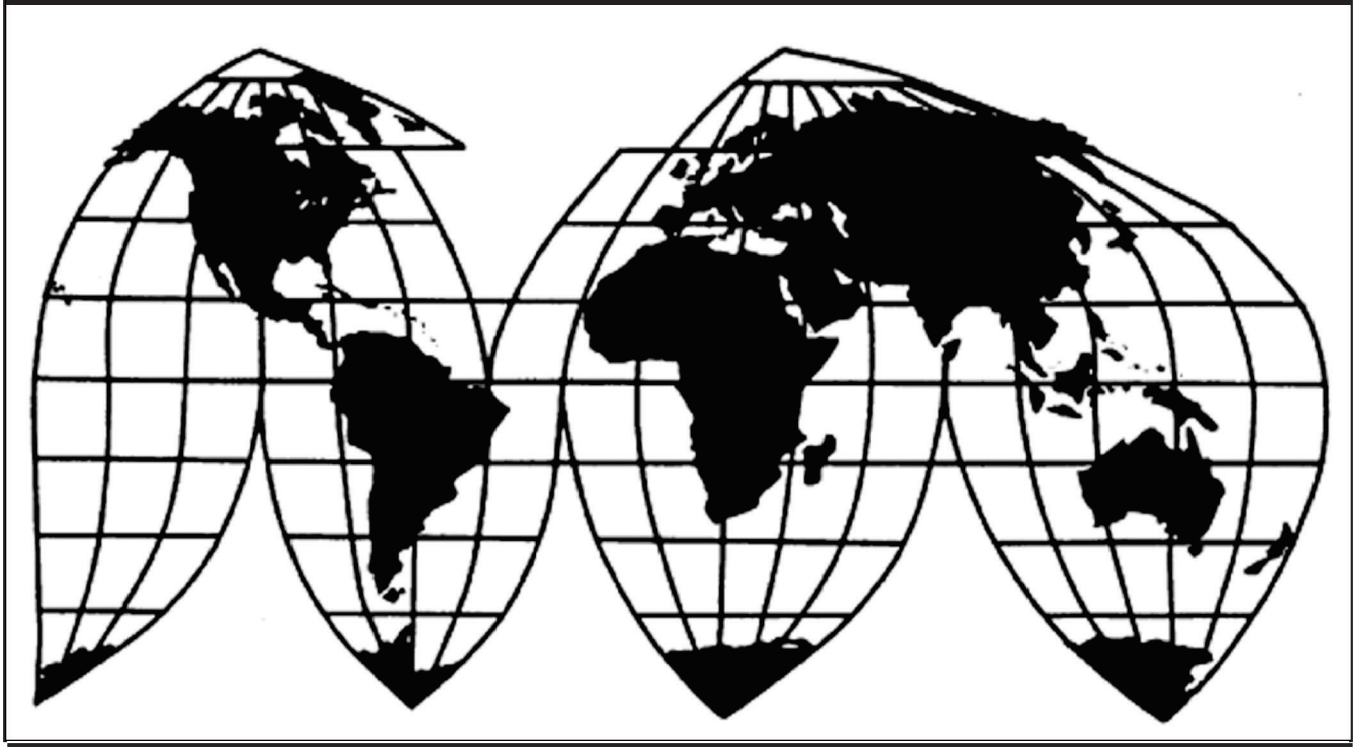
In the Matter of

CERTAIN STRONTIUM-RUBIDIUM RADIOISOTOPE INFUSION SYSTEMS, AND COMPONENTS THEREOF INCLUDING GENERATORS

337-TA-1110

Publication 5025 **February 2020**

U.S. International Trade Commission



Washington, DC 20436

U.S. International Trade Commission

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UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.

In the Matter of **CERTAIN STRONTIUM-RUBIDIUM RADIOISOTOPE INFUSION SYSTEMS, AND COMPONENTS THEREOF INCLUDING GENERATORS**	**Investigation No. 337-TA-1110**

NOTICE OF COMMISSION FINAL DETERMINATION OF NO VIOLATION OF SECTION 337; TERMINATION OF THE INVESTIGATION

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined to affirm with modification a final initial determination ("FID") of the presiding administrative law judge ("ALJ") finding no violation of section 337 of the Tariff Act of 1930, as amended. The investigation is terminated.

FOR FURTHER INFORMATION CONTACT: Houda Morad, Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone (202) 708-4716. Copies of non-confidential documents filed in connection with this investigation are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW., Washington, D.C. 20436, telephone (202) 205-2000. General information concerning the Commission may also be obtained by accessing its Internet server at *https://www.usitc.gov*. The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov*. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205-1810.

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation on May 1, 2018, based on a complaint, as amended, filed by Bracco Diagnostics Inc. of Monroe Township, New Jersey ("Bracco"). *See* 83 FR 19112 (May 1, 2018). The complaint, as amended, alleges violations of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337) ("section 337"), based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain strontium-rubidium radioisotope infusion systems, and components thereof including generators, by reason of infringement of U.S. Patent Nos. 9,814,826; 9,750,869; and 9,750,870 (collectively, "the asserted patents"). *See id.* The notice of investigation names Jubilant DraxImage Inc. of Kirkland, Québec, Canada; Jubilant Pharma Limited of Singapore; and Jubilant Life Sciences of Noida, Uttar Pradesh, India (collectively, "Respondents" or "Jubilant") as respondents in this

investigation. *See id.* The Office of Unfair Import Investigations is also a party to this investigation. *See id.*

On February 8, 2019, the ALJ issued an initial determination ("ID") (Order No. 27) finding by summary determination that Jubilant's RUBY Rubidium Elution System Version 3.0 directly infringes the asserted patents. *See* Order No. 27 (Feb. 8, 2019), *unreviewed*, Comm'n Notice (Mar. 8, 2019). In addition, the ID determines that Jubilant's RUBY Rubidium Elution System Version 3.1 and the RUBY Rubidium Elution System Version 4 do not directly infringe the asserted patents. *See id.* The ID (Order No. 27) declines to reach indirect infringement on summary determination. *See id.*

The ALJ conducted an evidentiary hearing on February 11-12 and 15-17, 2019, and on August 1, 2019, issued the FID finding no violation of section 337. Specifically, the FID finds that the domestic industry requirement is satisfied and that all the asserted claims are infringed but invalid as obvious over the prior art. The FID also contains the ALJ's Recommended Determination ("RD") recommending, should the Commission find a section 337 violation, that the Commission issue a limited exclusion order ("LEO") barring entry of articles that infringe the asserted claims. The RD does not recommend that the Commission issue a cease and desist order or impose a bond during the period of Presidential review. Furthermore, as directed by the Commission, the RD provides findings with respect to the public interest and recommends a determination that the public interest factors do not preclude entry of the proposed LEO.

On August 14, 2019, both Bracco and the Commission's Investigative Attorney ("IA") filed petitions for review of the FID. Bracco petitioned for review of the FID's findings with respect to invalidity, while the IA petitioned for review of the FID's findings with respect to domestic industry. On August 22, 2019, the parties filed responses to the respective petitions.

On September 30, 2019, the Commission determined to review the FID in part with respect to invalidity and domestic industry. *See* 84 FR 53177 (Oct. 4, 2019). The Commission determined not to review the remainder of the FID. *See id.*

Having considered the FID, the parties' petitions, responses thereto, and the record in this investigation, the Commission has determined to affirm with modification the FID's findings and conclusion of no violation of section 337. Specifically, as explained in the Commission Opinion issued concurrently herewith, 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. The Commission has further determined to affirm in part and vacate in part the FID's findings with respect to the domestic industry requirement. All findings in the FID that are not inconsistent with the Commission's final determination are affirmed. The investigation is terminated except with respect to the declassification proceeding presently before the Commission.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.

Lisa R. Barton
Secretary to the Commission

Issued: December 2, 2019

CERTAIN STRONTIUM-RUBIDIUM RADIOISOTOPE INFUSION SYSTEMS, AND COMPONENTS THEREOF INCLUDING GENERATORS

Inv. No. 337-TA-1110

PUBLIC CERTIFICATE OF SERVICE

I, Lisa R. Barton, hereby certify that the attached **NOTICE** has been served by hand upon the Commission Investigative Attorney, **Brian Koo, Esq.**, and the following parties as indicated, on **December 2, 2019**.

Lisa R. Barton, Secretary
U.S. International Trade Commission
500 E Street, SW, Room 112
Washington, DC 20436

On Behalf of Complainant Bracco Diagnostics Inc.:

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☒ Via Express Delivery
☐ Via First Class Mail
☐ Other:_____

On Behalf of Respondents Jubilant DraxImage Inc., Jubilant Pharma Limited, and Jubilant Life Sciences:

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PUBLIC VERSION

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.

In the Matter of **CERTAIN STRONTIUM-RUBIDIUM RADIOISOTOPE INFUSION SYSTEMS, AND COMPONENTS THEREOF INCLUDING GENERATORS**	**Inv. No. 337-TA-1110**

COMMISSION OPINION

On August 1, 2019, the presiding Administrative Law Judge ("ALJ") in the above-identified investigation issued a final initial determination ("FID") finding no violation of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337 ("section 337"). Having considered the FID, the parties' petitions, responses thereto, and the record in this investigation, the Commission has determined to affirm with modification the FID's findings and ultimate conclusion of no violation of section 337. Specifically, the Commission has determined to affirm the FID's conclusion with respect to the invalidity of the asserted claims and supplements the FID's findings on that issue. In addition, the Commission has determined to affirm in part and vacate in part the FID's findings with respect to the domestic industry requirement. All findings in the FID that are consistent with this opinion are affirmed.

I. BACKGROUND

A. Procedural Background

The Commission instituted this investigation on May 1, 2018, based on a complaint, as amended, filed by Bracco Diagnostics Inc. ("Bracco") of Monroe Township, New Jersey. *See* 83 *Fed. Reg.* 19112 (May 1, 2018). The complaint, as amended, alleges violations of section 337 based upon the importation into the United States, the sale for importation, and the sale

within the United States after importation of certain strontium-rubidium radioisotope infusion systems, and components thereof including generators, by reason of infringement of claims 1-3, 5, 9-14, 17-19, 26, and 28 of U.S. Patent No. 9,814,826 ("the '826 patent") (JX-1); claims 1-5, 8, 14, 24, and 27-30 of U.S. Patent No. 9,750,869 ("the '869 patent") (JX-2); and claims 1, 2, 8-13, 16, 17, 22, and 27 of U.S. Patent No. 9,750,870 ("the '870 patent") (JX-3) (collectively, "Asserted Patents"). *See id.* The notice of investigation names Jubilant DraxImage Inc. of Kirkland, Québec, Canada; Jubilant Pharma Limited of Singapore; and Jubilant Life Sciences of Noida, Uttar Pradesh, India (collectively, "Jubilant") as respondents in this investigation. *See id.* The Office of Unfair Import Investigations is also a party to this investigation. *See id.*

On August 8, 2018, the Commission partially terminated the investigation as to claims 10 and 26 of the '826 patent, claims 27 and 28 of the '869 patent, and claims 9 and 22 of the '870 patent based on the withdrawal of the allegations pertaining to those claims. *See* Order No. 15 (Aug. 8, 2019), *unreviewed*, Comm'n Notice (Sept. 6, 2019). On September 4, 2018, the ALJ partially terminated the investigation as to claim 13 of the '870 patent based on the withdrawal of the allegations pertaining to that claim. *See* Order No. 18 (Sept. 4, 2019), *unreviewed*, Comm'n Notice (Sept. 26, 2019).[1]

On February 8, 2019, the ALJ issued an ID (Order No. 27) granting Bracco's motion for summary determination that Jubilant's RUBY Rubidium Elution System Version 3.0 ("the Version 3 product") infringes the Asserted Patents. *See* Order No. 27 (Feb. 8, 2019), *unreviewed*, Comm'n Notice (Mar. 8, 2019). In addition, the ID grants Jubilant's motion for summary determination that Jubilant's RUBY Rubidium Elution System Version 3.1 ("the

[1] Hereinafter, "Asserted Claims" means claims 1-3, 5, 9, 11-14, 17-19, and 28 of the '826 patent, claims 1-5, 8, 14, 24, and 29-30 of the '869 patent, and claims 1, 2, 8, 10-12, 16, 17, and 27 of the '870 patent.

Version 3.1 product") and the RUBY Rubidium Elution System Version 4 ("the Version 4 product") do not directly infringe the Asserted Patents. *See id.* The ID (Order No. 27) declines to reach indirect infringement on summary determination. *See id.* at 20.

The ALJ conducted an evidentiary hearing on February 11-12 and 15-17, 2019, and on August 1, 2019, issued the FID finding no violation of section 337. Specifically, the FID finds that the domestic industry requirement is satisfied and that all the Asserted Claims are infringed but invalid as obvious over the prior art. In addition, the FID also contains the ALJ's recommended determination ("RD"), recommending, should the Commission find a violation of section 337, that the Commission issue a limited exclusion order ("LEO") barring entry of articles that infringe the Asserted Claims. However, the RD recommends delaying the effective date of the LEO by 12 months to allow sufficient time for facilities with infringing systems to switch to other models. The RD does not recommend that the Commission issue a cease and desist order ("CDO") or impose a bond during the period of Presidential review. Furthermore, as directed by the Commission, the RD provides findings with respect to the public interest and recommends a determination that the public interest factors do not preclude entry of the recommended remedy.

On August 14, 2019, both Bracco and the Commission's Investigative Attorney ("IA") filed petitions for review of the FID.[2] Bracco petitioned for review of the FID's findings with

[2] *See* Complainant Bracco Diagnostics Inc.'s Petition for Review of Initial Determination (hereinafter, "Bracco's Pet."); Office of Unfair Import Investigations' Petition for Review of the Final Initial Determination (hereinafter, "IA's Pet.").

respect to invalidity while the IA petitioned for review of the FID's findings with respect to domestic industry. On August 22, 2019, the parties filed responses to the petitions.[3]

On September 30, 2019, the Commission issued a notice determining to review the FID in part. *See* 84 *Fed. Reg.* 53177 (Oct. 4, 2019). Specifically, the Commission determined to review the FID's findings with respect to invalidity and domestic industry.

B. The Asserted Patents

The Asserted Patents are related and share the same specification. The Asserted Patents issued between September 5 and November 14, 2017.[4] *See* FID at 4. The Asserted Patents, titled "Integrated Strontium-Rubidium Radioisotope Infusion Systems," relate to computer-assisted medical devices that generate and infuse radiopharmaceuticals (*e.g.*, rubidium-82 or Rb-82) into a patient. *See* JX-1, '826 patent at Abstract, 1:27-30. The infused dose of radiopharmaceutical is absorbed by the cells of a target organ of the patient and emits radiation, which is detected by positron emission tomography ("PET"), thereby generating an image of the organ. *See id.* at 1:35-42.

For example, the common specification explains that:

> [C]ircuit **300** includes: an eluant reservoir **15**, for example, a bag, bottle or other container, containing saline as the eluant, . . . ; a syringe pump **33**, for pumping the eluant from reservoir **15**, and a pressure syringe **34** (or other device or sensor), for monitoring pumping pressure; a filter **37**, which may also serve as a bubble trap,

---

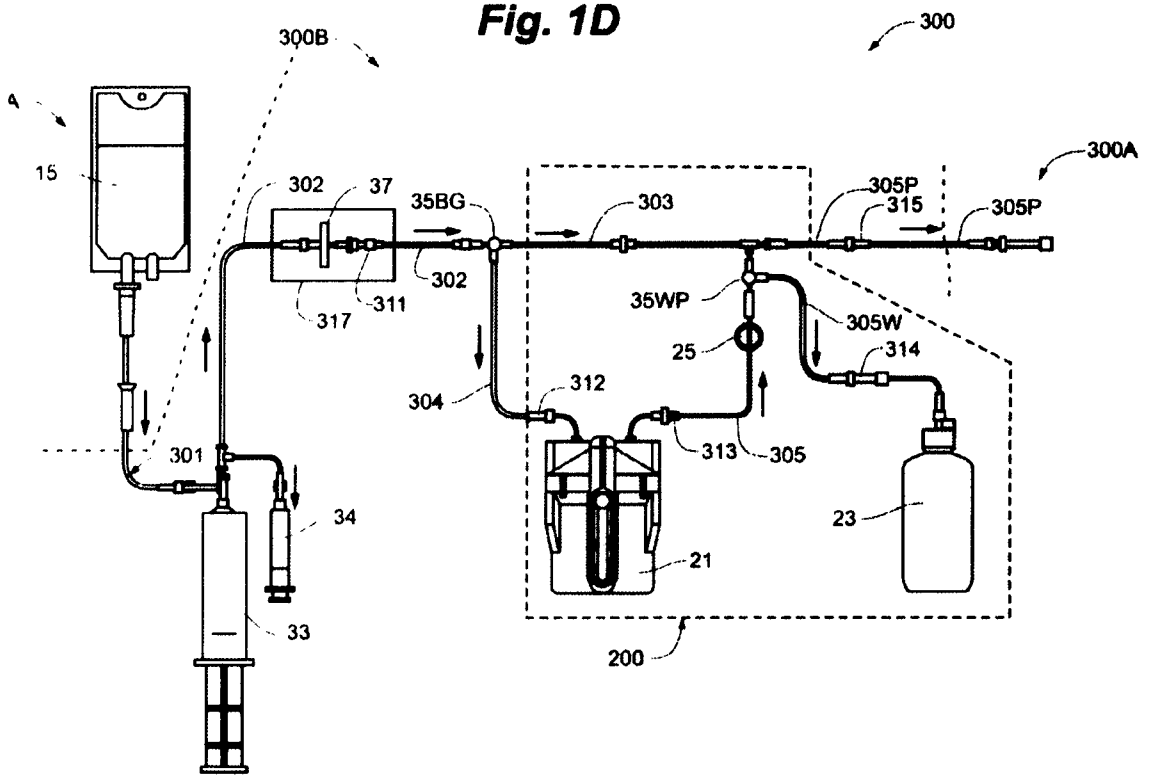
[3] *See* Complainant Bracco Diagnostics Inc.'s Response to Office of Unfair Import Investigations' Petition for Review of Initial Determination (hereinafter, "Bracco's Resp."); Respondents' Response to Complainant's Petition for Review (hereinafter, "Jubilant's Resp."); Office of Unfair Import Investigations' Response to Complainant's Petition for Review of the Final Initial Determination (hereinafter, "IA's Resp.").

[4] On their face, the earliest priority date of the Asserted Patents appears to be June 11, 2008. However, the parties agree that the relevant priority date for all three patents is June 11, 2009. Jubilant argued for a later priority date in the context of an invalidity (anticipation) challenge but the FID rejected that challenge and determined that the priority date of the Asserted Patents was indeed June 11, 2009. *See* FID at 122-25. Jubilant did not petition for review of the finding.

> for the pumped eluant; a radioisotope generator **21**, through which the filtered eluant is pumped to create a radioactive eluate, for example an eluate carrying Rubidium-82 that is generated by the decay of Strontium-82, via elution, within a column of generator **21**; and an activity detector **25**, for measuring the activity of the eluate discharged from generator **21**, in order to provide feedback for directing the flow of the eluate, via a divergence valve **35WP**, either to a waste bottle **23** or through a patient line **305p**, for example, to inject a dose of the radiopharmaceutical eluate into a patient."

See id. at 5:3-20, Figure 1D (reproduced below).[5]

Fig. 1D



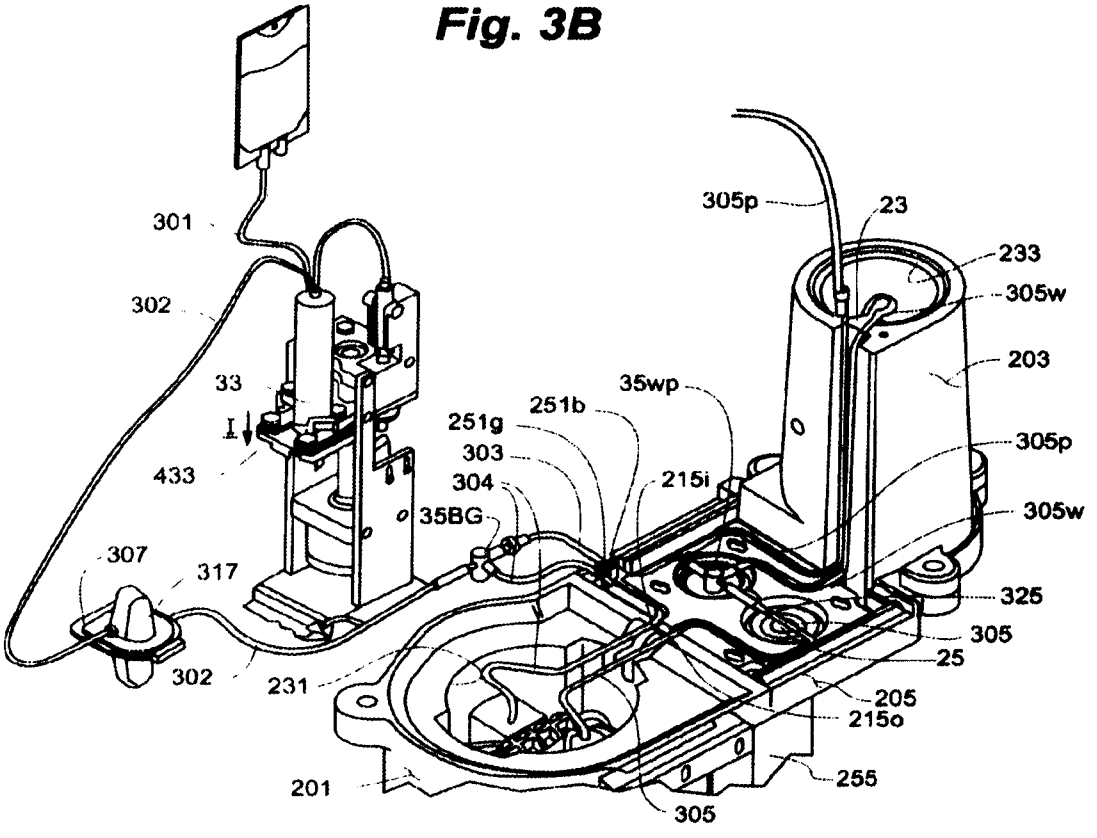
The specification also states that "circuit **300** [can be] expanded to include elements for an automated collection of eluate samples for activity measurements, via the on board dose calibrator." *See id.* at 8:13-16. The specification explains that "a sample collection reservoir

[5] As noted in the FID, "[a]s the generator ages, strontium starts to detach from the column and contaminate the eluate, posing a risk to patient health" (known as "strontium breakthrough"). To prevent any patient exposure from strontium breakthrough, operators must perform frequent quality-control checks on the generator. *See* FID at 7.

[can be] integrated into circuit **300**, downstream of divergence valve **35WP** and in communication with tubing line **305P**, in order to receive quality control test samples of eluate, via tubing line **305P**, and both the reservoir and the dose calibrator are located in a separate shielded well." *See id.* at 8:17-23.

The specification further explains that "[a]ctivity detector **25** is mounted in a shielded well **255** that extends downward from opening **325** (shown in FIG. 3B, reproduced below), and, with reference to FIG. 3B, tubing line **305** passes over opening **325** so that detector **25** can detect an activity of the eluate, which passes therethrough." *See id.* at 12:21-25.

Fig. 3B



The Asserted Claims recite a method or a system relating to a strontium-rubidium infusion system "on-board" a cart. *See, e.g.*, '826 patent at claim 1 (reproduced below). In particular, the system is configured to "determine a strontium breakthrough test result on [a] sample of the rubidium radioactive eluate filled into the eluate reservoir in the shielded well on-

board the cart while the eluate reservoir remains in the shielded well onboard the cart" and "not allow a patient infusion if the strontium breakthrough test result is greater than or equal to an allowed limit." *See id.*

Claims 1, 9, and 13 of the '826 patent are representative and recite (with disputed limitations in bold):

> **1.** A method of building an infusion system to deliver a rubidium radioactive eluate comprising:
>
> installing a ***first shielding compartment***,[6] a second shielding compartment, and a ***shielded well***[7] on a platform of a cart, wherein:
>
> the ***first shielding compartment*** has a first opening facing vertically upwardly,
>
> the first opening is configured for a strontium-rubidium radioisotope generator to be inserted into and removed from the first shielding compartment,
>
> the second shielding compartment has a second opening facing vertically upwardly,
>
> the second opening is configured for a waste bottle to be inserted into and removed from the second shielding compartment,
>
> ***the first opening is located at a lower elevation than the second opening***,[8] and
>
> the shielded well is configured to receive an eluate reservoir that is configured to receive a sample of the rubidium radioactive eluate;
>
> ***configuring a computer*** with a touch screen display for the infusion system to:
>
> ***fill the eluate reservoir in the shielded well on-board the cart with the sample of the rubidium radioactive eluate*** by pumping saline from a saline reservoir into the strontium-rubidium radioisotope generator via a saline tubing line thereby generating the rubidium radioactive eluate that is discharged through an eluate tubing line,
>
> ***determine a strontium breakthrough test result*** on the sample of the rubidium radioactive eluate filled into the eluate reservoir in the shielded well on-board the cart while the eluate reservoir remains in the ***shielded well onboard the cart, and not allow a***

[6] The "first shielding compartment" element is referred to, hereinafter, as "claim limitation (i)."

[7] The "shielded well" element is referred to, hereinafter, as "claim limitation (ii)."

[8] The element reciting "the first opening [] located at a lower elevation than the second opening" element is referred to, hereinafter, as "claim limitation (iii)."

patient infusion if the strontium breakthrough test result is greater than or equal to an allowed limit.[9]

9. The method of claim 2, further comprising configuring the computer to:

present on the touch screen display a screen for starting the patient infusion by touching a button on the touch screen display;

present on the touch screen display a screen reminding a user to insert the eluate reservoir in the shielded well on-board the cart;

present on the touch screen display a screen indicating that the patient infusion is in process, wherein the screen indicating that the patient infusion is in process displays a stop button to abort the patient infusion; and

present on the touch screen display the strontium breakthrough test result.[10]

13. The method of claim 12, wherein the infusion system is configured for the saline tubing line and the eluate tubing line to be routed through ***two tubing passageways formed in a perimeter surface of the first opening, wherein each of the two tubing passageways has a depth configured to prevent pinching or crushing of a corresponding tubing line routed therethrough when a first door is closed over the first opening.***[11]

An additional disputed limitation appears in claim 1 of the '869 patent which recites "[a]n infusion system on-board a cart comprising . . . ***an opening through the exterior shell*** configured to provide access to the strontium-rubidium radioisotope generator," "***a first door*** accessible via the opening through the exterior shell, the first door being configured to provide

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[9] The element reciting "configuring a computer . . . to fill the eluate reservoir . . . with the sample of the rubidium radioactive eluate, . . . determine a strontium breakthrough test result, . . . and not allow a patient infusion if the strontium breakthrough test result is greater than or equal to an allowed limit" is referred to, hereinafter, as "claim limitation (iv)."

[10] The elements reciting "present on the touch screen display a screen reminding a user to insert the eluate reservoir in the shielded well on-board the cart . . . and present on the touch screen display the strontium breakthrough test result it" are referred to, hereinafter, as "claim limitation (vii)."

[11] The element reciting "two tubing passageways formed in a perimeter surface of the first opening, wherein each of the two tubing passageways has a depth configured to prevent pinching or crushing of a corresponding tubing line routed therethrough when a first door is closed over the first opening" is referred to, hereinafter, as "claim limitation (v)."

access to the first shielding compartment and to close over the first opening," and "***a second door*** accessible via the opening through the top surface of the exterior shell, the second door being configured to provide access to the second shielding compartment and to close over the second opening."[12] *See* JX-2, '869 patent at 24:24-25:33. The '870 patent also recites several disputed claim limitations which are cumulative of the limitations discussed above.

C. Bracco's Domestic Industry Products

As noted in the FID, the domestic industry product is Bracco's CardioGen 1700 rubidium infusion system ("Model 1700").[13] *See* FID at 8. There is no dispute that the CardioGen1700 practices at least one claim of each of the Asserted Patents and thus satisfies the domestic industry requirement as to the "article[s]" protected by the patents. *See id.* at 128-29. The FID further determines that Bracco's investments with respect to the articles protected by the asserted patents are sufficient to satisfy the domestic industry requirement under subsections 337(a)(3)(A)-(C). *See id.* at 129-49. As noted above, the Commission determined to review the FID's findings with respect to domestic industry.

D. Jubilant's Accused Products

The accused products in this investigation are Jubilant's RUBY Rubidium Elution Systems (Versions 3, 3.1, and 4) as well as the generators (RUBY-FILL generators) and tubing sets (RUBY Sets) used with those systems.[14] *See* FID at 7. As noted above, the Commission previously determined that the Version 3 product directly infringes the Asserted Patents but that

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[12] The elements reciting "an opening through the exterior shell," "a first door," and "a second door" are referred to, hereinafter, as "claim limitation (vi)."

[13] Bracco's CardioGen 1700 is not on the market and is currently awaiting FDA approval.

[14] Jubilant's Version 3.1 and Version 4 products are not on the market and are currently awaiting FDA approval.

the Version 3.1 and 4 products do not directly infringe the Asserted Patents. *See* Order No. 27 (Feb. 8, 2019), *unreviewed*, Comm'n Notice (March 8, 2019). The FID finds that Jubilant indirectly infringes the Asserted Patents when it ships a RUBY-FILL generator or RUBY Set to a customer that possesses a Version 3 system. *See* FID at 127-28. No party petitioned for review of the FID's findings with respect to indirect infringement, and the Commission determined not to review these findings. *See* 84 *Fed. Reg.* at 53177.

II. STANDARD ON REVIEW

Commission Rule 210.45(c) provides that "[o]n review, the Commission may affirm, reverse, modify, set aside or remand for further proceedings, in whole or in part, the initial determination of the administrative law judge" and that "[t]he Commission also may make any findings or conclusions that in its judgment are proper based on the record in the proceeding." *See* 19 C.F.R. § 210.45(c). In addition, as explained in *Certain Polyethylene Terephthalate Yarn and Products Containing Same*, "[o]nce the Commission determines to review an initial determination, the Commission reviews the determination under a *de novo* standard." Inv. No. 337-TA-457, Comm'n Op., 2002 WL 1349938, *5 (June 18, 2002) (citations omitted). This is "consistent with the Administrative Procedure Act which provides that once an initial agency decision is taken up for review, 'the agency has all the powers which it would have in making the initial decision except as it may limit the issues on notice or by rule.'" *Id.* (citing 5 U.S.C. § 557(b)).

III. DISCUSSION

As discussed below, the Commission has determined to affirm with modification and to supplement the FID's findings with respect to the invalidity of the Asserted Claims. In addition,

the Commission has determined to affirm in part and vacate in part the FID's findings with respect to the domestic industry requirement.

A. Invalidity

The FID finds that all of the Asserted Claims are obvious over Klein[15] (RX-106) alone or in combination with Tate[16] (RX-103), the MedRad Intego system, which is the commercial embodiment of the Tate device[17] (RX-200C), Chaffin[18] (RX-96), IEC 62366[19] (RX-114), or Bracco's CardioGen-82 Model 510[20] (JX-112C; RX-357). *See* FID at 25-112. The FID also considers the evidence of secondary considerations but finds such evidence unpersuasive and insufficient to overcome the finding of *prima facie* obviousness. *See id.* at 112-121.

As explained below, the Commission has determined to affirm the FID with modification. The Commission supplements the FID's findings and conclusion of obviousness. The Commission finds that Jubilant has satisfied its burden on obviousness and has established by clear and convincing evidence that the Asserted Claims are obvious over Klein alone or in

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[15] Klein refers to a thesis published in 2006 describing a rubidium infusion system developed by Ran Klein as part of his graduate studies at the University of Ottawa. *See* FID at 25.

[16] Tate refers to U.S. Publication 2008/0177126 filed by MedRad on October 31, 2007.

[17] The MedRad Intego system is the commercial embodiment of the device disclosed in Tate. *See* FID at 35. The MedRad Intego system was sold and offered for sale in the United States prior to June 2009. *See id.*

[18] Chaffin refers to an ergonomics and biomechanics reference. *See* Chaffin, et al., Occupational Biomechanics, 2d ed. (1991). Chaffin teaches sensible ways to physically arrange heavy objects used by humans. *See* FID at 37.

[19] IEC 62366 is an international standard for medical device design. *See* FID at 38. As stated in the FID, "IEC 62366 teaches medical device developers to provide a user interface that enables users 'to be aware of the use of the correct consumable, the remaining amount of [the consumable], whether accessories might be used with the MEDICAL DEVICE, how to assemble them and how to check their correct functioning.'" *See* FID at 62-63.

[20] Bracco's CardioGen-82 Model 510 ("Model 510") is a strontium-rubidium cardiac PET infusion system first approved by the FDA in 1989. *See* FID at 26.

combination with Tate/Medrad, Chaffin, IEC 62366, or Model 510.[21] The Commission has also determined that Bracco has established copying but no other indicia of non-obviousness, and that such copying is insufficient to overcome Jubilant's strong showing of obviousness.

1. Disputed Claim Limitations

The FID identifies several claim limitations that are in dispute, including four limitations that appear in claim 1 of each of the Asserted Patents: (1) "a shielded well onboard the cart" ("claim limitation (i)"); (2) "a first shielding compartment for the generator" having "a first opening facing vertically upwardly" ("claim limitation (ii)"); (3) "the first opening [(of the generator compartment)] at a lower elevation than the second opening [(of the waste bottle compartment)]" ("claim limitation (iii)"); and (4) "a computer [configured] to fill an on-cart reservoir with a sample of radioactive material, determine a strontium breakthrough test result on the sample, and not allow a patient infusion if the strontium breakthrough test result is greater than or equal to an allowed limit." ("claim limitation (iv)"). *See* FID at 40-54. Bracco petitioned for review of the FID's findings with respect to each of the four above-identified limitations. *See* Bracco's Pet. at 25-52, 56-59.

In addition, Bracco petitioned for review of the FID's findings with respect to three additional limitations: (1) "'two tubing passageways formed in a perimeter surface of the first opening' where 'each of the two tubing passageways has a depth configured to prevent pinching or crushing of a corresponding tubing line routed therethrough when a/the first door is closed,'" which is recited in claim 13 of the '826 patent, claims 4 and 24 of the '869 patent, and claim 12

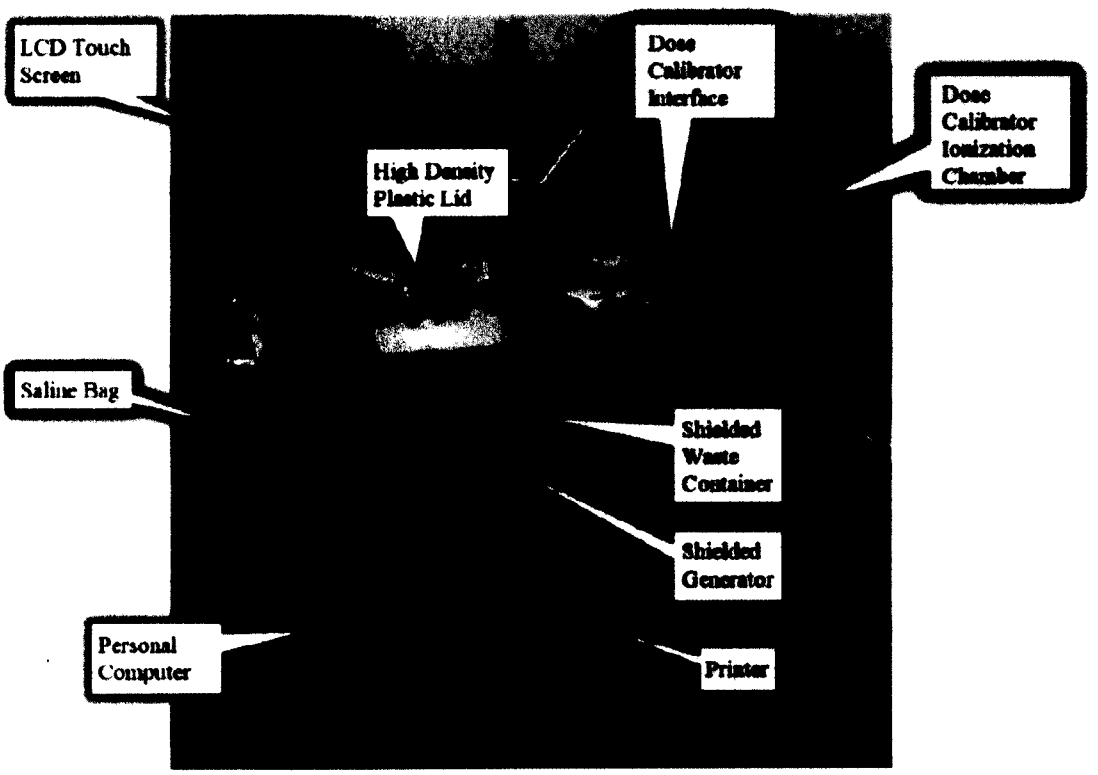
[21] Klein, Tate, and the user manual for Bracco's Model 510 were before the U.S. Patent and Trademark Office ("USPTO") during prosecution of the Asserted Patents. Based on the evidence presented in this investigation, the Commission finds that Jubilant satisfies the "added burden" of overcoming those references. *See McGinley v. Franklin Sports, Inc.*, 262 F.3d 1339, 1353 (Fed. Cir. 2001) (citation omitted).

of the '870 patent ("claim limitation (v)"); (2) "'opening through the top surface' and the first / second 'door,'" which are recited in claim 1 of the '869 patent ("claim limitation (vi)"); and (3) "reminders, warnings, or alerts," which are recited in claim 9 of the '826 patent and claim 8 of the '870 patent ("claim limitation (vii)"). *See id.* 52-56, 60-67.

2. Supplemental Analysis

(i) Claim Limitation (i)

There is no dispute that Klein does not expressly disclose a "shielded well on-board the cart" (claim limitation (i)). *See* FID at 40. But while Klein's dose calibrator sits on a laboratory shelf, *i.e.*, off the cart, the parties did not dispute that the dose calibrator satisfies the "shielded well" limitation. *See id.*; Jubilant's Resp. at 5 (citing Klein at RX-106.34 (showing the Klein system and dose calibrator on the laboratory shelf) (reproduced below as annotated)).



RX.0106.0034 (annotated)

The Commission agrees with the FID that the record evidence shows that Klein alone teaches or suggests a "shielded well on-board the cart" by clear and convincing evidence. *See* FID at 40-45. It is black letter law that "when a patent 'simply arranges old elements with each performing the same function it had been known to perform' and yields no more than one would expect from such an arrangement, the combination is obvious." *KSR Int'l. Co. v. Teleflex Inc.*, 550 U.S. 398, 416 (2007). As in *KSR*, there is no evidence in the record that "the [claimed] improvement is more than the predictable use of prior art elements according to their established functions." *See id.* at 417; *id.* ("If a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability."); *see also* FID at 44 (finding that "mov[ing] the Klein dose calibrator onto the cart" was "nothing more than routine design work well within the ability of a person of skill in the art") (citing Hr'g Tr. at 847:10-848:14 (Stone[22]), *id.* ("[T]he only two passages in the patent specification describing the dose calibrator on-board the cart simply announce that fact without describing any difficulty in making or using that arrangement.") (citing JX-1, '826 patent at 11:8-19, 27:9-12); *see also* Jubilant's Resp. at 33-34 ("A dose calibrator is a well-known component of a rubidium infusion system, and a movable cart provides a convenient location to place a dose calibrator in a rubidium infusion system, but it adds nothing to the nature or quality of the dose calibrator.") (citing *Anderson's-Black Rock v. Pavement Co.*, 396 U.S. 57 (1969); *KSR*, 550 U.S. at 416); IA's Resp. at 16-20 ("Dr. Stone's testimony . . . makes clear that Klein contemplates improvements to disclosed system.") (citing Hr'g Tr. at 823:13-18 (Stone)).

The FID also correctly finds that several design incentives would have motivated a person of ordinary skill in the art to move the dose calibrator on board the cart, including

[22] Dr. Robert Stone is Jubilant's technical expert in this investigation.

mobility, operational simplicity, and minimizing radiation exposure to the operator. *See* FID at 41-42 (citing Klein at RX-106.24-25, 27, 29, 38, 44, 46, 141; Hr'g Tr. at 623:9-22 (Stone) (describing the difficulty of repeatedly rolling the cart back to a stationary dose calibrator)), 619:17-620:1, 622:23-624:1 (Stone) (testifying that it would have been obvious to a person of ordinary skill in the art using the Klein system for commercial clinical applications to put components used together on the same cart)).

The Commission also finds that clear and convincing evidence in the record establishes that the combination of Klein with Tate or Medrad teaches or discloses a "shielded well on-board the cart." The parties did not dispute that Tate/Medrad disclose infusion systems that place dose calibrators (shown below in blue) on-board the cart. *See* Jubilant's Resp. at 40 (citing Tate at RX-103.5, Figure 1D; Medrad at RX-200C.18 (both reproduced below as annotated)).

