

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

JUBILANT DRAXIMAGE INC.,
Petitioner,

v.

BRACCO DIAGNOSTICS INC.,
Patent Owner.

IPR2018-01450
Patent 9,299,468 B2

Before HYUN J. JUNG, GEORGE R. HOSKINS, and
RICHARD H. MARSCHALL, *Administrative Patent Judges*.

JUNG, *Administrative Patent Judge*.

JUDGMENT
Final Written Decision
Determining All Challenged Claims Unpatentable
35 U.S.C. § 318(a)

I. INTRODUCTION

We have jurisdiction under 35 U.S.C. § 6. This Final Written Decision is issued pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73. For the reasons that follow, we determine that Petitioner has shown by a

preponderance of the evidence that claims 21–23 of U.S. Patent No. 9,299,468 B2 are unpatentable.

A. Background and Summary

Jubilant DraxImage Inc. (“Petitioner”) filed a Petition (Paper 1, “Pet.”) requesting institution of an *inter partes* review of claims 21–23 of U.S. Patent No. 9,299,468 B2 (Ex. 1001, “the ’468 patent”). Bracco Diagnostics Inc. (“Patent Owner”) filed a Preliminary Response. Paper 6. Pursuant to 35 U.S.C. § 314, we instituted an *inter partes* review of the ’468 patent. Paper 7 (“Dec. to Inst.”). In particular, we instituted review of claims 21–23 on all presented challenges. Dec. to Inst. 2, 14, 16, 19.

After institution, Patent Owner filed a Response (Paper 14, “PO Resp.”), to which Petitioner filed a Reply (Paper 15, “Pet. Reply”). Patent Owner thereafter filed a Sur-Reply (Paper 16, “PO Sur-Reply”). An oral hearing in this proceeding was held on October 29, 2019; a transcript of the hearing is included in the record (Paper 25, “Tr.”).

B. Real Parties in Interest

Petitioner states that the “real parties-in-interest for this Petition are Jubilant DraxImage Inc., Jubilant Pharma Limited, and Jubilant Life Science Limited.” Pet. 10.¹ Patent Owner states that “Bracco Diagnostics Inc. (‘Bracco’) is the owner of U.S. Patent No. 9,299,468” and “is the real party-in-interest.” Paper 4, 2.

C. Related Matters

The parties indicate that the ’468 patent has been asserted in *Bracco Diagnostics Inc. v. Jubilant DraxImage Inc.*, Case No. 3-18-cv-04422

¹ The Petition does not include page numbers for each page. Thus, we, like Patent Owner, identify page numbers by referring to the page of the PDF document. See PO Resp. 12 n.3.

(D.N.J.). Pet. 10; Paper 4, 2; PO Resp. 2; Ex. 1002 (complaint for patent infringement involving the '468 patent and others). The parties also indicate that the district court litigation is stayed pending resolution of Investigation No. 337-TA-1110 by the U.S. International Trade Commission (“ITC” or “Commission”). Pet. 10 (citing Exs. 1002–1004); PO Resp. 2 (citing Exs. 1002–1004); Ex. 1004 (order from civil action no. 3:18-cv-4422 granting joint motion to stay pending resolution of ITC Investigation No. 337-TA-1110).

In the ITC investigation filed March 27, 2018, Bracco Diagnostics, Inc. contends that Jubilant DraxImage Inc., Jubilant Pharma Limited, and Jubilant Life Sciences violate Section 337 of the Tariff Act of 1930 by importing strontium-rubidium infusion systems and components that infringe one of U.S. Patent Nos. 9,814,826; 9,750,869; and 9,750,870. Ex. 1003, 1, 14. The '468 patent is not part of the ITC investigation, but Patent Owner indicates that the investigation “involv[es] related patents.” PO Resp. 2 (citing Exs. 1002–1004). Patent Owner also states that “an ITC evidentiary hearing was held April 11–17[, 2019] relative to the related patents, and many of the same factual issues disputed there are also in dispute here.” *Id.*

Patent Owner subsequently filed a “Notice of Commission Determination to Review in Part a Final Initial Determination Finding No Section 337 Violation.” Paper 20; Ex. 2018 (notice from Investigation No. 337-TA-1110 issued Sept. 30, 2019). The notice states that a Final Initial Determination (“FID”) was issued on August 1, 2019, “the FID finds . . . all asserted claims are infringed but invalid as obvious over the prior art,”

petitions for review of the FID were filed, and the “Commission has determined to review the FID in part.” Ex. 2018, 2.

Petitioner filed a “Notice of Commission Final Determination of No Violation of Section 337; Termination of the Investigation.” Paper 26; Ex. 1047. According to Petitioner, “Ex. 1047 indicates that the Commission determined to affirm with modification and to supplement the prior Final Initial Determination’s findings with respect to the invalidity of the patent claims asserted in the 1110 Investigation.” Paper 26, 1 (citing Ex. 1047, 2); Ex. 1047, 2 (stating that “the Commission has determined to affirm with modification and to supplement the FID’s findings with respect to the invalidity of the asserted patent claims”).

Petitioner also filed a public version of a Commission Opinion for Investigation No. 337-TA-1110. Paper 27; Ex. 1048. Petitioner states that the “Commission Opinion addresses several issues that are relevant to the present *inter partes* review.” Paper 27, 1. According to Petitioner, “the Commission considered teachings of the Klein reference against claim elements that require a computer not to allow a patient infusion when a strontium breakthrough test result is greater than or equal to an allowed limit” and held that “Klein teaches or discloses such subject matter.” *Id.* (citing Ex. 1048, 24–26). Patent Owner has filed an appeal of the Commission Opinion. Ex. 2019.

The same patent is also challenged in IPR2018-01448, and a related patent that claims priority to common applications is challenged in IPR2018-01449. Pet. 10; Paper 4, 2; PO Resp. 1–2.

D. The ’468 Patent

The ’468 patent issued March 29, 2016, from an application filed August 8, 2014, which is a continuation of an application filed June 11,

of the eluant from generator 21. *Id.* at 4:65–67, 5:2–3, 5:6–7, 5:10–11. Activity detector 25 also provides feedback for directing the eluant via divergence valve 35WP to either waste bottle 23 or patient line 305p. *Id.* at 5:10–14. Divergence valve 35BG directs eluant to either tubing line 304 to generator 21 or to by-pass tubing line 303 and patient line 305p. *Id.* at 5:41–45.

“[A]ccording to alternate embodiments, system 10 includes an ‘on board’ dose calibrator for quality control tests, and circuit 300 is expanded to include elements for an automated collection of eluate samples for activity measurements, via the on board dose calibrator,” such as “downstream of divergence valve 35WP and in communication with tubing line 305P.” *Id.* at 8:4–12; *see also id.* at 18:56–60 (stating “some alternate embodiments . . . include an on board dose calibrator so that the entire sequence of sample collection and calculation steps . . . for the quality control procedures, may be automated”).

Also, in some embodiments, “computer 17 is coupled to a controller of system 10” and “monitor 172 of computer 17 not only displays indications of system operation for a user of system 10, but also serves as a device for user input (e.g. touch screen input).” *Id.* at 3:28–33.

E. Illustrative Claim

The ’468 patent has 29 claims, of which Petitioner challenges claims 21–23 in this proceeding. Of those, claim 21, reproduced below, is the only independent claim.

21. A mobile radioisotope generator system comprising:
 - a shielding assembly configured to contain a strontium/rubidium radioisotope generator that generates radioactive eluate via elution of an eluant and an infusion tubing

circuit comprising an eluate tubing line configured to convey eluate from the strontium/rubidium radioisotope generator;

means for measuring an activity of the eluate flowing through the eluate tubing line;

means for receiving eluate from the eluate tubing line and measuring breakthrough activity of the eluate; and

means for receiving activity data from the means for measuring the activity of the eluate and controlling the mobile radioisotope generator system based on the received activity data to deliver a dose of eluate to a patient during a patient infusion procedure,

wherein the means for receiving activity data and controlling the mobile radioisotope generator system is further configured to receive breakthrough activity data from the means for receiving eluate and measuring breakthrough activity, determine at least an activity of strontium-82 and an activity of strontium-85 in the eluate from the breakthrough activity data, and prevent the patient infusion procedure if the activity of strontium-82 or the activity of strontium-85 exceeds an allowable limit.

Ex. 1001, 25:52–26:10.

F. Prior Art and Asserted Grounds

Petitioner identifies the following references as prior art in the asserted grounds of unpatentability:

U.S. Patent Application Publication No. US 2008/0242915 A1, published October 2, 2008 (Ex. 1023, “Jackson”);

U.S. Patent Application Publication No. US 2011/0178359 A1, published July 21, 2011 (Ex. 1022, “Hirschman”); and

Ran Klein, *Precise ⁸²Rb Infusion System for Cardiac Perfusion Measurement Using 3D Positron Emission Tomography* (2006²) (Ex. 1014, “Klein”).

Also, the Petition is supported by the Declaration of Robert T. Stone, Ph.D. Ex. 1015. Petitioner also filed a Declaration of Venkatesh L. Murthy, M.D., Ph.D. Ex. 1017. Patent Owner filed a Declaration of Norbert J. Pelc, Sc.D. Ex. 2003. Deposition transcripts for Dr. Stone and Dr. Murthy were also filed. Exs. 2010, 2016. No deposition transcript for Dr. Pelc was filed.

Petitioner asserts that claims 21–23 would have been unpatentable on the following grounds:

Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis
21, 23	102(b) ³	Klein
22	103(a)	Klein, Hirschman, Jackson

Pet. 31–53.

² The cover page of Klein has a February 2005 date and 2005 copyright. Petitioner contends that Klein was publicly available in 2006. Pet. 25 (citing Ex. 1020 ¶ 4, attachments B, C).

³ The relevant sections of the Leahy-Smith America Invents Act (“AIA”), Pub. L. No. 112–29, 125 Stat. 284 (Sept. 16, 2011), took effect on March 16, 2013. The application from which the ’468 patent issued was filed in August 2014, but asserts continuation priority to several applications filed before March 2013. Because there is no argument in the record to suggest the AIA version of Title 35 applies to the ’468 patent, our citations to Title 35 are to the pre-AIA version.

II. ANALYSIS

A. *Legal Standards*

To prevail in its challenges, Petitioner must prove unpatentability by a preponderance of the evidence. 35 U.S.C. § 316(e); 37 C.F.R. § 42.1(d).

