop Module Model 10K Directions for Use* (Copyright 1990)	APP0210
1006	*Curriculum Vitae* of Stephen J. Bollish	APP0265
1007	Advanced Medical, Inc., Form 10-K for the Year Ended December 31, 1996	APP0270
1008	Alaris Medical Inc., Form 10-K for the Year Ended December 31, 1997	APP0390
1009	Declaration of Chuck Willhite Regarding TITRATOR	APP0510
1010	Albert Paul, "The Travail Involved in Getting FDA Approval … An Overview on what it Took to Get FDA Approval of a Medical Device with Computer Technology (a Recent Experience)" (IEEE 1988)	APP0514
1011	U.S. Patent No. 5,368,562 to Blomquist et al.	APP0517
1012	Baxter's original Complaint in Case No. 1:15-cv-9986 in the U.S. District Court for the Northern District of Illinois	APP0527
1013	The Court's Order Setting Patent Case Schedule from Case No. 1:15-cv-9986 in the U.S. District Court for the Northern District of Illinois (Doc. No. 48), dated May 24, 2016	APP0537
1014	The Local Patent Rules of the U.S. District Court for the Northern District of Illinois	APP0541
1015	Excerpts from Baxter's Initial Infringement Contentions in Case No. 1:15-cv-9986 in the U.S. District Court for the Northern District of Illinois, dated June 24, 2016	APP0555

PETITION FOR INTER PARTES REVIEW

OF U.S. PATENT NO. 5,782,805

Attachment C:

Word Count Compliance Certificate

WORD COUNT COMPLIANCE CERTIFICATE

I certify that this Petition conforms to the requirements of 37 CFR § 42.24(a)(1)(i). The length of this Petition, counted in compliance with § 42.24(a)(1) and relying on the word count of the word-processing system, is 13,618 words. This Petition was prepared using Microsoft Word 2010 and the word processing program has been applied specifically to include all text, including headings, footnotes, and quotations for word count purposes.

By: /s/ Kurt J. Niederluecke
Kurt J. Niederluecke

Dated: July 19, 2016

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