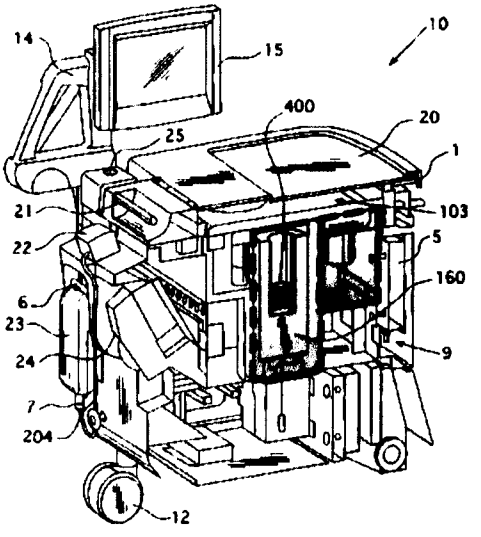
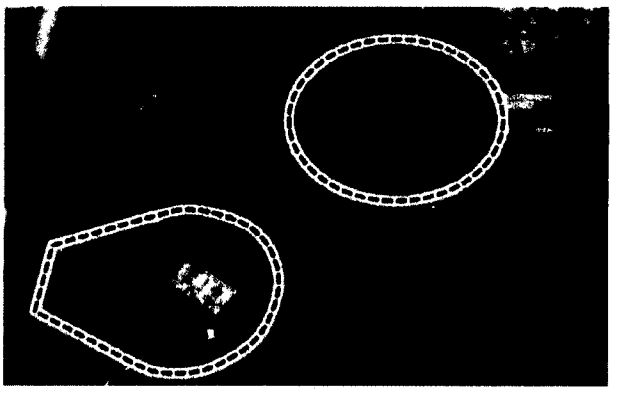


FIG. 1D

Tate at RX-103.5, Figure 1D (annotated)



Medrad at RX-200C.18 (annotated)

Bracco argued that Tate and Medrad are not analogous prior art and that the USPTO found Tate to be "too far afield." *See* Bracco's Pet. at 70. Bracco is wrong; the USPTO Examiner made no such finding. Indeed, neither the patentee nor the Examiner stated during prosecution of the parent patent application that Tate was non-analogous art. Rather, the

Examiner considered Tate relevant and pertinent prior art and cited it against the pending claims of the parent patent application. *See* CX-169, Prosecution History at 2139; *see also id.* at 2150 ("Tate et al. and Varrichio et al. are analogous art because they are from a similar problem solving area of using pumps to infuse liquid into a patient."). Moreover, the patentee distinguished Tate on the basis that it does not generate radiopharmaceuticals, not because it was non-analogous art. *See id.* at 2223-2224 ("Tate is directed to a fluid delivery system for delivering doses of pharmaceuticals to a patient. . . . Unlike the fluid delivery system of Tate, independent claim 1 recites a system that includes a radioisotope generator."). Subsequently, the Examiner withdrew the rejection over Tate but nowhere suggested that she considered Tate non-analogous or "too far afield," as Bracco contends. *See id.* at 2243, 2286. Rather, the prosecution history suggests no more than the typical negotiation between the patentee and the USPTO Examiner over the scope of relevant prior art.

Importantly, there is no requirement for analogous prior art to be similar in all respects. As the FID correctly notes, "[t]he field of endeavor of a patent is not limited to the specific point of novelty, the narrowest possible conception of the field, or the particular focus within a given field." *See* FID at 34 (citing *Unwired Planet, LLC v. Google Inc.*, 841 F.3d 995, 1001 (Fed. Cir. 2016)). Rather, as the FID determines, Tate and Medrad are analogous because "Tate is in the same field of endeavor as the present invention, as both are 'systems that . . . infuse radiopharmaceuticals, . . . including computer-facilitated maintenance and/or operation.'" *See id.* The FID also correctly finds that "Tate was directed to at least some of the same problems as the asserted patents, namely calculating and delivering accurate and effective doses of radiopharmaceuticals to patients, while reducing the exposure of administering or other medical personnel' caused by manual handling of samples for calibration." *See id.* at 35 (citing Tate,

RX-103.89-90; JX-1, '826 Patent at 1:25-30; Hr'g Tr. at 616:22-617:23, 867:11-17 (Stone); *id.* at 1113:25-1114:4 (Pelc[23])); FID at 33 ("Tate is directed to a system for use with fluorodeoxyglucose ('FDG'), a different radiopharmaceutical than the rubidium-82 described in the asserted patents" but "because 'radioisotopes, such as . . . Rubidium-82 . . .' and FDG are useful in medical imaging due to their 'relatively short half-lives,' systems that use these isotopes face the same problem of tracking the level of radioactivity delivered to the patient with each dose.") (citing RX-103.89, Tate); *id.* at 35-36 (finding Medrad "pertinent . . . for the same reasons addressed above concerning Tate"); *accord* Jubilant's Resp. at 26-27 (citing JX-1, '826 patent at 1:25-30; Tate at RX-103.89-90, 100; Hr'g Tr. at 616:22-617:23, 867:11-17 (Stone); Hr'g Tr. at 1113:25-1114:4 (Pelc)); *see also id.* at 27 ("Dr. Pelc ultimately admitted that FDG systems and rubidium systems 'have similarities and they have differences.'") (citing Hr'g Tr. at 1071:5-7 (Pelc)).[24]

Bracco also argued that there is no motivation to combine Tate or Medrad with Klein. *See* Bracco's Pet. at 74-75. Bracco focuses on the fact that Tate does not generate radiopharmaceuticals, but that is not dispositive because, as discussed above at page 16, there is no requirement that Tate disclose every claimed limitation. What is significant is that Tate is analogous prior art (both Tate and Klein relate to systems that infuse radiopharmaceuticals), and Tate discloses the missing claim limitation, *i.e.*, Tate places the dose calibrator on-board the cart in FDG systems. Given the design incentives discussed above and in the FID, and given that Tate expressly discloses placing a dose calibrator on-board the cart, a person of ordinary skill in

[23] Dr. Norbert J. Pelc is Bracco's technical expert in this investigation.

[24] The FID also notes that "Dr. Pelc testified to the contrary" but that "his testimony [is] less credible on this point than that of Dr. Stone's." *See* FID at 35 n.2 (citing Hr'g Tr. at 961:20-962:9 (Pelc)).

the art would be motivated to combine Klein with Tate and place Klein's dose calibrator on board Klein's cart. *See, e.g.*, Hr'g Tr. at 623:9-22 (Stone) (describing the difficulty of repeatedly rolling the cart back to a stationary dose calibrator)), 619:17-620:1, 622:23-624:1 (Stone) (testifying that it would have been obvious to a person of ordinary skill in the art using the Klein system for commercial clinical applications to put components used together on the same cart); *see also* FID at 55 ("Because 'the physical process' of radioactive transfer 'is well understood' and accounted for in Klein's model, a person of skill would know how to successfully implement Tate's on-board dose calibrator within the Klein system.") (citing Klein at RX-106.119); *accord* Jubilant's Resp. at 28. While Dr. Pelc testified that "a person of skill in the art would read [Klein] and say, the last thing in the world I want to do is compromise the accuracy of my dose calibrator" and "[s]o I would argue that Klein teaches against making the change proposed by Dr. Stone," the Commission finds that such testimony is conclusory and not credible in view of the level of skill in this art.[25] *See* Hr'g Tr. at 978:2-979:13 (Pelc).

The combination of Klein with Tate or Medrad "simply arranges old elements with each performing the same function it had been known to perform' and yields no more than one would expect from such an arrangement." *Sundance, Inc. v. DeMonte Fabricating Ltd.*, 550 F.3d 1356, 1367 (Fed. Cir. 2008) (citing *KSR*, 550 U.S. 417); *see also KSR*, 550 U.S. at 417 ("When a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one."), *id.* ("[I]f a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would

[25] *See* FID at 20 ("A person of ordinary skill in the art at the time of the inventions described in the asserted patents would have at least a master's degree in physics, electrical engineering, systems engineering, mechanical engineering, or a related field with at least two years of work experience with designing and/or developing nuclear medical devices or medical imaging devices."). The parties do not contest this level of skill in the art.

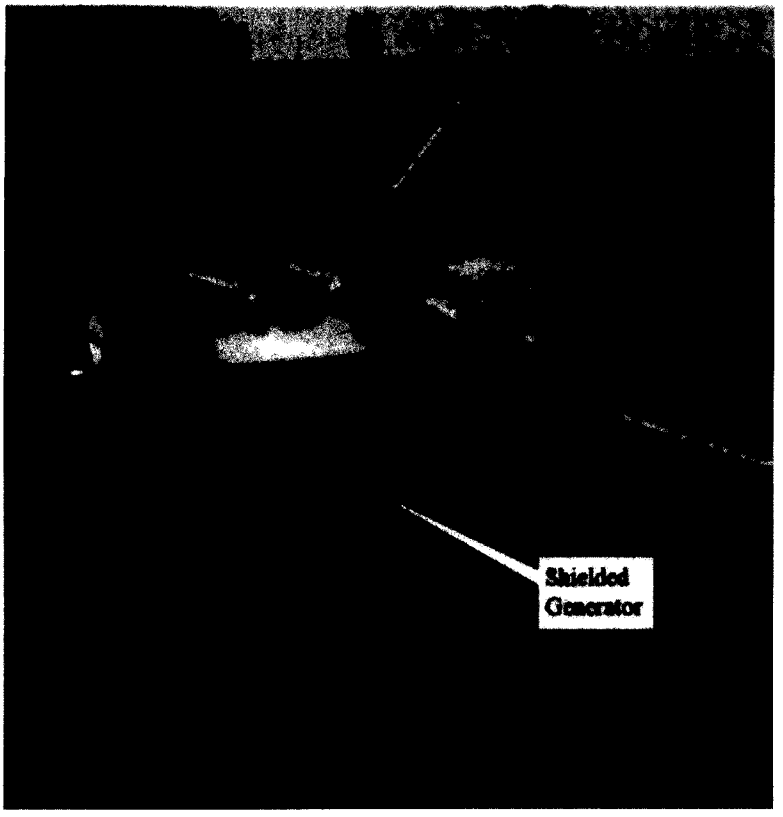
improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill.").

Thus, the Commission finds that Jubilant has established by clear and convincing evidence that Klein, alone or in combination with Tate/Medrad, teaches or discloses claim limitation (i). Accordingly, the Commission has determined to affirm and supplement the FID, as discussed above.

(ii) Claim Limitation (ii)

The parties disputed whether Klein teaches or suggests claim limitation (ii), *i.e.*, "a first shielding compartment" having "a first opening facing vertically upwardly." In particular, the parties disputed whether Klein's stack of lead rings teaches or discloses the "first shielding compartment" because the rings do not "completely enclose" the generator. *See* FID at 46; Bracco's Pet. at 58.

The FID finds that Klein's "stack of lead rings on the shelf housing the generator . . . is a 'first shielding compartment' [*i.e.*, claim limitation (ii),] as that term is understood by those of skill in the art." *See* FID at 46 (citing Hr'g Tr. at 727:6-14 (Stone)). The FID states that "when Klein's generator is in place for use, as shown in Klein Figure 2-3, the cart shelf forms a solid bottom for the compartment and there is no opening facing downwards." *See id.* (citing Klein at RX-106.33); *accord* Jubilant's Resp. at 59-62 (citing Klein at RX-106.33-34, Figure 2-3, reproduced below as annotated). The FID further notes that "even if the Klein compartment did have a bottom opening, nothing in the claim language would prohibit such a feature." *See* FID at 46.

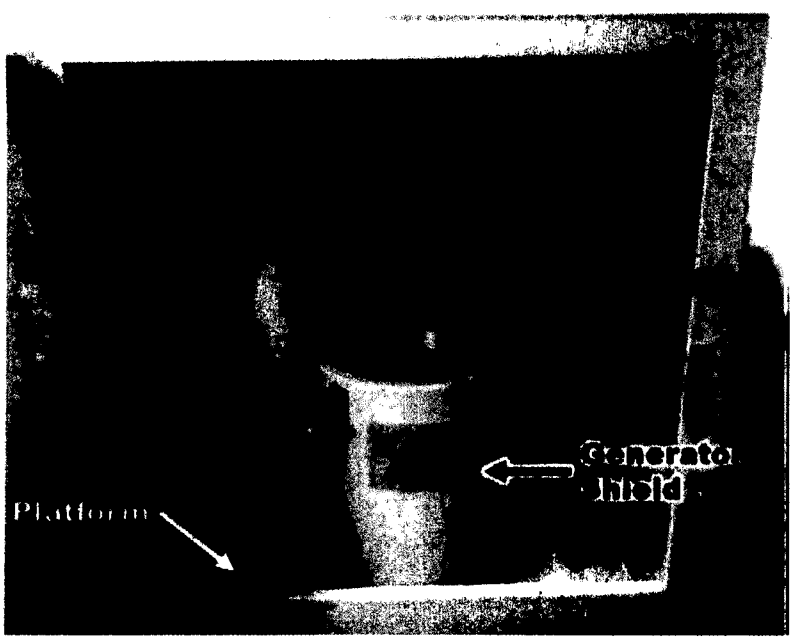


Bracco disagreed and argued that the stack of lead rings is not a shielding compartment because it is "an open-ended cylinder, and at least the bottom opening prevented the stack of rings from being the requisite shielding compartment." *See* Bracco's Pet. at 56 (citing (Hr'g. Tr. at 995:22-996:17 (Pelc)).

The Commission agrees with the FID that Klein's stack of lead rings corresponds to a "first shielding compartment." As the FID notes, "claim 1 does not require the compartment to be completely enclosed" and Klein's "stack of lead rings on the shelf housing the generator . . . is a 'first shielding compartment' [*i.e.*, claim limitation (ii),] as that term is understood by those of skill in the art." *See* FID at 46 (citing Hr'g Tr. at 727:6-14 (Stone)); *accord* Jubilant's Resp. at 61 ("The claims merely require that the compartment provide shielding, and Klein's rings indisputably do) (citing Klein at RX-106.33 ("[L]ead rings [] provide maximum radiation shielding.")); *see also* IA's Pet at 36-37. The Commission also agrees that Dr. Pelc's testimony

that "the word 'compartment' in the claim requires structure that must 'completely enclose' a portion of space" is unpersuasive and inconsistent with the claim language which requires that the shielding compartment have an "opening." *See* FID at 46 (citing Hr'g Tr. at 995:22-996:17 (Pelc)).

The Commission also finds that the FID correctly determines that Klein in combination with Model 510 teaches or discloses claim limitation (ii), *i.e.*, "a first shielding compartment" having "a first opening facing vertically upwardly." As the FID finds, "[i]t is . . . beyond dispute that the Model 510 has shielding compartments with openings facing vertically upwards." *See* FID at 57. Moreover, "as Dr. Stone credibly testified, a person of ordinary skill would be motivated to incorporate the upward-facing openings of the Model 510 in order to reduce radiation exposure of operators." *See id.* (citing Hr'g Tr. at 666:2-15 (Stone) (vertical openings in shielding "very common" as "it allows a user to approach a radioisotope source and be able to get easy access to it without being exposed to radiation")); *accord* Jubilant's Resp. at 62-63 (citing RX-357.10, reproduced below, as annotated).



Thus, design incentives would have motivated a person of ordinary skill in the art to combine Klein with Model 510 to arrive at the claimed invention. *See KSR*, 550 U.S. at 417 ("When a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one.").

Thus, the Commission finds that Jubilant established by clear and convincing evidence that Klein, alone or in combination with Model 510, teaches or discloses claim limitation (ii). Accordingly, the Commission has determined to affirm and supplement the FID, as discussed above.

(iii) Claim Limitation (iii)

As noted in the FID, the parties agreed that "Klein does not expressly show [that] the opening at the top of the shielded generator compartment [is] at a lower elevation tha[n] the opening at the top of the shielded waste bottle compartment" (claim limitation (iii)). *See* FID at 48. The FID finds that "claim element [(iii)] would be an obvious design choice in view of Klein, which discloses every component of the claimed invention in only a slightly different physical configuration." *See id.* at 49 (citing *KSR*, 550 U.S. at 421). The FID reasons that "[w]hen considering the arrangement of the openings of the generator compartment and the waste bottle compartment, the skilled artisan would have three choices: the generator compartment opening could be at a higher elevation than the waste bottle compartment opening, the two openings could be at the same elevation, or the generator compartment opening could be at a lower elevation than the waste bottle compartment opening." *See id* at 48; *accord* Jubilant's Resp. at 42-43. The FID also finds that the common specification of the asserted patents "entirely lacks any teaching of advantage to having the generator compartment opening higher than the waste bottle compartment opening." *See* FID at 48-49.

The FID thus finds that "[a] skilled artisan would find the arrangement in claim element [1.1.e] obvious even without consulting the Chaffin ergonomics reference." *See id.* The FID further states that "[t]o the extent that any teaching of Chaffin is necessary to arrive at the claimed invention, the claimed invention is obvious in view of Klein, Tate, and Chaffin." *See id.* at 56. The FID reasons that "[t]he generator in Klein is a weighty object that must be moved by a human every two months . . . , and an ordinary skilled designer would look to references like Chaffin to understand best practices for positioning the generator on the cart." *See id.* (citing Klein at RX-106.18-19); *accord* Jubilant's Resp. at 29-31; IA's Resp. at 26.

Bracco responded that Jubilant's corporate witness, Mr. Donnelly, testified that "it's common in the industry that you don't make changes if not necessary." *See* Bracco's Pet. at 43 (citing Hr'g Tr. at 349:7-19 (Donnelly)). Bracco also argued that "there simply is not room in the Klein Thesis's cart to access the generator in its shielding if moved to the lower shelf." *See id.* at 44.

The Commission finds that Jubilant established by clear and convincing evidence that Klein, alone or in combination with Chaffin or Bracco's Model 510, teaches or discloses claim limitation (iii). The Commission agrees with the FID that the generator elevation is an obvious design choice. *See* FID at 48-49. In addition, Chaffin supplies the motivation to have the generator at a lower elevation to "minimize the distance required to lift [heavier objects], thus reducing strain or injury to the person lifting the object." *See id.* at 56 (citing Chaffin, RX-96.170-178); *accord* IA's Resp. at 26. As noted by Jubilant, "Chaffin's teachings are clear, straightforward, and highly relevant to the design of medical devices. . . . The ID commits no error in finding this subject matter obvious over Klein and Chaffin." Jubilant's Resp. at 45-46 (citing Hr'g Tr. at 1083:6-15 (Pelc) ("I think that a designer of medical instruments would think about ergonomics, yes."); *id.* at 46 ("Dr. Stone's testimony . . . and other record evidence provide further support for the

[FID's] findings. For example, Bracco's prior art product, the Model 510, placed generators at a low elevation in a cart, also.") (citing RX-357, Model 510, reproduced above)); *see also* Hr'g Tr. 618:5-619:16 (Stone). Thus, design incentives would have motivated a person of ordinary skill in the art to combine Klein with Chaffin or Model 510 to arrive at the claimed invention. *See KSR*, 550 U.S. at 417 ("When a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one.").

The Commission further finds Bracco's argument that there is no "room in Klein's cart to access the generator in its shielding if moved to the lower shelf" unpersuasive. As Jubilant argued, "[a] skilled worker simply would select a larger cart to accommodate additional components." *See* Jubilant's Resp. at 45; *see also Tokai Corp. v. Easton Enters., Inc.*, 632 F.3d 1358, 1371-72 (Fed. Cir. 2011) ("It would have been obvious to one of ordinary skill and creativity to adapt the safety mechanisms of the prior art cigarette lighters, as disclosed in [the prior art], even if it required some variation in the selection or arrangement of particular components.").

Accordingly, the Commission has determined to affirm and supplement the FID with respect to claim limitation (iii), as discussed above.

(iv) Claim Limitation (iv)

Claim limitation (iv) requires "configuring a computer to fill an on-cart reservoir with a sample of radioactive material, determine a strontium breakthrough test result on the sample, and not allow a patient infusion if the strontium breakthrough test result is greater than or equal to an allowed limit." *See* FID at 49. The FID finds that although "Klein does not teach a computer interacting with a sample on-board the cart . . . Klein expressly discloses a computer . . . [which] controls a pump and valves to fill the dose calibrator reservoir with a test sample" and which "operate[s] a 'daily protocol,' [to] determine[] a strontium breakthrough test result on the

sample." *See id.* at 50 (citing Hr'g Tr. at 755:21-756:3 (Stone); Klein at RX-106.28-29, 39). *See id.* at 50; *accord* Jubilant's Resp. at 47-53; IA's Resp. at 32-34. The FID also finds that Klein discloses "a sample screenshot in Figure 3-12 (c), which shows some elution test runs grayed out to prevent user selection" and "the conditionality of 'options presented to the user' for starting a run, [include that] the software interface 'ensures that the daily protocol is followed, including a flush and calibration (including a test of breakthrough activity) at the start of each day.'" *See id.* at 51 (citing Klein at RX-106.64-65). The FID concludes that "[v]iewed together, these teachings indicate that the user would not be able to select the radio button on the touchscreen for a patient elusion without a successful breakthrough test." *See id.*

Bracco argued that "Klein only describes how the computer facilitates taking measurements to test for strontium breakthrough, and does not 'lock out' the system if breakthrough is detected." *See* Bracco's Pet. at 46. Bracco stated that "there is no dispute that Klein's computer requires running the daily protocol, and that the daily protocol includes taking activity measurements that can be used to perform breakthrough testing," but that "[t]here's nothing in the Klein thesis that says that based on the calculation of the breakthrough test, the computer prevents patient elutions." *See id.* at 49 (citing Hr'g Tr. at 983:7-9 (Pelc)). Bracco also acknowledged that Klein discloses that "[o]nce the daily [strontium-breakthrough] protocol has been completed successfully, patient elutions are enabled until the end of the day." *See id.* at 50 (citing Klein at RX-106.28). Bracco, however, argued that this is merely "an instruction to the operator," and "it's up to the operator to decide whether to carry on the patient elutions." *See id.* (citing Hr'g at 1077:25-1078:7 (Pelc)).

The Commission agrees with the FID that Klein's computer teaches or discloses claim limitation (iv). *See* FID at 49-54. Dr. Pelc's opinion is unpersuasive and inconsistent with

Klein. In particular, Dr. Pelc's opinion cannot be reconciled with Klein's express disclosure that "[t]he system ***must ensure compliance with the daily protocol*** . . . and ***successful*** breakthrough measurement ***must*** be completed in order to ***enable*** patient elutions for the remainder of the day." *See* Klein at RX-106.39 (emphasis added); *accord* IA's Resp. at 34. As noted by Jubilant, "Klein discloses that the computer performs a daily protocol, which ensures that the system is in proper operational order," "[a]t midnight each night, the computer disables patient infusions," and "[i]t re-enables them only after a daily 'flush' run and a successful 'calibration' run are performed." Jubilant's Resp. at 48 (citing Klein at RX-106.27-29). "Only after a calibration run with ***low Sr breakthrough*** has been successfully completed can patient elutions be carried out." *See id.* at 49 (citing Klein at RX-106.28).

Thus, the Commission finds that Jubilant established by clear and convincing evidence that Klein teaches or discloses claim limitation (iv), *i.e.*, "configuring a computer to fill an on-cart reservoir with a sample of radioactive material, determine a strontium breakthrough test result on the sample, and not allow a patient infusion if the strontium breakthrough test result is greater than or equal to an allowed limit." Accordingly, the Commission has determined to affirm and supplement the FID, as discussed above.

(v) Claim Limitation (v)

The parties disputed whether Klein, alone or in combination with Tate/Medrad, teaches or suggests two tubing passageways configured so that tubing is not pinched or crushed, *i.e.*, claim limitation (v). The FID finds that "Klein does not show two passageways formed in the perimeter surface of the opening of a compartment that has all of the features of the generator compartment required by claim 1, from which claim 13 [of the '826 patent] depends" but that "Klein's teachings would make such an arrangement obvious to person of ordinary skill." *See*

FID at 73. The FID reasons that "Klein provides a person of ordinary skill with motivation to avoid crushing or pinching tubing lines running into or out of a shielding compartment when the lid of that compartment is closed." *See id.* (citing Klein at RX-106.76 ("high pressure is an indication of a blockage or pinched line and could result in backwash through the pump head or rupturing of the saline lines.")); *accord* Jubilant's Resp. at 54-58; IA's Resp. at 27.

The FID also finds that claim limitation (v) is obvious over Klein in combination with Tate/Medrad. *See* FID at 74-77. The FID reasons that "Tate discloses forming a passageway in the perimeter surface of the opening into a shielded chamber for the radiopharmaceutical source." *See id.* at 75 (citing Tate, RX-103.19). The FID explains that "Tate's shielded well (element **111**, shown in yellow below) has a first opening in the top surface of the cart" and "Tate discloses a trough (element **113**, shown in green below) formed in the perimeter surface of that opening allowing a tubing line (element **210**, shown in blue below) to pass into the shielding compartment without being crushed while a cap (element **684**) is closed over the top of the compartment." *See id.* (citing Tate, RX-103.19 (Figure 6E, reproduced below)). And "[a]lthough Tate teaches only one passageway and one tubing line," the FID continues, "Klein teaches two tubing lines." *See id.* at 76. The FID finds that "[d]uplicating the tubing passageways of either Tate or Klein, to provide separate passageways for both the tubing line into and out of the generator, would have been obvious to one of skill in the art." *See id.* (citing *In re Harza*, 274 F.2d 669, 671 (C.C.P.A. 1960) (duplication of elements is not patentable unless a new or unexpected result is produced); Hr'g Tr. at 702:7-12 (Stone)).

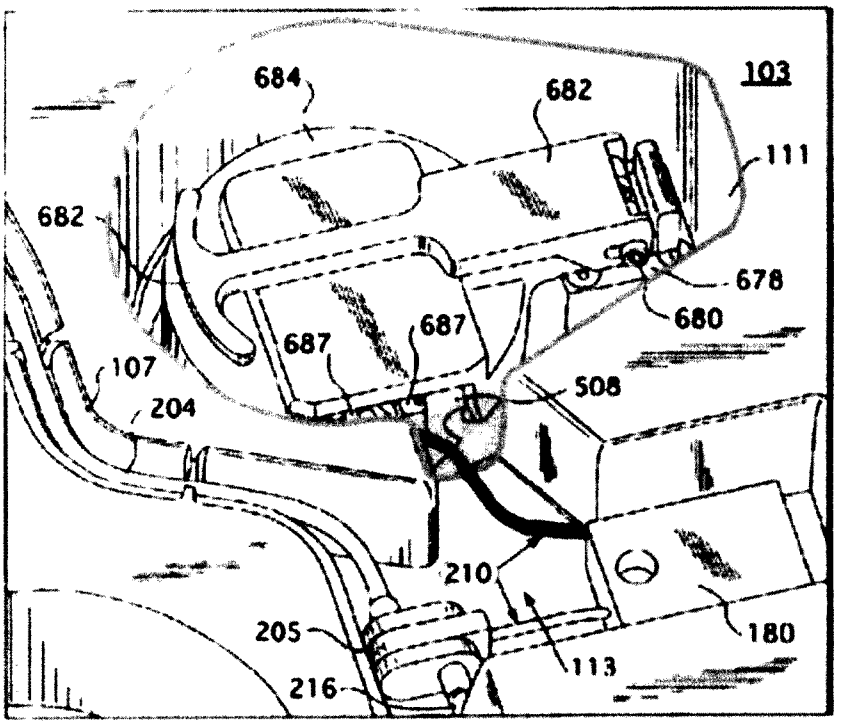


FIG. 6E

Thus, the FID concludes, "a person of ordinary skill would be motivated, as noted above, to incorporate Tate's passageway when moving the tubing below the top surface of Klein's cart in order to avoid crushing of tubing lines." *See id.* at 75-76 (citing Tate at RX-103.19, 93; RX-200C, Medrad at 18); *accord* IA's Resp. at 27-28; Jubilant's Pet. at 58-59.

Bracco argued that "neither Jubilant nor Staff identified any tubing passageways in Klein" and that "Jubilant's technical expert admitted at the hearing that Klein does not disclose this claim element." *See* Bracco's Pet. at 53 (citing Hr'g Tr. at 822:13-823:8 (Stone)). But Bracco did not address the FID's findings that claim limitation (v) is obvious over Klein in combination with Tate or Medrad (Bracco only disputed that Klein and Tate/Medrad are analogous art). *See* Jubilant's Pet. at 58-59.

The Commission agrees with the FID that Klein, alone or in combination with Tate or Medrad, teaches or discloses claim limitation (v). As the FID finds, "Klein provides a person of ordinary skill with motivation to avoid crushing or pinching tubing lines running into or out of a

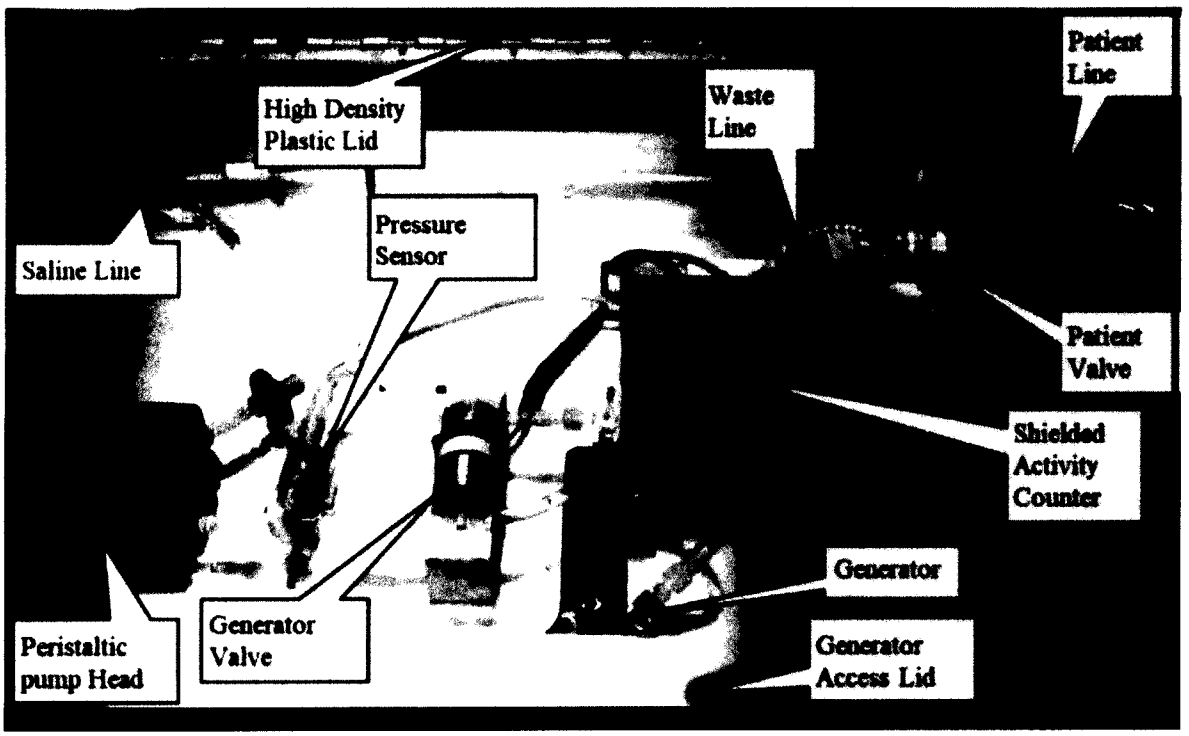
shielding compartment when the lid of that compartment is closed." *See* FID at 73 (citing Klein at RX-106.76). In addition, there is motivation to combine Klein with Tate or Medrad. *See id.* at 75-76. Bracco did not dispute the FID's findings with respect to Klein in combination with Tate or Medrad. And while Bracco argued that Tate and Medrad are not analogous art, the Commission disagrees as explained *supra* section (III)(A)(2)(i). The Commission finds that the FID correctly determined that "a person of ordinary skill would be motivated . . . to incorporate Tate's passageway when moving the tubing below the top surface of Klein's cart in order to avoid crushing of tubing lines." *See* FID at 75-77 (citing Klein at RX-106.46; Tate at RX-103.19, 93; Hr'g Tr. at 702:7-12 (Stone), 822:13-823:2 (Stone)); *see also id.* ("[A] person looking to commercialize Klein would be motivated to cover the visible tubing lines along the top surface of the cart, as those lines can be a source of radiation exposure.") (citing Klein at RX-106.46; Hr'g Tr. at 617:20-22 (Stone)). Thus, design incentives would have motivated a person of ordinary skill in the art to combine Klein with Tate or Medrad to arrive at the claimed invention. *See KSR*, 550 U.S. at 417 ("When a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one.").

For the reasons stated in the FID as supplemented above, the Commission finds that Jubilant established by clear and convincing evidence that Klein, alone or in combination with Tate or Medrad, teaches or discloses claim limitation (v). Accordingly, the Commission has determined to affirm and supplement the FID, as discussed above.

(vi) Claim Limitation (vi)

The FID finds that Klein discloses the elements of an "opening through the top surface" and the first / second "door" elements, which are recited in claim 1 of the '869 patent (claim

limitation (vi)). See FID at 85-86. The FID finds that Klein expressly discloses a "Generator Access Lid" on top surface of the exterior shell of the cart." *See id.* at 84 (citing Klein at RX-106.34 (Figure 2-4), indicating "Generator Access Lid" on top surface of cart, reproduced below).



The FID explains that "the Generator Access Lid disclosed in Klein is positioned over both the shielded generator compartment and the shielded waste bottle compartment." *See id.* at 85 (citing Hr'g Tr. at 661:19-662:12 (Stone)) (crediting the testimony of Dr. Stone that the opening beneath the lid would allow the waste bottle to be inserted and removed from the shielded waste container). The FID further finds that "the Generator Access Lid disclosed in Klein is a door," *i.e.*, the first door. *See id.* at 86 (citing Hr'g Tr. at 665:11-666:1 (testimony of Dr. Stone that Klein had "an access door . . . that could give access to the generator"), 686:1-24 (testimony of Dr. Stone that: "doors are conventional structures for shielding in my entire history of looking at radioisotopes and radioactive sources. They are very common."). Still further,

the FID finds that "Klein discloses that the shielded waste compartment has a lid," *i.e.*, the second door, and "[t]hat lid is a door." *See id.* (citing Klein at RX-106.35 ("the waste container was mounted on the top shelf inside a lead container with a lid," *i.e.*, the second door)).

Bracco argued that "the [FID] incorrectly [finds] that Klein discloses the element of an 'opening through the top surface' and the first / second 'door' elements" (claim limitation (vi)). *See* Bracco's Pet. at 60. Bracco faults the FID for "erroneously" relying on a document (a high quality copy of the Klein thesis) that is not in evidence and that is inconsistent with expert testimony relating to this claim element. *See id.* In addition, Bracco argued that the FID fails to explain how "the Generator Access Lid can be both 'the opening through the top surface of the exterior shell' and a first door 'accessible via the opening through the exterior shell.'" *See id.* at 62-63.

The Commission finds clear and convincing evidence that Klein teaches or discloses the claimed "opening" and first and second "door" elements. As noted by the IA, even though the outline of the generator access lid is not visible, "the annotated Klein figure discloses under no uncertain terms that a lid to access the generator exists on the top surface of the exterior shell of the cart." *See* IA's Resp. at 29 (citing Klein at RX-106.34, Figure 2-4, reproduced above); *accord* Jubilant's Resp. at 64-68. Thus, the Commission agrees with the IA that the absence of the "high quality copy of the Klein thesis" from the record "does not alter the fact that the [FID] cited and discussed figure 2-4" and that figure "expressly discloses the generator access lid that logically covers an opening on the exterior top surface of the shell." *See* IA's Resp. at 29.

The Commission also disagrees with Bracco that the FID conflates the opening with the door elements. The FID makes clear that the "door" is the "lid" and that the opening which is "beneath the lid would allow the waste bottle to be inserted and removed from the shielded waste container." *See* FID at 85 (citing Hr'g Tr. at 661:19-662:12 (Stone)); *id.* at 86 (stating that the "opening" is

covered by the Generator Access Lid, *i.e.*, the first door) (citing Klein at RX-106.34, Figure 2-3)); *see also* Hr'g Tr. at 665:11-666:1 (Stone) (testifying that Klein had "an access door . . . that could give access to the generator"); *accord* Jubilant's Resp. at 66-67.

The FID also correctly determines that "Klein discloses that the shielded waste compartment has a lid," *i.e.*, the second door. *See* FID at 86 (citing Klein at RX-106.35 (stating that "the waste container was mounted on the top shelf inside a lead container with a lid," *i.e.*, the second door)); *accord* Jubilant's Resp. at 67. Furthermore, the Commission finds that the FID properly relies on Dr. Stone's credible testimony that doors are "conventional" and "common" in this art. *See* FID at 86 (citing Hr'g Tr. at 686:1-24 (Stone) (testifying that "doors are conventional structures for shielding in my entire history of looking at radioisotopes and radioactive sources" and that "[t]hey are very common")).

Thus, the Commission finds that Jubilant established by clear and convincing evidence that Klein teaches or discloses claim limitation (vi). Accordingly, the Commission has determined to affirm and supplement the FID, as discussed above.

(vii) Claim Limitation (vii)

The FID finds that Klein, alone or in combination with IEC 62366, teaches or discloses the reminders, warnings, or alerts recited in claim limitation (vii). *See* FID at 61-63. Bracco disputed that Klein teaches a touch screen display showing "a screen reminding a user to insert the eluate reservoir" and "the strontium breakthrough test result." *See* Bracco's Pet. at 64-65.

The FID explains that "the computer in Klein's system communicates with the dose calibrator at the start of the daily protocol to make sure that the calibrator has the 'proper settings'" and "[i]f something is wrong with the dose calibrator, 'warnings are presented to the user with detailed explanations.'" *See* FID at 61 (citing Klein at RX-106.65). The FID further finds that "Klein also describes how to use a sensor to detect a physical property of a reservoir

and issue a warning if a user attempts to start an elution with the reservoir in the wrong condition." *See id.* (citing Klein at RX-106.44-45) (describing an overflow sensor in the waste reservoir). The FID concludes that "[i]n light of these disclosures, a person of ordinary skill in the art would find it obvious to display a reminder to the user to insert the eluate reservoir if the user attempts to start the calibration run without doing so." *See id.* at 62. The FID concludes that "Klein alone renders the reservoir reminder obvious" but "[t]o the extent that any teaching of IEC 62366 is necessary to arrive at the claimed invention, the invention is obvious in view of Klein and IEC 62366." *See id.* at 63.

The FID also finds that "Klein expressly discloses a touch screen display of the strontium breakthrough test result." *See id.* (citing Klein at RX-106.64 (Fig. 3-12(f) and (g)); *id.* at RX-106.41 ("On successful completion a grey screen must list statistics relevant to the elution . . . a separate window must list a comprehensive display of all statistics in addition to activity curves"); *id.* at RX-106.65); *accord* IA's Resp. at 38. In the alternative, the FID continues, "a person of ordinary skill in the art would find it obvious to display the results of the Klein system's breakthrough tests on Klein's touch screen." *See* FID at 62.

Bracco argued that "Dr. Stone admitted that the Klein thesis does not disclose configuring a computer to present on a touch screen display a screen reminding the user to insert the eluate reservoir in the shielded well on-board the cart." *See* Bracco's Pet. at 65 (citing Hr'g Tr. at 819:8-13 (Stone)). Bracco further argued that "[t]he [FID's] cited figures and text from Klein do not depict or mention the strontium breakthrough test result." *See id.* at 66.

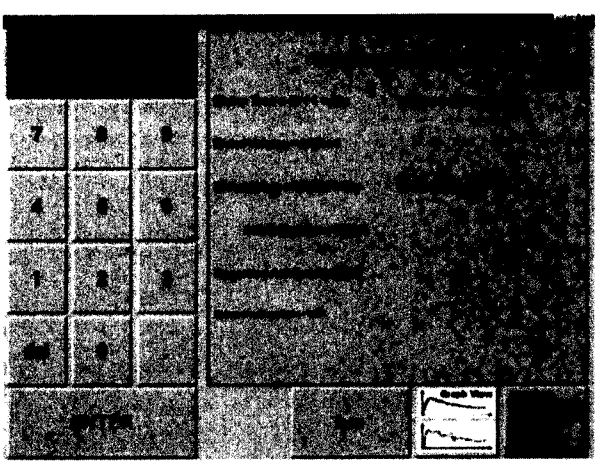
The Commission finds that the FID correctly determines that the elements relating to the eluate reservoir reminder and the strontium breakthrough test result (*i.e.*, claim limitation (vii)) are obvious over Klein alone or in combination with IEC 62366. As noted by the FID,

"Klein . . . describes how to use a sensor to detect a physical property of a reservoir and issue a warning if a user attempts to start an elution with the reservoir in the wrong condition." *See* FID at 61 (citing RX-106.44-45). And as noted by the IA, "[w]hether it is called a 'warning' or a 'reminder,' it is unreasonable to argue that this disclosure is somehow insufficient to disclose to a person of ordinary skill in the art that a warning or reminder to insert an eluate reservoir in the dose calibrator can be displayed on the screen." *See* IA's Resp. at 37-38; *accord* Jubilant's Resp. at 72 ("[A] skilled worker would have considered it obvious to display a reminder to insert an eluate reservoir if the user attempted to start a calibration run without doing so."). The Commission also agrees with Jubilant that "[t]he [IEC 62366] standard teaches medical device developers to build user interfaces that instruct users of the correct use of consumables," *e.g.*, eluate, including "the remaining amount of them." *See id.* at 74 (citing IEC 62366, RX-114.63). The Commission further agrees that there is motivation to combine Klein with IEC 62366. *See id.* at 75 (citing Hr'g Tr. at 1083:20-22 (Pelc)); *see also KSR*, 550 U.S. at 417 ("When a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one. If a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability.").