To anticipate a claim under 35 U.S.C. § 102, “a single prior art reference must expressly or inherently disclose each claim limitation.” *Finisar Corp. v. DirecTV Group, Inc.*, 523 F.3d 1323, 1334 (Fed. Cir. 2008). That “single reference must describe the claimed invention with sufficient precision and detail to establish that the subject matter existed in the prior art.” *Verve, LLC v. Crane Cams, Inc.*, 311 F.3d 1116, 1120 (Fed. Cir. 2002).

A claim is unpatentable under 35 U.S.C. § 103(a) if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of underlying factual determinations including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of ordinary skill in the art; and (4) objective evidence of nonobviousness. *See Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

B. *Level of Ordinary Skill in the Art*

Petitioner contends that a person having ordinary skill in the art would have a

graduate’s degree with some emphasis in equipment design, automation, or controls, such as electrical engineering, systems engineering, mechanical engineering, or a related field, or an undergraduate degree in such fields with two to three years’ work

experience in radioactive protection systems or in medical device product, automation, or instrumentation design and development, including work with prototypes and finished commercial products.

Pet. 18 (citing Ex. 1015 ¶¶ 32–42). Petitioner also contends that “[s]uch a person would have had a basic understanding, through education or experience, of general design control principles and processes and practices for partial or full automation of existing processes or test procedures.” *Id.* at 18–19 (citing Ex. 1015 ¶¶ 32–42). Petitioner further argues that Patent Owner’s proposed level of ordinary skill in the related ITC case is flawed because the claims challenged in this proceeding additionally recite a computer that automates procedures previously manually performed by medical personnel and “[m]edical personnel like those suggested by the Patent Owner lack the education and experience to develop the hardware and software controls for such computer-controlled systems or to design radiation shielding.” *Id.* at 19–20 (citing Ex. 1015 ¶¶ 32–42; Ex. 1021).

Patent Owner asserts that a person of ordinary skill in the art “would generally have a graduate degree in medicine and/or in a medical related science, including physics, chemistry, biology, physiology, and/or biophysics, and would generally have at least some clinical, research and/or design experience with respect to PET imaging and/or PET imaging systems.” PO Resp. 6 (citing Ex. 2003 ¶ 27). Patent Owner also asserts that “[a]n individual with an undergraduate degree along with significant experience could also be sufficiently skilled,” “the amount of experience following an undergraduate degree would depend on the level of formal education and amount of experience working with radiopharmaceuticals,” and “such a person may be working as part of a team.” *Id.* (citing Ex. 2003 ¶ 27); *see also id.* at 7 (citing Ex. 2003 ¶¶ 28–29).

Patent Owner argues that Petitioner’s proposed level of ordinary skill “does not actually require familiarity with elution of radioactive isotopes, PET imaging, or even systems employing any form of radioactive substance.” *Id.* at 6. Patent Owner further contends that “Petitioner has failed to show that the Challenged Claims are invalid under either party’s proposed level of skill.” *Id.* at 7.

In determining the level of ordinary skill in the art, various factors may be considered, including the “type of problems encountered in the art; prior art solutions to those problems; rapidity with which innovations are made; sophistication of the technology; and educational level of active workers in the field.” *In re GPAC Inc.*, 57 F.3d 1573, 1579 (Fed. Cir. 1995) (citation and internal quotation marks omitted).

Klein addresses the development of a system for eluting a constant rate of activity. *See* Ex. 1014, 1 (“The goal of this project is to develop a system that is capable of eluting ^{82}Rb at a constant rate of activity from a $^{82}\text{Sr}/^{82}\text{Rb}$ generator for use in a clinical and experimental setting.”). Jackson similarly describes “a need to improve the quality control of the administration of radiopharmaceuticals to patients” and “a need to reduce the exposure of people, such as PET technicians, to radioactivity during the manual steps of administering a radiopharmaceutical to patients.” Ex. 1023 ¶ 11. According to Hirschman, “a need exists for integrated systems and methods capable of the generation, preparation, and administration of pharmaceutical substances . . . such as radioactive pharmaceutical substances.” Ex. 1022 ¶ 18.

Based on the full record before us, because the asserted references describe the problems and solutions of accurately delivering radiopharmaceuticals, reducing radiation exposure to operators, and

integrating systems related to radiopharmaceuticals, we find that Petitioner’s proposed level of ordinary skill in the art, which includes understanding of equipment control, “radioactive protection systems,” and equipment design, is consistent with the prior art of record. Pet. 18 (citing Ex. 1015 ¶¶ 32–42). We, therefore, apply Petitioner’s proposed level of skill to our analysis.

We also determine that the parties’ competing proposals regarding the level of ordinary skill agree in certain aspects. For example, both parties propose at least a graduate degree, albeit in different concentrations of study. *See* Pet. 18 (“graduate’s degree with some emphasis in equipment design, automation, or controls, . . . or a related field”); PO Resp. 6 (“a graduate degree in medicine and/or in a medical related science”). Both parties also alternatively propose that the ordinarily skilled artisan would have had “an undergraduate degree in such fields with two to three years’ work experience in radioactive protection systems or in medical device product, automation, or instrumentation design and development, including work with prototypes and finished commercial products” (Pet. 18) or “an undergraduate degree along with significant experience,” “the amount of experience following an undergraduate degree would depend on the level of formal education and amount of experience working with radiopharmaceuticals.” (PO Resp. 6).

We further determine that Petitioner’s proposed ordinary skilled artisan with “an undergraduate degree in [equipment design, automation, or controls, or a related field] with two to three years’ work experience . . . in medical device product, automation, or instrumentation design and development” (*see* Pet. 18) would overlap, at least in part, Patent Owner’s proposal of a person having “a graduate degree in medicine and/or in a medical related science” and “at least some . . . design experience with respect to . . . PET imaging

systems” (see PO Resp. 6). We, thus, determine that any differences between the parties’ proposed level of skill would not affect our analysis below. *See also* Pet. Reply 2 (“Although the parties define [the person of ordinary skill in the art] differently, neither party argues that the differences between them are material to the outcome of this IPR.”).

C. Claim Construction

In the present *inter partes* review, claim terms in the ’468 patent, which is unexpired, are interpreted according to their broadest reasonable construction in light of the Specification of the ’468 patent. 37 C.F.R. § 42.100(b) (2017); *Cuozzo Speed Techs. LLC v. Lee*, 136 S. Ct. 2131, 2144–46 (2016) (upholding the use of the broadest reasonable interpretation standard).⁴

Petitioner states that “[a]ll claim terms have been assigned their ordinary and customary meaning in this analysis.” Pet. 20. In the Decision to Institute, we preliminarily interpreted means-plus-function terms of independent claim 21. Dec. to Inst. 9–10. Patent Owner responds that “construction of these means-plus-function terms is not critical to the outcome of this proceeding” because Patent Owner “agrees that the primary

⁴ On October 11, 2018, the Office revised its rules to harmonize the Board’s claim construction standard with that used in civil actions under 35 U.S.C. § 282(b) in federal district court. Changes to the Claim Construction Standard for Interpreting Claims in Trial Proceedings Before the Patent Trial and Appeal Board, 83 Fed. Reg. 51,340 (Oct. 11, 2018) (amending 37 C.F.R. § 42.100(b) effective November 13, 2018). This rule change does not apply here. *See* Paper 3, 1 (according filing date of August 22, 2018 to the Petition); PO Resp. 3 (stating that the “present IPR was filed before the new IPR rules regarding claim construction were implemented”).

reference of Klein includes items that meet all of the above means-plus-function elements.” PO Resp. 3. Patent Owner also provides comments on the means-plus-function terms. *Id.* at 3–6.

For “means for measuring an activity of the eluate flowing through the eluate tubing line,” we preliminarily determined that the function is “measuring an activity of the eluate flowing through the eluate tubing line” and the corresponding structure for performing the function is activity detector 25. Dec. to Inst. 9 (citing Ex. 1001, 5:10–15). “Patent Owner agrees that an activity detector is one structure in the [S]pecification that can perform the specified function.” PO Resp. 4 (citing Ex. 2003 ¶ 32).

For “means for receiving eluate from the eluate tubing line and measuring breakthrough activity of the eluate,” we preliminarily determined that the function is “receiving eluate from the eluate tubing line and measuring breakthrough activity of the eluate” and the corresponding structure for performing the function is a dose calibrator. Dec. to Inst. 9 (citing Ex. 1001, 18:56–60). “Patent Owner agrees that a dose calibrator is one structure in the [S]pecification that can perform the specified function.” PO Resp. 4 (citing Ex. 2003 ¶ 33).

For “means for receiving activity data from the means for measuring the activity of the eluate and controlling the mobile radioisotope generator system based on the received activity data to deliver a dose of eluate to a patient during a patient infusion procedure,” we preliminarily determined that the function is “receiving activity data from the means for measuring the activity of the eluate and controlling the mobile radioisotope generator system based on the received activity data to deliver a dose of eluate to a patient during a patient infusion procedure” and the corresponding structure

that performs the function is a controller of system 10. Dec. to Inst. 9–10 (citing Ex. 1001, 5:50–51).

“Patent Owner agrees that a controller is one structure in the [S]pecification that can perform the specified function” but “notes that the controller may be coupled to a computer, and some activities described in the [S]pecification may require the computer.” PO Resp. 5 (citing Ex. 1001, 3:28–29, 5:41–6:5, 6:43–46, 7:14–28, 13:13–24, 13:44–14:15, 21:45–50; Ex. 2003 ¶ 34). Patent Owner also argues that “Klein’s computer does not ‘prevent the patient infusion procedure if the activity of strontium-82 or the activity of strontium-85 exceeds an allowable limit.’” *Id.* (citing Ex. 2003 ¶ 35). We address the latter argument below in our analysis of Petitioner’s anticipation challenge.

Petitioner’s Reply does not present any additional arguments regarding any express interpretations. *See* Pet. Reply 3–4. Petitioner instead asserts that Patent Owner made admissions and that the issue about Klein’s computer preventing the patient infusion procedure if the activity of strontium-82 or strontium-85 exceeds an allowable limit would resolve the parties’ dispute. *See id.*

In view of the full record before us, because the parties do not dispute our preliminary interpretations of claim 21’s means-plus-function terms, we apply those interpretations to our analysis below. In particular, for “means for measuring an activity of the eluate flowing through the eluate tubing line,” we determine that the function is “measuring an activity of the eluate flowing through the eluate tubing line” and that the corresponding structure for performing the function is, at least, activity detector 25. Ex. 1001, 5:10–15 (describing “activity detector 25, for measuring the activity of the eluate discharged from generator 21”).