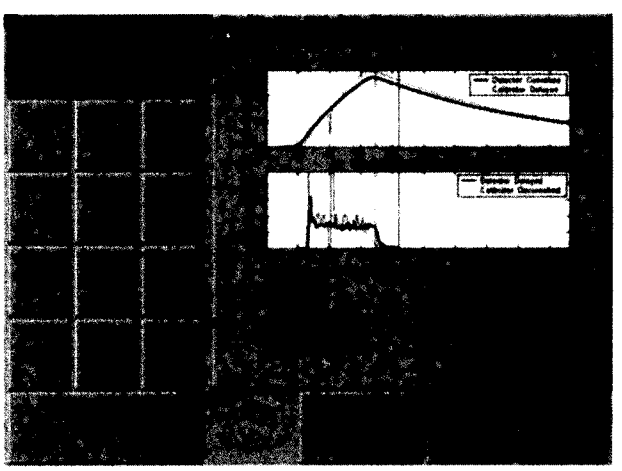
With respect to the "strontium breakthrough test result," the Commission finds that the FID correctly determines that "Klein expressly discloses a touch screen display of the strontium breakthrough test result" or, in the alternative, that "a person of ordinary skill in the art would find it obvious to display the results of the Klein system's breakthrough tests on Klein's touch screen." *See* FID at 62 (citing Klein at RX-106.64 (Figures 3-12(f) and (g)), RX-106.41 ("On successful completion a grey screen must list statistics relevant to the elution . . . a separate

window must list a comprehensive display of all statistics in addition to activity curves"), RX-106.65).

The Commission also agrees with the IA that "[i]t defies logic that Klein would disclose 'comprehensive display of all statistics' and 'test for communication and proper settings' with a confirmation that 'display[s] . . . all the inputs for the user to review,' but then specifically not display the result of the breakthrough test, whether it is measurement made by the system or calculated by the system." *See* IA's Resp. at 38; *accord* Jubilant's Resp. at 73 (citing Klein at RX-106.64, Figures 3-12(f) and (g), reproduced below); *see also id.* (citing Klein at RX-106.18-19) ("As Klein explains, the strontium breakthrough level is the most significant statistic obtained from a calibration run.").



Klein at RX-106.64 (Figure 3-12(f))



Klein at RX-106.64 (Figure 3-12(g))

Thus, the Commission finds that Jubilant established by clear and convincing evidence that Klein, alone or in combination with IEC 62366, teaches or discloses claim limitation (vii). Accordingly, the Commission has determined to affirm and supplement the FID, as discussed above.

(viii) Conclusion

Accordingly, the Commission finds that Jubilant established by clear and convincing

evidence that the asserted prior art teaches or discloses all of the limitations of the Asserted Claims.

3. Secondary Considerations

The FID finds that Bracco provided no evidence on the nexus between the claimed invention and the asserted indicia of non-obviousness, and instead "rel[ied] on an erroneous presumption of nexus." *See* FID at 114. The FID also suggests that the presumption only applies to the "commercial success" factor, which "Bracco does not advance." *See id.* at 113. The Commission agrees with Bracco that the FID incorrectly limits the presumption of nexus to "commercial success." *See WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1330 n.4 (Fed. Cir. 2016) (stating that the presumption of nexus is not limited to commercial success but applies to other indicia of non-obviousness including praise and copying).

The FID does analyze Bracco's indicia of non-obviousness "as if nexus had been shown" and concludes that they are unpersuasive and [deserve] little weight. *See id.* at 114. With respect to copying, the FID finds "strong evidence that Jubilant did not copy Bracco's design" and that the "circumstantial evidence on which Bracco relies" to establish such copying is "weak." *See id.* at 114-19; *accord* Jubilant Resp. at 77-80. The FID therefore determines to "accord no weight to this factor." *See* FID at 119.

As to "long felt but unresolved need," the FID finds that "Bracco points to no competent evidence tied to the novel elements of the asserted patents showing [such] long felt but unmet need." *See id.* at 119; *accord* Jubilant Resp. at 81-82. The FID reasons that "Klein describes no unsolved need" and that "having the dose calibrator on the bench was not a problem because, as explained above, it could just as easily be placed on the cart." *See* FID at 120. The FID

further states that "[i]t was a matter of design choice, not a matter of technical impediment." *See id.*

The FID similarly rejects Bracco's arguments with respect to "failure of others." *See id.* at 120-21; *accord* Jubilant Resp. at 83-85. The FID reasons that "Jubilant's Version 2.0 [product] was rejected by the FDA not because it lacked an on-board dose calibrator or any other features of the asserted patent claims but because it was not developed in compliance with FDA guidelines." *See* FID at 121.

Bracco responded that the presumption of nexus is not limited to commercial success. *See* Bracco's Pet. at 82 (citing *WBIP*, 829 F.3d at 1329-30); *accord* Jubilant's Resp. at 76-77. With respect to copying, Bracco argued that Jubilant hired Bracco's former employees, including "one of the named inventors of the asserted patents, Ms. Gelbach, as the Ruby-Fill product manager." *See* Bracco's Pet. at 87. Bracco also argued that contrary to the FID's suggestion, copying does not require the presence of a "commercial product." *See id.* at 89 (citing *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 567 F.3d 1314, 1328-29 (Fed. Cir. 2009)).

With respect to "long-felt need," Bracco argued that "there is substantial evidence that as early as 2003 there was an unmet need for a rubidium-based elution system configured for more efficient set up, maintenance and operation as described in the asserted patents." *See id.* at 90-92. Bracco further argued that "the inventions described in the asserted patents met this long-felt need because they provide for a system that reduces user input during set up, maintenance and operational procedures for each patient administration." *See id.* at 92.

Bracco also faults the FID for rejecting its arguments relating to "failure of others." *See id.* at 92-94. Bracco contends that "the evidence demonstrated that Jubilant failed to

commercialize an elution system until it gained access to Bracco's know-how in the form of published patent applications, and hiring Bracco's employees and contractors." *See id.* at 94.

After examining Bracco's arguments, the Commission finds that Bracco established copying, although not long-felt need or failure of others. Specifically, with respect to "long-felt need" and "failure of others," the Commission agrees with the FID that the evidence merely points to the passage of time rather than any specific or discernible unmet need. *See* FID at 119. The Commission also agrees with the FID that placing the dose calibrator on-board a cart was "a matter of design choice, not a matter of technical impediment." *See id.* at 120.

The Commission, however, agrees with Bracco that copying does not require a commercial product but may be based on a published patent or patent application, which in Bracco's case, was published in December 2009. *See DePuy Spine*, 567 F.3d at 1329 ("[W]e agree with the district court that [defendants'] initial attempt at making a rigid pedicle screw without a compression member, together with [defendants'] prompt adoption of the claimed feature soon after the patent issued, are relevant indicia of nonobviousness."). The record evidence, particularly the documentary evidence, shows that Jubilant designed a rubidium elution system with an on-board dose calibrator right around the time that Jubilant hired several Bracco former employees, including Ms. Gelbach, one of the inventors of the Asserted Patents.[26] *See* CX-386C (showing correspondence dated July 28, 2010 discussing the design of Jubilant's Version 3 product which includes an on-board dose calibrator); Hr'g Tr. 1046:15-20 (Pelc). Jubilant also hired North Pole Engineering, a software technology firm that worked with Bracco on the technology described in the Asserted Patents, which resulted in multiple North Pole

[26] The FID assigns little or no weight to the testimony of Messrs. Donnelly and Riddoch on this issue. *See* FID at 117. The Commission similarly disregards that testimonial evidence and finds the documentary evidence more persuasive.

Engineering team members being named as inventors on the asserted patents. *See id.* at 1029:16-18 (Pelc); *id.* at 1042:20-1044:4 (Pelc); CX-396C; *accord* Bracco's Pet. at 88. The evidence also shows that those employees were directly involved in design decisions for Jubilant's Version 3 Ruby-Fill product, which unlike the Versions 1 and 2, included the claimed on-board dose calibrator. *See* JX-13C; Hr'g Tr. at 1038:2-1039:11 (Pelc). And even though it is not clear whether Jubilant had a copy of the published patent publication, Jubilant had knowledge of that patent application or the substance of that application at least as of the date that Ms. Gelbach was hired in July 2010. Thus, the Commission finds sufficient circumstantial evidence in the record to establish copying in this case, at least with respect to the on-board dose calibrator.

Nevertheless, the Commission finds that the evidence of copying alone is insufficient to overcome Jubilant's strong showing of *prima facie* obviousness in this case. *See Sundance*, 550 F.3d at 1368 ("Secondary considerations of nonobviousness . . . simply cannot overcome this strong prima facie case of obviousness."); *Leapfrog Enters., Inc. v. Fisher-Price*, Inc., 485 F.3d 1157, 1162 (Fed. Cir. 2007) (finding substantial evidence of commercial success, industry praise, and long-felt need insufficient to overcome strong evidence of *prima facie* obviousness).

4. Conclusion

For the foregoing reasons, the Commission finds that Jubilant has established by clear and convincing evidence that the Asserted Claims are invalid as obvious over Klein, alone or in combination with other prior art. Accordingly, the Commission has determined to affirm with modification and to supplement the FID as discussed above.

B. Domestic Industry

The FID finds that Bracco has satisfied the domestic industry requirement under subsections 337(a)(3)(A) (significant investment in plant and equipment), 337(a)(3)(B) (significant employment of labor or capital), and 337(a)(3)(C) (substantial investment in engineering, research, and development). *See* 19 U.S.C. § 1337(a)(3)(A), (B), and (C). Specifically, the FID notes that Bracco paid its subcontractor [ ] for [ ] finished Model 1700 units and that such payment could be "a combination of (1) rent paid to [ ] for use of [ ] plant and equipment to manufacture the [ ] Model 1700 units; (2) payment for the work of [ ] employees who built the devices . . . ; and (3) payment for the materials used to make the devices." *See* FID at 139. Although the FID notes that "[o]nly the first category would be considered plant and equipment," the FID finds that "a significant proportion of the [ ] payment represents a significant investment in plant and equipment relating to [Bracco's] Model 1700," in satisfaction of subsection 337(a)(3)(A). *See* FID at 139-40.

The FID also finds that "[i]n 2016 and 2017, Bracco invested approximately [ ] in salaries for . . . employees" who support the FDA regulatory approval activities for the Model 1700 system, and that such "amount is a significant employment of labor and capital in the United States," in satisfaction of subsection 337(a)(3)(B). *See id.* at 143. The FID further credited "at least [ ] in salary to U.S.-based engineers for work on the Model 1700 in 2016 and 2017" and found that such amount qualifies as a significant employment of labor and capital in the United States, in satisfaction of subsection 337(a)(3)(B). *See id.* at 145.

Still further, the FID finds that "Bracco's expenditure of at least [ ] on [ ] for services to design and develop the Model 1700 would constitute a substantial investment in research and development to exploit the inventions claimed in the

asserted patents, consistent with section 337(a)(3)(C)" and that "[t]he same [ ] investment also would constitute a substantial employment of capital, consistent with section 337(a)(3)(B)." *See id.* at 146. The FID concludes that "[e]ven without FDA approval . . . Bracco's industry presently exists" and "the industry is not dwindling." *See id.* at 149.

The IA (but not Jubilant) petitioned for review of the FID's finding with respect to Bracco's investment under subsection 337(a)(3)(A) (significant investment in plant and equipment). The IA argued that "[t]he [FID] does not cite any evidence to support that 'a significant portion of the [ ] payment represents a significant investment in plant and equipment relating to the Model 1700.'" IA's Pet. at 7. The IA did not seek review of the FID's findings of domestic industry under subsections 337(a)(3)(B) and (C). *See id.* at 4-5.

Bracco responded that, because "[n]o party has petitioned for review of the [FID's] finding that a domestic industry exists under subsections 337(a)(3)(B) and (C) . . . granting the [IA's] petition would not change the determination that Bracco demonstrated that a domestic industry exists." *See* Bracco's Resp. at 1. In addition, Bracco argued that there is no dispute that "Bracco paid [ ] to purchase . . . [ ] units of the Model 1700 cart" and that "the [ ] Model 1700 carts constitute equipment under [subsection 337(a)(3)(A)]." *See id.* at 1-2.

The Commission agrees with the IA that the FID does not cite any evidence to support its finding that "a significant portion of the [ ] payment represents a significant investment in plant and equipment relating to the Model 1700." *See* FID at 139-40; *Lelo Inc. v. Int'l Trade Comm'n*, 786 F.3d 879, 884-85 & n.4 (Fed. Cir. 2015). Thus, the Commission has determined to vacate the FID's findings with respect to the domestic industry under subsection 337(a)(3)(A).

Because, however, Bracco has established that a domestic industry exists under subsections 337(a)(3)(B) and (C), the Commission affirms the FID's conclusion that Bracco has satisfied the domestic industry requirement.[27]

IV. CONCLUSION

For the foregoing reasons, the Commission has determined to affirm the FID with modification. The Commission supplements the FID's findings and conclusion of no violation of section 337 as discussed herein.

By order of the Commission.

Lisa R. Barton
Secretary to the Commission

Issued: December 11, 2019

[27] Commissioner Kearns observes that, because FDA regulatory approval is required for a strontium rubidium infusion system from any source, efforts to obtain FDA regulatory approval may not on their own distinguish a complainant's activities from those of an importer. He notes that the evidence submitted by Bracco does not describe the types of FDA-related activities its employees performed, including whether the activities are of a nature that can only be performed in the United States. *See* RX-310C, ¶¶ 13-14. He finds that the evidence cited in the FID on expenses for engineering and development related to the Model 1700 system performed by Bracco and by the [ ] are sufficient to establish a domestic industry under section 337(a)(3)(B).

CERTAIN STRONTIUM-RUBIDIUM RADIOISOTOPE INFUSION SYSTEMS, AND COMPONENTS THEREOF INCLUDING GENERATORS

Inv. No. 337-TA-1110

PUBLIC CERTIFICATE OF SERVICE

I, Lisa R. Barton, hereby certify that the attached **OPINION** has been served by hand upon the Commission Investigative Attorney, **Brian Koo, Esq.**, and the following parties as indicated, on **December 11, 2019**.

Lisa R. Barton, Secretary
U.S. International Trade Commission
500 E Street, SW, Room 112
Washington, DC 20436

On Behalf of Complainant Bracco Diagnostics Inc.:

Mark G. Davis, Esq.
GOODWIN PROCTER LLP
1900 N Street, NW
Washington, DC 20036

☐ Via Hand Delivery
☒ Via Express Delivery
☐ Via First Class Mail
☐ Other:_____

On Behalf of Respondents Jubilant DraxImage Inc., Jubilant Pharma Limited, and Jubilant Life Sciences:

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1050 Connecticut Avenue, NW
Washington, DC 20036

☐ Via Hand Delivery
☒ Via Express Delivery
☐ Via First Class Mail
☐ Other:_____

UNITED STATES INTERNATIONAL TRADE COMMISSION

Washington, D.C.

In the Matter of	
CERTAIN STRONTIUM-RUBIDIUM RADIOISOTOPE INFUSION SYSTEMS, AND COMPONENTS THEREOF INCLUDING GENERATORS	Investigation No. 337-TA-1110

NOTICE OF COMMISSION DETERMINATION TO REVIEW IN PART A FINAL INITIAL DETERMINATION FINDING NO SECTION 337 VIOLATION

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined to review in part a final initial determination ("FID") of the presiding administrative law judge ("ALJ") finding no violation of section 337 of the Tariff Act of 1930, as amended.

FOR FURTHER INFORMATION CONTACT: Houda Morad, Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone (202) 708-4716. Copies of non-confidential documents filed in connection with this investigation are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW., Washington, D.C. 20436, telephone (202) 205-2000. General information concerning the Commission may also be obtained by accessing its Internet server at *https://www.usitc.gov*. The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov*. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205-1810.

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation on May 1, 2018, based on a complaint, as amended, filed by Bracco Diagnostics Inc. of Monroe Township, New Jersey ("Complainant" or "Bracco"). *See* 83 FR 19112-13 (May 1, 2018). The complaint, as amended, alleges violations of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337) ("section 337"), based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain strontium-rubidium radioisotope infusion systems, and components thereof including generators, by reason of infringement of U.S. Patent Nos. 9,814,826; 9,750,869; and 9,750,870 (collectively, "the asserted patents"). *See id.* The notice of investigation names Jubilant DraxImage Inc. of Kirkland, Québec, Canada; Jubilant Pharma Limited of Singapore; and Jubilant Life Sciences of Noida, Uttar Pradesh, India (collectively, "Respondents" or "Jubilant") as respondents in this

investigation. *See id.* The Office of Unfair Import Investigations is also a party to this investigation. *See id.*

On February 8, 2019, the ALJ issued an ID (Order No. 27) finding by summary determination that Jubilant's RUBY Rubidium Elution System Version 3.0 directly infringes the asserted patents. *See* Order No. 27 (Feb. 8, 2019), *unreviewed*, Comm'n Notice (Mar. 8, 2019). In addition, the ALJ determined that Jubilant's RUBY Rubidium Elution System Version 3.1 and the RUBY Rubidium Elution System Version 4 do not directly infringe the asserted patents. *See id.* The ID (Order No. 27) declined to reach indirect infringement on summary determination. *See id.*

The ALJ conducted an evidentiary hearing on February 11-12 and 15-17, 2019, and on August 1, 2019, issued the FID finding no violation of section 337. Specifically, the FID finds that the domestic industry requirement is satisfied and that all the asserted claims are infringed but invalid as obvious over the prior art. In addition, the ALJ issued a Recommended Determination ("RD") recommending, should the Commission find a section 337 violation, that the Commission issue a limited exclusion order ("LEO") barring entry of articles that infringe the asserted claims. The RD does not recommend that the Commission issue a cease and desist order or impose a bond during the period of Presidential review. Furthermore, as directed by the Commission, the RD provides findings with respect to the public interest and recommends a determination that the public interest factors do not preclude entry of the proposed LEO.

On August 14, 2019, both Bracco and the Commission's Investigative Attorney ("IA") filed petitions for review of the FID. Bracco petitions for review of the FID's findings with respect to invalidity, while the IA petitions for review of the FID's findings with respect to domestic industry. On August 22, 2019, the parties filed responses to the respective petitions.

The Commission has determined to review the FID in part. Specifically, the Commission has determined to review the FID's findings with respect to invalidity and domestic industry. The Commission has determined not to review the remainder of the FID. At this time, the Commission does not request any briefing from the parties.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.

Lisa R. Barton
Secretary to the Commission

Issued: September 30, 2019

CERTAIN STRONTIUM-RUBIDIUM RADIOISOTOPE INFUSION SYSTEMS, AND COMPONENTS THEREOF INCLUDING GENERATORS

Inv. No. 337-TA-1110

PUBLIC CERTIFICATE OF SERVICE

I, Lisa R. Barton, hereby certify that the attached **NOTICE** has been served by hand upon the Commission Investigative Attorney, **Brian Koo, Esq.**, and the following parties as indicated, on **September 30, 2019**.

Lisa R. Barton, Secretary
U.S. International Trade Commission
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Washington, DC 20436

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- ☐ Via Express Delivery
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On Behalf of Respondents Jubilant DraxImage Inc., Jubilant Pharma Limited, and Jubilant Life Sciences:

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- ☐ Via Express Delivery
- ☒ Via First Class Mail
- ☐ Other:_____

PUBLIC VERSION

UNITED STATES INTERNATIONAL TRADE COMMISSION

Washington, D.C.

In the Matter of **CERTAIN STRONTIUM-RUBIDIUM RADIOISOTOPE INFUSION SYSTEMS, AND COMPONENTS THEREOF INCLUDING GENERATORS**	**INV. NO. 337-TA-1110**

INITIAL DETERMINATION ON VIOLATION OF SECTION 337 AND RECOMMENDED DETERMINATION ON REMEDY AND BOND

Administrative Law Judge Clark S. Cheney

(August 1, 2019)

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TABLE OF ABBREVIATIONS

CDX	Complainant's demonstrative exhibit
CIB	Complainant's initial post-hearing brief
CPB	Complainant's pre-hearing brief
CPX	Complainant's physical exhibit
CRB	Complainant's reply post-hearing brief
CX	Complainant's exhibit
Dep.	Deposition
JX	Joint Exhibit
RDX	Respondent's demonstrative exhibit
RIB	Respondent's initial post-hearing brief
RPX	Respondent's physical exhibit
RPB	Respondent's Pre-hearing brief
RRB	Respondent's reply post-hearing brief
RRX	Respondent's rebuttal exhibit
RX	Respondent's exhibit
SIB	Staff's initial post-hearing brief
SPB	Staff's Pre-hearing brief
SRB	Staff's reply post-hearing brief
Stip.	Stipulation of the parties
Tr.	Transcript

PUBLIC VERSION

UNITED STATES INTERNATIONAL TRADE COMMISSION

Washington, D.C.

In the Matter of **CERTAIN STRONTIUM-RUBIDIUM RADIOISOTOPE INFUSION SYSTEMS, AND COMPONENTS THEREOF INCLUDING GENERATORS**	**INV. NO. 337-TA-1110**

INITIAL DETERMINATION ON VIOLATION OF SECTION 337 AND RECOMMENDED DETERMINATION ON REMEDY AND BOND

Administrative Law Judge Clark S. Cheney

(August 1, 2019)

Pursuant to the Notice of Investigation, 83 Fed. Reg. 19112 (May 1, 2018), this is the final Initial Determination in the matter of *Certain Strontium-Rubidium Radioisotope Infusion Systems, and Components Thereof Including Generators*, Investigation No. 337-TA-1110. 19 C.F.R. §§ 210.10(b), 210.42(a)(1)(i).

For the reasons stated herein, I have determined that no violation of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. § 1330 or "section 337"), has occurred in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain strontium-rubidium radioisotope infusion systems, and components thereof, including generators, alleged to infringe U.S. Patent Nos. 9,814,826 ("the '826 patent"), 9,750,869 ("the '869 patent"), and 9,750,870 ("the '870 patent").

I. INTRODUCTION

A. Procedural History

On April 3, 2018, complainant Bracco Diagnostics Inc. ("Bracco") filed a complaint alleging violations of section 337 based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain strontium-rubidium radioisotope infusion systems, and components thereof, including generators, by reason of infringement of one or more of U.S. Patent No. 9,814,826 (JX-0001, hereinafter "the '826 patent"); U.S. Patent No. 9,750,869 (JX-0002, hereinafter "the '869 patent"); and U.S. Patent No. 9,750,870 (JX-0003, hereinafter "the '870 patent"). 83 Fed. Reg. 14294 (April 3, 2018).

On May 1, 2018, the Commission instituted this investigation to determine:

> whether there is a violation of subsection (a)(1)(b) of section 337 in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain strontium-rubidium radioisotope infusion systems, and components thereof including generators by reason of infringement of one or more claims 1-3, 5, 9-14, 17-19, 26, and 28 of the '826 patent; claims 1-5, 8, 14, 24 and 27-30 of the '869 patent; and claims 1, 2, 8-13, 16, 17, 22, and 27 of the '870 patent; and whether an industry in the United States exists, or is in the process of being established, as required by subsection (a)(2) of section 337.

83 Fed. Reg. 19112 (May 1, 2018).

The named respondents were Jubilant DraxImage Inc. of Quebec, Canada, Jubilant Pharma Limited of Singapore, and Jubilant Life Sciences of Uttar Pradesh, India (collectively "Jubilant"). *See id.* at 19113.

The Commission investigative staff ("Staff") is a party to this investigation. *Id.* at 19112.

On August 8, 2018, Administrative Law Judge Shaw granted Bracco's unopposed motion for termination of the investigation with respect to claims 10 and 26 of the '826 patent, claims 27 and 28 of the '869 patent, and claims 9 and 22 of the '870 patent. Order No. 15; *see also* Notice of a Comm'n Det. not to Review an Initial Det. Granting an Unopposed Mot. for Partial Term. of

the Inv. As to Certain Patent Claims (Sept. 6, 2018) (EDIS Doc. ID 655032). On September 20, 2018, Administrative Law Judge Shaw granted Bracco's unopposed motion for termination of the investigation with respect to claim 13 of the '870 patent. Order No. 18; *see also* Notice of a Comm'n Det. not to Review an Initial Det. Granting an Unopposed Mot. for Partial Term. of the Inv. As to a Patent Claim (Sept. 26, 2018) (EDIS Doc. ID 656868).

On February 8, 2019, I granted Bracco and Jubilant's cross motions for summary determination with respect to whether certain accused products and proposed products practiced the asserted patent claims. Order No. 27, *not reviewed*Notice of a Comm'n Det. not to Review an Initial Det. Granting Summary Det. as to Certain Patent Infringement Issues (March 12, 2019) (EDIS Doc. ID 669522).

I convened an evidentiary hearing on February 11-12 and 15-17, 2019, to determine whether section 337 has been violated by reason of the importation into the United States, the sale for importation, or the sale within the United States after importation of the infringing strontium-rubidium radioisotope infusion systems and components thereof.

B. The Parties

1. Complainant Bracco Diagnostics Inc.

Bracco is a corporation organized and existing under the laws of Indiana, with its headquarters and principal place of business located at 259 Prospect Plains Road, Building H, Monroe Township, NJ, 08831. Compl. at ¶ 5. Bracco is the owner by assignment of the asserted patents in this investigation. *See* '862 patent at Cover; '869 patent at Cover; '870 patent at Cover.

2. The Jubilant Respondents

Respondents Jubilant DraxImage Inc., Jubilant Pharma Limited, and Jubilant Life Sciences are related corporations. Response at ¶¶ 17-18. The companies sell a range of medical products,

including the radiopharmaceutical infusion and generation products at issue in this investigation. RPB at 2-3.

a) *Jubilant DraxImage Inc.*

Jubilant DraxImage Inc. is a Canadian corporation with its principal place of business at 16751 TransCanada Highway Kirkland, Quebec, Canada, H9H 4J4. Amended Response at ¶ 13. Jubilant DraxImage Inc. is a subsidiary of Jubilant Pharma Limited. *Id.* at 17.

b) *Jubilant Pharma Limited*

Jubilant Pharma Limited is a Singaporean corporation with its principal place of business at 6 Temasek Boulevard, #20-06 Suntec City Tower Four, Singapore, 038986. *Id.* at ¶ 15. Jubilant Pharma Limited is a subsidiary of Jubilant Life Sciences Limited. *Id.* at 18.

c) *Jubilant Life Sciences*

Jubilant Life Sciences Limited is an Indian company with its principal place of business at Plot 1-A Sector 16-A Institutional Area Noida, Uttar Pradesh, 201301, India. *Id.* at ¶ 16.

C. The Asserted Patents

Bracco asserts claims of three related patents in this investigation: the ’826 patent, the ’869 patent, and the ’870 patent. The appropriate priority date for the claimed inventions is disputed. On their face, all three patents claim priority to June 11, 2008. The parties agree that the earliest relevant priority date for all three patents is no earlier than June 11, 2009, the date Application No. PCT/US2009/047031 was filed. *See* CPB at 438; RPB at 91; SIB at 6. Jubilant alone asserts the priority date is later. RIB at 2-8. The named inventors on all three patents are Stephen E. Hidem, Aaron M. Fontaine, Janet L. Gelbach, Patrick M. McDonald, Kathryn M. Hunter, Rolf E. Swenson, and Julius P. Zodda. ’826 patent at Cover; ’869 patent at Cover; ’870 patent at Cover. All three

patents are assigned to Bracco. The asserted patents relate to strontium-rubidium elution and infusion systems used in positron emission tomography ("PET") for cardiac imaging.

1. U.S. Patent No. 9,814,826 (JX-0001)

U.S. Patent No. 9,814,826, titled "Integrated Strontium-Rubidium Radioisotope Infusion Systems," was issued by the U.S. Patent and Trademark Office ("PTO") on November 14, 2017, from U.S. Application No. 15/620,320, filed on June 12, 2017. Bracco asserts claims 1-3, 5, 9, 11-14, 17-19, and 28 of the '826 patent.

2. U.S. Patent No. 9,750,869 (JX-0002)

U.S. Patent No. 9,750,869, titled "Integrated Strontium-Rubidium Radioisotope Infusion Systems," was issued by the PTO on September 5, 2017, from U.S. Application No. 15/389,200, filed on December 22, 2016. Bracco asserts claims 1-5, 8, 14, 24, and 29-30 of the '869 patent.

3. U.S. Patent No. 9,750,870 (JX-0003)

U.S. Patent No. 9,750,870, titled "Integrated Strontium-Rubidium Radioisotope Infusion Systems," was issued by the PTO on September 5, 2017, from U.S. Application No. 15/490,484, filed on April 18, 2017. Bracco asserts claims 1, 2, 8, 10-12, 16-17, and 27 of the '870 patent.

D. The Technology at Issue

All three asserted patents are directed to the same technology and share the same specification. The patents describe a computer-controlled medical device that generates the radioisotope rubidium-82 (Rb-82) and safely infuses a patient with the isotope in conjunction with PET imaging of the patient's heart. The asserted claims are apparatus claims directed to the structure of the generator and infusion device, method claims for making the device, and method claims for using the device.

Rubidium-82 has been used as a radiation source for cardiac PET imaging for many decades, well before the invention in the patents at issue. *See, e.g.*, RX-0207 (CardioGen-82 Model 510 user manual); Tr. at 137:15-24, 589:18-590:8. Rubidium-82 is useful because of its relatively short half-life of 76 seconds and because it is absorbed by cardiac tissue proportionally to coronary-artery blood flow. RX-106.000017. Although the short half-life minimizes the patient's radiation exposure, it requires that rubidium-82 be generated on-demand for each patient infusion. *Id.* at .0017-0018.

For several decades, the medical imaging field has been generating rubidium-82 by passing .9% NaCl saline over another radioactive isotope, strontium-82 (Sr-82), in a device called a generator, a process called elution. RX-106.000018. The saline picks up rubidium atoms generated by the strontium as it decays and the resulting fluid, called an eluate, is infused into the patient.

Some additional details about strontium will be helpful to understand the risks of rubidium infusion and the field of the claimed inventions. Strontium-82 is created in a very large, very expensive piece of equipment called a cyclotron particle accelerator. Ideally, the product of the cyclotron would be pure strontium-82, but the resultant material may have strontium-85 (Sr-85) impurities. *Id.* Strontium-82 has a half-life of 25.5 days, and strontium-85 has a substantially longer 65-day half-life. *Id.* Because strontium shares chemical properties with calcium, the human body readily absorbs it and binds it to bones and teeth. *Id.* at .000019. Consequently, if either Sr-82 or Sr-85 is accidentally administered to a patient during infusion, the patient will have a radiation source in his or her body emitting radiation for months. *Id.* Bone marrow is also particularly susceptible to damage from radiation exposure, rendering strontium exposure particularly dangerous for patient health. *Id.*

Inside a strontium-rubidium generator, strontium-82 is affixed to a tin oxide (SnO2) column. RX-106.000018. As the generator ages, strontium eventually starts to detach from the column and contaminate the eluate, posing a risk to patient health. *Id.* Such an occurrence is known as strontium "breakthrough." *Id.* Strontium breakthrough can also be caused by a user putting the wrong solution into the generator. For example, one solution regularly used in medical settings, called ringer's lactate, can displace substantial amounts of strontium from the core. Tr. at 451:9-452:1. On at least six occasions, operators have mistakenly run ringer's lactate through a strontium-rubidium infusion system and injected a patient with strontium. Tr. at 433:18-24.

To prevent inadvertent patient exposure to strontium resulting from strontium breakthrough, operators must perform daily quality-control checks on the generator. RX-106 at .0019-.0020. In the prior art, such as with Bracco's CardioGen-82 device, operators performed breakthrough tests manually. The test involved the operator manually transporting the radioactive eluate for testing and required the operator to accurately perform complex calculations. Tr. at 428:23-431:14.

The asserted patents describe a strontium-rubidium infusion system "on-board" a cart. *See, e.g.*, '869 patent at claim 1. The system is configured to determine a strontium breakthrough test result from a sample on the cart and "not allow a patient infusion if the strontium breakthrough test result is greater than or equal to an allowed limit," such as would occur in a strontium breakthrough event. *See id.*

E. The Accused Products

The accused products in this investigation are Jubilant's RUBY Rubidium Elution Systems, the generators used in those systems, and the tubing sets used for the systems. Jubilant currently markets and sells the RUBY Rubidium Elution System Version 3 ("RUBY Version 3")

in the United States, and the Commission has already found that the RUBY Version 3 practices all asserted patent claims. *See* Order No. 27, *not reviewed* Comm'n Det. not to Review an Initial Det. Granting Summary Det. (March 12, 2019) (EDIS Doc. ID 669522). Jubilant is also seeking approval of the U.S. Food and Drug Administration ("FDA") to market the RUBY Rubidium Elution System Version 3.1 ("RUBY Version 3.1") and RUBY Rubidium Elution System Version 4 ("RUBY Version 4") in the United States. *See* Tr. at 323:9-11. The Commission has found the designs of those two devices do not practice any claim of the asserted patents. Comm'n Det. not to Review an Initial Det. Granting Summary Det. (March 12, 2019) (EDIS Doc. ID 669522).

All three RUBY Versions use the same generator, called the RUBY-FILL rubidium-82 generator. The generators have a one or two month life before they must be replaced. Tr. at 319:16-320:2. The eluate tubing for a rubidium infusion system must also be replaced regularly. *Id*. All three RUBY Versions use the same set of tubing called the RUBY Set. Tr. at 323:3-8. Typically, both Jubilant and Bracco sell their own branded tubing sets and generators, which are not interchangeable between the two manufacturer's systems. *See* CX-0033C ("RUBY-FILL 'Family' of Products"); CX-0566C (Gentilcore Dep. Tr.) at 149:3-150:1; RX-0411C (Troger Dep. Tr.) at 121:3-10; Tr. at 381:17-382:4; 876:20-25.

F. The Domestic Industry Products

Bracco's CardioGen 1700 rubidium infusion system is the only potential domestic industry product at issue in this investigation. There is no dispute that the CardioGen1700 practices at least one claim of each of the asserted patents. Tr. at 28:7-10. Because the CardioGen 1700 is not FDA approved, however, the parties dispute whether a domestic industry exists or is in the process of being established for products that practice the asserted patents.

II. JURISDICTION & IMPORTATION

A. Subject Matter Jurisdiction

Section 337 confers subject matter jurisdiction on the Commission to investigate, and if appropriate, to provide a remedy for, unfair acts and unfair methods of competition in the importation of articles into the United States and the sale of such articles. *See* 19 U.S.C. §§ 1337(a)(1)(B) and (a)(2). Bracco filed a complaint alleging a violation of section 337, and the Commission has subject matter jurisdiction over the complaint. *See Amgen, Inc. v. Int'l. Trade Comm'n*, 902 F.2d 1532, 1536 (Fed. Cir. 1990).

B. Personal Jurisdiction

Jubilant has appeared and participated in this investigation. The Commission therefore has personal jurisdiction over Jubilant. *See, e.g.*, *Certain Magnetic Tape Cartridges and Components Thereof*, Inv. No. 337-TA-1058, ID at 12 (Aug. 17, 2018) (EDIS Doc. No. 653306) (unreviewed in relevant part).

C. In Rem Jurisdiction

The parties have stipulated that Jubilant Labs has imported the RUBY Version 3.1 and Version 4, as well as the generators and tubing used for all three RUBY Versions (3, 3.1, and 4). RPB at 40; Stip. at ¶ 2 (EDIS Doc. ID 664016, at Ex. H). Accordingly, the Commission has *in rem* jurisdiction over the accused products. *See Sealed Air Corp. v. Int'l Trade Comm'n*, 645 F.2d 976, 985-86 (C.C.P.A. 1981) (noting that the Commission has jurisdiction over imported goods).

D. Importation

The RUBY Version 3 infusion device is made in the United States; it is not imported. But the generator and tubing sets used with Jubilant's products are imported. Specifically, the parties have stipulated that Jubilant DraxImage Inc. has imported the RUBY-FILL rubidium

generator and the RUBY Set. Stip. at ¶¶ 2, 4. The parties have also stipulated that Jubilant has imported other components of the system, including the RUBY Saline Line, the RUBY IN Line, and RUBY Connectors. *Id*. It is undisputed that Jubilant also imported prototypes of the RUBY Version 3.1 and Version 4 designs. Order No. 27 at 18. I find that the importation requirement of section 337 has been satisfied.

E. Standing

The evidence of record demonstrates that Bracco, as assignee of the asserted patents, has standing to bring its complaint. *See* '826 patent at Cover; '869 patent at Cover; '870 patent at Cover. Accordingly, I find that Bracco has standing in this investigation.

III. LEGAL PRINCIPLES

A. Claim Construction

"An infringement analysis entails two steps. The first step is determining the meaning and scope of the patent claims asserted to be infringed. The second step is comparing the properly construed claims to the device accused of infringing." *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995) (*en banc*) (internal citations omitted), *aff'd*, 517 U.S. 370 (1996). Claim construction resolves legal disputes between the parties regarding claim scope. *See Eon Corp. IP Holdings v. Silver Spring Networks*, 815 F.3d at 1314, 1319 (Fed. Cir. 2016).

Evidence intrinsic to the application, prosecution, and issuance of a patent is the most significant source of the legally operative meaning of disputed claim language. *See Bell Atl. Network Servs., Inc. v. Covad Commc'ns Grp., Inc.*, 262 F.3d 1258, 1267 (Fed. Cir. 2001). The intrinsic evidence includes the claims themselves, the specification, and the prosecution history. *See Phillips v. AWH Corp*, 415 F.3d 1303, 1314 (Fed. Cir. 2005) (*en banc*); *see also Markman*, 52 F.3d at 979. As the Federal Circuit explained in *Phillips*, courts must analyze each

of these components to determine the "ordinary and customary meaning of a claim term" as understood by a person of ordinary skill in the art at the time of the invention. 415 F.3d at 1313.

"It is a 'bedrock principle' of patent law that 'the claims of a patent define the invention to which the patentee is entitled the right to exclude.'" *Phillips*, 415 F.3d at 1312 (quoting *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1115 (Fed. Cir. 2004)). "Quite apart from the written description and the prosecution history, the claims themselves provide substantial guidance as to the meaning of particular claims terms." *Id.* at 1314; *see Interactive Gift Express, Inc. v. Compuserve Inc.*, 256 F.3d 1323, 1331 (Fed. Cir. 2001) ("In construing claims, the analytical focus must begin and remain centered on the language of the claims themselves, for it is that language that the patentee chose to use to 'particularly point[ ] out and distinctly claim[ ] the subject matter which the patentee regards as his invention.'"). The context in which a term is used in an asserted claim can be "highly instructive." *Phillips*, 415 F.3d at 1314. Additionally, other claims in the same patent, asserted or unasserted, may also provide guidance as to the meaning of a claim term. *Id.*

The specification "is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term." *Id.* at 1315 (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)). "[T]he specification may reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess. In such cases, the inventor's lexicography governs." *Id.* at 1316. "In other cases, the specification may reveal an intentional disclaimer, or disavowal, of claim scope by the inventor." *Id.* As a general rule, however, the particular examples or embodiments discussed in the specification are not to be read into the claims as limitations. *Id.* at 1323. In the end, "[t]he construction that stays true to the claim language and most naturally aligns with the

patent's description of the invention will be . . . the correct construction." *Id.* at 1316 (quoting *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998)).

When the intrinsic evidence does not establish the meaning of a claim, then extrinsic evidence (*i.e.*, all evidence external to the patent and the prosecution history, including dictionaries, inventor testimony, expert testimony, and learned treatises) may be considered. *Id.* at 1317. Extrinsic evidence is generally viewed as less reliable than the patent itself and its prosecution history in determining how to define claim terms. *Id.* "The court may receive extrinsic evidence to educate itself about the invention and the relevant technology, but the court may not use extrinsic evidence to arrive at a claim construction that is clearly at odds with the construction mandated by the intrinsic evidence." *Elkay Mfg. Co. v. Ebco Mfg. Co.*, 192 F.3d 973, 977 (Fed. Cir. 1999).

B. Validity

A patent is presumed valid. *See* 35 U.S.C. § 282; *Microsoft Corp. v. i4i Ltd. P'ship*, 131 S. Ct. 2238, 2242 (2011). A respondent who has raised patent invalidity as an affirmative defense has the burden of overcoming this presumption by clear and convincing evidence. *See Microsoft,* 131 S. Ct. at 2242.

1. Anticipation

Under 35 U.S.C. § 102, a claim is anticipated, and therefore invalid, when "the four comers of a single, prior art document describe every element of the claimed invention, either expressly or inherently, such that a person of ordinary skill in the art could practice the invention without undue experimentation." *Advanced Display Sys., Inc. v. Kent State Univ.*, 212 F.3d 1272, 1282 (Fed. Cir. 2000). To be considered anticipatory, the prior art reference must be enabling and describe the applicant's claimed invention sufficiently to have placed it in possession of a person

of ordinary skill in the field of the invention. *See Helifix Ltd. v. Blok-Lok, Ltd.*, 208 F.3d 1339, 1346 (Fed. Cir. 2000).

2. Obviousness

Under 35 U.S.C. § 103, a patent may be found invalid as obvious 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." 35 U.S.C. § 103(a). Because obviousness is determined at the time of invention, rather than the date of litigation, "[t]he great challenge of the obviousness judgment is proceeding without any hint of hindsight." *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co*., 655 F.3d 1364, 1375 (Fed. Cir. 2011).

The critical inquiry in determining the differences between the claimed invention and the prior art is whether there is an apparent reason to combine the known elements in the fashion claimed by the patent at issue. *See KSR Int'l Co. v. Teleflex, Inc*., 550 U.S. 398, 417-418 (2007) (hereinafter "*KSR*"). Thus, when a combination of several prior art references is asserted, "the burden falls on the patent challenger to show by clear and convincing evidence that a person of ordinary skill in the art would have had reason to attempt to make the composition or device, or carry out the claimed process, and would have had a reasonable expectation of success in doing so." *PharmaStem Therapeutics, Inc. v. ViaCell, Inc.*, 491 F.3d 1342, 1360 (Fed. Cir. 2007) (citations omitted). Though rare, "in appropriate circumstances, a patent can be obvious in light of a single prior art reference if it would have been obvious to modify that reference to arrive at the patented invention." *Arendi S.A.R.L. v. Apple Inc.*, 832 F.3d 1355, 1361 (Fed. Cir. 2016).

Prior art for an obviousness determination must be analogous to the claimed invention. *In re Clay*, 966 F.2d 656, 658 (Fed. Cir. 1992). Prior art is considered analogous when it meets at least one of two separate tests: "(1) whether the art is from the same field of endeavor, regardless

of the problem addressed and, (2) if the reference is not within the field of the inventor's endeavor, whether the reference still is reasonably pertinent to the particular problem with which the inventor is involved." *In re Bigio*, 381 F.3d 1320, 1325 (Fed. Cir. 2004) (citing *In re Deminski*, 796 F.2d 436, 442 (Fed.Cir.1986)).

Obviousness is a determination of law based on underlying determinations of fact. *Star Scientific*, 655 F.3d at 1374. The factual determinations behind a finding of obviousness include: (1) the scope and content of the prior art, (2) the level and content of the prior art, (3) the differences between the claimed invention and the prior art, and (4) secondary considerations of non-obviousness. *KSR*, 550 U.S. at 399 (citing *Graham v. John Deere Co*., 383 U.S. 1, 17 (1966)). Secondary considerations of non-obviousness include commercial success, long felt but unresolved need, and the failure of others. *Id.* Evidence of direct copying may also be an objective indicator of non-obviousness. *Apple Computer, Inc. v. Articulate Sys., Inc.*, 234 F.3d 14, 26 (Fed. Cir. 2000). When present, secondary considerations "give light to the circumstances surrounding the origin of the subject matter sought to be patented," but they are not dispositive on the issue of obviousness. *Geo. M. Martin Co. v. Alliance Mach. Sys. Int'l.*, 618 F.3d 1294, 1304-06 (Fed. Cir. 2010). For evidence of secondary considerations to be given substantial weight in the obviousness determination, its proponent must establish a nexus between the evidence and the merits of the claimed invention. *See W. Union Co. v. MoneyGram Payment Sys. Inc.*, 626 F.3d 1361, 1372-73 (Fed. Cir. 2010) (citing *In re GPAC Inc.*, 57 F.3d 1573, 1580 (Fed. Cir. 1995)).

C. Assignor Estoppel

Assignor estoppel is an equitable doctrine that prevents one who has assigned the rights to a patent from later contending that the patent is invalid. *Pandrol USA, LP v. Airboss Ry. Prods., Inc*., 424 F.3d 1161, 1166-67 (Fed. Cir. 2005). Those in privity with the assignor are likewise estopped from arguing the patent's invalidity. *MAG Aerospace Indus., Inc. v. B/E Aerospace, Inc*.,

816 F.3d 1374, 1379-81 (Fed. Cir. 2016); *Checkpoint Sys., Inc. v. All-Tag Sec. S.A.*, 412 F.3d 1331, 1336-37 (Fed. Cir. 2005).

Privity depends on the nature and extent of the relationship between the assignor and the other party. For example, "if an inventor assigns his invention to his employer company A and leaves to join company B, whether company B is in privity and thus bound by the doctrine will depend on the equities dictated by the relationship between the inventor and company B in light of the act of infringement. The closer that relationship, the more the equities will favor applying the doctrine to company B." *MAG Aerospace Indus.*, 816 F.3d at 1374.

The factors considered when examining assignor-estoppel privity include: (1) the assignor's leadership role at the new employer; (2) the assignor's ownership stake in the defendant company; (3) whether the defendant company changed course from manufacturing non-infringing goods to infringing activity after the inventor was hired; (4) the assignor's role in the infringing activities; (5) whether the inventor was hired to start the infringing operations; (6) whether the decision to manufacture the infringing product was made partly by the inventor; (7) whether the defendant company began manufacturing the accused product shortly after hiring the assignor; and (8) whether the inventor was in charge of the infringing operation. *Id*. (citing *Shamrock Techs., Inc. v. Med. Sterilization, Inc*., 903 F.2d 789, 793 (Fed. Cir. 1990)). The Federal Circuit has also considered whether the accused infringer availed itself of the knowledge and assistance of the named inventor to develop the accused product. *Intel Corp. v. U.S. Int'l Trade Comm'n*, 946 F.2d 821, 837-39 (Fed. Cir. 1991) (citing *Shamrock*, 903 F.2d at 793).

D. Infringement

In a section 337 investigation, the complainant bears the burden of proving infringement of the asserted patent claims by a preponderance of the evidence. *See Spansion Inc. v. Int'l Trade Comm'n*, 629 F.3d 1331, 1349 (Fed. Cir. 2010). This standard "requires proving that infringement

was more likely than not to have occurred." *Warner-Lambert Co. v. Teva Pharm. USA, Inc*., 418 F.3d 1326, 1341 n.15 (Fed. Cir. 2005). Section 271 of the Patent Act defines both direct infringement and the two categories of indirect infringement—active inducement of infringement and contributory infringement. 35 U.S.C. § 271(a), (b), and (c). There can be no indirect infringement absent direct infringement. *See Limelight Networks, Inc. v. Akamai Technologies, Inc.*, 134 S. Ct. 2111, 2117 (2014); *Aro Manufacturing Co. v. Convertible Top Replacement Co.*, 365 U.S. 341 (1961); *see also Met-Coil Sys. Corp. v. Korners Unltd., Inc.*, 803 F.2d 684, 687 (Fed. Cir. 1986) ("Absent direct infringement of the patent claims, there can be neither contributory infringement . . . nor inducement of infringement.") (citations omitted).

1. Direct Infringement

Direct infringement of an apparatus claim requires the accused device to contain each and every limitation set forth in a claim. C*entrak, Inc. v. Sonitor Techs., Inc.*, 915 F.3d 1360, 1371 (Fed. Cir. 2019). A method claim is directly infringed only if each step of the claimed method is performed. *Muniauction, Inc. v. Thomson Corp*., 532 F.3d 1318, 1328 (Fed. Cir. 2008) (distinguished on other grounds by *Travel Sentry, Inc. v. Tropp*, 877 F.3d 1370, 1383 (Fed. Cir. 2017)).

2. Inducement of Infringement

Section 271(b) of the Patent Act prohibits inducement of infringement: "[w]hoever actively induces infringement of a patent shall be liable as an infringer." 35 U.S.C. § 271(b). Inducement of infringement is the "active[] and knowing[] aid[ing] and abet[ing] [of] another's direct infringement." *See DSU Med. Corp. v. JMS Co.*, 471 F.3d 1293, 1305 (Fed. Cir. 2006) *(en banc)*. A violation of section 337 may arise from inducement of infringement via imported

articles. *Suprema, Inc. v. International Trade Com'n*, 796 F.3d 1338, 1351-52 (Fed. Cir. 2015) (*en banc*).

3. Contributory Infringement

Section 271(c) of the Patent Act prohibits contributory infringement. *See* 35 U.S.C. § 27l(c). "Under 35 U.S.C. § 27l(c), a party who sells a component with knowledge that the component is especially designed for use in a patented invention, and is not a staple article of commerce suitable for substantial noninfringing use, is liable as a contributory infringer." *Wordtech Sys., Inc. v. Integrated Networks Solutions, Inc.*, 609 F.3d 1308, 1316 (Fed. Cir. 2010). To establish contributory infringement in a section 337 investigation, it must be shown that "(1) there is an act of direct infringement in violation of section 337; (2) the accused device has no substantial non-infringing uses; and (3) the accused infringer imported, sold for importation, or sold after importation within the United States, the accused components that contributed to another's direct infringement." *Spansion*, 629 F.3d at 1353.

E. Domestic Industry

For a patent-based complaint, a violation of section 337 can be found "only if an industry in the United States, relating to the articles protected by the patent . . . concerned, exists or is in the process of being established." 19 U.S.C. § 1337(a)(2). This domestic industry requirement of section 337 is often described as having an economic prong and a technical prong. *InterDigital Commc'ns, LLC v. Int'l Trade Comm'n*, 707 F.3d 1295, 1298 (Fed. Cir. 2013); *Certain Stringed Musical Instruments and Components Thereof*, Inv. No. 337-TA-586, USITC Pub. 4120, 2009 WL 5134139 (Dec. 2009), Comm'n Op. at 12-14. The complainant bears the burden of establishing that the domestic industry requirement is satisfied. *See Certain Set-Top Boxes and Components Thereof*, Inv. No. 337-TA-454, ID at 294, 2002 WL 31556392 (June 21, 2002) (unreviewed by Commission in relevant part).

1. Economic Prong

Section 337(a)(3) sets forth the following economic criteria for determining the existence of a domestic industry in such investigations:

> (3) For purposes of paragraph (2), an industry in the United States shall be considered to exist if there is in the United States, with respect to the articles protected by the patent, copyright, trademark, mask work, or design concerned -
>
> (A) significant investment in plant and equipment;
>
> (B) significant employment of labor or capital; or
>
> (C) substantial investment in its exploitation, including engineering, research and development, or licensing.

Given that the statutory criteria are listed in the disjunctive, satisfaction of any one of them will be sufficient to meet the economic prong of the domestic industry requirement. *See Certain Variable Speed Wind Turbines and Components Thereof*, Inv. No. 337-TA-376, USITC Pub. 3003, (Nov. 1996), Comm'n Op. at 15.

2. Technical Prong

The technical prong of the domestic industry requirement is satisfied when the complainant in a patent-based section 337 investigation establishes that it is practicing or exploiting the patents at issue. *See* 19 U.S.C. § 1337(a)(2) and (3); *Certain Microsphere Adhesives, Process for Making Same and Prods. Containing Same, Including Self-Stick Repositionable Notes*, Inv. No. 337-TA-366, Comm'n Op. at 8, 1996 WL 1056095 (Jan. 16, 1996). "The test for satisfying the 'technical prong' of the industry requirement is essentially [the] same as that for infringement, *i.e.*, a comparison of domestic products to the asserted claims." *Alloc, Inc. v. Int'l Trade Comm'n*, 342 F.3d 1361, 1375 (Fed. Cir. 2003). To prevail, the patentee must establish by a preponderance of the evidence that the domestic product practices one or more claims of the patent. It is sufficient to show that the products practice any claim of that patent, not necessarily an asserted claim of that

patent. *See Certain Male Prophylactic Devices*, Inv. No. 337-TA-546, Comm'n Op. at 38 (Aug. 1, 2007).

IV. LEVEL OF ORDINARY SKILL IN THE ART

A person of ordinary skill in the art is a hypothetical person who is presumed to be aware of all pertinent prior art. *Custom Accessories, Inc. v. Jeffrey-Allan Industries, Inc.*, 807 F.2d 955, 962 (Fed. Cir. 1992). Determining the appropriate level of skill for this hypothetical person can involve consideration of the types of problems encountered in the art, prior art solutions to those problems, rapidity with which innovations are made, sophistication of the technology at issue, the educational level of active workers in the field, and the level of education of the inventors themselves. *Daiichi Sankyo Co. v. Apotex, Inc.*, 501 F.3d 1254, 1256 (Fed. Cir. 2007).

Bracco proposes that a person of ordinary skill in the art would possess "a graduate degree in medicine and/or in a medical related science, including physics, chemistry, biology, physiology, and/or biophysics, or a related field, and would generally have at least some clinical, research, and/or design experience with respect to PET imaging and/or PET imaging systems." CIB at 11 (citing CDX-0002.04). Bracco also asserts that an individual with a relevant undergraduate degree along with significant experience could be sufficiently skilled. *Id.* Further, according to Bracco, the amount of experience following an undergraduate degree would depend on the level of formal education and amount of experience working with radiopharmaceuticals. *Id*. In its reply, Bracco additionally argues that because the claims pertain to both the use and design of the claimed elution systems, its definition is more appropriate than that of Jubilant. CRB at 3.

Jubilant proposes that a person of ordinary skill in the art would possess a graduate 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 one

of those fields with two to three years' work experience in radioactive protection systems or in medical device product, automation, or instrumentation design and development, including working with prototypes and finished products. RDX-0002C.0083. Jubilant further notes that such 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. RDX-0002C.0083.

Finally, Staff proposes that a person of ordinary skill in the art would possess "at least a master's degree in physics, electrical engineering, systems engineering, mechanical engineering, or a related field with at least two years of work experience with designing and/or developing nuclear medical devices or medical imaging devices." SPB at 10. Staff allows that superior qualifications with respect to either education or experience may compensate for a deficit in the other. *Id.* Staff's proposal is closer to Jubilant's than Bracco's. *Id.* at 10-11.

No party, however, expressly contends that the different proposals will lead to different outcomes with respect to any issue before me, rendering any dispute immaterial. Nevertheless, to the extent I must make a determination about the appropriate level of skill in the art, I adopt the definition proposed by Staff. A person of ordinary skill in the art at the time of the inventions described in the asserted patents would have at least a master's degree in physics, electrical engineering, systems engineering, mechanical engineering, or a related field with at least two years of work experience with designing and/or developing nuclear medical devices or medical imaging devices. Superior qualification with respect to either education or experience may compensate for a deficit in either.

This definition is supported by credible expert testimony. *See, e.g.*, Tr. at 615:12-616:24 (testimony of Dr. Stone as to level of ordinary skill, rejecting Bracco's proposed definition because

the patents "deal[] with a system to inject a fluid safely" not "the practice of medicine" or "the [PET] imaging process"). I also find, as a factual matter, that this definition better matches the education level of workers in the field and the inventors themselves, as reflected in the record. *See, e.g.*, JX-0176C.012-24 (educational and professional background of inventor Janet Gelbach).

V. VALIDITY

A. Assignor Estoppel

Bracco contends that Jubilant is prohibited from challenging the validity of the asserted patents under the equitable doctrine of assignor estoppel. CIB at 35-38. Bracco's argument turns on facts relating to Janet Gelbach, one of the inventors listed on the asserted patents. *See, e.g.*, '826 patent at Cover (showing Janet Gelbach as a listed inventor and Bracco as assignee); '869 patent at Cover (same); '870 patent at Cover (same). Ms. Gelbach was an employee of Bracco at the time of the invention and she assigned her rights in the patents to Bracco. CX-147-150 (assignments without reservation of rights to challenge validity). Jubilant later hired Ms. Gelbach during the period of development of the RUBY Version 3. JX-0176C (Gelbach Dep. Tr.) at 120:7-13. Bracco contends that Ms. Gelbach and Jubilant are estopped from arguing the patent is invalid. CIB at 35. Jubilant and Staff disagree that Jubilant is estopped. RRB at 31-38; SIB at 141-145, SRB at 7.

No one disputes that Janet Gelbach is personally prohibited from challenging the validity of the asserted patents. *See Mentor Graphics Corp. v. Quickturn Design Sys., Inc.*, 150 F.3d 1374, 1378 (Fed. Cir. 1998) (because an assignor "has already been fully paid for the patent rights," public policy prohibits a challenge) (citing *Diamond Sci. Co. v. Ambico, Inc.*, 848 F.2d 1220 (Fed. Cir. 1988)). If Ms. Gelbach were the respondent, Jubilant would have carried its burden.

But Ms. Gelbach is not the respondent, Jubilant is. Bracco argues that Jubilant is in "privity" with Ms. Gelbach, thereby seeking to extend the equitable prohibition on her challenging

the patents to her new employer. CIB at 35. The Federal Circuit has laid out an eight-factor test to determine whether privity extends the estoppel in this context. *See Shamrock Techs., Inc. v. Med. Sterilization, Inc.*, 903 F.2d 789, 793 (Fed. Cir. 1990). Those factors are:

> (1) whether the assignor was a high level employee at his new employer;
> (2) whether the assignor owned shares in his new employer;
> (3) whether, as soon as the assignor was hired, the new employer built facilities for performing the infringing activity;
> (4) whether the assignor oversaw the design and construction of those new facilities;
> (5) whether the inventor was hired to start-up the infringing operations;
> (6) whether the decision to begin the infringing operation was made jointly by the assignor and the leadership of his new employer;
> (7) whether the defendant company began manufacturing the infringing product shortly after hiring the assignor; and
> (8) whether the inventor was in charge of the infringing operation.

Id.

An examination of the facts of *Shamrock* is helpful in understanding the list of factors. In *Shamrock*, an inventor joined the accused infringer as Vice President in charge of operations. *Shamrock*, 903 F.2d. at 794. Upon joining the infringer, he was given 50,000 shares of the accused infringer's stock. *Id.* The infringer built facilities to perform infringing acts as soon as the inventor was hired, and the inventor oversaw design and construction of those facilities. *Id.* The inventor was hired specifically to start up the infringing operations, and the inventor was in charge of those infringing operations. *Id.*

Now consider the facts here: Ms. Gelbach joined the accused infringer, Jubilant, as a Product Manager. Ms. Gelbach's primary role in that position was to "develop a marketing plan and commercialization plan for the PET products . . . specifically for the rubidium infusion system." JX-0176C (Gelbach Dep. Tr.) at 120:7-13. There is no evidence Ms. Gelbach has ever had any ownership interest in Jubilant. There is no evidence Jubilant built any new facilities to perform infringing acts as soon as Ms. Gelbach was hired. Ms. Gelbach did *not* oversee design

and construction of any facilities or even the design of products. The record shows Ms. Gelbach's responsibility was to "develop a marketing plan," while others on the team were tasked with project management and engineering responsibilities. *See* JX-013C.010 (project overview document between Jubilant and Kluge listing Ms. Gelbach's responsibility for V3 project as "Marketing product manager for the Rubidium Elution System").

Although Bracco argues Jubilant "changed course" to developing an infringing system shortly after hiring Ms. Gelbach, the record reflects Jubilant first began developing the Version 3 in 2010, and by no later than July 28, 2010, Jubilant had begun designs for a system with an on-board dose calibrator.[1] Tr. at 313:8-10 ("When did JDI first begin developing the Version 3? A: 2010."); *see* CX-0386C.0001 (Jubilant internal email dated July 28, 2010 stating "we [are] currently designing the V3 infuser cart and we are wondering how much lead shielding is needed for the generator . . . the dose calibrator chamber [vial inside . . .] the waste container. . . All this shielding is on the cart . . ."). Though Ms. Gelbach was hired no earlier than that July, Tr. 1046:17-20, there is record testimony that the development of the on-board dose calibrator began at least as early as May of that year. *See* Tr. at 316:18-317:9. And although Bracco argues Ms. Gelbach was hired to provide her insights as an inventor, she testified that she did not provide the idea to move the dose calibrator on-board the cart; she said the idea came from customers. JX-0176C (Gelbach Dep. Tr.) at 125:16-126:6.

Bracco also argues that, although Jubilant built no new facilities immediately upon hiring Ms. Gelbach (*Shamrock* factor (3)), Ms. Gelbach's hiring directly lead to the hiring of two former

[1] As demonstrated in Order No. 27 (granting summary determination of infringement) and in the obviousness analysis below, the on-board dose calibrator was a central point of dispute in this investigation.

Bracco contractors: medical device designers Worrell and Kluge. CIB at 36. But the record reflects that Jubilant had a preexisting relationship with Worrell, and that neither Worrell nor Kluge was hired for at least six months after Ms. Gelbach. Tr. at 313:20-21 ("in 2011, [Jubilant] hired Kluge Design and Worrell"), 314:16-315:12 (JDI had worked with Worrell in 2008).

These facts are a far cry from those before the *Shamrock* court in total, but particularly salient is the lack of any direct tie between Jubilant's financial position and Ms. Gelbach's. *Shamrock* directs that no privity exists between a "mere employee" and their employer. *Id.* Although *Shamrock* does not define "mere employee," in each case the *Shamrock* court cited as an example of privity, the assignor had an ownership or financial stake in the new company. *See, e.g., Douglass v. U.S. Appliance Corp.*, 177 F.2d 98, 99 and 101 (9th Cir. 1949) (assignor formed new corporation; "[t]he word 'privity' implies co-operation, but it also includes the thought of sharing and of participation in profits"); *U.S. Appliance Corp. v. Beauty Shop Supply Co.*, 121 F.2d 149, 151 (9th Cir. 1941) (company started by assignor and partner), *cert. denied*, 314 U.S. 680 (1941); *Stubnitz-Green Spring Corp. v. Fort Pitt Bedding Co.*, 110 F.2d 192, 195 (6th Cir. 1940) (assignor was principal stockholder); *Buckingham Prods. Co. v. McAleer Mfg. Co.*, 108 F.2d 192, 195 (6th Cir. 1939) (assignor was director and held 500 of 3000 shares); *Frick Co. v.Lindsay*, 27 F.2d 59, 61 (4th Cir. 1928) (wife and business partner estopped from challenging validity); *Mellor v. Carroll*, 141 F. 992, 993-94 (C.C.D. Mass. 1905) (assignor was part owner of company). Other Federal Circuit assignor estoppel cases follow that trend. *See, e.g., Diamond Scientific*, 848 F.2d at 1222 (assignor left Diamond and formed defendant company); *Carroll Touch, Inc. v. Electro Mech. Sys.*, 15 F.3d 1573, 1579 (Fed. Cir. 1993) (assignor was founder, president, principal executive officer and owner of controlling interest of defendant company); *Intel*, 157 F.3d 837-38 (holding assignor estoppel applied to assignor's company as well as joint development company

for which assignor spent 100% of time working and who would not have entered the agreement absent assignor's personal indemnification).

As noted above, there is no evidence that Ms. Gelbach has *ever* had *any* ownership stake in Jubilant. The evidence does not even reflect that Ms. Gelbach was a particularly senior employee, or that she had any substantial role in the design of the RUBY Version 3. I thus find that Ms. Gelbach was a "mere employee" of Jubilant, precluding a finding of privity.

Considering all of the facts and argument presented, I find that Jubilant was not in privity with Janet Gelbach. As a result, I find that Jubilant should not be estopped from challenging the validity of the asserted patents.

1. Staff Is Not Estopped

Bracco admits that assignor estoppel does not apply to Staff. CIB at 38. As discussed in detail below, Staff presented clear and convincing evidence that the patents are obvious. Thus, even if Bracco's estoppel argument was meritorious, it would not change the outcome of my validity determination.

B. Obviousness

Jubilant and Staff contend that the asserted patent claims are obvious in view of the prior art. They rely primarily on a thesis published in 2006 describing a rubidium infusion system developed by Ran Klein as part of his graduate studies at the University of Ottawa. CPB at 82-87 and SPB at 45-54, analyzing RX-106 (hereinafter "Klein" or "Klein thesis"); *see also* Klein, RX-0333, RX-0034. Jubilant and Staff argue that the Klein thesis, either alone or in combination with certain other references, render all asserted claims invalid as obvious.

Bracco largely concedes that the Klein thesis discloses a rubidium infusion system comprising all of the functional elements of the asserted patent claims, but Bracco contends the

arrangement of those elements in the configurations described by the patent claims would not have been obvious to a skilled artisan. *See* CRB at 29. Although scores of claim elements are at issue, the parties' dispute focuses on about a dozen. For ease of reference, I have organized my analysis into several sections below. Section 1 describes the main elements of the Klein thesis, identifies certain secondary prior art advanced in combination with Klein, and addresses arguments about whether that art is analogous. Section 2 compares the scope and content of the prior art to each asserted claim of each asserted patent, giving particular attention to the claim elements the parties dispute. Section 3 analyzes secondary considerations of non-obviousness in connection with the claimed inventions. Section 4 contains my conclusions after considering the totality of the record the evidence material to obviousness.

1. The Prior Art

a) *The Klein thesis*

This section contains factual findings about what the Klein thesis discloses. The Klein thesis describes a system to elute rubidium at a constant level of radioactivity "for use in a clinical and experimental setting." Klein at .000011. Klein explained that prior art cyclotrons used to generate radioactive material for imaging were known to be expensive and immobile. Klein at .000024-25. By the time of Klein's work, the disadvantages of cyclotrons had already motivated the development of mobile PET imaging systems to serve smaller communities. Klein at .000024-25. One such mobile system known to Klein was Bracco's CardioGen-82 Model 510 ("Model 510"), a rubidium elution system approved by the FDA in 1989 that was small enough and inexpensive enough to allow PET scanning to reach "regions of low population density as well as to less wealthy communities." *Id*. at .000017-18, -25.

Klein provided an overview of the components of his system in the diagram below:

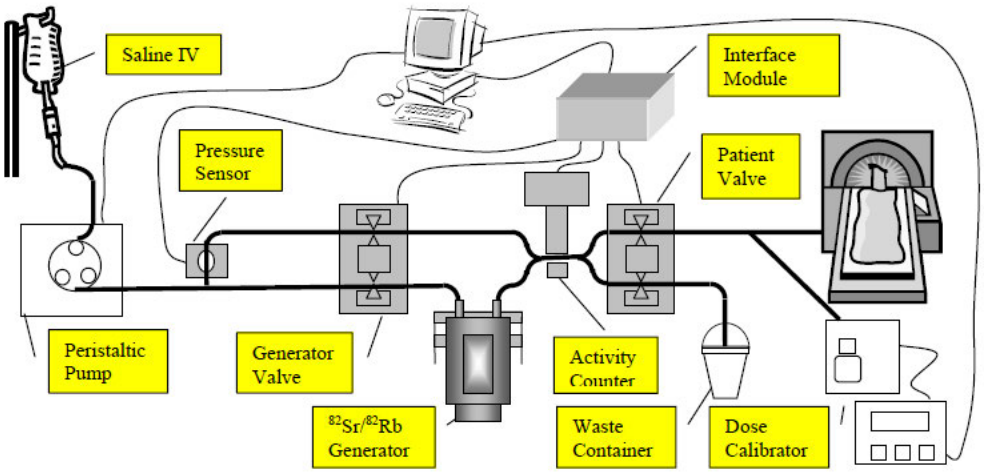


Figure 2-2 – Hardware component diagram of the RbES prototype [18] was not altered.

Id. at .000029.

Following the flow of fluid through the system diagram above provides an overview of the Klein system. The process starts with a reservoir of saline held in an IV bag or bottle connected to a pump, which permits the saline to flow through a strontium-rubidium (Sr-Rb) generator, then to an activity counter, and then to a patient. *Id.* The system executes different flow patterns using valves. A first valve, called the generator valve, is placed between the pump and the generator. It controls the flow of saline in two lines: a line into the generator and a saline bypass line. The line out of the generator contains radioactive material. It mixes with saline from the saline bypass line and flows past the activity counter. *Id.* at .000051. The activity monitor measures the radioactivity of the eluate in real time. *Id.* at .000043. A second valve, called the patient valve, is placed between the activity detector and the patient. *Id.* at .000029. The patient valve controls the flow of the radioactive eluate into two more lines, a line to the patient and a line to a waste bottle.

The Klein thesis discloses that the components of the system are arranged on a stainless steel cart. Klein explained "the cart must be moved around the imaging room" and time constraints

in moving the cart "can be tight." Klein at .000046. The following photo of the Klein cart appears in the thesis:

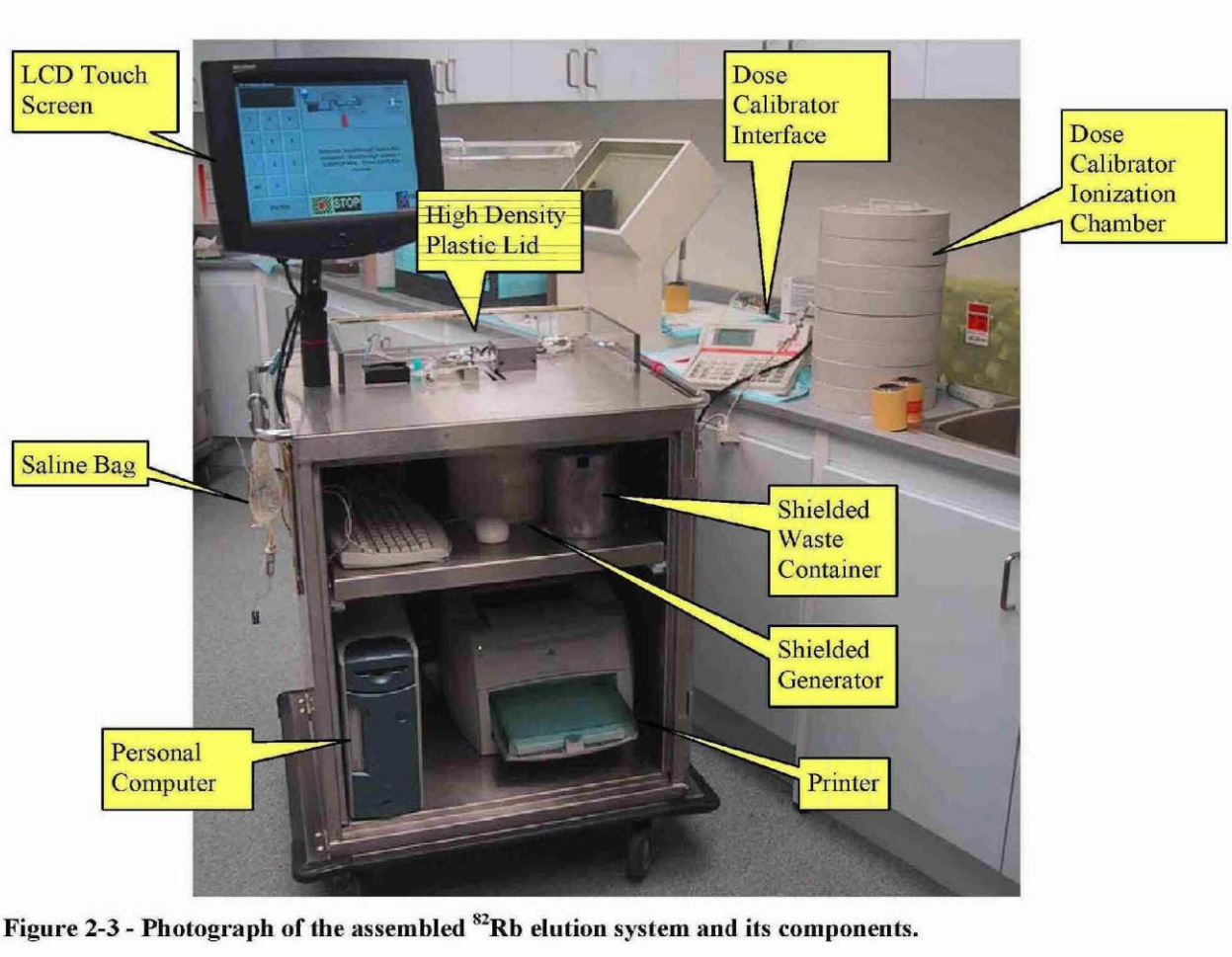


Figure 2-3 - Photograph of the assembled ^{82}Rb elution system and its components.

Id. at .000034. The yellow annotation bubbles are Klein's.

A pervasive concern in Klein's design was minimizing patient and operator exposure to radiation. *See, e.g., id.* at .000038, -44, -46. As shown in the photo and explained in the thesis text, Klein placed the rubidium generator within a column of stacked lead rings for shielding and placed the waste bottle within a lead shielded container having a lid. *Id.* at .000033-34. Both the generator and the waste bottle are located on the same shelf within the cart, with the opening to

the waste bottle container at a lower elevation than the top of the stacked lead rings around the generator. *Id.*

Klein's system also includes a dose calibrator. *Id* at .000056. The dose calibrator is used for both calibration and testing. During calibration, readings from the activity counter are compared to dose calibrator readings to calibrate the activity counter. *Id*. at .000033, .000053. During test runs, dose calibrator readings are used to verify the expected results. *Id*. Readings are also taken 20 minutes after the end of an elution to compare the breakthrough strontium-82 and strontium-85 activity. *Id.* at .000028, .000053, .000060-.000062. At the end of an elution, high levels of rubidium-82 activity will be present; due to its short half-life, the rubidium's activity decays exponentially over a short period compared to residual activity of any strontium, allowing for detection of breakthrough. *Id.* at .000060-.000061.

Klein used a dose calibrator that was commercially available at the time. *Id*. The dose calibrator includes a vial, which is placed within an ionization chamber. *Id.* at .0055-.0057. Although the dose calibrator possessed its own off-the-shelf shielding, Klein added additional shielding in the form of stacked lead rings. *Id.* at .000056. The system photo in Klein shows the dose calibrator sitting on the lab countertop, not on the stainless steel cart. *Id.* at 27-28 ("external dose calibrator").

The tubing and other system components of the infusion system were enclosed within a high density plastic enclosure on the top surface of the cart, again to shield the operator from radiation exposure. *Id.* at .000033. Klein annotated a closer photograph of the top of the cart:

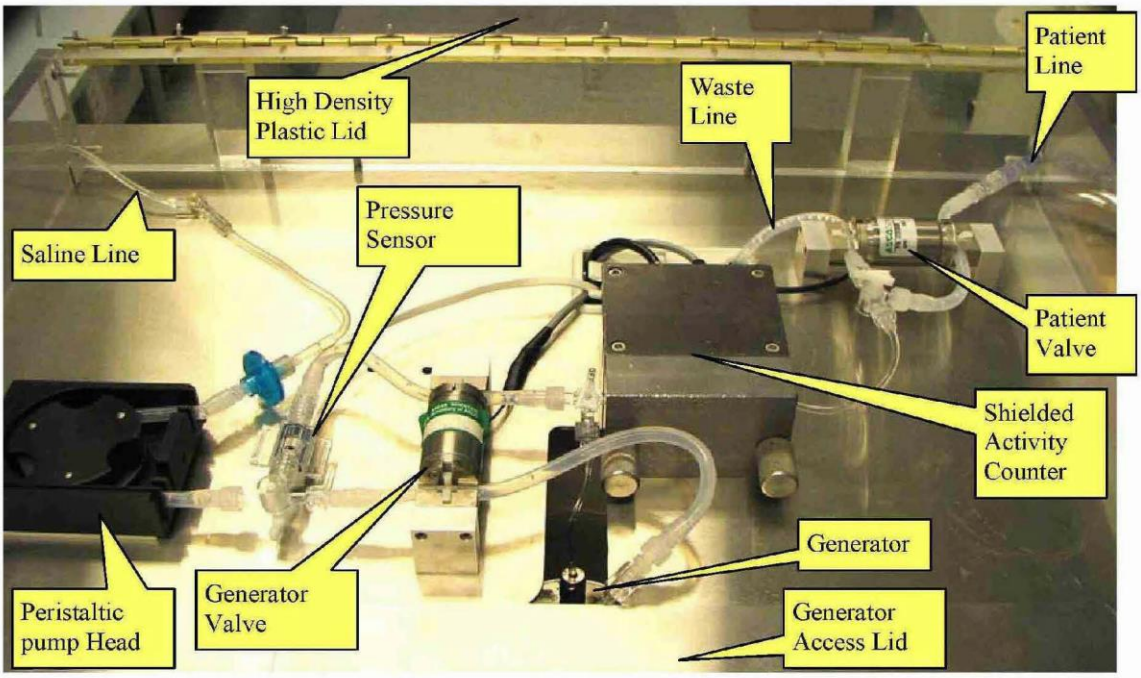


Figure 2-4 - Photograph of top cover of the ^{82}Rb elution system.

Id. at .000034. This detailed photograph shows that the constructed Klein device has components arranged as shown in Klein's block diagram of the system. *Compare id.* at .000034 *with id*. at .000029. In the bottom center of the photograph, the top of the generator is identified and visible beneath a stainless steel lid labeled "Generator Access Lid."

The Klein thesis also describes a computer for controlling the system, including a touch screen entering user commands. *Id.* at .000034 (FIG. 2-3), .000064 (FIG.3-12(c)). Software on the computer controls the pump and valves, which in turn sets the flow of the elution to the patient. *Id*. at .000029, -43. The computer controls the valves in response to real-time data gathered by the activity counter, the dose calibrator, and other sensors. *Id.*

Software on the computer enforces compliance with a daily safety protocol. *Id.* at .000027-28, -54. The software only enables patient elusions after completion of the protocol. *Id.*, *see also id.* at .000038-39, -43. The safety protocol includes a daily "flush" of the generator and all tubes to remove air bubbles and any strontium breakthrough from the system. *Id.* at .000028.

It also includes a "calibration run" to elute rubidium to the dose calibrator for strontium breakthrough testing and to calibrate readings from the activity counter. *Id.* at .000028, -33, -54. "Only after a calibration run with low SR breakthrough has been successfully completed can patient elutions be carried out." *Id.* at .000028. This "remove[s] operator intervention" in completion of the protocol. *Id.* Once the daily protocol completes successfully, patient elutions are enabled until the end of the day. *Id.* The system disables elutions at midnight each night, when the daily protocol expires. *Id.* at .000029.

b) *Secondary Prior Art*

Jubilant and Staff also advance obviousness arguments based on the Klein thesis in view of certain secondary prior art. That art includes a patent to Tate, an ergonomics reference authored by Chaffin, the Bracco Model 510 prior art device, and the MedRad Intego prior art device. Tr. at 119:5-12, 618:14-619:16. An overview of these secondary prior art references follows, though additional details are discussed in connection with relevant claims below.

(1) U.S. Publication 2008/0177126 ("Tate")

U.S. Publication 2008/0177126 is a patent application filed by MedRad on October 31, 2007 (RX-0103.000001) ("Tate"). Tate discloses "methods, systems, and components thereof for delivering . . . radiopharmaceuticals to patients for positron emission tomography (PET)." *Id.* at .000089 (1:002). Tate's system is a cart that includes a radiopharmaceutical source, a dose

calibrator, and a waste bottle in separate shielded recesses within an upper surface of the cart. *Id.* at .000092 (4:72). Figure 1E shows a cross-section view of Tate's fluid delivery system (10):

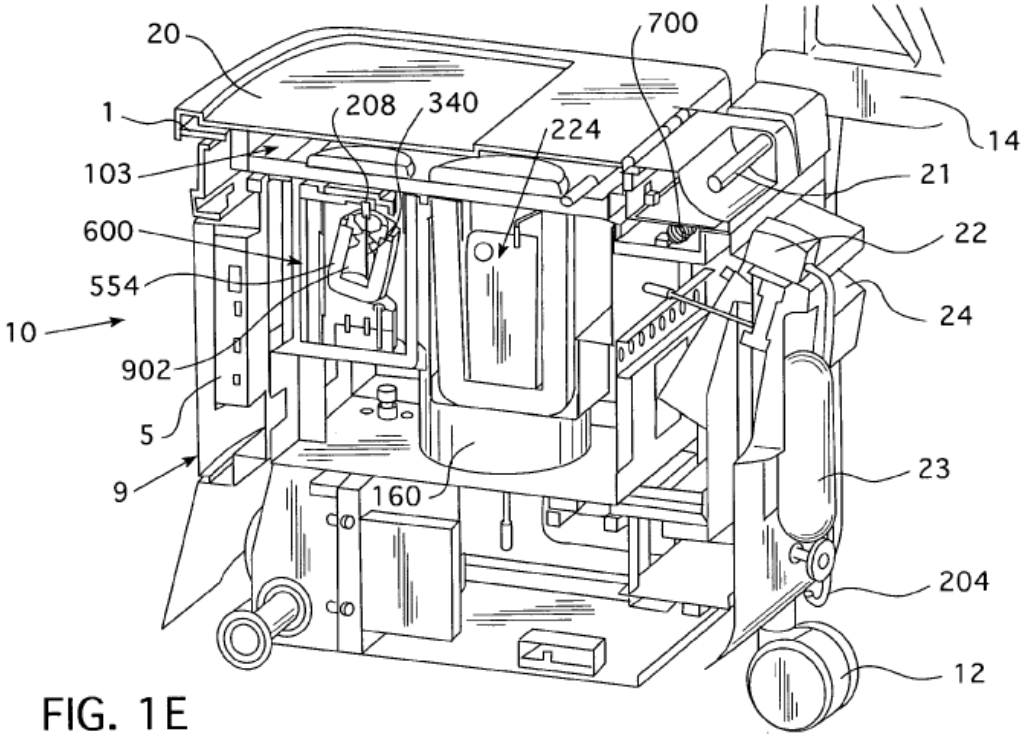


FIG. 1E

The recesses for the dose calibrator and the waste bottle open vertically upwards. *Id.* at .000093 (5:78). The upper surface also includes troughs or other depressions for tubing and the other elements necessary to deliver fluids containing the radiopharmaceuticals to patients without kinking or pinching. *Id.* at .000093 (5:78). Those elements are then enclosed by a lid (10) or cover (20), which includes radioactive shielding to minimize radiation exposure from the radiopharmaceutical source and waste receptacle. *Id.* at .000092 (4:72-73). The recess for the radioactive source is additionally covered by a cap. *Id.* .000097 (6:139-142).

Tate also discloses a touchscreen computer control system. *Id.* at .000100 (12:171-172). This system is intended to enable "(1) system preparation, (2) patient treatment, (3) injection history (i.e. obtaining information regarding previous treatments), and (4) system configuration."

Id. 13:182. Tate teaches using the computer to track consumables depleted during use, such as saline and the radiopharmaceutical. *Id.* at .000056 (FIG. 29), .000061 (FIG.32B).

Tate is directed to a system for use with fluorodeoxyglucose ("FDG"), a different radiopharmaceutical than the rubidium-82 described in the asserted patents. *Id.* at .000089. FDG is generated by a cyclotron, transferred to the location of the cart, and loaded in the cart as needed. *Id*. Tate explains, however, that because "radioisotopes, such as . . . Rubidium-82. . . ." and FDG are useful in medical imaging due to their "relatively short half-lives, systems that use these isotopes face the same problem of tracking the level of radioactivity delivered to the patient with each dose. *Id*.

Tate is concerned with "calculating and delivering accurate and effective doses of radiopharmaceuticals to patients, while reducing the exposure of administering or other medical personnel" caused by manual handling of samples for calibration. *Id.* at .000089-.000090. Tate suggests its teachings "can be used in a very wide variety of drug delivery and therapeutic procedures." *Id.* .000109 (¶0276). Tate advises accounting for the "elapsed time (and corresponding decrease in radioactivity level of the radioisotope)" between the time the radioactive material was created and the time it is administered to the patient. *Id.* (1:008).

Jubilant and Staff rely on Tate's teachings concerning an on-board dose calibrator, tubing passageways, and various computer functions.