For “means for receiving eluate from the eluate tubing line and measuring breakthrough activity of the eluate,” we determine that the function is “receiving eluate from the eluate tubing line and measuring breakthrough activity of the eluate” and that the corresponding structure for performing the function is, at least, a dose calibrator. Ex. 1001, 18:56–60 (stating that “some alternate embodiments . . . include an on board dose calibrator so that the entire sequence of sample collection and calculation steps . . . for the quality control procedures, may be automated”).

For “means for receiving activity data from the means for measuring the activity of the eluate and controlling the mobile radioisotope generator system based on the received activity data to deliver a dose of eluate to a patient during a patient infusion procedure,” we determine that the function is “receiving activity data from the means for measuring the activity of the eluate and controlling the mobile radioisotope generator system based on the received activity data to deliver a dose of eluate to a patient during a patient infusion procedure” and that the corresponding structure that performs the function is, at least, a controller of system 10 that may be coupled to a computer. Ex. 1001, 5:50–51 (describing a “controller . . . of system 10, which controller receives feedback from activity detector 25”), 5:53–61 (describing the operation of the controller and valves 35BG and 35WP based on feedback from activity detector 25).

Patent Owner further states that it “believes that no additional specific constructions are required at this time” but “reserves the right to put forth any additional specific constructions in these proceedings, should the need arise.” PO Resp. 5–6. Petitioner also agrees that, other than the means plus function terms, no other claim term need express interpretation. Tr. 8:14–19.

We agree with the parties that no other express interpretation is required for any claim term to resolve the parties' dispute regarding patentability. *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999) (construing explicitly only those claim terms in controversy and only to the extent necessary to resolve the controversy); *see also Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (applying *Vivid Techs.* in the context of an *inter partes* review).

D. Challenge Under 35 U.S.C. § 102(b)

As discussed below, the parties' disputes are related to whether Klein discloses all the limitations of independent claim 21. Patent Owner does not present any arguments specifically for dependent claim 23. *See generally* PO Resp.; PO Sur-Reply.

After reviewing the complete record, we conclude that Petitioner has shown by a preponderance of the evidence that Klein discloses all the limitations of independent claim 21 and dependent claim 23.

1. Klein (Ex. 1014)

Klein is a student thesis that “describes the development of a Rubidium-82 (^{82}Rb) infusion system for use in positron emission tomography (PET)” and “is based on a $^{82}\text{Sr}/^{82}\text{Rb}$ generator which produces ^{82}Rb activity continuously.” Ex. 1014, 1⁵; *see also id.* at 8 (“ ^{82}Rb can be supplied using a $^{82}\text{Sr}/^{82}\text{Rb}$ generator.”)

“The goal of this project is to develop a system that is capable of eluting ^{82}Rb at a constant rate of activity from a $^{82}\text{Sr}/^{82}\text{Rb}$ generator for use

⁵ Our citations to Klein are to the page numbers found in the bottom center of each page.

in a clinical and experimental setting.” *Id.* at 1. Klein “introduces the second generation ^{82}Rb elution system (RbES).” *Id.* Figure 2-2 of Klein is reproduced below. *Id.* at 19.

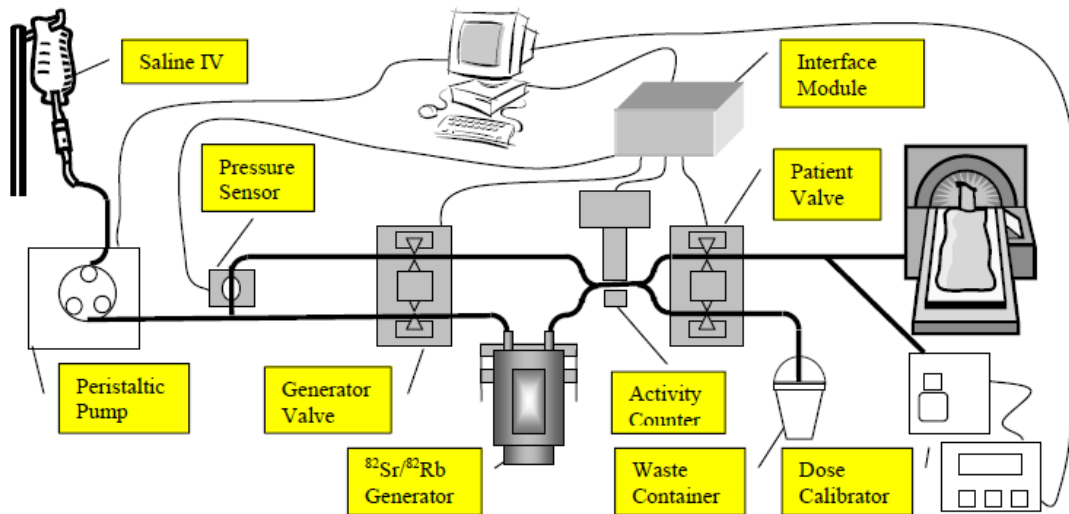


Figure 2-2 – Hardware component diagram of the RbES prototype [18] was not altered.

Figure 2-2 is a hardware component diagram of an RbES prototype. Ex. 1014, 19 Klein includes a personal computer that interfaces with sensors and actuators to allow flow of saline through a $^{82}\text{Sr}/^{82}\text{Rb}$ generator or a bypass line to the patient, dose calibrator, or waste container. *Id.* Klein states that “using a PC to control the system” allows for a “wide range of applications and devices that are readily supported” including “off-the-shelf user interface devices, as well as machine interfaces and data acquisition devices” *Id.* at 20.

“All the components are assembled in a stainless steel cart.” *Id.* at 23. The “generator was placed in the cart and surrounded by lead rings to provide maximum radiation shielding” from which “ ^{82}Rb is eluted in the form of $^{82}\text{RbCl}$ (eluate).” *Id.* at 8, 23; *see also id.* at 34 (stating that the “waste container is located on the top shelf inside the cart and is contained within lead shielding to minimize exposure to the operator”).

“All the saline lines were mounted on a modified top cover” (*id.* at 23), and “[a]lthough the generator and waste container are shielded by lead, the saline lines are a source of radiation during elutions” (*id.* at 36).

Klein also includes flow control valves, an activity counter, pumps, and a pressure sensor. *Id.* at 21–23. Klein states that “real-time software controls the pumps and valves” to “affect the flow of saline through the generator or its bypass line to the patient, dose calibrator, or waste container.” *Id.* at 19. The system acquires data from the activity counter and dose calibrator. *Id.* The “activity counter was included in the design to allow data collection and monitoring of the elution of activity” so as to “develop[] a controller capable of directing saline through the generator or its bypass line by actuating the generator valve in order to achieve a constant rate of activity using feedback from the activity counter.” *Id.* at 71.

According to Klein, the “system is required to operate in a clinical setting and therefore must be reliable, easy to operate, and above all, safe.” *Id.* at 26. Klein also states that “⁸²Sr and ⁸⁵Sr ‘breakthrough’ can result if the generator is used indefinitely” and “[i]n high quantities these compounds may have ill effects on health.” *Id.* at 9. Klein describes that if there is an indication of excessive strontium breakthrough, then “elution to patients should be avoided.” *Id.* at 10; *see also id.* at 33 (stating that the “amount of Sr breakthrough activity must be strictly limited to the Health Canada guidelines”).

The dose calibrator “is utilized in the system for both calibration and testing” and “is used to detect the breakthrough activity as part of the calibration test through measurement of ⁸²Rb activity.” *Id.* at 19, 23, 50. Klein’s system is calibrated “by monitoring an external dose calibrator during the calibration run” (*id.* at 17) and “[w]ait[s] for decay to read

breakthrough from dose calibrator” (*id.* at 64). The “dose calibrator is used to detect the breakthrough activity . . . through measurement of ^{82}Rb activity” and the “breakthrough of each isotope, $A_{82\text{Sr}}/A_{82\text{Rb}}$ and $A_{85\text{Sr}}/A_{82\text{Rb}}$, is calculated as a relative activity ratio of Sr activity to ^{82}Rb activity delivered.” *Id.* at 50–51.

Klein also describes a daily protocol “intended for routine system maintenance, system diagnostics, and clinical preparation of the system,” which includes a calibration run. *Id.* at 17–18. Klein states that “[o]nly after a calibration run with low Sr breakthrough has been successfully completed can patient elutions be carried out,” and “[o]nce the daily protocol has been completed successfully, patient elutions are enabled until the end of the day.” *Id.* at 18; *see also id.* at 33 (stating that the “issue is addressed by daily breakthrough tests as part of the daily protocol ensured by the system”), 43 (stating that “certain maintenance measures must be carried out as dictated by the daily protocol” and “Sr breakthrough must be measured and a complete system test must follow”), 50–52 (describing breakthrough measurement), 122 (stating “[d]aily calibration samples are used to test for the breakthrough of Sr activity; if significant Sr activity is detected, the generator cannot be used on humans”). Klein also states that the “ ^{82}Rb infusion system software must ensure that the protocol is followed (i.e. that each run is enabled only after the prerequisites have been completed successfully).” *Id.* at 44.

2. Claim 21

a) “A mobile radioisotope generator system”

Petitioner argues that Klein discloses a “mobile radioisotope generator system,” as recited by claim 21. Pet. 32 (citing Ex. 1014, 1, 24; Ex. 1015 ¶¶ 203–206). Petitioner also relies on a “[p]hotograph of the assembled ^{82}Rb

elution system and its components,” reproduced below. Ex. 1014, 24 (Fig. 2-3).

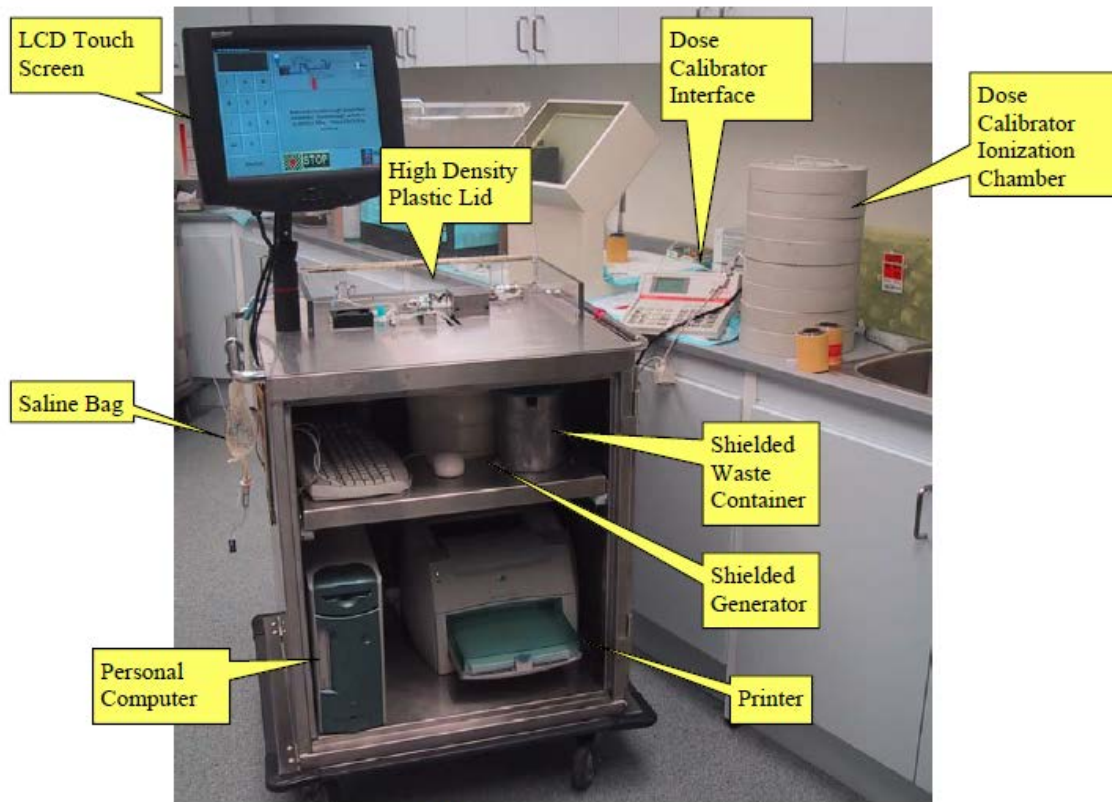


Figure 2-3 - Photograph of the assembled ^{82}Rb elution system and its components.

We find that Klein shows a “Shielded Generator” on a cart. Ex. 1014, 24 (Fig. 2-3); see Ex. 1014, 23 (“All the components are assembled in a stainless steel cart shown in Figure 2-3.”). We also find that a relied-upon portion of Klein states that it “describes the development of a Rubidium-82 (^{82}Rb) infusion system . . . based on a $^{82}\text{Sr}/^{82}\text{Rb}$ generator, which produces ^{82}Rb activity continuously.” *Id.* at 1. We further credit Petitioner’s declarant testimony regarding a “mobile radioisotope generator system” because Klein supports that testimony. Ex. 1015 ¶¶ 203–206 (citing Ex. 1014, 1, 23, 24 (Fig. 2-3)). Patent Owner does not provide a response specifically for a “mobile radioisotope generator system.” See generally PO Resp.; PO Sur-Reply.

Based on the full record, because Klein discloses a shielded $^{82}\text{Sr}/^{82}\text{Rb}$ generator on a stainless steel cart, Petitioner persuades us by a preponderance of the evidence that Klein teaches a “mobile radioisotope generator system.”

b) *“a shielding assembly configured to contain a strontium/rubidium radioisotope generator that generates radioactive eluate via elution of an eluant and an infusion tubing circuit comprising an eluate tubing line configured to convey eluate from the strontium/rubidium radioisotope generator”*

Petitioner argues that Klein discloses the shielding assembly required by claim 21. Pet. 32–34 (citing Ex. 1014, 8, 19, 23, 24, 36; Ex. 1015 ¶¶ 207–215).

We find that the relied-upon portions of Klein teach that a “generator was placed in the cart and surrounded by lead rings to provide maximum radiation shielding” from which “ ^{82}Rb is eluted in the form of $^{82}\text{RbCl}$ (eluate)” (Ex. 1014, 8, 23), “[a]ll the saline lines were mounted on a modified top cover” (*id.* at 23), “[a]lthough the generator and waste container are shielded by lead, the saline lines are a source of radiation during elutions” (*id.* at 36), and “real-time software controls the pumps and valves” to “affect the flow of saline through the generator or its bypass line to the patient, dose calibrator, or waste container” (*id.* at 19).

We also find that Figures 2-3 and 2-4 of Klein show, at least, a “Saline Line” (Fig. 2-4), “Shielded Activity Counter” (Fig. 2-4), “Personal Computer” (Fig. 2-3), “Shielded Waste Container” (Fig. 2-3), and “Shielded Generator” (Fig. 2-3) on a cart. Ex. 1014, 24. Figure 2-3 shows a “Dose Calibrator Ionization Chamber” but it is not on the cart. *Id.* We further find that Klein shows in its Figure 2-2 lines between components, such as a

“Saline IV,” “Activity Counter,” “Dose Calibrator,” and a “ $^{82}\text{Sr}/^{82}\text{Rb}$ Generator.” *Id.* at 19. We further credit Petitioner’s declarant testimony regarding the shielding assembly and infusion tubing circuit of claim 21 because Klein supports that testimony. Ex. 1015 ¶¶ 207–215 (citing Ex. 1014, 8, 19, 23, 24, 36). Patent Owner does not present any arguments specifically for these limitations of claim 21. *See generally* PO Resp.; PO Sur-Reply.

Based on the full record before us, because Klein discloses lead rings to provide radiation shielding to its $^{82}\text{Sr}/^{82}\text{Rb}$ generator from which ^{82}Rb is eluted, Petitioner persuades us by a preponderance of the evidence that Klein discloses “a shielding assembly configured to contain a strontium/rubidium radioisotope generator that generates radioactive eluate via elution of an eluant.” Also, based on the full record, because Klein discloses that ^{82}Rb is eluted and saline lines are a source of radiation during elutions, Petitioner persuades us by a preponderance of the evidence that Klein discloses “an infusion tubing circuit comprising an eluate tubing line configured to convey eluate from the strontium/rubidium radioisotope generator.”

c) “*means for measuring an activity of the eluate flowing through the eluate tubing line*”

Petitioner argues that Klein discloses “means for measuring an activity of the eluate flowing through the eluate tubing line.” Pet. 34–35 (citing Ex. 1014, 19, 24; Ex. 1015 ¶¶ 216–222).

As discussed above, for the above-quoted means-plus-function limitation, we determine that the corresponding structure for performing the function is, at least, activity detector 25. Ex. 1001, 5:10–15 (describing “activity detector 25, for measuring the activity of the eluate discharged from generator 21”); *see also* PO Resp. 4 (“Patent Owner agrees that an

activity detector is one structure in the [S]pecification that can perform the specified function.”).

We find that the relied-upon portions of Klein disclose that “[t]he system acquires data from a[n] . . . activity counter.” Ex. 1014, 19. We also find that Figures 2-2, 2-4, and 3-3 of Klein show an “Activity Counter” downstream of a generator (Figs. 2-2, 3-3) or “Shielded Activity Counter” coupled to tubing (Fig. 2-4). *Id.* at 19, 24, 41. We further credit the Petitioner’s declarant testimony regarding this limitation because Klein supports that testimony. Ex. 1015 ¶¶ 216–222 (citing Ex. 1014, 19, 24). Patent Owner does not present any arguments specifically for this limitation. *See* PO Resp. 3 (agreeing that Klein meets this limitation and others).

Based on the full record before us, because Klein discloses an activity counter downstream of a generator and coupled to tubing, an equivalent structure that performs the recited function, Petitioner persuades us by a preponderance of the evidence that Klein discloses “means for measuring an activity of the eluate flowing through the eluate tubing line.”

d) *“means for receiving eluate from the eluate tubing line and measuring breakthrough activity of the eluate”*

Petitioner contends that Klein discloses “means for receiving eluate from the eluate tubing line and measuring breakthrough activity of the eluate.” Pet. 36–37 (citing Ex. 1014, 19, 23, 24, 50; Ex. 1015 ¶¶ 223–230).

As discussed above, for the above-quoted means-plus-function limitation, we determine that the corresponding structure for performing the function is, at least, a dose calibrator. Ex. 1001, 18:56–60 (describing “an on board dose calibrator so that the entire sequence of sample collection and calculation steps . . . for the quality control procedures, may be automated”).

We find that the relied-upon portions of Klein disclose that “[t]he system acquires data from a . . . dose calibrator” that “is utilized in the system for both calibration and testing” and “is used to detect the breakthrough activity as part of the calibration test through measurement of ^{82}Rb activity.” Ex. 1014, 19, 23, 50. We also find that Figures 2-2 and 2-3 of Klein show a “Dose Calibrator” (Fig. 2-2) or “Dose Calibrator Ionization Chamber” (Fig. 2-3). *Id.* at 19, 24. We further credit the Petitioner’s declarant testimony regarding this limitation because Klein supports that testimony. Ex. 1015 ¶¶ 223–230 (citing Ex. 1014, 19, 23, 24, 50). Patent Owner does not present any arguments specifically for this limitation. See PO Resp. 3 (agreeing that Klein meets this limitation and others).

Based on the full record before us, because Klein discloses a dose calibrator that is used to detect breakthrough activity, the same or equivalent structure to that in the ’468 patent that performs the recited function, Petitioner persuades us by a preponderance of the evidence that Klein discloses “means for receiving eluate from the eluate tubing line and measuring breakthrough activity of the eluate.”

- e) *“means for receiving activity data from the means for measuring the activity of the eluate and controlling the mobile radioisotope generator system based on the received activity data to deliver a dose of eluate to a patient during a patient infusion procedure”*

According to Petitioner, Klein discloses “means for receiving activity data from the means for measuring the activity of the eluate and controlling the mobile radioisotope generator system based on the received activity data to deliver a dose of eluate to a patient during a patient infusion procedure.” Pet. 37–39 (citing Ex. 1014, 7, 19, 57, 71, Fig. 3-14; Ex. 1015 ¶¶ 231–238).

For this means-plus-function limitation, we determine that the corresponding structure that performs the function is, at least, a controller of system 10 that may be coupled to a computer. Ex. 1001, 5:50–51 (describing a “controller . . . of system 10, which controller receives feedback from activity detector 25”), 5:53–61 (describing the operation of the controller and valves 35BG and 35WP based on feedback from activity detector 25).