(a) Analogous Art

Bracco argues that Tate is not analogous art and thus should not be considered for obviousness of the patents. Bracco primarily argues that rubidium elution-infusion systems, which generate and infuse the short-lived rubidium-82, have many technical hurdles not present or

addressed in FDG systems, and therefore a person of skill in the art would not be motivated to combine the teachings of the two references. CIB at 16-26.

Bracco has sliced the art too thinly. Art is analogous when it is "from the same field of endeavor, regardless of the problem addressed" or, if not from the same field of endeavor, when "the reference is still reasonably pertinent to the particular problem with which the inventor is involved." *In re Bigio*, 381 F.3d 1320, 1325 (Fed. Cir. 2004) (toothbrush was analogous art to hairbrush). Put another way, a given piece of prior art need not address *all* of the *exact same* problems in order to be considered analogous to the claimed invention, as it need only be "reasonably pertinent to the particular problem with which the inventor is involved." *Id.* A reference is reasonably pertinent if, "even though it may be in a different field from the inventor's endeavor, it is one which, because of the matter with which it deals, logically would have commended itself to an inventor's attention in considering his problem." *In re Klein*, 647 F.3d 1343, 1348 (Fed. Cir. 2011).

I find that, as a factual matter, Tate is in the same field of endeavor as the present invention, as both are "systems that . . . infuse radiopharmaceuticals, . . . including computer-facilitated maintenance and/or operation." '826 Patent at 1:27-30. The field of endeavor of a patent is not limited to the specific point of novelty, the narrowest possible conception of the field, or the particular focus within a given field." *Unwired Planet, LLC v. Google Inc.*, 841 F.3d 995, 1001 (Fed. Cir. 2016). Here, based on the "explanations of the invention's subject matter in the patent application, including the embodiments, function, and structure of the claimed invention," *Bigio*, 381 F.3d at 1325, that field of endeavor is computerized devices to safely administer radiopharmaceutical tracers. *See* Tr. at 616:22-617:23 (Dr. Stone: "We are dealing with a system to inject a fluid safely."); 867:11-17 (Dr. Stone: "we are dealing with a device to administer

radiopharmaceutical"); '826 Patent at 1:25-30 ("The present invention pertains to systems that generate and infuse radiopharmaceuticals, and, more particularly, to systems including computer-facilitated maintenance and/or operation").[2]

I additionally find that Tate was directed to at least some of the same problems as the asserted patents, namely "calculating and delivering accurate and effective doses of radiopharmaceuticals to patients, while reducing the exposure of administering or other medical personnel" caused by manual handling of samples for calibration. Tate at .0089-.0090; *see also id.* ("The present invention relates to methods, systems and components thereof for delivering pharmaceutical substances to patients for imaging procedures and, more particularly, for delivering radiopharmaceuticals to patients for positron emission tomography (PET)"). Bracco's own expert Dr. Pelc admitted that the asserted patents are directed at least in part to that same problem. Tr. at 1113:25-1114:4 (Q. "Would you agree that the patents-in-suit are directed, at least in part, toward the problem of delivering radiopharmaceuticals to patients for positron emission tomography?" A. "Yes"). Because Tate is directed to solving one of the same problems as the asserted patents, I find it is reasonably pertinent to the problem to be solved and thus constitutes analogous prior art.

(2) MedRad Intego

The MedRad Intego system (*see, e.g.*, RX-200C) is essentially the commercial embodiment of the invention disclosed in the Tate patent. Indeed, the Intego system is marketed by the assignee of Tate. *See* Tate at Cover. The record shows the MedRad Intego system was publicly sold in the United States, offered for sale in the United States, and installed in the United States prior to June 2009. RX-0202C (April 2009 invoice showing installation of an Intego system in April 2009);

[2] Though Dr. Pelc testified to the contrary, I find his testimony less credible on this point than that of Dr. Stone's. *See* 961:20-962:9.

RX-0203C.0001 (May 2009 order for delivery of Intego system in Massachusetts); RX-0203C.0002 (October 2008 price quote for Intego system offered to customer in Tennessee); JX-0176C at 167:8-170:5 (testimony that Janet Gelbach saw an Intego system at a trade show no later than June 2009). The MedRad Intego system is thus prior art under 35 U.S.C. §§ 102(a) and (g). I further find it is pertinent art for the same reasons addressed above concerning Tate. *See supra* V.B.1.b)(1)(a).

Bracco challenges the use of the MedRad Intego as prior art. First, Bracco argues that the MedRad Intego user manual (RX-200) may not be considered when analyzing proposed combinations of prior art. CRB at 11-12. Bracco apparently misapprehends the relevance of that manual. Neither Jubilant nor Staff rely on the MedRad Intego manual as a prior art printed publication. *See, e.g.*, SIB at 44 ("Bracco asserts that Jubilant is relying on a MedRad Intego manual . . . However, the evidence establishes that the Medrad Intego System. . . "); RIB at 21 (listing "The Medrad Intego PET Infusion System" as the relevant art). Instead, the manual, bearing a 2009 copyright date, is advanced as corroborating evidence of the features embodied in the Intego system offered for sale by MedRad in 2008 and installed for use in April 2009, prior to the asserted patents' priority date of June 11, 2009.

Bracco next asserts the MedRad Intego manual was subject to a confidentiality provision when it was given to customers. That contention is irrelevant because no party relies on the manual as an invalidating printed publication. Bracco's contention is also unsupported by the record. There is no evidence in the record that the manual was subject to confidentiality agreements, and the non-party that produced the manual in discovery has since withdrawn its confidentiality designation. Bracco does not argue, and certainly points to no evidence, that clinicians using the MedRad Intego system were subject to the type of nondisclosure agreement that would qualify the

use as experimental. *Compare New Railhead Mfg. v. Vermeer Mfg. Co.*, 298 F.3d 1290, 1298-1300 (Fed. Cir. 2002) (finding that performance of the claimed method of drilling in rock at a commercial jobsite under public land, hidden from view, constituted public use); *Baxter Int'l v. COBE Labs.*, 88 F.3d 1054 (Fed. Cir. 1996) (finding that a scientist's use of a machine implementing the claimed method in a laboratory at the National Institutes of Health, without the public's awareness of the method employed by the machine, was a prior public use); *Elec. Battery Co. v. Shimadzu*, 307 U.S. 5, 20 (1939) ("The ordinary use of a machine or the practise [sic] of a process in a factory in the usual course of producing articles for commercial purposes is a public use"), *with W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1550 (Fed. Cir. 1983) (no public use where company told all employees that the prior art machine was confidential and required them to sign confidentiality agreements, thus concealing the machine and viewer of the machine could not learn anything of its processes of operation); *Motionless Keyboard Co. v. Microsoft Corp.*, 486 F.3d 1376 (Fed. Cir. 2007) (finding that the prior art user was required to sign a non-disclosure agreement related to the prior art, thus concealing the prior art).

Jubilant and Staff rely on features of the MedRad Intego system that are similar to the features they highlight in the Tate patent, including an on-board dose calibrator, tubing passageways, and various computer functions.

(3) Chaffin, et al., *Occupational Biomechanics*, 2d ed. (1991) (RX-0096)

Occupational Biomechanics, 2d ed. (1991) (RX-0096), is an ergonomics and biomechanics reference authored by Chaffin, et al. (hereinafter "Chaffin"). Chaffin teaches sensible ways to physically arrange heavy objects used by humans. For example, Chaffin teaches that heavier objects should be placed so as to minimize the distance required to lift them in order to reduce strain or injury to the person lifting the object. *See* RX-0096.0170-.0178.

Jubilant and Staff rely on Chaffin for its teachings concerning the relative heights of openings for heavy objects, such as the generator.

(4) IEC 62366

IEC 62366 (RX-0114) is an international standard for medical device design. IEC 62366 teaches medical device developers to provide a user interface that enables users "to be aware of the use of the correct consumable, the remaining amount of [the consumable], whether accessories might be used with the MEDICAL DEVICE, how to assemble them and how to check their correct functioning." IEC 62366 at .0063.

Jubilant and Staff rely on IEC 62366 for its teachings relating to various computer warnings based on system state and readiness, such as tracking consumable use and reminding a user to replace or empty system components.

(5) Bracco CardioGen-82 Model 510

The Bracco CardioGen-82 Model 510 is a strontium-rubidium cardiac PET infusion system first approved by the FDA in 1989. Tr. at 589:18-590:3. Until the introduction of the RUBY Version 3, the Model 510 was the only rubidium infusion system available in the United States. *Id*. Although the Model 510 shares the same core operational principles and much of the same physical configuration as the systems described in the asserted patents, *see* Tr. 137:15-138:6, the Model 510 lacked many of the features claimed in the patents, including an on-board dose calibrator and computer. JX-112C at .0003 (Model 510 system controlled by instrument panel), .0009 (Model 510 had manual breakthrough testing); Tr. at 1069:4-20 (Model 510 lacks computer).

Jubilant and Staff rely on the Model 510 for its teachings relating to configuration of various physical components of a rubidium infusion system, such as the openings of shielding compartments facing vertically upwards.

2. Comparing the Claims to the Prior Art

a) *'826 Patent*

Bracco asserts claims 1-3, 5, 9, 11-14, 17-19, and 28 of the '826 patent. Due to intermediate dependencies, the structure recited in claim 10 is also at issue for the purposes of my invalidity analysis.

(1) Claim 1

Claim 1 of the '826 patent follows, with disputed limitations emphasized:

[1] A method of building an infusion system to deliver a rubidium radioactive eluate comprising:
- [1.1] installing **a first shielding compartment**, a second shielding compartment, and **a shielded well on a platform of a cart**, wherein:
  - [1.1.a] **the first shielding compartment** has a first opening facing vertically upwardly,
  - [1.1.b] the first opening is configured for a strontium-rubidium radioisotope generator to be inserted into and removed from **the first shielding compartment**,
  - [1.1.c] the second shielding compartment has a second opening facing vertically upwardly,
  - [1.1.d] the second opening is configured for a waste bottle to be inserted into and removed from the second shielding compartment,
  - [1.1.e] **the first opening is located at a lower elevation than the second opening**, and
  - [1.1.f] **the shielded well** is configured to receive an eluate reservoir that is configured to receive a sample of the rubidium radioactive eluate;
- [1.2] configuring **a computer** with a touch screen display for the infusion system to:
  - [1.2.a] fill the eluate reservoir in **the shielded well** on-board the cart with the sample of the rubidium radioactive eluate by pumping saline from a saline reservoir into the strontium-rubidium radioisotope generator via a saline tubing line thereby generating the rubidium radioactive eluate that is discharged through an eluate tubing line,
  - [1.2.b] determine a strontium breakthrough test result on the sample of the rubidium radioactive eluate filled into the eluate reservoir in **the shielded well on-board the cart** while the eluate reservoir remains in **the shielded well on-board the cart**, and

> [1.2.c] not allow a patient infusion if the strontium breakthrough test result is greater than or equal to an allowed limit.

Jubilant and Staff assert this claim is obvious in light of Klein, either alone or in certain combinations of other prior art. Bracco argues that Klein does not teach (1) a shielded well on-board a cart, (2) a first shielded compartment configured for a generator, (3) a generator compartment opening lower than a waste bottle compartment opening, and (4) a computer configured in the manner claimed. I address the parties' arguments below.

(a) Klein Thesis Alone

I begin my obviousness determination by considering whether the invention of claim 1 would have been obvious in view of only the Klein thesis. While I have considered the claim and the prior art as a whole, I organize my findings around the four claim limitations particularly disputed by Bracco.

"shielded well on-board the cart"

The parties dispute whether Klein discloses the shielded well recited in claim 1. Limitation [1.1] requires that the shielded well be installed on a platform of the cart, limitation [1.1.f] states that the well has an eluate reservoir, and element [1.2.b] states that a computer determines a strontium breakthrough test result on radioactive material in the eluate reservoir. Limitation [1.2.b] also requires that the test result is determined while the shielded well and reservoir are "on-board the cart." The parties agree that Klein does not teach a shielded well on-board the cart. Jubilant and Staff argue, however, that Klein's dose calibrator would meet all of the claim limitations relating to the shielded well if that dose calibrator were located on Klein's cart. RIB at 25, 40-41; SIB at 41. Jubilant and Staff argue it would have been obvious to a person of ordinary skill in the art reading Klein to make a rubidium infusion system with the dose calibrator on the cart. *See, e.g.*, RIB at 25; SIB at 41. Bracco argues that a person of skill in the art would not be

motivated to put Klein's dose calibrator on the cart because doing so "poses significant technical challenges." CIB at 44.

I find the Klein thesis expressly discloses at least three motivations for building a system with the dose calibrator on-board the cart. The first motivation is mobility. Klein explains that prior art cyclotrons used to generate radioactive material for imaging were known to be expensive and immobile. Klein at .000024-25. By the time of Klein's work, the disadvantages of cyclotrons had already motivated the development of mobile PET imaging systems to serve smaller communities. *Id*. Klein also expressly states that one of his design objectives was to make a system that could be "moved around the imaging room" because time constraints in performing imaging were known to be "tight." *Id.* at .000046. Reading these teachings, a person of skill in the art would readily understand that having the dose calibrator on the cart would allow the entire Klein system to be moved around the imaging room quickly and would make it easier to transport the system to remote locations. Experts from both parties corroborated that a person of skill in the art would be motivated by these factors. *See, e.g.*, Tr. at 623:9-22 (Jubilant's expert Dr. Sone describing the difficulty of repeatedly rolling the cart back to a stationary dose calibrator); 964:19-20 (Bracco's expert Dr. Pelc testifying that "everything with respect to handling rubidium is very rushed"); *id*. at 987:9-14 (same).

Second, Klein teaches that one goal of his project was to achieve a system for "routine clinical use," which requires "operational simplicity." Klein at .000024. Klein also contemplates additional refinements as part of "preparing the system for distribution to external facilities." Klein at .000141. Moving the dose calibrator onto the cart would simplify operation by eliminating a step of connecting and disconnecting the dose calibrator whenever the cart is moved. Dr. Stone's testimony corroborates that a person of skill in the art motivated to commercialize the Klein system

would make such modifications. Dr. Stone's experience in commercializing prototypes for medical devices is undisputed. *See* Tr. at 581:20-585:15. Dr. Stone credibly testified that it would have been obvious to a skilled person preparing the Klein system for commercial clinical use to put components used together on the same cart. Tr. at 619:17-620:1; 622:23-624:1.

Third, Klein teaches that it was known that, when designing a device used to administer radioactive material, choices should be made to minimize the operator's exposure to radiation. *See, e.g.*, Klein at .000027, -38, -44, -46.[3] Reading these teachings, a person of skill in the art would readily understand that putting the dose calibrator on the cart would shorten and enclose within shielding the tubing carrying radioactive material from the lead-shielded generator to the lead-shielded calibrator, thereby minimizing exposure to the operator. *See* Klein at .000029 (Figure 2-2).

Significantly, Bracco does not address the passages in Klein containing the express motivations for moving the dose calibrator identified above. Instead, Bracco criticizes Staff's assertion that Bracco got the idea to put the dose calibrator on its cart from customers. RRB at 41-42. Bracco's subjective motivations for developing its own system are immaterial to an obviousness determination, and I do not rely on them.[4] *Otsuka Pharma. Co. v. Sandoz Inc.*, 678 F.3d 1280, 1296 (Fed. Cir. 2012) (an "inventor's own path never leads to a conclusion of obviousness; that is hindsight"). The standard for obviousness is an objective one. *KSR*, 550 U.S.

[3] This principle is known as ALARA and is widely recognized in the medical imaging field. Tr. at 504:7-505:1, 913:2-16.

[4] Bracco's expert Dr. Pelc did not believe that Jubilant's expert Dr. Stone relied on this evidence either. *See* Tr. at 977:24-978:1 ("In my view, Dr. Stone is relying more on the person of skill in the art thinking of moving the dose calibrator on board the cart" than on testimony about customer comments from former Bracco employee Janet Gelbach).

at 419. The Klein reference alone provides ample evidence that a person of skill in the art at the time of the invention would have been motivated to put the dose calibrator on the cart.

Bracco also argues that Klein "teaches against carelessly changing its dose calibrator arrangement" because the dose calibrator is a sensitive instrument that could be influenced by background radiation if it is used in another configuration. RRB at 43. Bracco's argument ignores Klein's express teachings about how to overcome difficulties like "radiation from the surroundings." *See* Klein at .000056. Klein explains that even in the configuration Klein built, "[t]he exact region of measurement of the dose calibrator [was] unknown and dependent on its geometry." Klein at .000057. But that was not an impediment to Klein's invention. Klein developed a method of analyzing dose calibrator readings that "accounts for all available data and therefore decreases the effect of noise" in dose calibrator measurements. *Id.* at .000057-58. Because "the physical process" of radioactive transfer "is well understood" and accounted for in Klein's model, a person of skill would know how to successfully rearrange the components Klein expressly discloses. *Id*. at .000119.

Other record evidence corroborates that conclusion. For example, even though Klein expressly acknowledged unknowns about detection geometry and background noise with his system, Bracco's expert Dr. Pelc admitted that Klein had no problems obtaining accurate measurements from the dose calibrator in those conditions. Tr. at 978:17-22; 997:1-4. And although Dr. Pelc said a skilled artisan would "think twice" before rearranging components in Klein's system, he did *not* testify that such an artisan would be unable to successfully rearrange parts. Tr. at 988:1-8. Instead, he admitted Klein advises an artisan rearranging parts to "make sure [to] consider delay time and decay of the radioisotope" in the eluate tubes as the length of those tubes change. *Id*. When Dr. Pelc was directly asked if a person of skill in the art at the

relevant time would know how to compensate for changes in tube length, he did not say "no"; he said "it's complicated." Tr. at 989:16-22. But complicated changes can still be obvious to skilled artisans. *See In re Greene*, 217 F.3d 860 (Fed. Cir. 1999) (level of complexity in adopting claimed invention "is not a telling question in an obviousness inquiry").

Bracco next cites evidence purporting to show that Jubilant had difficulty developing adequate shielding "between the waste pot and dose calibrator" when designing the accused RUBY Version 3 system. CRB at 44. Bracco contends this evidence shows it would not be obvious to move the Klein dose calibrator onto the cart. *Id.* Bracco's argument is unconvincing. Again, the standard for obviousness is an objective one. *KSR*, 550 U.S. at 419. At best, the cited Jubilant emails are anecdotal evidence of a few designers' subjective experience. Even considering Jubilant's emails as somehow probative of the state of the art generally, the evidence does not support Bracco's conclusion. The emails show nothing more than routine design work well within the ability of a person of skill in the art. *See* Tr. at 847:10-848:14.

Although Bracco claims that a skilled artisan would have difficulty resolving a host of technical issues in order to build a system with the dose-calibrator on-board the cart, it is interesting to note none of the asserted patents describe any such difficulty. Indeed, the only two passages in the patent specification describing the dose calibrator on-board the cart simply announce that fact without describing any difficulty in making or using that arrangement. *See, e.g.*, '826 patent at 11:8-19, 27:9-12. I need not and do not rely on disclosures from the asserted patents in my obviousness analysis. But if those succinct disclosures are enabling to a person of ordinary skill in the art at the time of the invention, as Bracco contends (*see* CRB at 2), then such a person would need little guidance indeed on how to build a system with the dose calibrator on-board the cart.

After considering the evidence in record as a whole, I find that a person of ordinary skill in the art would be motivated to relocate Klein's dose calibrator onto the cart so that the entire system would be mobile, so that operation would be simplified, and so that the operator would be better shielded from radiation in the tube leading from the generator into the dose calibrator. *See, e.g.*, Klein at .000024., -38, -44, -46, 141. Klein teaches principles that would allow a skilled artisan to successfully rearrange the components. *Id.* at .000057-58, -119. Putting the dose calibrator on the cart in Klein therefore would have been obvious. *In re Kuhle*, 526 F.2d 553, 555 (CCPA 1975) (the particular placement of a component in a device was obvious matter of design choice); *In re Japikse*, 181 F.2d 1019, 1023 (CCPA 1950) (shifting the position of a component from prior art position would not have modified the operation of the device and was therefore unpatentable); *In re Larson*, 340 F.2d 965, 968 (CCPA 1965) ("the use of a one piece construction instead of the structure disclosed in [the prior art] would be merely a matter of obvious engineering choice.").[5]

"first shielding compartment"

Limitations [1.1.a] and [1.1.b] require a first shielding compartment for the generator. Staff and Jubilant argue that Klein discloses installing a column of lead rings on the shelf of the cart for shielding the generator. SPB at 45; JPB at 110-11. They contend the lead structure corresponds to the claimed first shielding compartment. *Id*. Bracco argues the stack of lead rings have an

[5] In making this determination, I have considered the claim as a whole as well as Bracco's arguments concerning secondary considerations of non-obviousness. *In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*, 676 F.3d 1063, 1079 (Fed. Cir. 2012). I explain my analysis of secondary considerations *infra* part V.B.3.

opening facing upwards and an opening facing downwards and thus "cannot be the first shielding compartment." CPB at 48-50 (citing Tr. at 995:22-996:17). To support this position, Bracco relies on the opinion of its expert Dr. Pelc that the word "compartment" in the claim requires structure that must "completely enclose" a portion of space. *Id.* Jubilant argues in response that Dr. Pelc's definition contradicts claim elements [1.1.a] through [1.1.e], all of which teach openings in the first and second shielded compartments, indicating that the compartments do not completely enclose an area. RRB at 111-112.

I find that Klein teaches a first shielding compartment. Contrary to Dr. Pelc's opinion, claim 1 does not require the compartment to be completely enclosed. Instead, claim 1 requires that the shielding compartment have an "opening." Dr. Pelc cites no evidence intrinsic to the '826 patent to support his opinion that the word "compartment" should be limited beyond its ordinary meaning, and I therefore give his opinion little weight. *See Phillips*, 415 F.3d at 1313.

Bracco next argues that Klein's lead compartment does not disclose limitation [1.1.a] because it has an opening facing "downwards." CPB at 48-50. Bracco is factually and legally incorrect. Factually, when Klein's generator is in place for use, as shown in Klein Figure 2-3, the cart shelf forms a solid bottom for the compartment and there is no opening facing downwards. Klein at .000033. Legally, even if the Klein compartment did have a bottom opening, nothing in the claim language would prohibit such a feature. *See Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 811 (Fed. Cir. 1999) (absent special circumstances, infringement is not avoided by the presence of elements or steps in addition to those specifically recited in the claim). I find that the stack of lead rings on the shelf housing the generator in the Klein thesis is a "first shielding compartment" as that term is understood by those of skill in the art. *See* Tr. at 727:6-14.

Bracco additionally argues that the generator in the Klein thesis "was not inserted into" the first shielded compartment as purportedly required by limitation [1.1.b]. CRB at 50. Instead, Bracco contends, Klein placed the generator on a cart and afterwards placed lead rings surrounding it. *Id*. Bracco's contention is again premised on an incorrect reading of limitation [1.1.b]. The claim does not require inserting a generator into a pre-formed compartment. The claim recites "[a] method of building an infusion system" comprising a step of "installing a first shielding compartment" wherein that compartment has an opening "configured for a strontium-rubidium radioisotope generator to be inserted into and removed." According to Bracco's own description, Klein performed that step. When Klein built his infusion system, he installed a shielding compartment of lead rings on the cart. Klein at .000033. The photograph of the Klein device shows the generator inside the lead ring shielding compartment, so clearly the compartment is "configured" to be an appropriate size for housing the generator. *Id*. at .000034. Additionally, the photograph shows the lead rings around the generator are uniformly sized, so the structure has nothing that would impede inserting and removing the generator through the top opening of the lead shield. Moreoever, Klein confirms that the generator can be removed from the compartment with its disclosure of a "Generator Access Lid" in Figure 2-4 and Klein confirms that the generator was in fact replaced at least four times. *Id.*; *see also id.* at .000116; Tr. at 665:11-666:1 (testimony of Dr. Stone that Klein had "an access door . . . that could give access to the generator"). . Limitation [1.1.b] is disclosed in Klein.

"the first opening at a lower elevation than the second opening"

Claim limitation [1.1.e] requires the top opening of the first shielding compartment (the one for the generator) to be at a lower elevation than the top opening of a second shielding compartment (the one for the waste bottle). The photograph of the system in the Klein thesis shows a shielded generator and a shielded waste bottle on a shelf in the cart cabinet. Klein at

.000034. All parties agree, however, that Klein does not expressly show the opening at the top of the shielded generator compartment at a lower elevation that the opening at the top of the shielded waste bottle compartment. SIB at 40; RIB at 38-39; CRB at 31.

Jubilant and Staff propose that the Klein thesis, viewed in combination with an ergonomics and biomechanics reference called Chaffin, renders obvious an invention with openings at different heights. SIB at 51 (citing Tr. at 833:3-9); RIB 112-116. Bracco, on the other hand, argues that Klein teaches away from the rearrangement of its components as advocated by Jubilant and Staff. CRB at 35-36 (citing Klein at .000049 ("The layout of the saline lines, sensors and actuators is crucial to implementing a physical system that is easy to control.")).

I have already determined that a person of skill in the art reading Klein would be motivated to move the dose calibrator onto the cart. Such a move would prompt the artisan to consider how the various components of the system should be arranged on the cart, particularly because Klein expressly advises those of skill to consider how a physical configuration can affect measurements of radioactivity. Klein at .000057-58, -119. Klein also contains express motivation to refine the system for commercialization. *See* Klein at .000024, -141. Corroborating that chain of logic, Dr. Stone credibly testified that a person of skill with the motivation to commercialize the Klein system would consider how the components are arranged. Tr. at 616:25-618:4.

When considering the arrangement of the openings of the generator compartment and the waste bottle compartment, the skilled artisan would have three choices: the generator compartment opening could be at a higher elevation than the waste bottle compartment opening, the two openings could be at the same elevation, or the generator compartment opening could be at a lower elevation than the waste bottle compartment opening. The patent entirely lacks *any* teaching of advantage to having the generator compartment opening higher than the waste bottle

compartment opening. I find that claim element [1.1.e] would be an obvious design choice in view of Klein, which discloses every component of the claimed invention in only a slightly different physical configuration. *See KSR* at 421; *In re Weber*, 312 F.2d 810, 813 (C.C.P.A. 1963) (holding claimed subject matter "would be no more than an obvious reversal of arrangement and not patentable."); *In re Gazda*, 219 F.2d 449, 451 (C.C.P.A. 1955) (claimed subject-matter unpatentable as obvious where "only a matter of choice amounting to a mere reversal of parts"); *In re Kuhle*, 526 F.2d at 555; *In re Japikse*, 181 F.2d 1019 (C.C.P.A. 1950). A skilled artisan would find the arrangement in claim element [1.1.e] obvious even without consulting the Chaffin ergonomics reference.

"computer"

Claim limitations [1.2]-[1.2.c] require configuring a computer to fill an on-cart reservoir with a sample of radioactive material, determine a strontium breakthrough test result on the sample, and not allow a patient infusion if the strontium breakthrough test result is greater than or equal to an allowed limit. Jubilant and Staff contend Klein expressly teaches a computer that fills a dose calibrator reservoir, performs a strontium breakthrough test, and locks out a patient infusion if the test fails. RIB at 85-86, 120-122; SIB at 52-53. According to Jubilant and Staff, the only difference between the Klein system and the claimed computer is that Klein's computer coordinates a test in a dose calibrator that is not on the cart. *See, e.g.*, RIB at 88; SIB at 54. Jubilant and Staff contend an invention with the computer in claim element [1.2] would have been obvious in view of Klein. RIB at 85-87; SIB at 51-54.

Bracco concedes that Klein teaches running a daily strontium breakthrough test on the system. *See* CRB at 52 (citing Klein at .00043, .00132). Bracco also concedes that if the Klein system detects significant strontium activity, "the generator cannot be used on humans." *See id*. However, Bracco disputes the contention that Klein's computer will "lock out" a patient elution if

breakthrough is detected. *Id*. at 52-55. And, of course, Bracco maintains that the Klein computer does not perform a break-through test on a sample in a reservoir on-board the cart. *Id*. at 55.

I find that Klein does not teach a computer interacting with a sample on-board the cart, but Klein expressly discloses a computer with all other elements in limitations [1.2] to [1.2.c]. The Klein computer controls a pump and valves to fill the dose calibrator reservoir with a test sample. *See, e.g.*, Tr. at 755:21-756:3; Klein at .000029. Klein also discloses configuring the computer control system to operate a "daily protocol," which determines a strontium breakthrough test result on the sample. Klein at .000028, -39.

With respect to lock-out of patient elutions, Bracco's understanding of Klein is incorrect. Klein discloses that computer software in his system "remove[s] operator intervention" and "enable[s]" infusion to a patient "only after the prerequisites have been completed successfully." *Id.* at .000027-28, -54. These features are in keeping with Klein's "first concern" that the "design must have multiple robust mechanisms to ensure that in any case of failure, the patient is not at risk." *Id.* at .000042. One prerequisite for a patient infusion is successful completion of a daily safety protocol. *Id*. at .00028. The safety protocol includes a "calibration run" to elute rubidium to the dose calibrator for strontium breakthrough testing. *Id.* at .000028, -33, -54. Klein's system detects values and compares them to an expected range. *Id*. at .000078 ("Patient elution and test runs are tested for discrepancy with the expected values of eluted activity."); .000062 ("to confirm that the breakthrough is less than" an allowed amount, the system must wait sufficient time before breakthrough measurement). If a value is out of range, an error is generated and "the program is halted." *Id*. at .000063-64 (Figure 3-12(d), screenshot with the caption "Out of range data"). "The sequence will not continue until all errors are resolved." *Id*. at .000063.

Klein also describes what an operator sees when the operator is locked out from performing patient elusions. A user interacts with the computer using a touchscreen that displays "buttons and radio buttons." *Id*. at .000031, -40. But these buttons are available to the user "only at relevant states" and are "immediately removed at the end of each state." *Id*. at .000040-41. Klein explains that these restrictions "limit the user input to ensure validity" of the process. *Id*. at .000040. Klein expressly teaches that when a user wants to start an elution run, "[t]he options presented to the user vary," depending on several conditions. *Id*. at .000063-65. Klein illustrates this point with a sample screenshot in Figure 3-12 (c), which shows some elution test runs grayed out to prevent user selection. *Id*. at .000064. In the same paragraph where Klein describes the conditionality of "options presented to the user" for starting a run, he states the software interface "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 .000065. Viewed together, these teachings indicate that the user would not be able to select the radio button on the touchscreen for a patient elusion without a successful breakthrough test.

Klein is also express when distinguishing between action taken by the operator and action performed by the system. For example, "[t]he screen can…be pressed" by a user to initiate a pre-run sequence, but if errors are detected by the system during that sequence "an appropriate message is displayed and *the program is halted*." *Id*. at .000063 (emphasis added). "*The sequence will not continue* until all errors are resolved." *Id*. (emphasis added). Klein expressly states the system will only "*enable* patient elutions" with a successful breakthrough measurement. Klein at .000039 (emphasis added); *see also id*. at .000028. If there were no system lock-out, as Bracco contends, then there would be no need to "enable" patient elutions. *See also id.* at .000029 (system disables patient elusion runs each night at midnight, when the validation from the calibration run expires),

.000075 (showing error code 40009, "No calibration file found for today. Conduct calibration run before proceeding."). Klein clearly states, "*Only* after a calibration run with low Sr breakthrough has been successfully completed *can* patient elutions be carried out." *Id.* at .000028 (emphasis added), .000043 ("The amount of Sr breakthrough activity must be strictly limited to the Health Canada guidelines. This issue is addressed by daily breakthrough tests as part of the daily protocol *ensured by the system*.") (emphasis added). Viewed together, these disclosures show that the system will not enable an operator to perform patient elutions unless "low Sr breakthrough has been successfully completed." *Id.*

Bracco contends that the ability to enter manual test results shows there is no lock-out in Klein. Bracco's expert Dr. Pelc focuses on a passage where Klein teaches that "[i]f the the dose calibrator is not sufficiently sensitive to measure breakthrough, the activity can be entered manually after measurement in a more sensitive device." *See* CRB at 43 (citing Klein at .000053). Bracco is incorrect, as additional context from Klein demonstrates. Klein describes a special case in which, depending on the sensitivity of the dose calibrator selected for the system and the radioactivity of rubidium in a test sample, the dose calibrator might not accurately measure strontium breakthrough. Klein at .000062. In that circumstance, Klein teaches that "automatic measurement" of strontium breakthrough may be "skipped" and the system allows the operator to "manually enter the breakthrough activity from a more sensitive instrument." *Id.*

The special circumstance highlighted by Bracco does not negate Klein's other fulsome disclosures. *See Application of Reynaud*, 331 F.2d 625, 628 (C.C.P.A. 1964) (prior art may be relied upon "for all that it discloses"). The system Klein actually built and tested did not require manual entry of breakthrough data due to poor readings from a dose calibrator. Klein described the dose calibrator he selected for his system as "the gold standard" (Klein at .000033), and it is

undisputed that Klein had no problems obtaining accurate measurements from the dose calibrator he used. Tr. at 978:17-22; 997:1-4d. The system Klein built performed "automatic measurement" of strontium breakthrough. *Id*. at .000062. Klein also states, unequivocally, that "*[o]nly* after a calibration run with low Sr breakthrough has been successfully completed" did the system "*enable*" patient elusions. *Id*. at .000028 (emphasis added).

Bracco's expert Dr. Pelc seemed to testify that allowing manual entry of breakthrough data was actually just hypothetical in the Klein thesis; he said Klein was "envisioning the *possibility*" of a system state that allowed manual entry of breakthrough data. *See* Tr. at 984:8-23 (emphasis added). But even if Klein's statement were not hypothetical, there would be no "*successful* breakthrough measurement" in a system where the dose calibrator is not sensitive enough or in a run where the eluted rubidium activity is insufficient to measure breakthrough. *See* Klein at .000039 (emphasis added). Without a successful breakthrough measurement, the calibration run would not have been "successfully completed." *See id*. at .000028. Without a successful calibration run, Klein expressly states the system would not "enable patient elutions." Klein at .000028, -39. I find that a person of ordinary skill in the art would understand the software on the Klein computer will not allow a patient elution until the computer determines that results from a strontium breakthrough test are acceptable.

Alternatively, to the extent that Klein does not expressly teach a computer that will "not allow a patient infusion if the strontium breakthrough test result is greater than or equal to an allowed limit," I find that a system having this lock-out feature would have been obvious to a person of skill in the art reading Klein. Klein instructs the skilled artisan that the elution system "must have multiple robust mechanisms to ensure that in any case of failure the patient is not at risk." Klein at .000042. Klein advises the person of skill to "remove operator intervention" to

enforce compliance with a daily safety protocol, including breakthrough testing. *Id.* at .000027-.000028. With that motivation in mind, Klein teaches that "[i]f errors are detected during the initial testing an appropriate message is displayed and the program is halted . . . The sequence will not continue until all errors are resolved." *Id*. at .000063. Klein also illustrates a software state machine that does not allow the software to progress to the next step in a protocol unless the desired state is achieved. *Id*. at .000073 ("If the transition condition is met for the current state an initialization of the next state is executed…").

I have already explained why a person of skill in the art would have been motivated to move Klein's dose calibrator onto the cart, and why such a person would have been able to successfully build and use a system with that configuration. No changes to Klein's computer system would be necessary when the dose calibrator is on the cart. Viewing the record evidence as a whole, an invention having the computer lock-out described in claim 1 would have been obvious.

Conclusion

It is rare that a single prior art reference renders a claimed invention obvious. But this is one of those rare circumstances. I find the rubidium infusion system shown in the Klein thesis includes all of the same functional components recited in claim 1, but Klein physically arranges the components differently than the claim. For the reasons discussed above, and after considering secondary indicia of non-obviousness advanced by Bracco,[6] I find that rearranging the components in Klein would have been obvious to a person of ordinary skill in the art at the time of the invention. claim 1 is therefore invalid under 35 U.S.C. § 103.

[6] I fully address Bracco's arguments concerning secondary indicia *infra* part IV.D.2.

(b) Klein Thesis in Combination with Tate and Chaffin

Jubilant and Staff argue a person of ordinary skill in the art would look to combine the teachings of the Klein thesis with the Tate patent and a chapter on occupational ergonomics from Chaffin. Jubilant and Staff contend that Tate teaches a computer controlling radioactive elusions based on calibration readings from a dose calibrator on-board the cart. RIB at 19-20, 25; SIB at 43-44. They also assert that the Chaffin reference would lead an artisan designing an infusion system to place the heavy generator at a lower elevation than the waste bottle. RIB at 112-113; SIB at 50. Jubilant and Staff contend the invention in claim 1 and would have been obvious in light of Klein, Tate, and Chaffin.

I have previously explained the motivations expressed in Klein that would lead one of skill to the claimed invention. Those same motivations (mobility, simplicity, and reducing radiation exposure) would lead one of skill to combine Klein and Tate. Tate discloses a dose calibrator on-board a radiopharmaceutical infusion system, and I have already determined that a person of skill would understand from Klein how to adapt the Klein system for a different physical configuration. To review, Klein expressly teaches how to overcome difficulties like "radiation from the surroundings" and unknowns introduced by system geometry. *See* Klein at .000056-57. Klein's method of analyzing dose calibrator readings "accounts for all available data and therefore decreases the effect of noise" in dose calibrator measurements. *Id.* at .000057-58. Because "the physical process" of radioactive transfer "is well understood" and accounted for in Klein's model, a person of skill would know how to successfully implement Tate's on-board dose calibrator within the Klein system. *See id*. at .000119. The combination of Klein and Tate, even without Chaffin, render the claimed invention obvious.

Staff and Jubilant suggest a person of ordinary skill would be motivated to further combine Klein and Tate with Chaffin, an occupational safety reference. Chaffin teaches that heavier objects should be placed so as to minimize the distance required to lift them in order to reduce strain or injury to the person lifting the object. *See* RX-0096.0170-.0178. Bracco largely admits that Chaffin is relevant prior art, but denies that the record reflects any motivation to combine it with Klein and Tate. *See* Tr. at 1083:6-15 (Bracco's expert, Dr. Pelc, agrees that a medical device designer would be interested in teachings of ergonomics); CRB at 32-33.

Chaffin teaches sensible ways to physically arrange heavy objects used by humans. To the extent that any teaching of Chaffin is necessary to arrive at the claimed invention, the claimed invention is obvious in view of Klein, Tate, and Chaffin. The generator in Klein is a weighty object that must be moved by a human every two months (Klein at .000018-19), and an ordinary skilled designer would look to references like Chaffin to understand best practices for positioning the generator on the cart. Of the limited options available for positioning the generator, having the generator compartment opening lower than the opening of the waste bottle compartment would have been obvious, as I described above. *See KSR* at 421; *Weber*, 312 F.2d at 813; *Gazda*, 219 F.2d at 451 *Kuhle*, 526 F.2d at 555; *Japikse*, 181 F.2d at 1023.

For the reasons discussed above, and after considering secondary indicia of non-obviousness advanced by Bracco, I find the invention of claim 1 would have been obvious in view of Klein and Tate, or in view of Klein, Tate, and Chaffin. Claim 1 is therefore invalid under 35 U.S.C. § 103.

(c) Klein Thesis in Combination with the MedRad Intego Device and Chaffin

Jubilant and Staff also propose a combination nearly identical to Klein-Tate-Chaffin, replacing Tate with the MedRad Intego. As I noted in section VI.B.1.b)(2), the MedRad Intego system is the commercial embodiment of the invention disclosed in the Tate patent.

For the same reasons as outlined above in the Klein-Tate-Chaffin analysis, and after considering secondary indicia of non-obviousness advanced by Bracco, I find the proposed combination of Klein and the MedRad Intego device, and the proposed combination of Klein, the MedRad Intego device, and Chaffin each render obvious claim 1 of the '826 patent.

(d) Klein Thesis in Combination with CardioGen, Tate/Medrad Intego, Model 510, and Chaffin

Jubilant and Staff also contend that a person of skill in the art would consider the Bracco CardioGen-82 Model 510 device (RX-0357) in combination with Klein, Tate/MedRad Intego, and Chaffin. Jubilant and Staff particularly point to the Model 510 for elements [1.1.a] and [1.1.c] concerning upwards facing openings for the generator compartment and the waste bottle compartment.

There is no dispute that the Model 510 is prior art. It is also beyond dispute that the Model 510 has shielding compartments with openings facing vertically upwards. And as Dr. Stone credibly testified, a person of ordinary skill would be motivated to incorporate the upward-facing openings of the Model 510 in order to reduce radiation exposure of operators. Tr. at 666:2-15 (vertical openings in shielding "very common" as "it allows a user to approach a radioisotope source and be able to get easy access to it without being exposed to radiation"). Additionally, I have determined above that the relative heights of the compartment openings constitute an obvious design choice with no expressed benefit over the prior art. *See KSR* at 421; *Weber*, 312 F.2d at

813; *Gazda*, 219 F.2d at 451 *Kuhle*, 526 F.2d at 555; *Japikse*, 181 F.2d at 1023. Accordingly, for the reasons discussed above, and after considering secondary indicia of non-obviousness advanced by Bracco, I find the invention of claim 1 would have been obvious in view of Klein, the Model 510 system, Tate/MedRad Intego, and Chaffin. Claim 1 is therefore invalid under 35 U.S.C. § 103.

(2) Claim 2

Claim 2 of the '826 patent recites the following:

> [2] The Method of claim 1, further comprising configuring the computer to:
> [2.1] measure a radioactivity of the sample of the rubidium radioactive eluate while the sample is flowing through the eluate tubing line to the eluate reservoir;
> [2.2] measure a calibration radioactivity of the sample while the sample remains in the eluate reservoir in the shielded well on-board the cart; and
> [2.3] compare the radioactivity of the sample measured while flowing through the eluate tubing line with the calibration radioactivity of the sample measured in the eluate reservoir in the shielded well on-board the cart.