We find that the relied-upon portions of Klein disclose that “[t]he system acquires data from a[n] . . . activity counter” (Ex. 1014, 19) and that “an activity counter was included in the design to allow data collection and monitoring of the elution of activity” so as to “develop[] a controller capable of directing saline through the generator or its bypass line by actuating the generator valve in order to achieve a constant rate of activity using feedback from the activity counter” (*id.* at 71). We also find that Figure 2-2 of Klein shows a personal computer that is coupled to the “Activity Counter” (*id.* at 19) and Figure 3-14 shows an “Expected Activity” as an input (*id.* at 57). We further credit the Petitioner’s declarant testimony because Klein supports that testimony. Ex. 1015 ¶¶ 231–238 (citing Ex. 1014, 7, 19, 57, 71). Patent Owner does not present any arguments specifically for these limitations. See PO Resp. 3 (agreeing that Klein meets this limitation and others).

Based on the full record before us, because Klein discloses a controller and computer that receives feedback from the activity counter and actuates a generator valve to achieve a constant rate of activity, Petitioner persuades us by a preponderance of the evidence that Klein discloses the same or equivalent structure to that in the ’468 patent that performs the recited function and, thus, discloses “means for receiving activity data from the means for measuring the activity of the eluate and controlling the mobile

radioisotope generator system based on the received activity data to deliver a dose of eluate to a patient during a patient infusion procedure.”

- f) “*wherein the means for receiving activity data and controlling the mobile radioisotope generator system is further configured to receive breakthrough activity data from the means for receiving eluate and measuring breakthrough activity*”

Petitioner contends that Klein discloses “wherein the means for receiving activity data and controlling the mobile radioisotope generator system is further configured to receive breakthrough activity data from the means for receiving eluate and measuring breakthrough activity.” Pet. 39–40 (citing Ex. 1014, 17, 20, 64; Ex. 1015 ¶¶ 242–243).

As discussed above, we find that Klein discloses the same or equivalent structures for “means for receiving activity data and controlling the mobile radioisotope generator system” (Klein’s controller and computer) and “means for receiving eluate and measuring breakthrough activity” (Klein’s dose calibrator). We find that the relied-upon portions of Klein disclose that “using a PC to control the system” allows for a “wide range of applications and devices that are readily supported” including “off-the-shelf user interface devices, as well as machine interfaces and data acquisition devices” (Ex. 1014, 20) and that Klein’s system is calibrated “by monitoring an external dose calibrator during the calibration run” (*id.* at 17) and “[w]ait[s] for decay to read breakthrough from dose calibrator” (*id.* at 64). We further credit Petitioner’s declarant testimony regarding this limitation because the record supports it. Ex. 1015 ¶¶ 242–243 (citing Ex. 1014, 17, 20, 64). Patent Owner does not present any arguments specifically for this limitation. *See generally* PO Resp.; PO Sur-Reply.

Based on the full record, because Klein discloses a computer that receives breakthrough data from a dose calibrator, Petitioner persuades us by

a preponderance of the evidence that Klein discloses the same or an equivalent structure to that in the '468 patent that performs the recited function of “receiv[ing] breakthrough activity data from the means for receiving eluate and measuring breakthrough activity.”

- g) *“wherein the means for receiving activity data and controlling the mobile radioisotope generator system is further configured to . . . determine at least an activity of strontium-82 and an activity of strontium-85 in the eluate from the breakthrough activity data”*

Petitioner contends that Klein discloses “wherein the means for receiving activity data and controlling the mobile radioisotope generator system is further configured to . . . determine at least an activity of strontium-82 and an activity of strontium-85 in the eluate from the breakthrough activity data.” Pet. 41 (citing Ex. 1014, 50–51; Ex. 1015 ¶ 244).

As discussed above, we find that Klein discloses the same or equivalent structure for “means for receiving activity data and controlling the mobile radioisotope generator system” (Klein’s controller and computer). We find that the relied-upon portions of Klein teach that the “dose calibrator is used to detect the breakthrough activity as part of the calibration test through measurement of ^{82}Rb activity” and the “breakthrough of each isotope, $A_{82\text{Sr}}/A_{82\text{Rb}}$ and $A_{85\text{Sr}}/A_{82\text{Rb}}$, is calculated as a relative activity ratio of Sr activity to ^{82}Rb activity delivered.” Ex. 1014, 50–51. We also credit Petitioner’s declarant testimony regarding this limitation because the record supports it. Ex. 1015 ¶ 244 (citing Ex. 1014, 50–51). Patent Owner does not present any arguments specifically for this limitation. *See generally* PO Resp.; PO Sur-Reply.

Based on the full record before us, because Klein discloses that it calculates ^{82}Sr and ^{85}Sr activities relative to ^{82}Rb activity during breakthrough testing and because Klein's computer is coupled to its dose calibrator that is configured to detect breakthrough during a calibration test, Petitioner persuades us by a preponderance of the evidence that Klein discloses the same or an equivalent structure to that in the '468 patent that performs the function of "determin[ing] at least an activity of strontium-82 and an activity of strontium-85 in the eluate from the breakthrough activity data."

- h) *"wherein the means for receiving activity data and controlling the mobile radioisotope generator system is further configured to . . . prevent the patient infusion procedure if the activity of strontium-82 or the activity of strontium-85 exceeds an allowable limit"*

(1) Parties' Positions

Petitioner contends that Klein discloses "wherein the means for receiving activity data and controlling the mobile radioisotope generator system is further configured to . . . prevent the patient infusion procedure if the activity of strontium-82 or the activity of strontium-85 exceeds an allowable limit." Pet. 41–42 (citing Ex. 1014, 18, 33, 44, 55, 122; Ex. 1015 ¶¶ 239–241, 245–253).

Patent Owner responds that Klein does not disclose expressly a computer that prevents patient infusions if a strontium breakthrough test result exceeds an allowable limit. PO Resp. 1, 10, 13–20. Patent Owner notes that Petitioner's arguments and evidence that Klein's computer prevents infusion if breakthrough test results exceed an allowable limit are the same in this proceeding and the related proceedings, IPR2018-01448 and IPR2018-01449. *Id.* at 10–13.

According to Patent Owner, Petitioner implicitly acknowledges that Klein does not expressly state that a computer prevents infusions if breakthrough test results exceed an allowable limit, and the relied-upon portions of Klein fail to disclose expressly such a computer. *Id.* at 13–14 (citing Pet. 31, 41–42). Also, according to Patent Owner, although Klein resets at midnight and prohibits infusions until a daily protocol is completed, the computer of Klein does not prevent infusions if breakthrough test results exceed an allowable limit, because the “decision is left to the operator.” *Id.* at 14–15 (citing Ex. 2003 ¶¶ 95–96).

Patent Owner contends that Klein’s computer merely “facilitates testing for strontium breakthrough.” *Id.* at 15 (citing Ex. 1014, 53–55). In Patent Owner’s view, Klein describes an experiment for observing excessive breakthrough, and the experiment would have been complicated or impossible if Klein’s computer prevented infusions based on breakthrough testing. *Id.* (citing Ex. 1014, 122; Ex. 2003 ¶ 97). Patent Owner also argues that Klein does not describe its computer preventing infusions or having to override the system after breakthrough was observed, and thus, one of ordinary skill in the art would have understood that an operator must prevent infusions if breakthrough is detected. *Id.* at 15–16.

Patent Owner further argues that (1) Klein discloses an operator may manually enter breakthrough activity from a more sensitive instrument, (2) Klein does not state clearly that the system is locked out until breakthrough activity is entered, (3) Klein lists error messages, none of which pertain to locking out based on breakthrough testing, and (4) Klein discloses that automatic testing of activity can fail so that the system could not determine breakthrough and may not be locked out. *Id.* at 16 (citing Ex. 1014, 52, 54, 61, Fig. 3-12; Ex. 2003 ¶¶ 98–99). Patent Owner also

directs us to its declarant's testimony in the related ITC proceeding. *Id.* at 16–17 (citing Ex. 2012, 983:10–984:23). Further, based on Figure 3-15 of Klein, which includes the step “Wait for Breakthrough Reading,” Patent Owner argues that the daily protocol is satisfied if Klein's system can acquire data from the dose calibrator. *Id.* at 17–19 (citing Ex. 1014, Fig. 3-15; Ex. 2003 ¶¶ 100–101; Ex. 2003, 981:22–983:9). Patent Owner asserts that Petitioner is also relying on express anticipation, not inherent anticipation. *Id.* at 19–20.

Petitioner replies that Klein discloses a computer that “disables patient elutions each night,” and Patent Owner's declarant agrees. Pet. Reply 4 (citing Ex. 1014, 18, 19, 29, 44; Ex. 2012, 981:9–10), 6–8 (citing Ex. 1014, 18, 19, 29, 44, Fig. 2-1; Ex. 1015 ¶¶ 259–263; Ex. 2012, 981:9–14, 1078:8–1079:12). Petitioner argues that Klein discloses a computer-controlled infusion system with touchscreens that enable or disable buttons based on Klein's operational state, thereby locking out elutions. *Id.* at 5–6 (citing Pet. 14–17; Ex. 1014, 19, 30–31, 53–54, Fig. 3-12(c); Ex. 1015 ¶¶ 259–263).

Petitioner also replies that anticipation “does not demand word-for-word correspondence between prior art and the claims” and that one of ordinary skill in the art would “recognize immediately from Klein's disclosure that the computer ‘prevent[s] the patient infusion procedure if the activity of strontinum-82 [sic] or the activity of strontium-85 exceeds an allowable limit.’” *Id.* at 8–9.

Regarding Patent Owner's arguments that Klein's breakthrough experiments suggest that its computer does not prevent infusions, Petitioner replies that those experiments were not patient infusion procedures, Klein distinguishes the experiments from patient procedures, Klein never suggests that those experiments involved patient procedures, and Klein prevents

patient infusion procedure as required by claim 21. *Id.* at 9–11 (citing PO Resp. 14; Ex. 1014, 53, 122, Fig. 3-15; Ex. 1015 ¶¶ IX.B.5). Petitioner argues that claim 21 does not require that the computer disable all operation, only patient infusion procedures. *Id.* at 11.

Regarding Patent Owner’s argument based on Klein’s manual entry of breakthrough results, Petitioner replies that Klein teaches that manual entry is not normally done, manual entry would still be consistent with Klein’s computer performing lockout, manual entry of breakthrough measurements would also ensure that the daily protocol is followed, and “automated breakthrough testing suffices in many cases,” thus operating as required by claim 21. *Id.* at 11–12 (citing Ex. 1014, 43, 64).