Jubilant and Staff assert claim 2 is obvious in light of the combinations of prior art advanced above in connection with claim 1. Staff and Jubilant argue that Klein discloses all of the additional limitations of claim 2 not already addressed. *See* RIB at 87-88; SIB at 54-55. In response, Bracco raises no dispute about claim 2 beyond its contention that Klein does not disclose a "shielded well on-board the cart."

Klein discloses measuring the radioactivity of the eluate while the sample is flowing to the reservoir in the dose calibrator using an activity counter [2.1]. Tr. at 731:20-732:18 (citing Klein at .000029). Klein also teaches measuring the calibration radioactivity while the sample is in the dose calibrator. *Klein* at .000028 (describing the calibration constant (as calculated by sample eluate in the dose calibrator) as a "measure of the [in-line radioactivity counter]'s efficiency"). Klein teaches comparing those two measurements. *Id.* at .000053 ("integral activity recorded from

the dose calibrator is used to calibrate the activity counter and verify that the calibration constant is within tolerance"), .000080 (figures showing calibration results comparing detector and calibrator measurements). I have previously explained why it would have been obvious to make the Klein system with the dose calibrator on the cart. Such a system would have each limitation of claim 2. The other combinations of prior art advanced by Jubilant and Staff with respect to claim 1 also would have each element of claim 2. For the reasons discussed above, and after considering secondary indicia of non-obviousness advanced by Bracco, I find the invention of claim 2 would have been obvious.

(3) Claim 3

Claim 3 of the '826 patent recites the following:

> [3] The Method of claim 1, further comprising installing a dose calibrator in the shielded well on-board the cart, wherein the dose calibrator is in communication with the computer to measure the strontium breakthrough test result and the calibration radioactivity of the sample pumped into the eluate reservoir.

Jubilant and Staff assert claim 3 is obvious in light of the combinations of prior art advanced above in connection with claim 1. Staff and Jubilant argue that Klein discloses all of the additional limitations of claim 3 not already addressed. *See* RIB at 87-88; SIB at 55. Bracco does not dispute these contentions beyond its argument that Klein does not disclose a "shielded well on-board the cart." *See* CRB at 40.

The dose calibrator of Klein communicates with the computer to measure breakthrough and calibration radioactivity. *See, e.g.*, Klein at .000060 (the dose calibrator detects breakthrough activity as part of the calibration test), -65 ("dose calibrator is tested for communication" with computer). I have previously explained why it would have been obvious to make the Klein system with the dose calibrator on the cart. Such a system would have each limitation of claim 3. The other combinations of prior art advanced by Jubilant and Staff with respect to claim 1 also would

have each element of claim 3. For the reasons noted above, and after considering secondary indicia of non-obviousness advanced by Bracco, I find the invention of claim 3 would have been obvious.

(4) Claim 5

Claim 5 of the '826 patent recites the following:

> [5] The method of claim 2, further comprising configuring the computer to allow a user to: initiate a purging process through the touch screen display to purge a patient tubing line of air, wherein the patient tubing line is in fluid communication with the eluate tubing line.

Jubilant and Staff assert claim 5 is obvious in light of the combinations of prior art advanced above in connection with claim 1. Staff and Jubilant argue that Klein discloses all of the additional limitations of claim 5 not already addressed. *See* RIB at 87-88; SIB at 55. In response, Bracco does not expressly dispute that Klein discloses all of the additional limitations of claim 5.

Klein discloses a flush run initiated by the operator on a touch to remove air bubbles from the system. Klein at .000028, -40, -54. For the reasons discussed above, and after considering secondary indicia of non-obviousness advanced by Bracco, I find the invention of claim 5 would have been obvious. *See* Tr. at 747:19-749:13, 765:21-766:8; Klein at .000029, -53, -54, -64.

(5) Claim 9

Claim 9 of the '826 patent recites the following:

> [9.0] The method of claim 2, further comprising configuring the computer to:
> [9.1] present on the touch screen display a screen for starting the patient infusion by touching a button on the touch screen display;
> [9.2] present on the touch screen display a screen reminding a user to insert the eluate reservoir in the shielded well on-board the cart;
> [9.3] present on the touch screen display a screen indicating that the patient infusion is in process, wherein the screen indicating that the patient infusion is in process displays a stop button to abort the patient infusion; and
> [9.4] present on the touch screen display the strontium breakthrough test result.

Jubilant and Staff assert claim 9 is obvious in light of the combinations of prior art advanced above in connection with claim 1. Staff and Jubilant argue that those combinations also disclose all of the additional limitations of claim 9 not already addressed, as outlined below.

(a) Klein Thesis Alone

Staff, but not Jubilant, argues that Klein alone discloses all of the additional limitations of claim 9, which concern the display of certain messages on the computer system touch screen. *See* SIB at 57. Bracco does not dispute that Klein discloses displaying a start button (limitation [9.1]) but disputes that Klein discloses displaying a reminder to insert the eluate reservoir (limitation [9.2]), displaying elution progress and a stop button (limitation [9.3]), and displaying the strontium breakthrough test result (limitation [9.4]). *See* CRB at 46-48.

I find Klein expressly discloses the start button of limitation [9.1]. Klein teaches a graphical user interface having large buttons displayed on a touch screen. Klein at .000031, -.000040. To start an elution, the system displays the screen shown in Figure 3-12 (e) of Klein. *Id.* at .000064. The screen prompts the user, "Start Constant Activity Elution?" and displays "Yes" and "No" buttons. *Id.*

With respect to the dose calibrator reservoir reminder (limitation [9.2]), I find that the computer in Klein's system communicates with the dose calibrator at the start of the daily protocol to make sure that the calibrator has the "proper settings." Klein at .000065. If something is wrong with the dose calibrator, "warnings are presented to the user with detailed explanations." *Id.* Klein also describes how to use a sensor to detect a physical property of a reservoir and issue a warning if a user attempts to start an elution with the reservoir in the wrong condition. *Id.* at .000044-45 (describing an overflow sensor in the waste reservoir). In light of these disclosures, a person of

ordinary skill in the art would find it obvious to display a reminder to the user to insert the eluate reservoir if the user attempts to start the calibration run without doing so.

I find that Klein expressly discloses the progress display and stop button found in limitation [9.3]. Klein states that "progress bars must be included for each stage of the elution so as to facilitate monitoring of the system" and that "an emergency stop button must be enabled throughout the elution." Klein at .000041; *see also id*. at .000065, -75, -76. Patient infusions are a type of elution disclosed by Klein. *See, e.g.*, *id.* at .0000053. Klein also shows a screen shot of a progress message and stop button. Klein at .000064 (Fig. 3-12 (h)).

I find that Klein expressly discloses a touch screen display of the strontium breakthrough test result. Klein at .000064 (Fig. 3-12(f) and (g)); *see also id*. at .000041 ("On successful completion a grey screen must list statistics relevant to the elution . . . a separate window must list a comprehensive display of all statistics in addition to activity curves"), .000065. In the alternative, a person of ordinary skill in the art would find it obvious to display the results of the Klein system's breakthrough tests on Klein's touch screen.

For the reasons discussed above, and after considering secondary indicia of non-obviousness advanced by Bracco, I find the invention of claim 9 would have been obvious in view of the Klein thesis.

(b) Klein Thesis in Combination with IEC 62366

With respect to the dose calibrator reservoir reminder in element [9.2], Jubilant and Staff also argue that a person of ordinary skill would combine Klein with an international standard for medical device design known as IEC 62366. RIB at 92-94, 126-129; SIB at 57-60. IEC 62366 teaches medical device developers to provide a user interface that enables users "to be aware of the use of the correct consumable, the remaining amount of [the consumable], whether accessories

might be used with the MEDICAL DEVICE, how to assemble them and how to check their correct functioning." IEC 62366 at .0063.

Jubilant and Staff argue that because Klein discloses warnings to replace generators (Klein at .000064) and waste bottles (*id.* at .000044-.0045), a person of ordinary skill would have reason to consider warnings about other consumables, as advised in IEC 62366. Jubilant and Staff argue the eluate reservoir is just such a consumable. Bracco's sole argument concerning IEC 62366 is that "[e]ven if a [person of skill in the art] were to look to this directive, it does not require the particular alert of the claims—reminder to insert the eluate reservoir." CRB at 47.

I have determined above that Klein alone renders the reservoir reminder obvious. To the extent that any teaching of IEC 62366 is necessary to arrive at the claimed invention, the invention is obvious in view of Klein and IEC 62366.

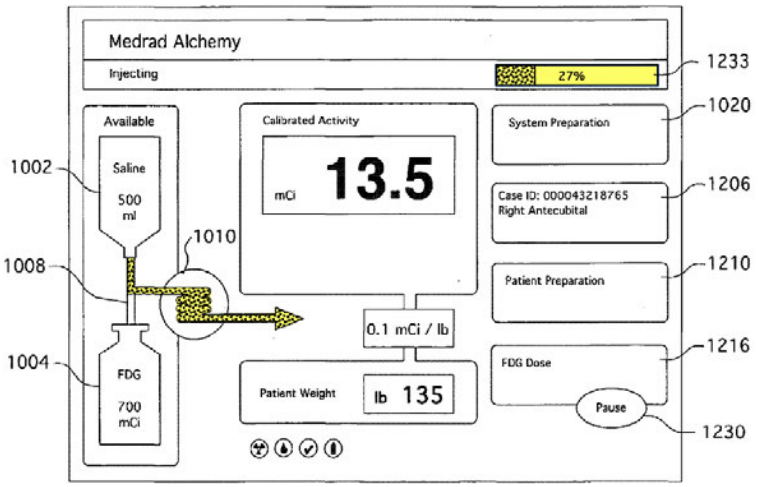
For the reasons discussed above, and after considering secondary indicia of non-obviousness advanced by Bracco, I find the invention of claim 9 would have been obvious in view of the Klein thesis and IEC 62366.

(c) Klein Thesis in Combination with IEC 62366 and Tate/MedRad Intego

Jubilant, but not Staff, also propose a combination of Klein with Tate/MedRad Intego as teaching the progress display and stop button (limitation [9.3]) and the display of the breakthrough test result (limitation [9.4]). RIB at 128 (citing Tate at .0059, .0105 (¶0232) (describing progress bar 1233 and highlighting of fluid path 1008 during injections), 129-130 (citing Tate at .000039 and Intego at .0039).

With respect to element [9.3], Bracco argues that "[t]he image Jubilant cites from Tate . . . relates to a screen showing a progress bar" but that "showing a progress bar does not indicate that

a patient infusion is in process." CRB at 48 (citing Tr. at 1000:1-11 (Dr. Pelc)). Bracco's point is not well taken. The figure in Tate expressly shows that the progress bar is for "injecting":



Tate at .000059. In the context of the PET infusion system of Tate, a person of skill in the art would understand a progress bar for "injecting" to be a progress bar for a patient infusion. As noted above, I find that Klein expressly disclosed the progress display and stop button of element [9.3]. To the extent that any teaching of Tate is necessary to arrive at the claimed invention, the invention is obvious in view of Klein and Tate.

With respect to element [9.4], Jubilant argues that Tate/MedRad Intego "display results of PET infusion system quality control tests," thus rendering element [9.4] obvious. RIB at 130. Bracco responds that Tate and the MedRad Intego are FDG systems, which do not perform strontium breakthrough tests. Consequently, Bracco argues, neither disclose the presenting strontium breakthrough test results on touch screen. CRB at 48.

As noted above, I find Klein expressly discloses displaying a strontium breakthrough test result. Accordingly, an invention having limitation [9.4] would have been obvious to a person of skill in the art in view of Klein and Tate/MedRad Intego.

(6) Claim 10 (Unasserted)

Claim 10 of the ’826 patent, which is not asserted but is relevant due to intermediate dependencies of other asserted claims, recites the following:

> [10.0] The method of claim 9, further comprising configuring the computer to allow the user to:
>
> [10.1] log into the computer by entering a user login credential on the touch screen display,
>
> [10.2] enter a patient ID on the touch screen display,
>
> [10.3] enter a patient dose on the touch screen display, and
>
> [10.4] enter a flow rate on the touch screen display.

Jubilant and Staff assert claim 10 is obvious in light of the combinations of prior art advanced above in connection with claims 1 and 9. Staff and Jubilant argue that Klein discloses all of the additional limitations of claim 10 not already addressed. SIB at 60-6 and RIB at 94-95. Bracco does not appear to dispute that Klein alone discloses all of the additional limitations of claim 10 not otherwise addressed.

Klein alone discloses all of the additional elements of claim 10. *See* Klein at .000040 (touch screen of Klein is sole user interface with system), .000063 (disclosing prompt for user ID code, as in element [10.1]), .000065 (patient ID [10.2], patient dose [10.3], flow rate [10.4]). Accordingly, an invention having all of the elements of limitation [10] would have been obvious to a person of skill in the art in view of Klein alone or the art combinations analyzed above in connection with claims 1, 2, and 9.

(7) Claim 11

Claim 11 of the ’826 patent recites the following:

> [11] The method of claim 10, further comprising configuring the computer to:
>
> [11.1] track time passed from completion of pumping the sample of the rubidium radioactive eluate into the eluate reservoir to measuring the strontium breakthrough test result,
>
> [11.2] track a volume of saline remaining in the saline reservoir,
>
> [11.3] provide an alert via the touch screen display when the volume of saline remaining in the saline reservoir is below a predetermined volume threshold,

> [11.4] track a volume of the rubidium radioactive eluate discharged from the strontium-rubidium radioisotope generator to the waste bottle, and
> [11.5] present on the touch screen display a screen reminding the user to empty the waste bottle.

Jubilant and Staff assert claim 11 is obvious in light of the combinations of prior art advanced above in connection with claims 1, 2, 9, and 10. Staff and Jubilant argue that those combinations disclose all of the additional limitations of claim 11 not already addressed.

(a) Klein Thesis Alone

Staff, but not Jubilant, argues that Klein alone renders the additional claims of claim 11 obvious. SIB at 61-63. Bracco appears to concede that Klein discloses limitation [11.1], a computer that tracks time from completion of pumping an eluate sample into the eluate reservoir to determine the strontium breakthrough test. *See* CRB at 52 (acknowledging the computer in Klein performed the daily protocol, which included time tracking). Bracco also did not contest Staff's assertion that Klein discloses tracking eluate discharged into a waste bottle and reminding the use to empty the waste bottle as described in limitations [11.4] and [11.15]. *Id*. at 55-57. Bracco contends, however, that Klein does not disclose tracking saline as required by limitations [11.2] and [11.3]. CRB at 55-57.

I find Klein discloses the time tracking of limitation [11.1]. Klein at .000028 ("the activity in the dose calibrator is registered 30 minutes after the end of the elution to compute the breakthrough"); Tr. at 763:-24-764:18 (testimony of Dr. Stone). I also find Klein discloses limitations [11.4] and [11.5]. Klein discloses tracking the volume of eluate in a waste bottle using an electro-optic level switch and displaying a reminder to empty the bottle when the switch is triggered. Klein at .000044-45.

As for the saline tracking limitations in [11.2] and [11.3], Klein discloses real-time software to control of the flow of saline from a saline bag into a generator. Klein at .000029. The computer accurately computes the volume of eluted saline, a critical value for the algorithms that control the Klein system. *Id*. at .000012. When the computer determines that the volume of eluted saline passes a threshold, the computer displays an alert to the user on a touch screen display. Klein at .000064 (Figure 3-12(b)), -78. Klein discloses that these capabilities can be used to determine when the amount of eluted saline has passed 90% of the volume allowed by the generator specifications. *Id.* When that volume is reached, the user is reminded to replace the generator. *Id*. Klein teaches the saline supply must be replaced just as the generator must be replaced when exhausted. *Compare* Klein at .000028 *with id*. at .000018-19.

Klein does not expressly disclose using his saline tracking and alert system to determine how much saline is left in the saline bag. However, such a use of the system would have been obvious to a person of skill in the art. Klein states two of his main goals are to automate the infusion system and allow monitoring from a distance. *Id*. at .000036. Bracco's expert testified that a user of the Klein system would visually track the remaining volume of saline in the bag Klein discloses. Tr. at 856:3-14. Motivated by Klein's goals of automation and remote monitoring, it would have been obvious to a person of ordinary skill in the art to automate the visual inspection of remaining saline. *See In re Venner*, 262 F.2d 91, 95 (C.C.P.A. 1958) ("It is well settled that it is not 'invention' to broadly provide a mechanical or automatic means to replace manual activity which has accomplished the same result.") Having the Klein computer keep track of remaining saline also furthers Klein's goal of monitoring while the user is away from the system. *See* Klein at .000039, -46 (distance is the best shielding for an operator, and the operator may be

several meters from the device). And Klein teaches structures and methods to monitor saline volume and set an alert based on reaching a threshold. Klein at .000064 (Figure 3-12(b)), -78.

For the reasons discussed above, and after considering secondary indicia of non-obviousness advanced by Bracco, I find the invention of claim 11 would have been obvious in view of the Klein thesis.

(b) Klein Thesis in Combination with IEC 62366

IEC 62366 teaches medical device developers to provide a user interface that enables users "to be aware of the use of the correct consumable [and] the remaining amount" of the consumable. IEC 62366 at .0063. Jubilant and Staff both argue that the Klein thesis in combination with IEC 62366 renders the additional limitations of claim 11 obvious. SIB at 63; RIB at 95-96. In response, Bracco argues that Jubilant's expert Dr. Stone admitted that IEC 62366 does not disclose using a computer to track consumables. CRB at 57 (citing Tr. at 866:6-867:10),IEC 62366 at .0063.

As noted above, Klein discloses a computer to track saline elution and provide warnings. To the extent that any teachings beyond Klein are necessary to arrive at the invention of claim 11, IEC 62366 in combination with Klein only would have made the invention more obvious.

For the reasons discussed above, and after considering secondary indicia of non-obviousness advanced by Bracco, I find the invention of claim 11 would have been obvious in view of the Klein thesis and IEC 62366.

(c) Klein Thesis in Combination with MedRad Intego

Jubilant and Staff also argue that Klein in combination with the MedRad Intego device renders the additional limitations of claim 11 obvious. RIB at 96; SIB at 63. Jubilant contends that the MedRad Intego system tracks saline and provides alerts, as in limitations [11.2] and [11.3]. RIB at 132-133; *see also* SIB at 63.

Bracco responds that the Intego device is not pertinent art because it is an FDG system. CRB at 56. However, as explained above, *supra* V.B.2.a)(1), the Intego device is pertinent art. Bracco also argues that the saline in the Klein system is used for rubidium generation, but the saline in the Intego system is not used to generate a radiopharmaceutical, so it would not be obvious to combine those references. *Id.*

It is true that Klein uses saline to generate a rubidium eluate, but Klein also discloses using saline to "transport" radioactive tracer into the patient's body. Klein at .000049. The Intego system similarly uses saline to transport FDG into the patient's body. RX-200C (Intego manual) at .0014 ("the dose of FDG / saline is injected into the patient."); Tr. at 817:12-818:4. A person of skill in the art would understand that a sufficient supply of saline is necessary for both systems and would be motivated to understand the way each system addresses that issue.

I have explained above why a person of skill in the art would have been motivated to use the saline monitoring and alert system of Klein to monitor the remaining saline in a saline bag. To the extent that any additional understanding is necessary for a skilled artisan to arrive at the claimed invention, the Intego device provides that understanding. When a user installs a new saline bag with the Intego system, the computer prompts the user to enter the volume of saline. RX-200C.0057. The Intego system then monitors saline usage and displays an alert when the saline level falls below a threshold. *Id*. at .0116.

For the reasons discussed above, and after considering secondary indicia of non-obviousness advanced by Bracco, I find the invention of claim 11 would have been obvious in view of the Klein Thesis and the MedRad Intego device.

(8) Claim 12

Claim 12 of the ’826 patent recites the following:

> [12.0] The method of claim 11 further comprising configuring the computer to allow the user to:
>
> > [12.1] initiate a generator column wash through the touch screen display, wherein a predetermined amount of saline is pumped through the strontium-rubidium radioisotope generator and directed to the waste bottle during the generator, column wash, and
> >
> > [12.2] initiate a purging process through the touch screen display to purge a patient tubing line of air, wherein the patient tubing line is in fluid communication with the eluate tubing line.

Jubilant and Staff assert claim 12 is obvious in light of the combinations of prior art advanced above in connection with claims 1, 2, 9, 10, and 11. Staff and Jubilant argue that those combinations disclose all of the additional limitations of claim 12 not already addressed. RIB at 96-98; SIB at 63-65. Bracco does not address these arguments.

For the reasons discussed above, and after considering secondary indicia of non-obviousness advanced by Bracco, I find the invention of claim 12 would have been obvious. *See* Tr. at 765:21-766:8, 747:19-749:13; Klein at .000029, .000053, .000054, .000064.

(9) Claim 13

Claim 13 of the ’826 patent recites the following:

> [13.0] The method of claim 12, wherein the infusion system is configured for the saline tubing line and the eluate tubing line to be routed through
> [13.1] two tubing passageways formed in a perimeter surface of the first opening, wherein
> [13.2] each of the two tubing passageways has a depth configured to prevent pinching or crushing of a corresponding tubing line routed therethrough when a first door is closed over the first opening.

Jubilant and Staff assert claim 13 is obvious in light of the combinations of prior art advanced above in connection with claims 1, 2, 9, 10, 11, and 12. Staff and Jubilant argue that

those combinations also disclose or render obvious all of the additional limitations of claim 13 not already addressed, as outlined below.

(a) Klein Thesis Alone

Staff argues that Klein discloses or renders obvious all additional limitations of claim 13. Staff argues that a person of ordinary skill in the art would recognize that Klein's system was not "market-ready" and would therefore be motivated to consolidate and hide components when commercializing the system. SIB at 65 (citing Tr. at 617:20-22).

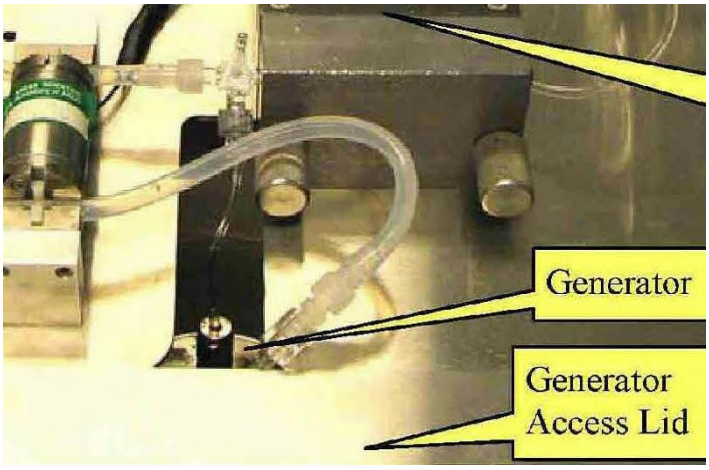
Bracco responds that Klein fails to teach either "tubing passageways" [13.1] or "a first door" [13.2], and Klein has no motivation to change the physical arrangement of the disclosed system. CRB at 58-63.

I find Klein discloses three different shielding compartments with lids or doors and passageways for tubes to enter and exit those compartments without being pinched when those lids or doors are closed.

First, Klein discloses the generator compartment discussed above in connection with claim 1. Klein expressly points out a "Generator Access Lid" over that compartment in a photograph of the Klein system. *See* Klein at .000034 (Figure 2-4); Tr. at 665:11-666:1 (testimony of Dr. Stone that Klein had "an access door . . . that could give access to the generator"). Klein's generator access door is located proximately above the first opening of the first shielding compartment, and thus "closes over" that opening. *Id.*

Klein also shows a tubing passageway that is configured so that tubing is not pinched or crushed when the Generator Access Lid is closed. *See* Klein at .000034 (Figure 2-4, excerpt 1 below). In Figure 2-4, the passageway is the opening in the stainless steel surface seen at the tip of the yellow "Generator" annotation bubble. The passageway has a depth sufficient to allow for

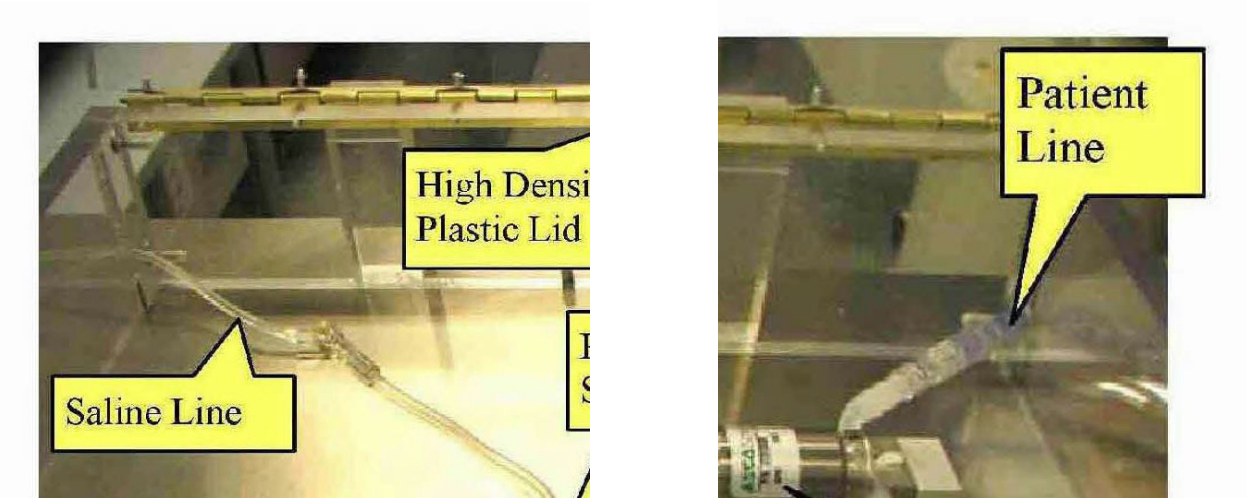
tubes to run into the generator shielding compartment without being crushed when the first door (the "Generator Access Lid" in Figure 2-4) is closed, as pictured. *Id.*



Klein Figure 2-4, Excerpt 1

Second, Klein discloses a shielding enclosure comprised of high-density plastic on top of the cart to limit radiation exposure from tubing. Klein at .000046. The plastic shielding compartment has two tubing passageways formed in its perimeter to allow tubing to enter and exit the compartment without being crushed when the plastic lid of the enclosure is closed. *See* Klein at .000034 (Figure 2-4, excerpts 2 and 3 below). Those passageways are square-shaped notches in the vertical perimeter of the high-density plastic enclosure. In Figure 2-4, one of those passageways is shown in the left rear corner of the plastic enclosure, where the saline line enters

the enclosure. Another passageway is in the right rear corner of the plastic enclosure, where the patient line exits the enclosure:



Klein Figure 2-4, Excerpt 2 *Klein Figure 2-4, Excerpt 3*

Third, Klein discloses a shielding compartment for the waste bottle. *See* Klein at .000034 (Figure 2-3). Figure 2-4 shows a "Waste Line" tube running into that compartment. *Id*. (Figure 2-4). Klein expressly discloses that the shielded waste container has a lid. *Id*. at .000025 ("the waste container was mounted … inside a lead container with a lid.").

Klein does not show two passageways formed in the perimeter surface of the opening of a compartment that has all of the features of the generator compartment required by claim 1, from which claim 13 depends. But Klein's teachings would make such an arrangement obvious to person of ordinary skill. Klein provides a person of ordinary skill with motivation to avoid crushing or pinching tubing lines running into or out of a shielding compartment when the lid of that compartment is closed. *See* Klein at. 000076 ("high pressure is an indication of a blockage or pinched line and could result in backwash through the pump head or rupturing of the saline lines."). Klein also discloses the means for avoiding crushing or pinching: passageways formed in the

perimeter of a shielding compartment. Klein further discloses two passageways formed in the perimeter of the plastic shielding compartment, one for the saline line and one for the patient line.

Forming two tubing passageways in the perimeter surface of the opening of a generator compartment as required by the claim would be an obvious alternative design choice operating on the same principle disclosed by Klein. *See Philips Lighting N. Am. Corp.*, 727 F. App'x at 681 (affirming rejection of patent as "obvious matter of design choice" where two prior art designs "were known in the art, recognized as solutions to the particular problem, and functionally equivalent"); Tr. at 822:13-823:2. Upon review of the evidence cited and after considering secondary indicia of non-obviousness, I find that Klein alone renders an invention having the additional elements of claim 13 obvious.

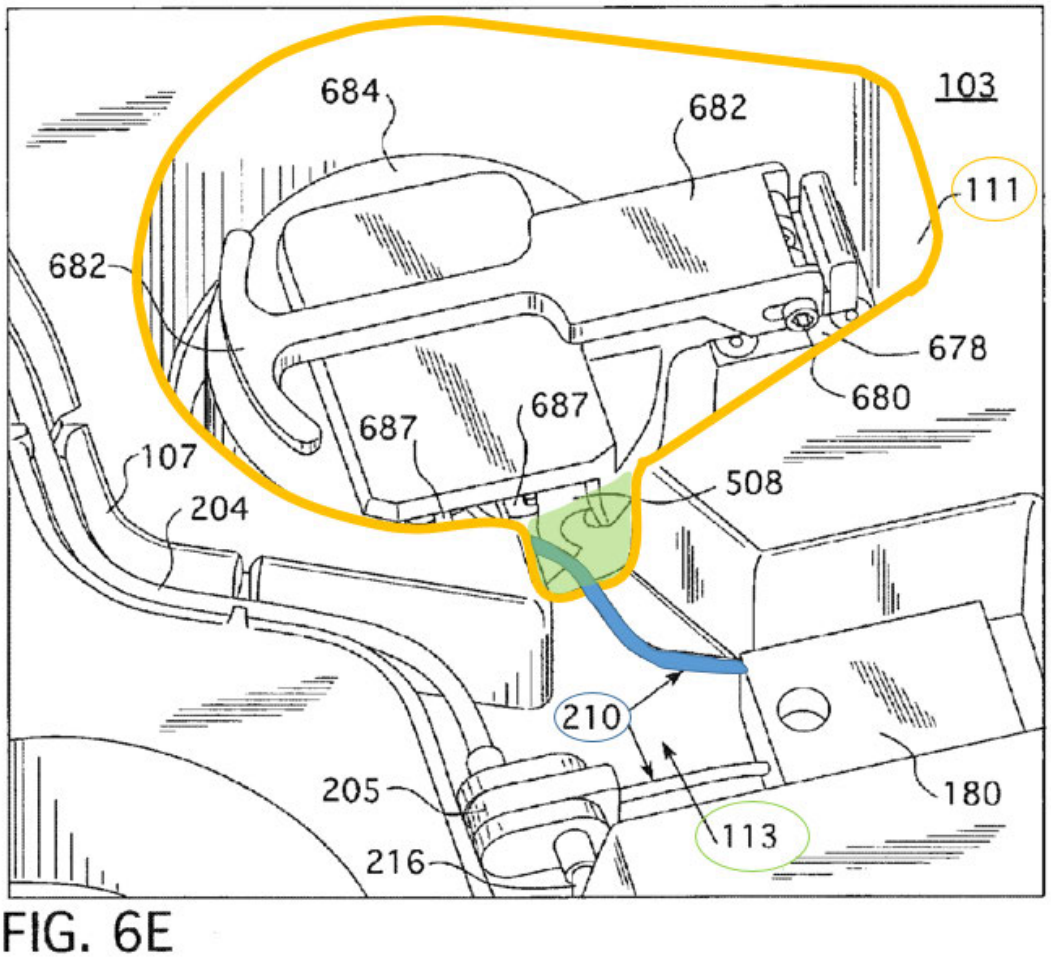
(b) Klein Thesis in Combination with Tate and/or MedRad Intego

Staff and Jubilant both argue that a person of ordinary skill would find claim 13 obvious in light of Klein combined with Tate and/or the Intego device. SIB at 66-67; RIB at 98-99. They argue that because Klein was not "market-ready," Tr. at 617:20-22, a person of skill would look to hide tubing and make other improvements; by looking at Tate and Intego, the person of skill would know to include two passageways of sufficient depth to not pinch the tubing lines flowing into the generator when the lid over the generator is closed. Although they acknowledge Tate and the Intego device show only one such passageway, they argue it would be obvious to a person of skill in the art to use two passageways to accommodate the needs of a rubidium system. *Id.* They also note that Tate teaches "a recess or trough" to accommodate tubing that "holds the tubing in place and prevents it from getting kinked or tangled" on the top surface of the cart over which the shielded lid closes. *Id.* (citing Tate at .000093 ¶ 0078).

Bracco argues that Tate and the FDG Intego system are not pertinent art, that Tate and the Intego device do not show even a first passageway for tubing, and that the lid disclosed by Tate would not function if combined with Klein as Jubilant and Staff propose. CRB at 60-63.

As noted above, I find that Tate and the Intego device are pertinent art, *see supra* V.B.1.b). I find that a person looking to commercialize Klein would be motivated to cover the visible tubing lines along the top surface of the cart, as those lines can be a source of radiation exposure. *See* Klein at .000046; Tr. at 617:20-22. And both Klein and Tate present the motivation to avoid crushing and pinching of tubing lines when configuring system layout. *See* Klein at. 000076 ("high pressure is an indication of a blockage or pinched line and could result in backwash through the pump head or rupturing of the saline lines"); Tate at .000093 ¶¶ 0078-79 (describing troughs for tubing lines to prevent kinking, including a "second trough that leads to a first well").

Tate discloses forming a passageway in the perimeter surface of the opening into a shielded chamber for the radiopharmaceutical source. Tate at .000019. Tate's shielded well (element 111, show in yellow below) has a first opening in the top surface of the cart. *Id.* Tate discloses a trough (element 113, shown in green below) formed in the perimeter surface of that opening allowing a tubing line (element 210, shown in blue below) to pass into the shielding compartment without being crushed while a cap (element 684) is closed over the top of the compartment. I find that a person of ordinary skill would be motivated, as noted above, to incorporate Tate's passageway when moving the tubing below the top surface of Klein's cart in order to avoid crushing of tubing lines.



Tate Figure 6E (annotated)

Although Tate teaches only one passageway and one tubing line, Klein teaches two tubing lines. Duplicating the tubing passageways of either Tate or Klein, to provide separate passageways for both the tubing line into and out of the generator, would have been obvious to one of skill in the art. *See In re Harza*, 274 F.2d 664, 671 (C.C.P.A. 1960) (duplication of elements is not patentable unless a new or unexpected result is produced."); Tr. at 702:7-12.

I further find that Tate discloses channels formed in a surface for tubing lines to prevent obstruction of those tubing lines when a hinged lid is closed over them. Tate at .000093 ¶ 0078. The MedRad Intego device shows a similar passage. RX-0200C at .0018. Forming such passageways in the perimeter surface of the first opening rather than the opening for the generator

access lid would be an obvious alternative design choice operating on the same principle. *See Philips Lighting N. Am. Corp.*, 727 F. App'x at 681 (affirming rejection of patent as "obvious matter of design choice" where two prior art designs "were known in the art, recognized as solutions to the particular problem, and functionally equivalent."); Tr. at 822:13-823:2.

For the foregoing reasons, and after considering secondary indicia of non-obviousness, I find that Klein in combination with Tate and/or the MedRad Intego device renders an invention with the additional elements of claim 13 obvious.

(10) Claim 14

Claim 14 of the '826 patent recites the following:

> [14.0] The method of claim 13, wherein the infusion system further comprises
> [14.1] an exterior shell extending upwardly above the platform, wherein the platform and the exterior shell, collectively define an interior space of a cabinet structure,
> [14.2] a handle configured for the user to grasp in order to move the infusion system, and
> [14.3] four wheels mounted to an underside of the platform of the cabinet structure.

Jubilant and Staff assert claim 14 is obvious in light of the combinations of prior art advanced above in connection with claims 1, 2, 9, 10, 11, 12, and 13. Jubilant and Staff both argue the Klein thesis alone discloses all of the additional elements of claim 14. SIB at 67-68; RIB at 99-100. Jubilant and Staff contend the Model 510 system, the Tate patent, and the Intego device also each independently have the elements recited in claim 14. *Id*. Bracco does not appear to rebut that contention in its briefs.

I find that Klein, the Model 510 system, the Tate patent, and the Intego device each fully disclose the additional elements of claim 14. *See* Klein at .000034; RX-0207.0013 (Model 510); Tate at .002; RX-200C at .0042 (Intego manual).

For the foregoing reasons, and after considering secondary indicia of non-obviousness, I find that Klein alone or in combination with the Model 510 system, the Tate patent, or the Intego device renders an invention with the additional elements of claim 14 obvious.

(11) Claim 17

Claim 17 of the '826 patent recites the following:

> The method of claim 14, wherein the infusion system further comprises a dose calibrator in the shielded well on-board the cart and wherein the dose calibrator is in communication with the computer to measure the strontium breakthrough test result.

Jubilant and Staff assert claim 17 is obvious in light of the combinations of prior art advanced above in connection with claims 1, 2, 9, 10, 11, 12, 13, and 14. SIB at 69; RIB at 101-102.

Klein discloses a dose calibrator located in a shielded well in communication with a computer. Klein at .000060 (the dose calibrator detects breakthrough activity as part of the calibration test performed by computer), -65 ("dose calibrator is tested for communication" with computer). For the reasons discussed above in connection with claim 1, it would have been obvious to move the dose calibrator in Klein on-board the cart.

For the foregoing reasons, and after considering secondary indicia of non-obviousness, I find that Klein alone renders an invention with the additional elements of claim 17 obvious. The other art combinations analyzed above in connection with claim 1 also render obvious an invention with the additional elements of claim 17.

(12) Claim 18

Claim 17 of the '826 patent recites the following:

> [18.0] The method of claim 17,
>
> [18.1] wherein the cabinet structure has a lowermost portion and the platform has a lower surface,

> [18.2] the first opening is at a first elevation,
> [18.3] the second opening is at a second elevation,
> [18.4] the first elevation is between approximately 1 foot and approximately 2 feet, with respect to the lowermost portion of the cabinet structure, and the second elevation is between approximately 2 feet and approximately 3 feet, with respect to the lower surface of the platform.

Jubilant and Staff assert claim 18 is obvious in light of the combinations of prior art advanced above in connection with claims 1, 2, 9, 10, 11, 12, 13, 14, and 17. Staff and Jubilant argue that, for the reasons discussed concerning limitation [1.1.e] of claim 1, it would have been obvious to a person of skill in the art to modify Klein to place the generator at a lower elevation. SIB at 69-70; RIB at 102-103. They also point to the testimony of Dr. Stone to that effect. *Id*. (citing Tr. at 617:20-619:20, 699:16-700:21, 833:3-9). Bracco rests on the same arguments it advanced in connection with claim 1. CRB at 39.

I credit Dr. Stone's testimony estimating the heights of elements of the Klein cart and surroundings. His description of hypothetical elevations of repositioned components is also reasonable. Tr. at 699:17-700:21. For the same reasons given in connection with claim 1, an invention with the specific heights and other arrangement limitations in claim 18 are obvious design choices with no discernible benefit over any other possible choice. *See KSR* at 421.

For the foregoing reasons, and after considering secondary indicia of non-obviousness, I find that Klein alone renders an invention with the additional elements of claim 18 obvious. The other art combinations analyzed above in connection with claim 1 also render obvious an invention with the additional elements of claim 18.

(13) Claim 19

Claim 19 of the '826 patent recites the following:

[19.0] The method of claim 1, further comprising configuring the computer to:

> [19.1] control a fluid communication between the strontium-rubidium radioisotope generator and the saline reservoir,
> [19.2] control a fluid communication between the eluate tubing line and the eluate reservoir,
> [19.3] control a fluid communication between the eluate tubing line and the waste bottle,
> [19.4] place the eluate tubing line in fluid communication with a patient,
> [19.5] pump a dose of the rubidium radioactive eluate to the patient; and
> [19.6] flush the rubidium radioactive eluate remaining in at least a portion of the eluate tubing line into the patient by pumping saline from the saline reservoir to the eluate tubing line through a by-pass line that by-passes the strontium-rubidium radioisotope generator.

Jubilant and Staff assert claim 19 is obvious in light of the combinations of prior art advanced above in connection with claim 1. Staff and Jubilant argue that Klein discloses or renders obvious all of the additional limitations of claim 19 not already addressed. SIB at 71-72; RIB at 104-105. Bracco does not appear to dispute that Klein discloses all of the additional elements of claim 19.

I find that Klein describes a computer that controls fluid communication between the generator and the saline reservoir via the pump and generator valve, controls fluid communication between the eluate tubing line and the eluate reservoir via the patient valve, and controls a fluid communication between the eluate tubing line and the waste bottle via the patient valve. Klein at .000029-30, -53-55. Klein further describes a computer that places the eluate tubing line output from the generator in fluid communication with a patient via the patient valve, pumps a dose of the rubidium radioactive eluate to the patient, and flushes the eluate remaining in a portion of the eluate tubing line downstream of the patient valve into the patient by pumping saline from the saline reservoir through a by-pass line that by-passes the generator. *Id.*; Tr. at 739:1-741:7.

For the foregoing reasons, and after considering secondary indicia of non-obviousness, I find that Klein alone renders an invention with the additional elements of claim 19 obvious. The

other art combinations analyzed above in connection with claim 1 also render obvious an invention with the additional elements of claim 19.

(14) Claim 28

Claim 28 of the '826 patent recites the following:

> [28] The method of claim 1, further comprising configuring the computer to allow a user to: initiate a generator column wash through the touch screen display, wherein a predetermined amount of saline is pumped through the strontium-rubidium radioisotope generator and directed to the waste bottle during the generator column wash**.**

Jubilant and Staff assert claim 28 is obvious in light of the combinations of prior art advanced above in connection with claim 1. Staff and Jubilant argue that Klein discloses or renders obvious all of the additional limitations of claim 28 not already addressed. SIB at 72-73; RIB at 105-106. Bracco does not appear to dispute that Klein discloses all of the additional elements of claim 19.