Petitioner also argues that Patent Owner’s declarant testimony that a calibration run would be successful even if high strontium breakthrough levels were detected is inconsistent with a plain reading of Klein and not credible. *Id.* at 12–13 (citing PO Resp. 16–18; Ex. 1014, Fig. 3-15; Ex. 2012, 981:22–983:9). Petitioner further argues that Klein’s breakthrough tests are completed successfully “only when test results show low strontium breakthrough.” *Id.* at 13 (citing Ex. 1014, 18, 29, 33, 44). Petitioner additionally argues that Klein’s software, not the operator, enables patient elution runs because Klein’s computer disables elutions each night and re-enables elutions only after breakthrough test results meet allowable limits. *Id.* (citing Ex. 1014, 29, 33, 44).

Patent Owner replies that “Petitioner’s case is predicated on reading into Klein something that does not exist – an express disclosure of the computer preventing patient infusions based on strontium breakthrough test results” and “rel[ies] on piecemeal quotations from Klein.” PO Sur-Reply 1 (citing Pet. Reply 7–8); *see also id.* at 2 (arguing that Petitioner “relies on

selectively excerpting the record and mere attorney argument”). Patent Owner also argues that its declarant provided testimony in the ITC proceeding regarding Klein’s breakthrough testing and that the testimony is unchallenged. *Id.* at 1–3 (citing Ex. 2012, 971:4–19, 1078:21–23).

Patent Owner contends that Klein does not disclose a computer preventing patient infusion if breakthrough test results exceed an allowable limit and “Petitioner conflates the issues by pointing to disclosures in Klein relating to whether/when the system is locked out due to expiration of system calibration, not due to breakthrough results exceeding an allowable limit.” *Id.* at 3 (citing PO Resp. 13–20; Pet. Reply 5–13). According to Patent Owner, Petitioner incorrectly contends that Patent Owner’s declarant agreed that Klein’s system is locked out until breakthrough testing is performed. *Id.* at 3–4 (citing Pet. Reply 7). Patent Owner argues that its declarant testimony is consistent with the portions of Klein relied upon by Petitioner. *Id.* at 4 (citing Pet. Reply 8; Ex. 1014, 17; Ex. 2012, 983:7–9; 982:25–983:6).

Patent Owner also argues that Petitioner misreads Klein’s statement that “[o]nly after a calibration run with low Sr breakthrough has been successfully completed can patient elutions be carried out” and Petitioner selectively quotes Klein. *Id.* at 4 (citing Pet. Reply 13; Ex. 1014, 18). Patent Owner asserts that none of the relied-upon portions of Klein expressly discloses a computer preventing infusion procedures based on breakthrough testing results. *Id.* at 4–5 (citing Pet. Reply 13; Ex. 1014, 44; Ex. 2003 ¶ 95). Patent Owner states that “there is no question that Klein requires that the calibration protocol is followed” but “Klein does not disclose that the computer prevents patient infusions if a strontium breakthrough test result exceeds an allowable limit.” *Id.* at 5 (citing Ex. 1014, 44).

Patent Owner further replies that Petitioner did not depose Patent Owner's declarant Dr. Pelc and relies on attorney arguments to contend that one of ordinary skill in the art would understand Klein discloses a computer preventing infusion procedures. *Id.* at 5–6 (citing Pet. Reply 8, 9). Patent Owner also argues that Petitioner implicitly admits that Klein does not disclose such a computer because Petitioner relies on declarant testimony. *Id.* at 6 (citing Pet. Reply 8; Ex. 1015 ¶ 252). Patent Owner likens Klein's disclosures to a CardioGen 510 User Manual, which does not disclose a computer performing breakthrough testing or preventing patient infusions. *Id.* at 6–7 (citing Ex. 1021, 31, 34–35). Patent Owner, thus, contends that Klein does not disclose a computer preventing infusions, as contended by Petitioner, but instead “teaches that the decision to perform patient infusions based on a strontium breakthrough test result is left to the operator.” *Id.* at 7 (citing Pet. Reply 7; Ex. 2003 ¶¶ 95–96).

Patent Owner also points to Klein's statement that “[i]f the eluted ⁸²Rb activity is insufficient to accurately measure breakthrough, the automatic measurement is skipped,” and argues that one of ordinary skill in the art would not have understood Klein to be disclosing that its computer prevents patient elutions when skipping the automatic measurement, or a requirement for manual entry when the skipping occurs. *Id.* at 7–8 (citing Pet. Reply 11; Ex. 1014, 52; Ex. 2012, 983:10–984:23).

Regarding Petitioner's argument that “if significant Sr activity is detected, ***the generator cannot be used on humans***,” Patent Owner contends that “Klein does not mention the computer preventing a patient infusion due to such significant Sr activity” but Klein supports Patent Owner's declarant's analysis that “the operator, not the computer, makes the decision.” *Id.* at 8 (citing Pet. Reply 11; Ex. 2003 ¶ 97).

(2) *Whether Klein Discloses a Computer Preventing a Patient Infusion Procedure if Strontium Activity Exceeds an Allowable Limit*

We find that Petitioner’s relied-upon portions of Klein disclose that (1) “[o]nce the daily protocol has been completed successfully, patient elutions are enabled until the end of the day” (Ex. 1014, 18); (2) the “amount of Sr breakthrough activity must be strictly limited to the Health Canada guidelines” (*id.* at 33); (3) “[t]his issue is addressed by daily breakthrough tests as part of the daily protocol ensured by the system” (*id.*); (4) the “⁸²Rb infusion system software must ensure that the protocol is followed (i.e. that each run is enabled only after the prerequisites have been completed successfully)” (*id.* at 44); (5) “it ensures that the daily protocol is followed, including a flush and calibration (including a test of breakthrough activity) at the start of each day” (*id.* at 55); and (6) “[d]aily calibration samples are used to test for the breakthrough of Sr activity; if significant Sr activity is detected, the generator cannot be used on humans” (*id.* at 122). *See also* Pet. 41–42 (citing Ex. 1014, 18, 33, 44, 55, 122; Ex. 1015 ¶¶ 239–241, 245–253).

We, thus, find that, because Klein’s software ensures the daily protocol is followed and patient elutions or runs are “**enabled**” once the daily protocol is completed successfully, one of ordinary skill in the art would have understood that Klein teaches a computer that is configured via software to prevent or not enable patient infusion if the daily protocol is not completed successfully. *See also* Ex. 1014, 17–18 (describing that the “protocol consists of a system flush and a calibration run” and that “[a]lthough the outline remains unchanged, the protocol was slightly

modified to remove operator intervention where automation was introduced”).

As for breakthrough testing, Klein expressly discloses that “Sr breakthrough . . . is tested for on a daily basis as part of the daily protocol” (Ex. 1014, 122), the “amount of Sr breakthrough activity must be strictly limited to the Health Canada guidelines” (*id.* at 33), and “[t]his issue is addressed by daily breakthrough tests as part of the daily protocol ensured by the system” (*id.*). We, thus, find that one of ordinary skill in the art would have understood that Klein discloses breakthrough testing is part of the daily protocol that must be completed successfully to enable patient elutions.

We also find that a relied-upon portion of Klein teaches that “[d]aily calibration samples are used to test for the breakthrough of Sr activity” and “if significant Sr activity is detected, the generator cannot be used on humans.” *Id.* at 122. As discussed above, we find that Klein discloses that it calculates ^{82}Sr and ^{85}Sr activities relative to ^{82}Rb activity during breakthrough testing. Thus, Klein expressly discloses that “if the activity of strontium-82 or the activity of strontium-85 exceeds an allowable limit,” that is, if significant Sr activity indicating breakthrough is detected, then the generator should not be used and, therefore, a patient infusion procedure will not be enabled.

Based on the full record, because Klein discloses software that ensures the daily protocol, which includes breakthrough testing, is followed and patient elutions are enabled only if the daily protocol is completed successfully, Petitioner persuades us by a preponderance of the evidence that Klein discloses the same or equivalent structure (Klein’s controller and computer) to that in the ’468 patent that performs the function of

“prevent[ing] the patient infusion procedure if the activity of strontium-82 or the activity of strontium-85 exceeds an allowable limit.”⁶

Turning to Patent Owner’s argument that an operator prevents infusions if breakthrough is detected, Petitioner persuades us that Klein’s software, not an operator, enables patient infusions only if the daily protocol, which includes breakthrough testing, is completed successfully. Also, Klein’s disclosures of manually entering breakthrough activity from a more sensitive instrument if such activity is not available from the dose calibrator, and Klein’s description of a breakthrough experiment, do not address if operator intervention is required when readings are available from the dose calibrator and when there is no breakthrough experiment.

During oral hearing, Patent Owner’s counsel argued that independent claim 21 recites four steps of measuring activity, calculating a strontium activity, comparing a strontium activity to an allowable limit, and preventing infusion if the strontium activity exceeds the limit. Tr. 47:4–48:18, 49:16–20, 73:17–20. Patent Owner’s counsel contended that Klein discloses a computer that performs the first step, automatically measuring activity, but not the other three steps. *See, e.g., id.* at 48:6–18, 58:8–16, 59:16–60:5,

⁶ Although the parties did not present or brief a broader interpretation, these limitations could be interpreted more broadly than implied by the parties’ arguments. For example, the limitation at issue does not exclude any and all operator intervention because a computer can still be configured to prevent a procedure even if additional operator action is required. *See* Tr. 19:15–20:16 (Petitioner’s counsel answering questions about possible broader interpretation), 48:19–49:15 (Patent Owner’s counsel answering questions about possible broader interpretation). For our analysis, because the parties dispute whether Klein’s computer, standing alone, prevents a procedure without operator intervention if a strontium activity exceeds an allowable limit, we have applied the parties’ implied, narrower interpretation.

60:14–61:17, 70:23–71:3. Petitioner’s counsel objected to these arguments because they were not the arguments previously presented. *See id.* at 73:17–20, 95:14–96:3.

We agree with Petitioner that Patent Owner did not assert explicitly in its authorized briefing that independent claim 21 requires four steps, only one of which is completed automatically. We view these arguments as beyond the scope of Patent Owner’s arguments in its briefing in this case, and thus, determine that these arguments were waived. Even if these arguments could be said to be within the scope of what was previously presented, we determine them to be unpersuasive, because Klein discloses software that ensures the daily protocol, which includes breakthrough testing, is followed and patient elutions are enabled only if the daily protocol is completed successfully. Thus, Petitioner persuades us by a preponderance of the evidence that one of ordinary skill in the art would have understood that Klein discloses a computer measuring activity, calculating a strontium activity, comparing a strontium activity to an allowable limit, and preventing infusion if the strontium activity exceeds the limit.