I find that Klein discloses a computer that initiates a generator column wash, called a "flush run," through the touch screen control of the Klein system's computer. Klein at .000029, -64. Klein discloses that during the flush run, a predetermined amount of saline (50mL) is flushed a through the system, including the generator to the waste bottle, to clear the lines and generator of air bubbles and strontium breakthrough. *Id*. at .000053 ("Flush Run - flushing of all the lines in the system as well as a 50ml flush of the generator at 15ml/min. Ensures flushing of air bubbles in the saline and Sr breakthrough from the generator."); *id*. at .000054 ("Flush Bypass-to-Waste - The volume in the lines from the pump head to the patient valve (Point P) is flushed through the bypass to the waste container in order to remove air bubbles and activity that may remain from a previous run.").

For the foregoing reasons, and after considering secondary indicia of non-obviousness, I find that Klein alone renders an invention having the additional elements of claim 28 obvious. The

other art combinations analyzed above in connection with claim 1 also render obvious an invention with the additional elements of claim 28.

b) *'869 Patent*

Bracco asserts claims 1-5, 8, 14, 24, and 29-30 of U.S. Patent No. 9,750,869. Due to intermediate dependencies, claims 28 and 29 are also at issue for the purposes of the invalidity analysis.

(1) Claim 1

Claim 1of the '869 patent recites the following:

[1] An infusion system on-board a cart comprising:
[1.1] a cabinet structure that comprises:
[1.1.a] a platform, an exterior shell that extends upwardly above the platform and has a front side; a rear side; two sidewalls connecting the front side to the rear side; and a top surface; wherein the platform and the exterior shell, collectively define an interior space of the cabinet structure and
[1.1.b] wherein the interior space of the cabinet structure is configured to receive a strontium-rubidium radioisotope generator having an inlet tubing port configured to receive saline and an outlet tubing port configured to discharge a rubidium radioactive eluate,
[1.1.c] an opening through the exterior shell configured to provide access to the strontium-rubidium radioisotope generator within the interior space of the cabinet structure, and
[1.1.d] an opening through the top surface of the exterior shell configured to provide access for inserting a waste bottle into or removing the waste bottle from the interior space of the cabinet structure;
[1.1.e] a computer with a touch screen display configured to receive an input from a user for controlling operation of the infusion system, wherein the touch screen display is mounted on a vertical post having a top end extending above the cabinet structure;
[1.2] a first shielding compartment in the interior space of the cabinet structure having a first opening facing vertically upwardly through which the strontium-rubidium radioisotope generator can be inserted into and removed from the first shielding compartment;
[1.3] a first door accessible via the opening through the exterior shell, the first door being configured to provide access to the first shielding compartment and to close over the first opening;

> [1.4] a second shielding compartment having a second opening facing vertically upwardly through which the waste bottle can be inserted into and removed from the second shielding compartment;
> [1.5] a second door accessible via the opening through the top surface of the exterior shell, the second door being configured to provide access to the second shielding compartment and to close over the second opening;
> [1.6] wherein the first opening is located at a lower elevation than the second opening;
> [1.7] a radioactivity detector positioned to measure radioactivity of the rubidium radioactive eluate flowing through an eluate tubing line in fluid communication with the outlet tubing port of the strontium-rubidium radioisotope generator;
> [1.8] a shielded well on-board the cart configured to receive an eluate reservoir, wherein the eluate reservoir is configured to receive a test sample; and
> [1.9] wherein the computer of the infusion system is configured to:
>
> > [1.9.a] provide a stop button on the touch screen display to abort a function of the infusion system in response to a user input activating the stop button,
> > [1.9.b] pump saline from a saline reservoir positioned outside of the interior space of the cabinet structure into the strontium-rubidium radioisotope generator through the inlet tubing port of the strontium-rubidium radioisotope generator thereby generating the rubidium radioactive eluate that is discharged through the outlet tubing port,
> > [1.9.c] fill the eluate reservoir in the shielded well on-board the cart with the test sample of the rubidium radioactive eluate,
> > [1.9.d] determine a strontium breakthrough test result on the test sample filled into the eluate reservoir in the shielded well on-board the cart while the eluate reservoir remains in the shielded well on-board the cart, and
> > [1.9.e] not allow a patient infusion if the strontium breakthrough test result is greater than or equal to an allowed limit.

Jubilant and Staff assert this claim is obvious in light of Klein, either alone or in combination with other prior art. SIB at 74-85; RIB at 33-45.

I incorporate by reference my prior analysis of the Klein thesis alone and combinations of Klein with other prior art discussed above in connection with the '826 patent. I briefly highlight below the claim limitations particularly disputed by Bracco.

"shielded well on-board the cart"

Klein discloses a shielded well that receives an eluate reservoir that is configured to receive a test sample of eluate from the generator, such operation controlled by the computer. *See* Tr. at 693:18-694:18; Klein at. 000029, -57, -62 (describing computer operation of elution tests eluting

to the dose calibrator). As noted above concerning claim 1 of the '826 patent, a person of ordinary skill in the art would find it obvious to move Klein's shielded well and dose calibrator on-board the cart. *See also* Tr. at 757:14-25.

"first shielding compartment"

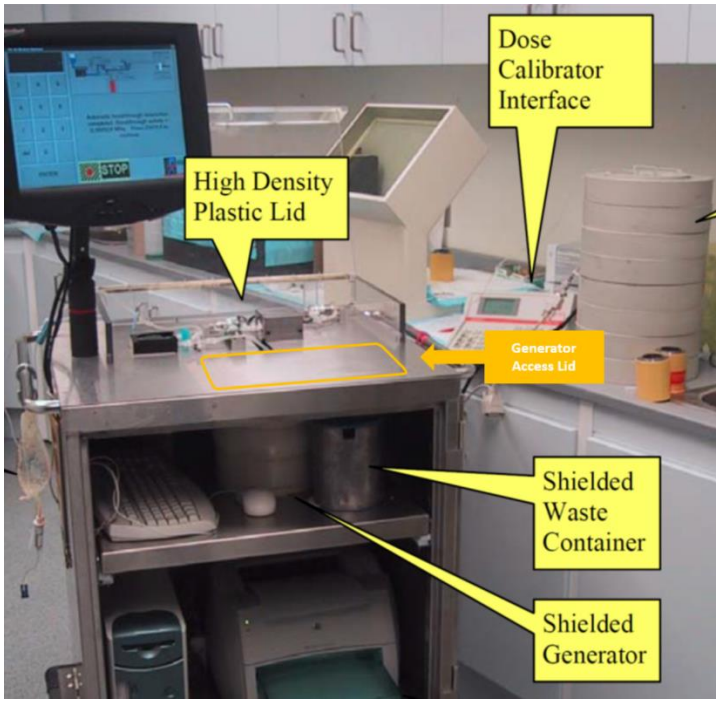
As discussed above, Klein discloses a first shielding compartment having a first opening facing vertically upwardly through which the generator can be inserted into and removed from the first shielding compartment. *Supra* V.B.2.a)(1)(a) (analysis of '826 patent claim 1). I find that the first shielding compartment of Klein is within the interior space of the cabinet structure of Klein's system. *See, e.g.*, Klein at .0034.

"opening through the exterior shell"

Bracco argues that Klein does not disclose an "opening through the top surface of the exterior shell" configured to provide access for inserting into or removing the waste bottle from the interior space of the cabinet, as required by element [1.1.d]. CRB at 65.

I find Klein expressly discloses a "Generator Access Lid" on top surface of the exterior shell of the cart. *See* Klein at .000034 (Figure 2-4, indicating "Generator Access Lid" on top surface of cart). It is difficult to see the perimeter of that lid in Klein's photographs, but by enlarging a high quality copy of the Klein thesis in the record,[7] the perimeter of the lid can be discerned. For example, the left edge of the lid is visible in Figure 2-4 below the center of the yellow call-out box labeled "Generator Valve." The rounded top right corner of the lid is visible in the lower right corner of Figure 2-4, with the edge of the lid seen extending to the right of the yellow call-out box labeled "Generator Access Lid." My observation of the perimeter of the lid is shown below in an orange annotation of Figure 2-3 of Klein:

[7] *See* http://www.sce.carleton.ca/faculty/adler/publications/2005/rklein-MASc-thesis-2005.pdf



Klein at .000034 (Figure 2-3, annotated).

As shown above, the Generator Access Lid disclosed in Klein is positioned over both the shielded generator compartment and the shielded waste bottle compartment. I credit the testimony of Dr. Stone that the opening beneath the lid would allow the waste bottle to be inserted and removed from the shielded waste container. *See* Tr. at 661:19-662:12.

"first door"

Bracco disputes that Klein discloses "a first door accessible via the opening through the exterior shell" to provide access to the first shielding compartment and to "close over" the first opening, as required by elements [1.3].[8] CRB at 63.

[8] Although Bracco contends it is "undisputed" that Klein does not disclose a first door, Bracco is mistaken. *See, e.g.*, SIB at 78 (arguing the generator access lid constitutes a first door).

The Generator Access Lid disclosed in Klein is a door. *See* Tr. at 665:11-666:1 (testimony of Dr. Stone that Klein had "an access door . . . that could give access to the generator"), 686:1-24 (testimony of Dr. Stone that "doors are conventional structures for shielding in my entire history of looking at radioisotopes and radioactive sources. They are very common."). The opening covered by Klein's Generator Access Lid is in the exterior shell of the cart. Klein at .000034. The opening is located the generator shielding compartment, and it gives access to the generator. *Id.*

"second door"

The parties agree that Klein discloses the second shielding compartment and second opening for a waste bottle required by element [1.4], but Bracco disputes that Klein discloses a "second door accessible via the opening through the top surface of the exterior shell" with the door "configured to . . . close over the second opening" of element [1.5]. CRB at 63.

Klein discloses that the shielded waste compartment has a lid. Klein at .000035 ("the waste container was mounted on the top shelf inside a lead container with a lid."). That lid is a door. That door is accessible through an opening in the exterior shell over the shielded waste container, which opening is covered by the Generator Access Lid. *See* Klein at .000034 at Figure 2-3 (annotated above).

"lower elevation"

I have addressed this limitation above in connection with element [1.1.e] of the '826 patent.

"computer"

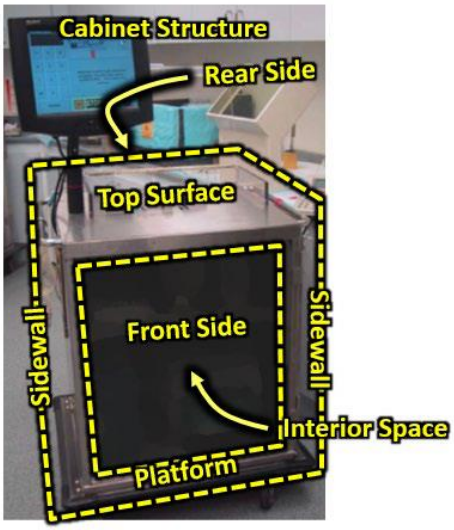
Klein discloses all of the limitations of elements [1.9.a]-[1.9.e] other than those concerning the location of the dose calibrator. *See* Tr. at 691:12-696:9. Specifically, as noted above in connection with claim 9 of the '826 patent, the computer in Klein discloses a stop button to abort the operation of the infusion system via the LCD touch screen. *Id.* at 691:12-24; Klein at .000064 (Fig. 3-12(h)). Klein discloses a computer controlling a peristaltic pump to pump saline from a

saline reservoir positioned outside the interior space of the cabinet structure into the generator through the inlet tubing port of the generator thereby generating the rubidium eluate that is discharged through the outlet tubing port. Tr. at 691:25-693:17; Klein at .000029 (system flow diagram), .000034 (photograph of system). And as discussed concerning elements [1.2.c] and [1.2.b] of the '826 patent, Klein discloses that as part of the "daily protocol" the computer determines a strontium breakthrough test result of the test sample filled into the eluate reservoir in the shielded well while the eluate reservoir remains in the shielded well. *Supra* V.B.2.a)(1).

The only limitations of elements [1.9.a]-[1.9.e] not disclosed by Klein are those concerning the dose calibrator being located on-board the cart. I have addressed why a person of skill in the art would be motivated to put Klein's dose calibrator on the cart in connection with claim 1 of the '826 patent above.

Remaining Elements and Conclusion

Klein discloses most of the remaining limitations of claim 1 of the '869 patent, and I have identified those disclosures at length above in connection with the '826 patent, *supra* V.B.2.a)(1)(a). Klein discloses an infusion system on-board a cart with a cabinet structure, in accordance with limitation [1.1] of the '869 patent. Klein at .000034. The system in Klein had a platform, an exterior shell extending upwardly above the platform with front and rear sides connected by sidewalls, and a top surface collectively defining an interior space of the cabinet, as required by element [1.1.a] of the '869 patent. *Id.* (annotated version reproduced below); *id.* (door hinges and edge of attached door visible on right side of cart); Tr. at 862:13-863:10 (noting that system pictured in Klein had a door that closed over the front side attached at hinges on juncture of the front side and right sidewall).



Klein discloses an interior space of the cart that receives a generator having tubing ports to receive saline and output/discharge radioactive rubidium eluate, and an opening in the exterior shell to access the generator as in limitations [1.1.b] and [1.1.c] of the '869 patent. Tr. at 660:7-661:4; Klein at .000029, .000034 (disclosing "Generator Access Lid").

Klein also discloses a cart having a computer with an LCD touch screen mounted on a post above the cabinet structure, as required by limitation [1.1.e] of the '869 patent. *See* Klein at .000034 (disclosing screen mounted on post above shell), .000064 (Fig. 3-12(c) demonstrating touchscreen data input), .000040-.000041 ("The interface must be solely through the touch screen.").

Klein further discloses a radioactivity counter positioned to measure radioactivity of the rubidium radioactive eluate flowing through an eluate tubing line in fluid communication with the outlet tubing port of the strontium-rubidium radioisotope generator, as in limitation [1.7] of the '869 patent. Tr. at 689:16-690:13; Klein at .000040, .000043-.000044.

For the reasons discussed above, and after considering secondary indicia of non-obviousness advanced by Bracco, I find claim 1 of the '869 patent is invalid under 35 U.S.C. § 103.

I further find that the combinations of art discussed in connection with claim 1 of the ’826 patent would also render claim 1 of the ’869 patent obvious for the same reasons.

(2) Claim 2

Claim 2 of the ’869 patent recites the following:

[2.0] The infusion system of claim 1, further comprising:
[2.1] the strontium-rubidium radioisotope generator in the first shielding compartment in the interior space of the cabinet structure, and
[2.2] the eluate reservoir located in the shielded well on-board the cart and in fluid communication with the eluate tubing line.

Jubilant and Staff assert claim 2 is obvious in light of the combinations of prior art advanced above in connection with claim 1 of the ’869 patent. Jubilant and Staff argue that Klein alone discloses and/or renders obvious all the additional limitations of claim 2 not already addressed. Bracco responds that Jubilant and Staff have failed to show a combination of prior art disclosing or rendering obvious either a “first shielding compartment” or a “shielded well on-board the cart.” CRB at 39-46 (shielded well), 48-51 (first shielding compartment).

For the reasons laid out above concerning the corresponding claim limitations of claim 1 of the ’826 patent, and after considering secondary indicia of non-obviousness, I find that Klein, either alone or in combination with the other asserted prior art, renders an invention with all of the additional elements of claim 2 obvious.

(3) Claim 3

Claim 3 of the ’869 patent recites the following:

[3.0] The infusion system of claim 2, wherein
[3.1] the cabinet structure has a lowermost portion and the platform has a lower surface,
[3.2] the first opening is at a first elevation,
[3.3] the second opening is at a second elevation,
[3.4] the first elevation is between approximately 1 foot and approximately 2 feet, with respect to the lowermost portion of the cabinet structure, and the second

> elevation is between approximately 2 feet and approximately 3 feet, with respect to the lower surface of the platform.

Jubilant and Staff assert claim 3 is obvious in light of the combinations of prior art advanced above in connection with claims 1 and 2. Staff and Jubilant argue that prior art discloses or renders obvious all of the additional limitations of claim 3 not already addressed. SIB at 87-88; RIB at 47-48.

The additional claim elements here are fundamentally identical to claim 18 of the '826 patent. For substantially the same reasons as laid out concerning that claim, *supra* V.B.2.a)(12), and after considering secondary indicia of non-obviousness, I find that claim 3 of the '869 patent is rendered obvious by Klein, either alone or in combination with the other asserted prior art.

(4) Claim 4

Claim 4 of the '869 patent recites the following:

> [4.0] The infusion system of claim 1, wherein the first shielding compartment comprises
> [4.1] two tubing passageways formed in a perimeter surface of the first opening, and
> [4.2] each of the two tubing passageways has a depth configured to prevent pinching or crushing of a corresponding tubing line routed therethrough when the first door is closed thereover.

Jubilant and Staff assert claim 4 is obvious in light of the combinations of prior art advanced above in connection with claim 1. Staff and Jubilant argue that prior art discloses or renders obvious all of the additional limitations of claim 4 not already addressed. SIB at 89-91; RIB at 48-49.

This claim is fundamentally identical to claim 13 of the '826 patent. For substantially the same reasons as laid out concerning that claim, *supra* V.B.2.a)(9)(a), I find that claim 4 of the '869 patent is rendered obvious by Klein alone, as well as Klein in combination with Tate and/or the MedRad Intego device.

(5) Claim 5

Claim 5 of the ’869 patent recites the following:

> [5] The infusion system of claim 1, wherein the opening through the exterior shell configured to provide access to the strontium-rubidium radioisotope generator within the interior space of the cabinet structure is through the front side of the exterior shell.

Jubilant and Staff assert claim 5 is obvious in light of the combinations of prior art advanced above in connection with claim 1. Staff and Jubilant argue that prior art discloses or renders obvious all of the additional limitations of claim 5 not already addressed. SIB at 91-92; RIB at 49-50.

Klein discloses that a front side opening of the exterior shell provides access to the strontium-rubidium radioisotope generator within the interior of the cabinet. *Klein* at. 0034; Tr. at 703:17-704:9.

For the foregoing reasons, and after considering secondary indicia of non-obviousness, I find that Klein, either alone or in combination with the other asserted prior art references, renders claim 5 of the ’869 patent obvious.

(6) Claim 8

Claim 8 of the ’869 patent recites the following:

> [8] The infusion system of claim 1, wherein the infusion system is configured to determine the strontium breakthrough test result on the test sample at least once a day.

Jubilant and Staff assert claim 8 is obvious in light of the combinations of prior art advanced above in connection with claim 1. Staff and Jubilant argue that prior art discloses or renders obvious all of the additional limitations of claim 8 not already addressed. SIB at 92-93; RIB at 50.

This claim is fundamentally identical to multiple previously addressed claims, such as elements [1.2.b] and [1.2.c] of the ’826 patent. As with those claims, Klein alone renders the

additional limitations of claim 8 obvious. As discussed above concerning elements [1.2.c] and [1.2.b] of the '826 patent, Klein discloses that as part of the "daily protocol" the computer determines a strontium breakthrough test result of a test sample. Klein at .000028, .000039. The system software of Klein requires successful completion of the daily protocol, including a breakthrough test with acceptable results, in order for patient elutions to be enabled for the day. *Id.* at .000028 ("Only after a calibration run with low Sr breakthrough has been successfully completed can apatient elutions be carried out."), .000029 (flow chart showing calibration run as necessary precondition to patient elutions resetting daily at midnight), .000039 ("Successful breakthrough measurement must be completed in order to enable patient elutions for the remainder of the day.").

For the foregoing reasons, and after considering secondary indicia of non-obviousness, I find that Klein, either alone or in combination with the other asserted prior art, renders claim 8 of the '869 patent obvious.

(7) Claim 14

Claim 14 of the '869 patent recites the following:

> [14.0] The infusion system of claim 1, wherein the computer of the infusion system is further configured
>
> > [14.1] to track a volume of the saline remaining in the saline reservoir and
> > [14.2] to alert the user via the touch screen display when the volume of the saline remaining in the saline reservoir is below a predetermined volume threshold.

Jubilant and Staff assert claim 14 is obvious in light of the combinations of prior art advanced above in connection with claim 1. Staff and Jubilant argue that prior art discloses or renders obvious all of the additional limitations of claim 14 not already addressed. SIB at 93-94; RIB at 51.

This claims is fundamentally identical to claim elements [11.2] and [11.3] of the '826 patent. For substantially the same reasons as discussed in relation thereto, *supra* V.B.2.a)(7), and after considering secondary indicia of non-obviousness, I find that Klein, either alone or in combination with the other asserted prior art, renders claim 14 of the '869 patent obvious.

(8) Claim 24

Claim 24 of the '869 patent recites the following:

[24.0] The infusion system of claim 1, further comprising:
[24.1] a hanger configured to hold the saline reservoir at an elevation above the top surface of the exterior shell,
[24.2] a handle configured for the user to grasp in order to move the infusion system,
[24.3] four wheels mounted to an underside of the platform,
[24.4] a power inlet port for connecting the infusion system to a power source, and
[24.5] a printer configured to print a document concerning a patient infusion or a quality control test result generated by the infusion system;
[24.6a] wherein the first shielding compartment comprises two tubing passageways formed in a perimeter surface of the first opening,
[24.6b] each of the two tubing passageways has a depth configured to prevent pinching or crushing of a corresponding tubing line routed therethrough when the first door is closed thereover,
[24.6c] the first door is mounted via a hinge,
[24.6d] access to an operation of the computer is regulated through a user login credential,
[24.6e] the strontium breakthrough test result is for at least one of strontium-82 and strontium-85, and
[24.6f] the exterior shell further includes a saline tubing opening configured for a saline tubing line to pass from the saline reservoir outside of the exterior shell to the interior space of the cabinet structure; and
[24.7] wherein the computer of the infusion system is further configured to:
[24.7a] determine the strontium breakthrough test result on the test sample at least once a day,
[24.7b] pump saline through the strontium-rubidium radioisotope generator at a rate less than approximately 70 ml/min,
[24.7c] track a volume of the rubidium radioactive eluate discharged from the strontium-rubidium radioisotope generator to the waste bottle and to control the touch screen display to display a user screen guiding the user to empty the waste bottle, and
[24.7d] track a volume of the saline remaining in the saline reservoir and to alert the user via the touch screen display when the volume of the saline remaining in the saline reservoir is below a predetermined volume threshold.

Jubilant and Staff assert claim 24 is obvious in light of the combinations of prior art advanced above in connection with claim 1. Staff and Jubilant argue that prior art discloses or renders obvious all of the additional limitations of claim 24 not already addressed. SIB at 95-104; RIB at 52-57.

There is no serious dispute that Klein and the other prior infusion systems disclose many of the additional claim limitations of claim 24. For example, Klein teaches an infusion system with hangers [24.1], handles [24.2], and wheels [24.3]. Klein (at .000034); *see also* Tate at .0002, RX-200C at .0042 (Intego manual). Though Klein's saline bag hangs off the side of the cart in the photograph in Figure 2-3 (Klein at .000034), rather than above the top surface as in limitation [24.1], Figure 2-2 of Klein illustrates the saline bag positioned above all of the elements on the cart. Klein at .000029. In any event, rearranging known elements in known configurations for known results constitutes an obvious design choice. *KSR* at 421.

The power inlet of limitation [24.4] is likewise disclosed by Klein. *See* Klein at .000046 (the system "is plugged into a wall socket at all times."). And Klein discloses a printer for printing infusion data, as in limitation [24.5]. Klein at .000034; *see also* Tate at .000002, ¶75 (printer 23), RX-200C at .0091 (Intego manual showing a printer).

As for the tubing passageways in limitations [24.6a] and [24.6b], Klein alone (or alternatively Klein in combination with Tate and/or the MedRad Intego device renders an invention having those elements obvious, as I have explained above in connection with claim 4 of the '869 patent and claim 13 of the '826 patent.

As discussed in relation to limitation [10.1] of the '826 patent, Klein discloses restriction of access by user login credentials, which corresponds to limitation [24.6d]. Klein also discloses limitation [24.6e] as it performs a strontium breakthrough test result for both strontium-82 and

strontium-85. Klein at .000061 (disclosing the formula and method of calculating breakthrough of strontium-82 and strontium-85). Klein additionally discloses limitation [24.6f] as the Klein device has an opening in the exterior shell to allow saline line to pass from the saline reservoir into the interior space of the cart. *See* Klein at .000034 (Fig. 2-3 and 2-4 disclosing "Saline Bag" with "Saline Line" running from exterior reservoir to interior space of cart); Tr. at 712:15-713:6.

For the same reasons discussed concerning claim 8 of the '869 patent, *supra* V.B.2.b)(6), Klein discloses limitations [24.7] and [24.7a].

Klein discloses the limitation [24.7b]: Klein discloses performing "flush runs" and "calibration runs" that pump saline through the generator at a rate of 15 ml/min, which is less than the claimed limit of 70 ml/min. *See, e.g.*, Klein at .000053 ("50 ml flush of the generator at 15ml/min.").

For the same reasons discussed concerning claim elements [11.2] and [11.5] of the '826 patent, Klein also discloses elements [24.7c] and [24.7d]. *See supra* V.B.2.a)(7)(a).

Bracco argues that [24.7c]'s requirement of displaying "a user screen guiding the user to empty the waste bottle" is distinct from presenting "a screen reminding the user to empty the waste bottle." *Id.* CRB at 57 n.6. But Bracco provides no argument why "a user screen guiding the user to empty the waste bottle" would not be met by Klein's disclosure of an automated warning of the waste bottle overflow. *See* Klein at .000044-45 (mechanism for warning about overflow). Indeed, I find that Klein specifically discloses displaying a warning on its touchscreen guiding the user to empty the waste bottle. *Id.* at .0075 ("If at any point the flag changes to a value other than zero, the elution will terminate with the error message screen" with error 70001 "Waste container full. Empty container and restart elution.").

Limitation [24.6c] concerns mounting the door over the generator compartment by a hinge. As noted above in relation to claim element [1.9], Klein discloses both doors and hinges. *See, e.g.*, Klein at .000034 (Fig. 2-3 showing hinged door on side of cart); *id.* (Fig. 2-4 showing hinged lid on top of cart); Tr. at 862:13-863:10 (noting that system pictured in Klein had a door that closed over the front side attached at hinges on juncture of the front side and right sidewall). Dr. Stone testified credibly that it was commonplace in the art for shielding compartments to have enclosures including doors mounted in a variety of ways, including hinges. Tr. at 711:3-12. Indeed, doors attached by hinges are among the most common mechanical elements in the world. Combining familiar elements, such as doors and hinges, according to known methods, is obvious when the combination does no more than yield predictable results. *KSR* at 401. Nowhere does the '869 patent teach any specific advantage or unexpected result of a hinged door design. Limitation [24.6c] is simply matter of design choice. *See Philips Lighting N. Am. Corp. v. Wangs All. Corp.*, 727 F. App'x 676, 681 (Fed. Cir. 2018) (affirming rejection of patent as "obvious matter of design choice" where two prior art designs "were known in the art, recognized as solutions to the particular problem, and functionally equivalent."); *KSR* at 421 ("When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation of ordinary skill and common sense.").

I also find that Tate discloses a door over the first shielding compartment attached via a hinge. Tate at .000079.

For the foregoing reasons, and after considering secondary indicia of non-obviousness, I find that Klein, either alone or in combination with the other asserted prior art, renders claim 24 obvious.

(9) Claim 27 (Unasserted)

Claim 27 of the '869 patent recites the following:

> [27.0] The infusion system of claim 24, further comprising
> [27.1] a dose calibrator located in the shielded well on-board the cart and in communication with the computer,
> [27.2] wherein the dose calibrator is configured to determine the strontium breakthrough test result; and
> [27.3] wherein the opening through the exterior shell configured to provide access to the strontium-rubidium radioisotope generator within the interior space of the cabinet structure is through the front side of the exterior shell.

Jubilant and Staff assert claim 27 is obvious in light of the combinations of prior art advanced above in connection with claim 1 and claim 24 of the '869 patent. Staff and Jubilant argue that prior art discloses or renders obvious all of the additional limitations of claim 27 not already addressed. SIB at 104-105; RIB at 57-59.

I find that Klein alone discloses or renders obvious an invention with all the additional limitations of claim 27. *See* Tr. at 716:20-718:12. As discussed above regarding multiple other claim elements, I find that Klein discloses an infusion system with a dose calibrator located in a shielded well in communication with the computer that determines the breakthrough test result. Klein at .000029 and .000057. Klein discloses that the dose calibrator detects strontium breakthrough activity as part of the calibration run. *Id.* at .000060-.000061. And for the same reasons as discussed above concerning claim 1 of the '826 patent, it was obvious to relocate the dose calibrator in the shielded well of Klein on-board the cart. Klein further discloses a front side opening of the exterior shell that could provide access to the generator within the interior of the

cabinet. Klein at .000034 (showing the entire front side of the exterior shell was a moveable door with access to the first shielding compartment containing the generator).

For the foregoing reasons, and after considering secondary indicia of non-obviousness, I find that Klein, either alone or in combination with the other asserted prior art, renders claim 27 of the '869 patent obvious.

(10) Claim 28 (Unasserted)

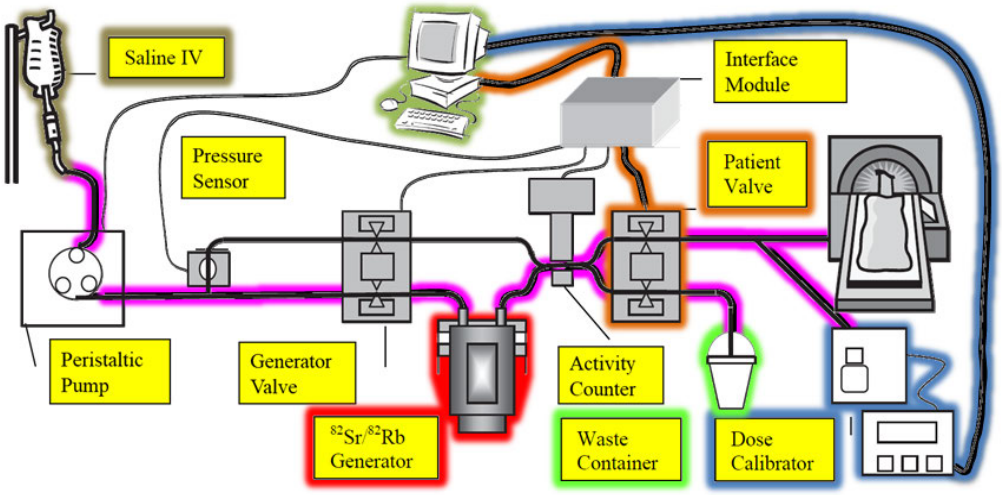
Claim 28 of the '869 patent recites the following:

> [28.0] The infusion system of claim 27, further comprising:
> [28.1] the strontium-rubidium radioisotope generator with the inlet tubing port configured to receive saline and the outlet tubing port configured to discharge the rubidium radioactive eluate,
> [28.2] the eluate reservoir located inside the shielded well on-board the cart and in fluid communication with the eluate tubing line,
> [28.3] a waste tubing line in fluid communication with the eluate tubing line and the waste bottle, and
> [28.4] a valve configured to control fluid flow between the eluate tubing line and the waste bottle via the waste tubing line.

Jubilant and Staff assert claim 28 is obvious in light of the combinations of prior art advanced above in connection with claims 1, 24, and 27. Staff and Jubilant argue that prior art discloses or renders obvious all of the additional limitations of claim 28 not already addressed. SIB at 106-107; RIB at 59-61.

Klein renders an invention with the additional limitations of this claim obvious. *See* Tr. at 718:10-721:12. I find that Klein discloses a system having a generator (red, in the figure below) with an inlet port (pink) that receives saline from the saline IV (brown) and an outlet port (also pink) that discharges eluate, satisfying limitation [28.1]. Klein at .000029 (as annotated in SIB at 106, reproduced below). The system also has an eluate reservoir (blue) in a shielded well in communication with an eluate tubing line (pink) from the generator (red), satisfying limitation

[28.2]. *Id.* Klein further teaches a waste tubing line (pink) in fluid communication with the eluate tubing line (pink) and the waste bottle (bright green), satisfying limitation [28.3]. *Id.* The Klein system has a valve (orange) that controls flow between the eluate tubing line (pink) and the waste bottle (bright green) via the waste tubing line (pink), satisfying limitation [28.4]. *Id.* And for the same reasons as discussed above concerning claim 1 of the '826 patent, it would have been obvious to relocate the dose calibrator in the shielded well of Klein on-board the cart.



For the foregoing reasons, and after considering secondary indicia of non-obviousness, I find that Klein, either alone or in combination with the other asserted prior art, renders claim 28 obvious.

(11) Claim 29

Claim 29 of the '869 patent recites the following:

> [29.0] The infusion system of claim 28, wherein the computer of the infusion system is configured to:
>
> > [29.1] measure an activity of the test sample filled into the eluate reservoir in the shielded well on-board the cart while the eluate reservoir remains in the shielded well on-board the cart, wherein the activity is measured with the dose calibrator in the shielded well on-board the cart, and
> >
> > [29.2] calibrate the infusion system based on the activity measured by the dose calibrator.

Jubilant and Staff assert claim 29 is obvious in light of the combinations of prior art advanced above in connection with claims 1, 24, and 27. Staff and Jubilant argue that prior art discloses or renders obvious all of the additional limitations of claim 29 not already addressed. SIB at 107-108; RIB at 61-62.

Klein discloses and/or renders obvious an invention with all additional limitations of claim 29. Tr. at 721:9-723:7. Klein describes a computer that calibrates the activity counter by measuring activity of a test sample while it is in the shielded well of the dose calibrator. Klein at .000034 (showing system configuration), .000055-.000060 (describing use of dose calibrator to calculate calibration constant for use with activity monitor). For the same reasons as discussed above concerning claim 1 of the '826 patent, it was obvious to relocate the dose calibrator in the shielded well of Klein on-board the cart.

For the foregoing reasons, and after considering secondary indicia of non-obviousness, I find that Klein, either alone or in combination with other prior art, renders claim 29 obvious.

(12) Claim 30

Claim 30 of the '869 patent recites the following:

> [30.0] The infusion system of claim 29, wherein
> [30.1] the cabinet structure has a lowermost portion and the platform has a lower surface,
> [30.2] the first opening is at a first elevation,
> [30.3] the second opening is at a second elevation,
> [30.4] the first elevation is between approximately 1 foot and approximately 2 feet, with respect to the lowermost portion of the cabinet structure, and the second elevation is between approximately 2 feet and approximately 3 feet, with respect to the lower surface of the platform.

Jubilant and Staff assert claim 30 is obvious in light of the combinations of prior art advanced above in connection with claims 1, 24, 27, 28, and 29. Staff and Jubilant argue that prior

art discloses or renders obvious all of the additional limitations of claim 30 not already addressed. SIB at 108-110; RIB at 62-63.

The additional claim limitations here are identical to those of claim 3. For the same reasons as laid out concerning that claim, *supra* V.B.2.b)(3), and after considering secondary indicia of non-obviousness, I find that claim 30 of the '869 patent is rendered obvious by Klein, either alone or in combination with the other asserted prior art.

c) *'870 Patent*

Bracco asserts claims 1, 2, 8, 10-12, 16-17, and 27 of U.S. Patent No. 9,750,870. Due to intermediate dependencies, claims 9 and 13 are also at issue for the purposes of the invalidity analysis.

(1) Claim 1

Claim 1 of the '870 patent recites the following:

> [1.0] A method of using an infusion system on-board a cart to deliver a rubidium radioactive eluate comprising:
>
> > [1.1] installing a saline reservoir on the infusion system, wherein the infusion system comprises a platform and an exterior shell extending upwardly above the platform, and wherein the platform and the exterior shell, collectively define an interior space of a cabinet structure;
> > [1.2] placing the saline reservoir in fluid communication through a saline tubing line with an inlet tubing port of a strontium-rubidium radioisotope generator located in a first shielding compartment in the interior space of the cabinet structure, wherein the strontium-rubidium radioisotope generator further comprises an outlet tubing port configured to discharge the rubidium radioactive eluate, and wherein the first shielding compartment has a first opening facing vertically upwardly;
> > [1.3] inserting a waste bottle into a second shielding compartment on-board the cart, wherein the second shielding compartment on-board the cart has a second opening facing vertically upwardly and being at a higher elevation than the first opening;
> > [1.4] placing the waste bottle in fluid communication with the outlet tubing port of the strontium-rubidium radioisotope generator through an eluate tubing line;
> > [1.5] wherein a computer on-board the cart is configured to control the fluid communication between the waste bottle and the outlet tubing port, and

> [1.6] wherein the computer has a touch screen display mounted on a vertical post with a top end extending above the cabinet structure;
> [1.7] inserting an eluate reservoir in a shielded well on-board the cart;
> [1.8] placing the eluate reservoir in fluid communication with the eluate tubing line, wherein the computer is further configured to control the fluid communication between the eluate reservoir and the eluate tubing line;
> [1.9] pumping a sample of the rubidium radioactive eluate into the eluate reservoir in the shielded well on-board the cart;
> [1.10] measuring a radioactivity of the sample of the rubidium radioactive eluate flowing through the eluate tubing line with a radioactivity detector on-board the cart while the sample of the rubidium radioactive eluate is flowing through the eluate tubing line;
> [1.11] measuring a calibration radioactivity of the sample pumped into the eluate reservoir in the shielded well on-board the cart while the eluate reservoir remains in the shielded well on-board the cart;
> [1.12] comparing the radioactivity of the sample of the rubidium radioactive eluate flowing through the eluate tubing line measured by the radioactivity detector on-board the cart while the sample of the rubidium radioactive eluate is flowing through the eluate tubing line with the calibration radioactivity of the sample pumped into the eluate reservoir in the shielded well on-board the cart; and
> [1.13] determining a strontium breakthrough test result on the sample pumped into the eluate reservoir in the shielded well on-board the cart while the eluate reservoir remains in the shielded well on-board the cart, wherein the computer of the infusion system is further configured to not allow a patient infusion if the strontium breakthrough test result is greater than or equal to an allowed limit.

The parties' arguments concerning this claim are largely derivative of arguments relating to similar claims of the '826 patent and '869 patent. I incorporate by reference my prior analysis of the Klein thesis alone and combinations of Klein with other prior art discussed above in connection with the '826 patent and the '869 patent. Below I briefly examine each limitation of claim 1 of the '870 patent, referring to relevant prior analysis where appropriate.

Klein discloses a method for using an infusion system that is on-board a cart to deliver rubidium-82 eluate, as in element [1.0]. Tr. at 724:10-15; Klein at .000005. Klein discloses installing a saline reservoir on the infusion system comprising a platform and exterior shell that define an interior space of a cabinet structure, as in limitation [1.1]. *Id.* at .000029 (system diagram), .000034 (system photographs). Klein likewise discloses all of limitation [1.2]. Klein

describes placing the saline reservoir in fluid communication with the generator via a tubing line and input port. *Id.* at .000029 (system diagram), .000034 (system photograph). The generator is inside the cabinet within a first shielding compartment (the stacked lead rings) with an upwardly-facing opening. *Id.* at .000033 (lead rings around generator as shielding), .000034 (Fig. 2-4 showing the generator is visible through an upward opening of the lead rings).

Klein describes inserting a waste bottle into a shielding compartment on-board the cart, wherein the shielding compartment has a second opening facing vertically upward, as in limitation [1.3]. *See supra* V.B.2.a)(1)(a) (discussions of claim limitations [1.1.c] and [1.1.d] of claim 1 of the '826 patent). Although Klein's second shielding compartment has an upward opening at a lower elevation than the first opening, for the reasons discussed in connection with limitation [1.1.e] in claim 1 of the '826 patent, the relative opening heights are an obvious design choice with no patentable distinction over the prior art.

Klein discloses placing the waste bottle in fluid communication with the outlet tubing port of the generator through an eluate tubing line, as in limitation [1.4]. *See, e.g., Klein* at .000029 (system diagram). Klein likewise discloses limitation [1.5], as it describes configuring the computer to control the path of eluate from the generator to either the patient output port or the waste bottle via control of a valve. Tr. at 728:23-729:14; Klein at .000029 ("[R]eal-time software controls the pumps and valves. These in turn affect the flow of saline through the generator or its bypass line to the patient, dose calibrator, or waste container."), .000057 (discussing computer control of valves).

Klein also discloses a cart having a computer with an LCD touch screen mounted on a post above the cabinet structure, as required by limitation [1.6]. *See id.* at .000034 (disclosing screen

mounted on post above shell), .000064 (Fig. 3-12(c) demonstrating touchscreen data input), .000040-41 ("The interface must be solely through the touch screen").

Concerning limitation [1.7], as discussed multiple times above, *see supra* V.B.2.a)(1)(a), Klein describes inserting an eluate reservoir (such as a vial) within a shielded well of the dose calibrator. *See* Tr. at 730:3-13; Klein at .000057. For the reasons set forth above in connection with claim 1 of the '826 patent, relocating that shielded well assembly to the cart would have been obvious.

Concerning elements [1.8] and [1.9], Klein describes configuring the system to place the eluate reservoir in fluid communication with the eluate tubing line and configuring the computer to control that communication, as well as pumping a sample of the eluate into the eluate reservoir in the shielded well. Tr. at 731:6-23; Klein at .0029 ("[R]eal-time software controls the pumps and valves. These in turn affect the flow of saline through the generator or its bypass line to the patient, dose calibrator, or waste container."). For the reasons set forth above concerning claim element 1 of the '826 patent, relocating that shielded well assembly to the cart was obvious.