3. *Claim 23*

Claim 23 depends directly from claim 21 and recites:

wherein the shielding assembly is configured to further contain a waste reservoir and the infusion tubing circuit further includes a waste tubing line and a divergence valve, the waste tubing line being configured to provide fluid communication between the strontium/rubidium radioisotope generator and the waste reservoir via the divergence valve, and

the means for receiving activity data, receiving breakthrough activity data, and controlling the mobile radioisotope generator system is configured to control the divergence valve to direct eluate to the waste reservoir until the activity data indicates a threshold amount of radioactivity in the eluate, and, upon

receiving an indication that the eluate has the threshold amount of radioactivity, control the divergence valve to direct eluate to the means for receiving eluate from the eluate tubing line and calculating breakthrough activity within the eluate.

Ex. 1001, 26:17–34.

Petitioner argues that Klein discloses all the limitations of claim 23. Pet. 42–45 (citing Ex. 1014, 19, 41, 44–45, 63; Ex. 1015 ¶¶ 254–263).

We find that Figure 2-2 of Klein shows a “Waste Container” and a line between “⁸²Sr/⁸²Rb Generator” and “Waste Container” through a “Patient Valve.” Ex. 1014, 19. We also find that Figure 3-3 of Klein shows a line between “Point G Generator Output” and “Waste” through “Point P Patient Valve.” *Id.* at 41. As discussed above for claim 21, we determine that Klein discloses that “[a]lthough the generator and waste container are shielded by lead, the saline lines are a source of radiation during elutions.” *Id.* at 36.

At pages 44–45, we find that Klein describes a “general set of events” that is “common to most elutions” that includes a “generator flush . . . while the activity counter readings are monitored” and “[i]f a minimum threshold activity is not reached within a given time, the elution sequence is aborted.” According to Klein, in “Waiting for Threshold,” it “[e]lutes from generator to waste until the threshold activity is reached.” *Id.* at 63.

We further credit Petitioner’s declarant testimony regarding claim 23 because the relied-upon portions of Klein support that testimony. Ex. 1015 ¶¶ 254–263 (citing Ex. 1014, 19, 41, 44–45, 63). Patent Owner does not present any arguments specifically for claim 23. *See generally* PO Resp.; PO Sur-Reply.

Based on the full record, because Klein teaches a waste container, patient valve, and tubing between the valve, the waste container, and a

$^{82}\text{Sr}/^{82}\text{Rb}$ generator, and because Klein's computer acquires data from the dose calibrator for detecting breakthrough activity during which minimum activity must be reached during elution from generator to waste before eluting to a patient, Petitioner persuades us by a preponderance of the evidence that Klein discloses the limitations of claim 23.

E. Challenge Under 35 U.S.C. § 103(a)

As discussed above, the parties dispute whether Klein discloses all the limitations of independent claim 21. Patent Owner does not present any arguments specifically for dependent claim 22. *See generally* PO Resp.; PO Sur-Reply.

We conclude that Petitioner has shown by a preponderance of the evidence that Klein discloses all the limitations of claim 21; that Klein combined with Jackson and Hirschman teach or suggest each limitation of claim 22; that a person of ordinary skill in the art would have had a reason to combine Klein, Hirschman, and Jackson; and that a person of ordinary skill in the art would have had a reasonable expectation of success in combining those references. The parties do not present any objective evidence of nonobviousness.

1. Scope and Content of the Prior Art

Klein is discussed above.

a) Hirschman (Ex. 1022)

Hirschman relates to "methods and systems and associated components for the generation, preparation, transportation, and administration of fluid radiopharmaceutical substances to human . . . subjects." Ex. 1022 ¶ 3. Hirschman describes known infusion systems that include a generator of a strontium-rubidium radiopharmaceutical for use in diagnostic imaging procedures. *Id.* ¶¶ 9, 10. One embodiment relates to an

integrated radiopharmaceutical patient treatment system that includes a radiopharmaceutical fluid delivery system for infusing such a fluid into a patient and an integrated system controller operably associated with parts of the integrated radiopharmaceutical patient treatment system to control and coordinate their operations. *Id.* ¶ 22. Figure 3 of Hirschman is reproduced below.

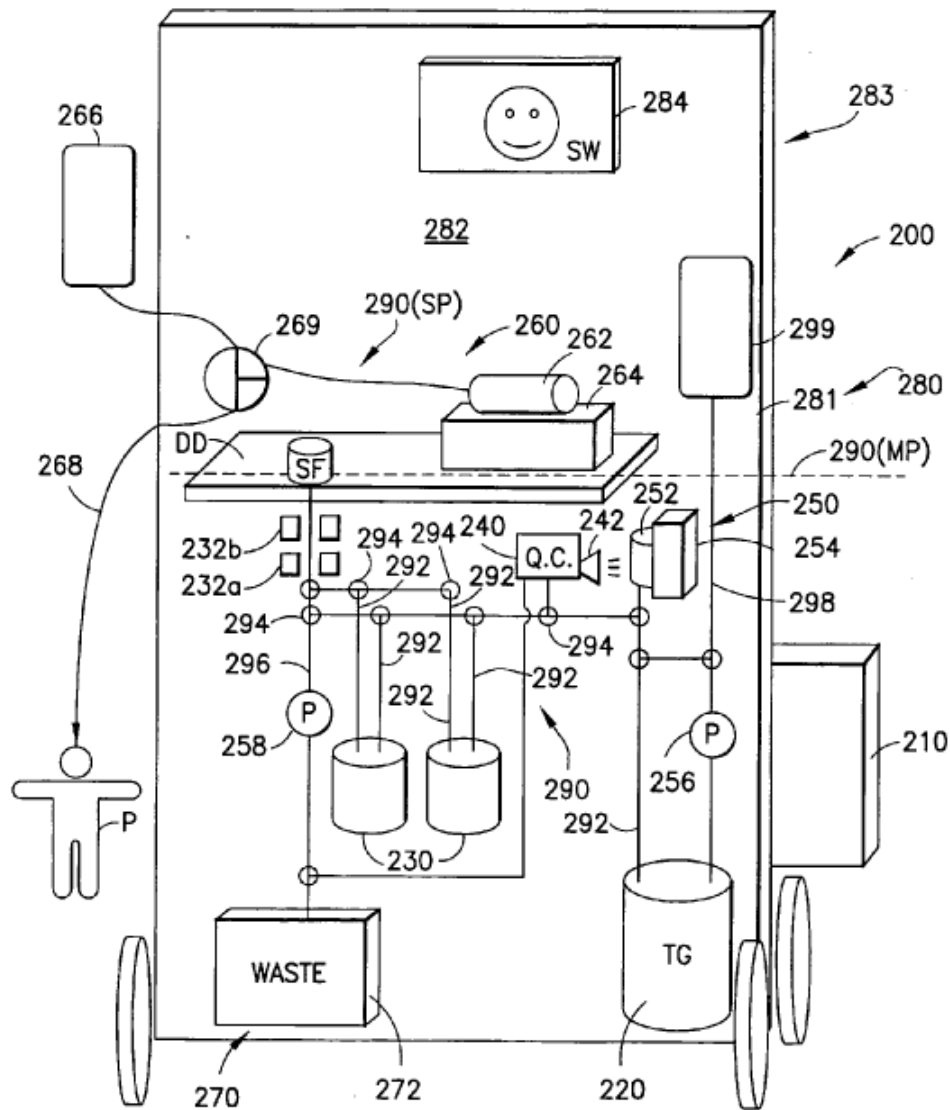


FIG.3

Figure 3 is a schematic representation of a radiopharmaceutical system that creates a radionuclide and processes it into a radiopharmaceutical that is delivered to a patient. *Id.* ¶ 39. Portable or mobile system 200 includes control computer 210, radionuclide generation module 220, patient administration/injection module or delivery area 260, and other subsystems or modules. *Id.* ¶¶ 121, 122, 126, 130.

Control computer 210 includes graphic user interface 212 (shown in Figures 4A–4B) and a label printer (not shown), RFID reading/writing subsystem (not shown), and a memory stick, such as a USB memory drive. *Id.* ¶¶ 123, 124, 142. For embodiments, in which “information is written as a bar code, stored on an RFID tag, written to a USB memory stick, or otherwise encoded and associated with a radiopharmaceutical container, patient injection module 260 . . . is designed to read the encoded information.” *Id.* ¶ 153.

Control computer 210 can also communicate with an information system to populate automatically and update “patient information, expected patient injection times, and radiopharmaceutical production schedules.” *Id.* ¶ 125. Hirschman states that “automatic population of patient information, expected patient injection times, and radiopharmaceutical production schedules” is “used to update the information in the HIS system” and “creates workflow efficiencies as well as eliminates steps which could otherwise lead to data entry errors” *Id.* Fluid delivery system control 1036 includes communications interface 1040 so that “communications connection may be made to an HIS (Hospital Information System)” and “procedure results and notes” are “communicated to physicians, patient records, and other appropriate systems.” *Id.* ¶ 187.

b) Jackson (Ex. 1023)

Jackson “relates generally to positron emission tomography.”

Ex. 1023 ¶ 2. It states that, “[i]n conventional positron emission tomography control systems, an individual dose of a premeasured radiotracer is administered to an individual patient.” *Id.* ¶ 3.

An example of Jackson’s apparatus “includes a control system that is operably coupled to the local area network, to receive status information from, and send commands to, any one of the device[s] in the system” and an injector system for a radiopharmaceutical. *Id.* ¶¶ 16, 17, 22, Fig. 4. Jackson indicates that, other than cyclotron 101, radioisotopes can be produced by a radioisotope generator and states that “[r]ubidium-82 is produced by a radioisotope generator.” *Id.* ¶ 34.

System 100 can include quality control unit 110 that “monitors the amount of radioactivity and other measures of quality” *Id.* ¶ 36; *see also id.* ¶¶ 36–38 (describing the functions and components of quality control unit 110). System 100 can also include control system 146 that “is operable to receive status information from and send commands to,” for example, quality control device 110, injector systems 122, 124, and computers 142, 144. *Id.* ¶ 48. According to Jackson, “a computer program in the control system 146 stores production and dosing data” and “system 100 provides for a more centralized storage of records in the preparation, delivery, monitoring and injection of radiotracers to patients, which reduces disjoint[ed] management and control of those functions that conventional systems exhibit.” *Id.* ¶ 50. Also, “computer 1202 can operate in a networked environment using logical connections to one or more remote computers” that can be a local-area network or wide-area network and

“[s]uch networking environments are commonplace in offices, enterprise-wide computer networks, intranets, and the Internet.” *Id.* ¶ 135.

2. *Claim 22*

Claim 22 depends directly from claim 21 and recites “wherein the means for receiving activity data, receiving breakthrough activity data, and controlling the mobile radioisotope generator system is configured to electronically transfer quality control test information and infusion information to one or more remote computers.” Ex. 1001, 26:11–16.

Petitioner argues that Klein, Hirschman, and Jackson teach the limitations of claim 22. Pet. 51–53 (citing Ex. 1014, 17, 26; Ex. 1015 ¶¶ 264–287; Ex. 1022 ¶¶ 125, 187; Ex. 1023 ¶¶ 48–50, 136, Fig. 1).

As discussed above, based on the full record, Petitioner persuades us by a preponderance of the evidence that Klein discloses all the limitations of claim 21, from which claim 22 depends.

We also find that the relied-upon portions of Hirschman teach that its “[c]ontrol computer 210 is also optionally configurable to communicate with an imaging suite’s information system, for example, an HIS system . . . to update the information in the HIS system with actual injection times, volumes, and activity levels, along with any observations during the procedure” (Ex. 1022 ¶ 125), its fluid delivery system control 1036 includes communications interface 1040 so that “communications connection may be made to an HIS (Hospital Information System)” (*id.* ¶ 187), and “procedure results and notes” are “communicated to physicians, patient records, and other appropriate systems” (*id.*).

We further find that the relied-upon portions of Jackson teach that its “system 100 includes a control system 146” that “is operable to receive status information from . . . quality control device 110” (Ex. 1023 ¶ 48) and

that has a computer program for “stor[ing] production and dosing data” so that “system 100 provides for a more centralized storage of records in the preparation, delivery, monitoring and injection of radiotracers to patients” (*id.* ¶ 50).

We additionally credit Petitioner’s declarant testimony regarding claim 22 because the record supports it. Ex. 1015 ¶¶ 264, 277–287 (citing Ex. 1014, 17, 26; Ex. 1022 ¶¶ 125, 187; Ex. 1023 ¶¶ 48–50, 136, Fig. 1). Patent Owner does not provide arguments specifically for claim 22. See *generally* PO Resp.; PO Sur-Reply; see *also* Pet. Reply 2 (stating that “Bracco makes no specific challenge to Ground 2”), 15 (stating that “Bracco presented no argument to Ground 2”).

Based on the full record before us, because Hirschman teaches a computer communicating infusion procedure data to another information system and Jackson teaches receiving and storing information from a quality control device, we determine that Klein, Hirschman, and Jackson teach the limitations of claim 22.

a) Reason to Combine the References

Petitioner argues that “Klein, Jackson, and Hirschman are all directed to similar subject matter.” Pet. 46 (citing Ex. 1014, 26; Ex. 1015 ¶ 266; Ex. 1022 ¶¶ 18–20; Ex. 1023 ¶¶ 13, 50). Petitioner also argues that Hirschman provides explicit motivation for transferring electronic information to remote computers so as to create workflow efficiencies and minimize data entry errors. *Id.* at 46–47 (citing Ex. 1015 ¶¶ 267, 268; Ex. 1022 ¶¶ 124, 125, 142). Petitioner further argues that Jackson teaches that networking environments allow remote control and monitoring of infusion systems. *Id.* at 47 (citing Ex. 1015 ¶ 269; Ex. 1023 ¶¶ 134–136).

According to Petitioner, electronic data provides numerous, recognized advantages, such as improving reliability, privacy, security, and protection. *Id.* at 47–48 (citing Ex. 1015 ¶ 270). Petitioner also asserts that “[i]t would have been routine . . . to consider alternatives to paper record keeping” related to infusion systems, and information in machine readable formats were well known. *Id.* at 48–49 (citing Ex. 1014, 29, 31; Ex. 1015 ¶ 271; Ex. 1021, 23–24, 34–38; Ex. 1022 ¶¶ 83, 124, 238).

Petitioner, thus, argues that one of ordinary skill in the art would have been motivated to automate Klein’s record keeping to transfer automatically electronic records and thus improve reliability, redundancy, resistance to single-aspect failure, protection of information through backup features, and accuracy. *Id.* at 49–50 (citing Ex. 1015 ¶ 275). Petitioner also argues that accurate record keeping “would be routine to a [person of ordinary skill in the art] developing human use medical devices for radiopharmaceuticals at the time under the applicable regulatory frameworks.” *Id.* at 50 (citing Exs. 1028–1031). Petitioner further argues that “there is nothing to suggest that a [person of ordinary skill in the art] would not have a reasonable expectation of success in combining these teachings to improve the record keeping process associated with Klein’s infusion system.” *Id.*

Patent Owner does not provide arguments regarding Petitioner’s asserted reason to combine the references to arrive at claim 22. *See generally* PO Resp.; PO Sur-Reply; *see also* Pet. Reply 2 (stating that “Bracco makes no specific challenge to Ground 2”), 15 (stating that “Bracco presented no argument to Ground 2”).

Based on the full record, we agree with Petitioner that these references are directed to similar subject matter. Ex. 1014, 26; Ex. 1022 ¶¶ 18–20; Ex. 1023 ¶¶ 13, 50. Petitioner also persuades us by a preponderance of the

evidence that one of ordinary skill in the art would have been motivated to combine the references to increase workplace efficiencies, reduce data loss, and increase reliability based on Hirschman and Jackson. Ex. 1022 ¶ 125 (stating that “automatic population of patient information, expected patient injection times, and radiopharmaceutical production schedules” is “used to update the information in the HIS system” and “creates workflow efficiencies as well as eliminates steps which could otherwise lead to data entry errors”); Ex. 1023 ¶ 135 (stating that “computer 1202 can operate in a networked environment using logical connections to one or more remote computers” that can be a local-area network or wide-area network and “[s]uch networking environments are commonplace in offices, enterprise-wide computer networks, intranets, and the Internet”).

We also determine that, based on Hirschman and Jackson, one of ordinary skill in the art would have had a reasonable expectation of success in making Petitioner’s proposed combination. We additionally credit Petitioner’s declarant testimony regarding the reason to combine because the record supports it. Ex. 1015 ¶¶ 265–275 (citing Ex. 1014, 26, 29, 31; Ex. 1021, 23–24, 34–38; Ex. 1022 ¶¶ 18–20, 124, 125, 142; Ex. 1023 ¶¶ 13, 50, 134–136; Ex. 1025 ¶¶ 75, 205, 235, 240–241; Ex. 1038, ix, 5–6, 21).

3. Objective Evidence of Nonobviousness

Petitioner states that it “is unaware of any secondary considerations evidence involving the subject matter of claim 22” and “unaware of any long felt need, skepticism by others or objective evidence that would suggest the electronic record keeping and data transfer of claim 22 is somehow non-obvious.” Pet. 50; Ex. 1015 ¶ 276. Patent Owner does not present any

objective evidence of nonobviousness. *See generally* PO Resp.; PO Sur-Reply.

4. *Weighing the Graham Factors*

“Once all relevant facts are found, the ultimate legal determination [of obviousness] involves weighing of the fact findings to conclude whether the claimed combination would have been obvious to an ordinary artisan.”

Arctic Cat Inc. v. Bombardier Recreational Prods. Inc., 876 F.3d 1350, 1361 (Fed. Cir. 2017) (quoting *In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*, 676 F.3d 1063, 1068–69 (Fed. Cir. 2012)).

Above, based on full record before us, we provide our factual findings regarding (1) the level of ordinary skill in the art, (2) the scope and content of the prior art, (3) any differences between the claimed subject matter and the prior art, and (4) objective evidence of nonobviousness.

In particular, we find that (1) Petitioner’s proposed level of ordinary skill in the art is consistent with the prior art of record, (2) Klein, Hirschman and Jackson teach all the limitations of claim 22, (3) one of ordinary skill in the art would have had a reason to modify Klein in view of Hirschman and Jackson with a reasonable expectation of success, and (4) there is no objective evidence of nonobviousness in the record. Weighing these underlying factual determinations, a preponderance of the evidence persuades us that claim 22 of the ’468 patent is unpatentable over Klein, Hirschman, and Jackson.

F. *Patent Owner’s Remaining Arguments*

Petitioner describes what it believes the *CardioGen-82 Infusion System User’s Guide* (rev. 07, 2004) from Bracco Diagnostics Inc. (Ex. 1021, “Bracco Manual”) discloses. Pet. 25–29. Petitioner also lists the Bracco Manual as one of the references asserted against the challenged

claims. *Id.* at 31. The Bracco Manual, however, is not specifically relied upon in the challenges to claims 21–23. *See id.* at 32–53.

Patent Owner presents arguments that the Bracco Manual does not qualify as a printed publication. PO Resp. 20 (citing Pet. 25–29, 31); PO Sur-Reply 8–10. Because our analysis of Petitioner’s challenges to claims 21–23 does not rely on the Bracco Manual, we do not need to reach in this proceeding whether the Bracco Manual qualifies as a printed publication. *See also* Pet. Reply 15 (stating that “Bracco’s criticisms of the Bracco Manual (Ex. 1021) . . . go to no material issue remaining in dispute”); PO Sur-Reply 8–10 (arguing that Petitioner has provided no evidence that the Bracco Manual is a printed publication and, thus, it does not indicate the background knowledge possessed by the ordinarily skilled artisan in 2008).

III. CONCLUSION⁷

In summary:

Claims	35 U.S.C. §	Reference(s)/Basis	Claims Shown Unpatentable	Claims Not shown Unpatentable
21, 23	102(b)	Klein	21, 23	
22	103(a)	Klein, Hirschman, Jackson	22	
Overall Outcome			21–23	

⁷ Should Patent Owner wish to pursue amendment of the challenged claims in a reissue or reexamination proceeding subsequent to the issuance of this decision, we draw Patent Owner’s attention to the April 2019 *Notice Regarding Options for Amendments by Patent Owner Through Reissue or Reexamination During a Pending AIA Trial Proceeding*. *See* 84 Fed. Reg. 16,654 (Apr. 22, 2019). If Patent Owner chooses to file a reissue application or a request for reexamination of the challenged patent, we remind Patent Owner of its continuing obligation to notify the Board of any such related matters in updated mandatory notices. *See* 37 C.F.R. § 42.8(a)(3), (b)(2).

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that claims 21–23 of U.S. Patent No. 9,299,468 B2 have been shown, by a preponderance of the evidence, to be unpatentable; and

FURTHER ORDERED that, because this is a Final Written Decision, the parties to the proceeding seeking judicial review of the decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

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Patent 9,299,468 B2

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