Klein also discloses an in-line radioactivity detector on-board the cart that measures radioactivity of eluate flowing through tubing, as in limitation [1.10]. Tr. 731:20-732:18 (citing Klein at .000029, -56).

Klein further discloses using the dose calibrator to measure radioactivity of a test sample pumped into the dose calibrator vial in the shielded well, as in limitation [1.11]. Klein at .000053. Klein's computer is configured to compare radioactivity of the eluate flowing through the tubing line with radioactivity of the sample in the dose calibrator, satisfying limitation [1.12]. *Id.*; *see also id*. at .000028, .000053 ("integral activity recorded from the dose calibrator is used to calibrate the activity counter and verify that the calibration constant is within tolerance"). For the reasons

set forth above in connection with claim 1 of the ’826 patent, relocating that shielded well assembly to the cart would have been obvious. Klein thus renders obvious an invention having limitations [1.11] and [1.12].

Limitation [1.13] is substantively identical to limitation [1.2] of claim 1 of the ’826 patent. For the reasons set forth above in connection with the ’826 patent, Klein renders obvious an invention with limitation [1.13]. *See supra* V.B.2.a)(1)(a).

I thus find the rubidium infusion system shown in the Klein thesis includes all of the same functional components recited in claim 1, but Klein physically arranges the components differently than the claim. For the reasons discussed above, and after considering secondary indicia of non-obviousness advanced by Bracco, I find that rearranging the components in Klein would have been obvious to a person of ordinary skill in the art at the time of the invention. Claim 1 is therefore invalid under 35 U.S.C. § 103. I further find that the prior art combinations discussed above in connection with claim 1 of the ’826 patent and claim 1 of the ’869 patent would render claim 1 of the ’870 patent obvious for substantially the same reasons.

(2) Claim 2

Claim 2 of the ’870 patent recites the following:

> [2.0] The method of claim 1 further comprising:
> > [2.1] placing the eluate tubing line in fluid communication with a patient, wherein the computer is further configured to control the fluid communication between the eluate tubing line and the patient;
> > [2.2] pumping a dose of the rubidium radioactive eluate to the patient; and
> > [2.3] flushing the rubidium radioactive eluate remaining in at least a portion of the eluate tubing line into the patient by pumping saline from the saline reservoir to the eluate tubing line through a by-pass line that by-passes the strontium-rubidium radioisotope generator, wherein the computer is further configured to control fluid communication via the by-pass line.

Jubilant and Staff assert claim 2 is obvious in light of the combinations of prior art advanced above in connection with claim 1 of the ’870 patent. Staff and Jubilant argue that the

prior art discloses or renders obvious all of the additional limitations of claim 2 not already addressed. SIB at 118-120; RIB at 70-71.

I find that Klein alone discloses all of the additional elements of claim 2. Klein describes a computer that controls fluid communication between the eluate tubing line output from the generator and a patient via the patient valve, as in limitation [2.1]. *See, e.g.*, Klein at .000029 ("[R]eal-time software controls the pumps and valves. These in turn affect the flow of saline through the generator or its bypass line to the patient, dose calibrator, or waste container."). The computer of Klein also pumps doses of the eluate to the patient via the pump, as in limitation [2.2]. *Id.* And Klein discloses computer operation of a post-elution patient flush that flushes the remaining radioactive eluate into the patient through a line that bypasses the generator. *Id.*; *see also id.* at .000055 ("Bypass-to-Patient Flush – The final state flushes saline through the bypass to the patient outlet in order to push the activity in the lines to the patient outlet.").

For the foregoing reasons, and after considering secondary indicia of non-obviousness, I find that Klein, either alone or in combination with the other asserted prior art, renders the invention in claim 2 obvious.

(3) Claim 8

Claim 8 of the '870 patent recites the following:

> [8.0] The method of claim 2 wherein the computer of the infusion system is further configured to:
>
> > [8.1] present on the touch screen display a screen for starting the patient infusion by touching a button on the touch screen display;
> > [8.2] present on the touch screen display a screen reminding a user to insert the eluate reservoir in the shielded well on-board the cart;
> > [8.3] present on the touch screen display a screen indicating that the patient infusion is in process, wherein the screen indicating that the patient infusion is in process displays a stop button to abort the patient infusion; and
> > [8.4] present on the touch screen display the strontium breakthrough test result.

Jubilant and Staff assert claim 8 is obvious in light of the combinations of prior art advanced above in connection with claims 1 and 2. Staff and Jubilant argue that the prior art discloses or renders obvious all of the additional limitations of claim 8 not already addressed. SIB at 120-123; RIB at 71-74.

The additional elements of claim 8 are identical to those of claim 9 of the '826 patent. For those reasons set forth above in connection with that claim, and after considering secondary indicia of non-obviousness, claim 8 of the '870 patent is obvious in light of the Klein thesis alone or in combination with the other asserted prior art. *See supra* V.B.2.a)(5).

(4) Claim 9 (Unasserted)

Claim 9 of the '870 patent recites the following:

> [9.0] The method of claim 8, further comprising:
> [9.1] logging into the computer by entering a user login credential on the touch screen display,
> [9.2] entering a patient ID on the touch screen display,
> [9.3] entering a patient dose on the touch screen display,
> [9.4] entering a flow rate on the touch screen display.

Jubilant and Staff assert claim 9 is obvious in light of the combinations of prior art advanced above in connection with claims 1, 2, and 8. Staff and Jubilant argue that the prior art discloses or renders obvious all of the additional limitations of claim 9 not already addressed. SIB at 124; RIB at 74.

The additional elements of claim 9 are substantively identical to those of claim 10 of the '826 patent. For those reasons set forth above concerning that claim, and after considering secondary indicia of non-obviousness, claim 9 of the '870 patent is obvious in light of the Klein thesis alone or in combination with the other asserted prior art. *See supra V.B.2.a)(6).*

(5) Claim 10

Claim 10 of the ’870 patent recites the following:

> [10.0] The method of claim 9, wherein the computer of the infusion system is further configured to:
>
> [10.1] track a volume of saline remaining in the saline reservoir,
>
> [10.2] provide an alert via the touch screen display when the volume of saline remaining in the saline reservoir is below a predetermined volume threshold, and
>
> [10.3] present on the touch screen display a screen reminding the user to empty the waste bottle.

Jubilant and Staff assert claim 10 is obvious in light of the combinations of prior art advanced above in connection with claims 1, 2, 8, and 9. Staff and Jubilant argue that the prior art discloses or renders obvious all of the additional limitations of claim 10 not already addressed. SIB at 124; RIB at 74.

Limitations [10.1], [10.2], and [10.3] are identical to limitations [11.2], [11.3], and [11.5] in claim 11 of the ’826 patent. For the reasons discussed above in connection with claim 11 of the ’826 patent, and after considering secondary indicia of non-obviousness, I find the invention of claim 10 of the ’870 patent is obvious in view of the Klein thesis alone or in combination with the other asserted prior art. *See supra* V.B.2.a)(7).

(6) Claim 11

Claim 11 of the ’870 patent recites the following:

> [11.0] The method of claim 10, further comprising:
>
> [11.1] initiating a generator column wash through the touch screen display, wherein a predetermined amount of saline is pumped through the strontium-rubidium radioisotope generator and directed to the waste bottle during the generator column wash, and
>
> [11.2] initiating a purging process through the touch screen display to purge a patient tubing line of air, wherein the patient tubing line is in fluid communication with the eluate tubing line.

Jubilant and Staff assert claim 11 is obvious in light of the combinations of prior art advanced above in connection with claims 1, 2, and 8-10. Staff and Jubilant argue that the prior

art discloses or renders obvious all of the additional limitations of claim 11 not already addressed. SIB at 126-26; RIB at 75-77.

The additional limitations of claim 11 are substantially identical to those of claim 12 of the '826 patent. For the reasons discussed concerning claim 12 of the '826 patent, and after considering secondary indicia of non-obviousness, claim 11 of the '870 is rendered obvious in light of the Klein thesis alone or in combination with the other asserted prior art. *See supra* V.B.2.a)(8).

(7) Claim 12

Claim 12 of the '870 patent recites the following:

> [12.0] The method of claim 11, wherein the saline tubing line and the eluate tubing line are routed through
>
> > [12.1] two tubing passageways formed in a perimeter surface of the first opening, wherein
> >
> > [12.2] each of the two tubing passageways has a depth configured to prevent pinching or crushing of a corresponding tubing line routed therethrough when a first door is closed over the first opening.

Jubilant and Staff assert claim 12 is obvious in light of the combinations of prior art advanced above in connection with claims 1, 2, and 8-11. Staff and Jubilant argue that the prior art discloses or renders obvious all of the additional limitations of claim 12 not already addressed. SIB at 128-130; RIB at 77-78.

The additional limitations of claim 12 are substantially identical to those of claim 13 of the '826 patent. For the reasons discussed concerning claim 13 of the '826 patent, and after considering secondary indicia of non-obviousness, claim 12 of the '870 patent is rendered obvious in light of the Klein thesis alone or in combination with the other asserted prior art. *See supra* V.B.2.a)(9).

(8) Claim 13 (Unasserted)

Claim 13 of the ’870 patent recites the following:

> [13.0] The method of claim 12, wherein the infusion system further comprises:
> [13.1] a handle configured for the user to grasp in order to move the infusion system, and
> [13.2] four wheels mounted to an underside of the platform of the cabinet structure.

Jubilant and Staff assert claim 13 is obvious in light of the combinations of prior art advanced above in connection with claims 1, 2, and 8-12. Staff and Jubilant argue that the prior art discloses or renders obvious all of the additional limitations of claim 13 not already addressed. SIB at 130; RIB at 78-79.

The additional limitations of claim 13 are substantially identical to limitations [14.2] and [14.3] in claim 14 of the ’826 patent. For the reasons discussed above in connection with claim 14 of the ’826 patent, and after considering secondary indicia of non-obviousness, claim 13 of the ’870 patent is rendered obvious in light of the Klein thesis alone or in combination with the other asserted prior art. *See supra* V.B.2.a)(10).

(9) Claim 16

Claim 16 of the ’870 patent recites the following:

> [16] The method of claim 13, wherein the infusion system further comprises a dose calibrator in the shielded well on-board the cart and in communication with the computer to determine the strontium breakthrough test result.

Jubilant and Staff assert claim 16 is obvious in light of the combinations of prior art advanced above in connection with claims 1, 2, and 8-13. Staff and Jubilant argue that the prior art discloses or renders obvious all of the additional limitations of claim 16 not already addressed. SIB at 131; RIB at 79-80.

The additional limitations of claim 16 are substantially identical to those of claim 17 of the ’826 patent. For the reasons discussed above in connection with claim 17 of the ’826 patent, and

after considering secondary indicia of non-obviousness, claim 16 of the ’870 patent is rendered obvious in light of the Klein thesis alone or in combination with the other asserted prior art. *See supra* V.B.2.a)(11).

(10) Claim 17

Claim 17 of the ’870 patent comprises:

> [17.0] The method of claim 16, wherein
> [17.1] the cabinet structure has a lowermost portion and the platform has a lower surface,
> [17.2] the first opening is at a first elevation,
> [17.3] the second opening is at a second elevation,
> [17.4] the first elevation is between approximately 1 foot and approximately 2 feet, with respect to the lowermost portion of the cabinet structure, and the second elevation is between approximately 2 feet and approximately 3 feet, with respect to the lower surface of the platform.

Jubilant and Staff assert claim 17 is obvious in light of the combinations of prior art advanced above in connection with claims 1, 2, 8-13, and 16. Staff and Jubilant argue that the prior art discloses or renders obvious all of the additional limitations of claim 17 not already addressed. SIB at 131-33; RIB at 81.

The additional limitations of claim 17 are substantially identical to those of claim 18 of the ’826 patent. For the reasons discussed above in connection with claim 18 of the ’826 patent, and after considering secondary indicia of non-obviousness, claim 17 of the ’870 patent is obvious in light of the Klein thesis alone or in combination with the other asserted prior art. *See supra* V.B.2.a)(12).

(11) Claim 27

Claim 27 of the ’870 patent recites the following:

> [27] The method of claim 1, wherein the computer of the infusion system is further configured to track time passed from completion of pumping the sample of the rubidium

radioactive eluate into the eluate reservoir to determining the strontium breakthrough test result.

Jubilant and Staff assert claim 27 is obvious in light of the combinations of prior art advanced above in connection with claim 1. Staff and Jubilant argue that prior art discloses or renders obvious all of the additional limitations of claim 27 not already addressed. SIB at 133; RIB at 82.

The additional limitations of claim 27 are substantially identical to those of limitation [11.1] in claim 11 of the '826 patent. For the reasons discussed above in connection with claim 11 of the '826 patent, and after considering secondary indicia of non-obviousness, claim 27 of the '870 patent is obvious in light of the Klein thesis alone or in combination with the other asserted prior art. *See supra* V.B.2.a)(7); *see also* Tr. at 763:-24-764:18 (testimony of Dr. Stone); Klein at .000028 ("the activity in the dose calibrator is registered 30 minutes after the end of the elution to compute the breakthrough"); CRB at 52 (acknowledging the computer in Klein tracks the time after performing a breakthrough test).

3. Secondary Considerations Bearing on Obviousness

Bracco provides several arguments directed to secondary considerations bearing on the obviousness of the asserted claims. Though I have considered the proffered evidence and arguments in considering each claim, I ultimately find them unpersuasive and give them little weight. I address each category proffered by Bracco in turn.

a) *Nexus*

To begin, Bracco erroneously relies on statements in *Brown & Williamson Tobacco Corp. v. Philip Morris Inc.*, 229 F.3d 1120, 1129 (Fed. Cir. 2000) and *Polaris Indus., Inc. v. Arctic Cat,*

Inc., 882 F.3d 1056, 1072 (Fed. Cir. 2018) (citing the same language in *Brown & Williamson*) for the proposition that "nexus is presumed when the patentee shows that the evidence is tied to a specific product and that product 'embodies the claimed features and is coextensive with them." CIB at 5, 34-35. Despite the loose language in *Polaris*, the two cases Bracco relies on are discussing the "commercial success" factor from *Graham*—a factor Bracco does not advance. *Cf. Iron Grip Barbell Co. v. USA Sports, Inc.,* 392 F.3d 1317, 1324 (Fed. Cir. 2004) ("[N]exus may be inferred when the patentee shows both that there is commercial success, and that the thing (product or method) that is commercially successful is the invention disclosed and claimed in the patent.").

As Bracco more correctly recognized, "for evidence of secondary considerations to be given substantial weight in the obviousness determination, its proponent must establish a nexus between the evidence and the merits of the claimed invention." *See W. Union Co. v. MoneyGram Payment Sys. Inc.*, 626 F.3d 1361, 1372-73 (Fed. Cir. 2010) (citing *In re GPAC Inc.*, 57 F.3d 1573, 1580 (Fed. Cir. 1995)); *see also In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*, 676 F.3d 1063, 1079 n.6 (Fed. Cir. 2012) (when examining evidence of secondary considerations "courts must exercise care in assessing proffered evidence of objective considerations, giving such evidence weight only where the objective indicia are attributable to the inventive characteristics of the discovery as claimed in the patent."); *Ormco Corp. v. Align Tech., Inc.*, 463 F.3d 1299, 1311-12 (Fed. Cir. 2006) ("evidence of commercial success, *or other secondary considerations*, is only significant if there is a nexus between the claimed invention and" the cited factor) (emphasis added). Bracco was required to make such a showing of nexus for its evidence of copying, unmet need, and failure of others to be given weight. *See, e.g., Wm. Wrigley Jr. Co. v. Cadbury Adams USA LLC*, 683 F.3d 1356, 1364 (Fed. Cir. 2012) ("Just as with

the commercial success analysis, a nexus between the copying and the novel aspects of the claimed invention must exist for evidence of copying to be given significant weight in an obviousness analysis."). Because Bracco has not expressly proffered any argument or evidence on such nexus at all, instead relying on an erroneous presumption of nexus, *see* CIB at 34-35, I accord its arguments for objective indicia little weight. Nevertheless, in the interest of thoroughness, I have considered the each of Bracco's arguments as if nexus had been shown. My analysis of those arguments follows.

b) *Copying*

Though Bracco asserts that there "is substantial evidence that Jubilant used Bracco information to develop a system that infringes the [a]sserted [p]atents," CPB at 17, it never identifies what Bracco information, specifically, it alleges Jubilant copied. I infer from Bracco's brief an allegation that three specific features of the asserted patents were copied: "[1] an on-board dose calibrator, [2] determining a strontium breakthrough test on-board the cart, [3] configuring a computer to not allow a patient infusion if there is strontium breakthrough." CIB at 24-25. The first two features both relate to placing the dose calibrator on-board the cart, and the third was a feature present in the Klein thesis on which Jubilant had been basing its development since at least 2007. *See supra* V.B.2.a)(1) ("computer," concerning element [1.2.c]); Tr. at 307:5-11; RX-78C. As such, the only element that could plausibly have been copied is the placement of the dose calibrator "on-board the cart."

To show copying of the on-board dose calibrator, Bracco cites the "design shift" in Jubilant's development timeline, relying on *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 567 F.3d 1314 (Fed. Cir. 2009). In *DePuy Spine*, the Federal Circuit affirmed a legal determination by a district court that an asserted patent was nonobviousness where underlying factual findings

showed a change in the defendants' design one month after the patent was published. *Id*. at 1328-29. But the Circuit was only reviewing those factual findings for clear error, in a context where the accused infringer did not allege that it independently conceived the idea. *Id*. at 1324, 1329. *DePuy Spine* does not stand for the proposition that any design change after publication of a patent is *per se* copying. Secondary considerations are fact-dependent. *W. Union Co. v. MoneyGram Payment Sys., Inc.*, 626 F.3d 1361, 1369 (Fed. Cir. 2010) ("An obviousness determination is not the result of a rigid formula disassociated from the consideration of the facts of a case."). For example, in *Iron Grip*, the defendant abandoned a non-infringing design and produced an infringing design after the asserted patent issued, but the court held that fact "does not establish that [the defenant] engaged in copying." 392 F.3d at 1325; *see also Wyers v. Master Lock Co.*, 616 F.3d 1321, 1246 (Fed. Cir. 2010) ("Not every competing product that falls within the scope of a patent is evidence of copying, otherwise every infringement suit would automatically confirm the non-obviousness of the patent.").

"Copying requires proof of replication *of a specific product*, not just the making of a product that arguably falls within the scope of the patent's claims." *Iron Grip*, 392 F.3d at 1325. Here, it is undisputed that when Jubilant designed a system with a dose calibrator on-board the cart, Bracco had no product with an on-board dose calibrator. Tr. at 313:8-10 ("When did JDI first begin developing the Version 3? A: 2010."); *see* CX-0386C.0001 (Jubilant internal email dated July 28, 2010 stating "we [are] currently designing the V3 infuser cart and we are wondering how much lead shielding is needed for the generator . . . the dose calibrator chamber [vial inside . . .] the waste container. . . All this shielding is on the cart . . ."). Bracco's only existing products in the critical time frame were its legacy Model 510 system and possibly its [redacted] "NextGen" device. Both of those systems [redacted] and [redacted]

[redacted] Tr. at 175:11-176:2. By the time Jubilant's design included an on-board dose calibrator, Bracco [redacted] of its old designs that would eventually lead to a design specification requiring an on-board dose calibrator. And implementation of that design specification in a specific product was [redacted]. *See* Tr. at 174:9-176:2, 183:22-184:12; JX-0058C, JX-0112C.0009-12. When the various former Bracco employees and former Bracco contractors were hired by Jubilant, there was no product design those employees and contractors could convey to Jubilant.

The patents at issue here are also insufficient to be the basis of any alleged copying. The patent figures do not illustrate a dose calibrator "on board the cart," Tr. at 1057:5-20, and Bracco's own expert admitted that the patents are devoid of any description of "the steps a person should take" to achieve an on-board dose calibrator and other implementation details. *Compare* Tr. at 1057:5-1059:4, *with* '826 patent at 8:12-28, 19:13-29. And even if the patents did have such details, there is no direct evidence Jubilant ever accessed or consulted Bracco's patents during the development of the RUBY Version 3. Tr. at 1034:1-8, 1084:14-1085:8.

Bracco has cited nothing even vaguely similar to "direct evidence such as disassembling a patented prototype, photographing its features, and using the photograph as a blueprint to build a virtually identical replica, . . . or access to, and substantial similarity to, the patented product," factors the court considered in *Iron Grip*, 392 F.3d at 1325. Indeed, Bracco's experts admitted there is no direct evidence Jubilant copied Bracco's technology. *See* Tr. at 1034:1-5, 1084:8-20, 1085:1-8

The sole fact witness presented at the hearing with knowledge of Jubilant's development process was Mr. Donnelly, Medical Device Product Manager at Jubilant. Mr. Donnelly testified that Jubilant had the idea to put the dose calibrator on board the cart around May 2010, and his

understanding was based on his review of Jubilant documents. Tr. at 316:18-317:9. Bracco argues that Mr. Donnelly could not have personal knowledge of Jubilant's actions around 2010 because he did was not employed at Jubilant until November 2013. Bracco also objects in its post-hearing brief that the documents he relied on were not admitted in the hearing. It is possible that Mr. Donnelly's testimony was based on RX-0515C, which I previously ruled was inadmissible for untimely disclosure. *See* CRB at 73; Order No. 33. But Bracco did not ask Mr. Donnelly which documents he had in mind when Mr. Donnelly was on the stand. Nor did Bracco object when the testimony was elicited. Bracco failed to preserve any objection as to the basis of Mr. Donnelly's knowledge. Mr. Donnelly's testimony may be unsupported hearsay to which I accord little weight, but it is still largely unrebutted sworn testimony from a witness I was able to personally observe, and light evidence is still heavier than no evidence at all.

Bracco attempts to contradict Mr. Donnelly's testimony with deposition testimony of Jubilant's corporate representative Mr. Riddoch, who stated he believed Ms. Gelbach contributed the idea of Jubilant's on-board dose calibrator after her hiring in the summer of 2010. CIB at 22. But Mr. Riddoch also stated that Ms. Gelbach got the idea for an on-board dose calibrator from customers. CX-0570C at 120:11-22. Not surprisingly, Bracco asks me to credit Mr. Riddoch's testimony that Jubilant got the idea for an on-board dose calibrator from Ms. Gelbach but reject Mr. Riddoch's testimony that Ms. Gelbach got the idea from customers. Bracco's inconsistency undermines its argument. In any event, I decline to give much weight to the hearsay in Mr. Riddoch's deposition testimony.

Instead, I give more weight to unambiguous documentary evidence indicating that Jubilant had already begun designing a cart with the dose calibrator on board as early as July 28, 2010. CX-0386C.0001 ("We [are] currently designing the V3 infuser cart and we are wondering how

much lead shielding is needed for the generator . . . the dose calibrator chamber [vial inside . . .] the waste container. . . All this shielding is on the cart . . . .”). Ms. Gelbach was hired no earlier than the same month as that design document, and she was not hired as an engineer or senior manager. Tr. 1046:17-20. I find it unlikely that a newly hired non-engineer convinced Bracco to shift a major design initiative without creating a single written document to that effect.

Bracco also points to documents showing Jubilant’s awareness of Bracco’s patents. Some undisputed facts belie that argument. It is undisputed that the RUBY Version 3 was submitted to the FDA with the allegedly copied features in August 2013. RX-0017; JX-0200.04-48. The documents Bracco points to are from years after Jubilant submitted its device to the FDA and years after Jubilant had shown its system at a trade show. *See* CIB at 27-29 (citing JX-0017C.022-.023; Tr. at 1031:2-24, 1032:3-1033:10, 1033:11-23; CX-0409C.004; CX-0408C.001). Jubilant’s awareness of Bracco’s patents *after* Jubilant had already brought its product to market does not indicate copying the invention in those patents.

Even if Bracco’s evidence of alleged copying were from the correct time frame, all of the cited documents are a far cry from those the Federal Circuit has countenanced as indicative of copying. *See Akamai Techs., Inc. v. Cable & Wireless Internet Servs., Inc.*, 344 F.3d 1186, 1196-97 (Fed. Cir. 2003) (accused infringer’s “redesign process was documented in the record in internal emails from [their] engineers discussing [the patent holder’s] approach, identifying weaknesses in [the accused infringer’s] approach, and ultimately deciding to switch to the [patentee’s] system.”). The only example Bracco cites of Jubilant having affirmative possession of Bracco design details during the relevant time is a user manual for Bracco’s legacy product, the Model 510, which has been on the market since 1989 and does not have an on-board dose calibrator. *See* CX-0401C.001; Tr. at 1085:1-3.

In any event, despite Bracco's focus on copying, "a showing of copying is only equivocal evidence of non-obviousness in the absence of more compelling objective indicia of other secondary considerations." *Geo. M. Martin Co. v. All. Mach. Sys. Int'l, LLC*, 618 F.3d 1294, 1305 (Fed.Cir.2010) (finding a patent owner's reliance on an accused infringer's internal memos suggesting copying to be "hardly compelling" because evidence of other secondary considerations, while present, was minimal) (quoting *Ecolochem, Inc. v. S. Cal. Edison Co.*, 227 F.3d 1361, 1380 (Fed. Cir. 2000)); *see also Am. Innotek, Inc. v. United States*, 128 Fed. Cl. 135, 167 (2016), *aff'd*, 706 F. App'x 686 (Fed. Cir. 2017). Given the strong evidence that Jubilant did *not* copy Bracco's design, as well as the weak and circumstantial evidence on which Bracco relies, and the lack of more compelling evidence with respect to other factors, *see infra* IV.D.1.c.1 and 2, I accord no weight to this factor.

c) *Long-felt but Unresolved Need*

Bracco points to no competent evidence tied to the novel elements of the asserted patents showing a long felt but unmet need. I find no evidence in the record of when the need arose, how long it was felt, or how the inventions in the asserted claims solved it. *See Perfect Web Techs., Inc. v. InfoUSA, Inc.*, 587 F.3d 1324, 1332 (Fed. Cir. 2009). Those deficiencies undermine Bracco's argument on this point.

Turning to the evidence Bracco did marshal, Bracco first points to its own failure, as the sole provider of rubidium infusion systems, to create a product embodied by the asserted patents. But "the mere passage of time without the claimed invention is not evidence of nonobviousness," and Bracco cites no evidence that Bracco was aware of an unmet need to improve its own system during that time. *Iron Grip*, 392 F.3d at 1325. Bracco next points to a generic claim from its 2009 PCT application that "there is a need for new system configurations that facilitate more efficient

set up, maintenance and operation." CIB at 31. But any number of patents contain boilerplate sentences in the background of the invention describing a need for more efficiency. I find that statement to be too vague to give any weight.

Finally, Bracco points to Klein's failure to fully anticipate the asserted patents. CIB at 32. But Klein describes no unsolved need. For Klein, having the dose calibrator on the bench was not a problem because, as explained above, it could just as easily be placed on the cart. It was a matter of design choice, not a matter of technical impediment. *See In re Gershon*, 372 F.2d 535, 539 (C.C.P.A. 1967) ("The failure of the prior art to mention a problem may be due to the fact that in practice the problem is not a serious one or that a large number of satisfactory solutions is readily apparent.").

I find Bracco has not presented sufficient evidence of a long-felt but unmet need or a nexus between such a need and the novel features of the claimed inventions. I give this factor no weight in my analysis of obviousness.

d) *Failure of Others*

Bracco argues Jubilant tried to obtain FDA approval of a RUBY Version 2 but failed, and that failure indicates the claimed inventions were not obvious at the relevant time. CIB at 33-34. Bracco points to *Knoll Pharm. Co. v. Teva Pharm. USA, Inc.*, 367 F.3d 1381, 1385 (Fed. Cir. 2004) to argue that failure to achieve FDA approval *is* proof of a failure of others. But *Knoll Pharmaceutical* stands only for the proposition that FDA rejections "may be relevant" to the obviousness inquiry, and it reversed solely because the district court had not applied the correct standard of review at summary judgment. *See Allergan, Inc. v. Sandoz Inc.*, 726 F.3d 1286, 1291 (Fed. Cir. 2013) (citing *Knoll Pharmaceutical* for the proposition that "FDA approval *may* be *relevant* to the obviousness inquiry.") (emphasis added).

The record reflects that Jubilant's Version 2.0 was rejected by the FDA not because it lacked an on-board dose calibrator or any other features of the asserted patent claims but because it was not developed in compliance with FDA guidelines. *See, e.g.*, Tr. at 312:25-313:5; 316:16-25; JX-0178C, 38:6-19. I find, as a factual matter, there is no nexus between Jubilant's failure to obtain FDA approval and the features of the claimed invention. The Federal Circuit has made clear such a connection is required. *See AstraZeneca LP v. Breath Ltd.*, 603 Fed. Appx. 999, 1003 (Fed. Cir. 2015) (secondary considerations evidence properly rejected when FDA record identified issues separate from absence of claimed features as cause of rejection); *Ormco Corp*., 463 F.3d at 1313 (rejecting failure of others evidence for lack of connection of failure to claimed features of asserted patents).

Bracco also relies broadly on a theory that Jubilant failed "to commercialize" the RUBY Versions 1 and 2, and succeeded only by creating the infringing Version 3. *See* CIB at 33-34. But as noted above, I find nothing in the record supports a claim that Jubilant's failure, or eventual success, to get to market was related to technical failings, let alone tied to novel features of the asserted patents. A "failure to commercialize" for reasons entirely disconnected from the technology claimed by the patents does not constitute evidence the patents were nonobvious. *See AstraZeneca*, 603 Fed. Appx. at 1003.

None of the evidence cited by Bracco shows the devices of others failed "because the devices lacked the claimed features" of the inventions. *Ormco*, 463 F.3d at 1313. I give Bracco's evidence no weight in my obviousness analysis.

e) *Simultaneous Invention*

Jubilant asserts, for the first time in its post-hearing brief, that it invented the on-board dose calibrator "simultaneously" with Bracco. RIB at 140. Because this argument was not presented in its prehearing brief, however, it is waived. GR 11.2.

4. Conclusion

Considering both the evidence of obviousness and secondary considerations together, I conclude that all of the asserted claims are obvious in light of the prior art. *See Eli Lilly & Co. v. Perrigo Co.*, 718 F. App'x 953, 956 (Fed. Cir. 2017) (affirming finding of obviousness where panel was "satisfied that the district court thoroughly considered all the arguments and evidence presented before reaching its decision"); *In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*, 676 F.3d at 1079 (same).

C. Anticipation

Jubilant alone[9] argues that the asserted patents are invalid as anticipated by the RUBY Version 3 system. RIB at 2-8. Jubilant's argument is elegant. It starts with the proposition that the Commission has already determined that the RUBY Version 3 infringes the asserted patents. *See* Order No. 27. Necessarily then, if the RUBY Version 3 was in public use or on-sale prior to the priority date of the patents, it would anticipate them. *Peters v. Active Mfg. Co.*, 129 U.S. 530, 537 (1889) ("That which infringes, if later, would anticipate, if earlier.").

The asserted patents were filed in December 2016, but all parties agree that the earliest possible priority date for the asserted claims in this investigation is the date a parent PCT application was filed in 2009. *See* '826 patent at Cover, '869 patent at Cover, '870 patent at Cover.

[9] Staff argues Jubilant has failed to meet its burden on anticipation. SRB at 13-15.

Jubilant contests Bracco's claim of priority to 2009, and it's easy to see why. If Bracco's priority date were limited to the date of the 2016 application, Jubilant's RUBY Version 3 would render the claims anticipated. RIB at 2-8.

To get the benefit of priority to its earlier applications, Bracco must meet the requirements of 35 U.S.C. § 120: (1) the earlier application has § 112 support for the later-filed claims, (2) there is an overlap of named inventors with the earlier filing, (3) the applications were co-pending, and (4) the application contains or is amended to contain a specific reference to the earlier filed application. 35 U.S.C. § 120. When a patent application satisfies all of these requirements, it is "as though [it were] filed on the date of the prior application." *Id.* "For a patent's claims to be entitled to an earlier priority date, the patentee must *demonstrate* that the claims meet the requirements of 35 U.S.C. § 120." *Nat. Alternatives Int'l, Inc. v. Iancu*, 904 F.3d 1375, 1380 (Fed. Cir. 2018) (emphasis in original). The Federal Circuit has instructed that "when neither the PTO nor the Board has previously considered priority," the trier of fact may place the burden on the patent owner to "come forward with evidence to prove entitlement to claim priority to an earlier filing date." *Id.* (citing *PowerOasis, Inc. v. T-Mobile USA, Inc.*, 522 F.3d 1299, 1305-06 (Fed. Cir. 2008)).

Jubilant does not dispute that the asserted claims have § 112 support in at least the 2009 PCT application, satisfying the first element of § 120. Tr. at 1130:3-1131:19; 807:16-20; *see also* 955:17-956:3 (no written description issue). And Jubilant does not dispute that the asserted patents satisfy the co-pendency and specific reference requirements. *See* RIB at 2-8. But Jubilant argues Bracco has failed to meet its burden of showing an overlap in named inventors between the asserted patents and the prior application to which they draw priority, because, according to Jubilant, Bracco has not provided evidence of the true inventors on the asserted claims. RIB at 2.

But all § 120 requires is that the subsequent patent *name* an inventor or joint inventor in common with the prior application. 35 U.S.C. § 120 ("An application . . . which names *an* inventor or joint inventor in the previously filed application.") (emphasis added). The record is clear that the asserted patents list at least one inventor in common with the 2009 PCT; in fact, they list all of them. *Compare* '826 patent at Cover (listing Hidem, Fontaine, Gelbach, McDonald, Hunter, Swenson, and Zodda as inventors), '869 patent at Cover (same), and '870 patent at Cover (same), *with* JX-202.0001 (same). When a patent issues, a presumption attaches that it names the true inventor(s) of the invention(s) described in the patent. *Trovan, Ltd. v. Sokymat SA, Irori*, 299 F.3d 1292, 1303 (Fed. Cir. 2002). Thus even if I shifted the burden to Bracco, it has shown it is entitled to the priority date of the 2009 PCT application. To the extent Jubilant is challenging entitlement to earlier priority date under § 120 by challenging the asserted patents' listed inventors, it was Jubilant, not Bracco, that bore that burden. *See Tech. Licensing Corp. v. Videotek, Inc*., 545 F.3d 1316, 1328 (Fed. Cir. 2008) (under all circumstances, burden of showing invalidity is on the challenger; *prima facie* showing of entitlement to priority under § 120 is all that is required of patentee).

Jubilant's inventorship argument hinges on an overlap in claim elements between the asserted patents and elements in other earlier related patents, namely U.S. Patent Nos. 7,862,534 ("the '534 patent"); 8,317,674 ("the '674 patent"); and 8,708,352 ("the '352 patent"). Jubilant asserts that those overlapping elements include the tubing circuit, shielding assembly, and cabinet structure. RIB at 4-6. The '534 and '674 patents list six and eight inventors each, respectively, but none in common with the seven inventors named in all three asserted patents. *See* RIB at 4. Similarly, the '352 patent names six inventors, five of whom are not named in any of the three asserted patents. *Id.* Jubilant argues that if the overlapping features were previously claimed to

be invented by the inventors named in the '534, '674, and '352 patents, at least some of those inventors should be named as inventors in the asserted patents. RIB at 2-8. But even where two "patents contain 'overlapping subject matter,' that alone is insufficient to prove by clear and convincing evidence that" an inventor on the first patent invented part of the invention in the second patent." *Trovan*, 299 F.3d at 1303. To succeed in challenging priority under § 120, Jubilant needed to prove by clear and convincing evidence that *none* of the inventors named in the asserted patents was properly listed, such that there was *no* overlap with the 2009 PCT. *Id;* 35 U.S.C. § 120. Merely pointing to overlapping subject matter between claims of the asserted patents and the earlier patents is insufficient to overcome the presumption of true inventorship that follows an issued patent. *Id*. I additionally note that Jubilant relies on an overlap of mere claim *elements*, without an analysis of the invention as a whole. That is a deficient showing. *Trovan*, 299 F.3d at 1302 (inventorship analysis is done by examining contribution to *claim*, rather than individual elements).

In sum, I find no reason that Bracco is not entitled to a 2009 priority date. Jubilant has not shown by clear and convincing evidence that the asserted patents are invalid as anticipated.

VI. INFRINGEMENT

As noted above, I have found that the defense of patent invalidity due to obviousness is meritorious for every asserted patent claim. It follows, then, that Jubilant is not liable for infringement. *Commil USA, LLC v. Cisco Sys., Inc*., 135 S. Ct. 1920, 1929, 191 L. Ed. 2d 883 (2015) ("To be sure, if at the end of the day an act that would have been an infringement or an inducement to infringe pertains to a patent that is shown to be invalid, there is no patent to be infringed."). Nevertheless, in the interest of thoroughness, below I make findings about whether

Jubilant's actions would have constituted infringement under 35 U.S.C. § 271 if the asserted patents were valid.

I previously found, and the Commission affirmed, that the RUBY Version 3 practices each element of the asserted patent claims and the RUBY Version 3.1 and Version 4 do not. Comm'n Det. not to Review an Initial Det. Granting Summary Det. (Mar. 8, 2019); Order No. 27 at 7. The Commission also affirmed that Jubilant induced infringement of method claims of the '870 patent by instructing users on how to use the RUBY Version 3 system and that Jubilant induced infringement of the method claims of the '826 patent by instructing its contract manufacturer, Kluge Design Inc., on how to build the RUBY Version 3 system. *Id.* The Commission additionally affirmed a determination that Jubilant contributorily infringed the asserted patents by selling the imported RUBY-FILL rubidium generator for use with the RUBY Version 3 system. *Id.* at 8.

Presuming validity, the central remaining infringement question is whether Jubilant indirectly infringes the asserted patent claims when it imports and sells generators and tubing sets used with the RUBY infusion systems. All three RUBY systems—the infringing Version 3 and the non-infringing Version 3.1 and 4—use the same imported RUBY-FILL generators and RUBY Sets. The fact that the RUBY Version 3.1 and Version 4 do not infringe the asserted patents raises a question as to potential non-infringing uses for the imported generators and tubing sets. Bracco asserts that regardless of whether Version 3.1 and Version 4 infringe, Jubilant still induces infringement by importing and selling generators and tubing sets to customers that own the infringing RUBY Version 3. CPB at 13-17. Staff largely agrees with these contentions. SPB at 15. Jubilant did not address these contentions in its briefs. I address these issues below.

1. Inducement of Infringement

The record shows that Jubilant knows which generators and tubing sets are manufactured for, imported for, and sold to each customer, and Jubilant knows which customers have infringing RUBY Version 3 systems. *See* Tr. at 319:16-321:15. Jubilant instructs Version 3 customers to use the imported RUBY-FILL generator and RUBY Set with the Version 3 system. *See* CX-0007 (package insert directing customers to use generators only with a RUBY elution system); *see also* Order 27. And Jubilant has been aware, at least since my determination on February 8, 2019, that the accused generators and tubing sets practice the patent claims when used with the RUBY Version 3 infusion system. Comm'n Det. Not to Review an Initial Det. Granting Summary Det. (March 12, 2019) (EDIS Doc. ID 669522). I find that Jubilant intends to cause practice of the patent claims every time it ships a RUBY-FILL generator or RUBY Set to a customer that possesses a Version 3 system. *Vanda Pharm. Inc. v. W.-Ward Pharm. Int'l Ltd.*, 887 F.3d 1117, 1133 (Fed. Cir. 2018) ("A person can be liable for inducing an infringing use of a product even if the product has substantial noninfringing uses. . . .").

The fact that the RUBY Version 3.1 and Version 4 systems do not practice the patent claims does not save Jubilant from a finding of inducement. It is undisputed that there is currently no use of the RUBY Version 3.1 or Version 4 in the United States by third parties because those systems have not been approved by the FDA. *See, e.g.*, Tr. at 323:9-18. Consequently, the only use for an imported RUBY-FILL generator or an imported RUBY Set is to practice the patent claims with the Version 3 system, and I find Jubilant intends that use. It may well be that the facts relevant to inducement will change if different Jubilant products are approved by the FDA, but such an analysis must wait for another day and a different factual record.

2. Contributory Infringement

The resolution of the contributory infringement issue should by now be apparent. It is undisputed that currently there are no substantial uses for the accused generators and tubing sets other than to practice the patent claims. I find that the RUBY-FILL generator and RUBY Set have no substantial use with the RUBY Version 3.1 or Version 4 because those systems have not been approved by the FDA. Presuming patent validity, the importation and sale of generators and tubing sets with no substantial non-infringing use constitutes contributory infringement. 35 U.S.C. § 271(c); *see* Order No. 27; Comm'n Det. not to Review an Initial Det. Granting Summary Det. (March 12, 2019) (EDIS Doc. ID 669522). And again, any change in FDA approval will require additional fact finding beyond the record presently before me.

VII. DOMESTIC INDUSTRY

A violation of section 337 can be found "only if an industry in the United States, relating to the articles protected by the patent . . . concerned, exists or is in the process of being established." 19 U.S.C. § 1337(a)(2). Because I find the patents are invalid, the patents protect no articles and Bracco necessarily cannot satisfy the domestic industry requirement. *Certain Vision-Based Driver Assistance System Cameras and Components Thereof*, Inv. No. 337-TA-907, USITC Pub. 4866, (February 2019), Comm'n Op. at 36. Nevertheless, in the interest of thoroughness, below I make findings about whether Bracco's own design practices the asserted patent. I also consider Bracco's investments related to its design.

A. Technical Prong

It is undisputed that the Bracco Model 1700 elution system practices at least one claim of each of the asserted patents. Tr. at 28:7-24; RRB at 5. Jubilant contends, however, that the Model

1700 cannot be a domestic industry "article" because it is not for sale in the United States. I address that argument in my economic prong analysis below. To the extent that the two-prong domestic industry analysis can be separated, I find that the technical prong of the domestic industry requirement would be satisfied if the asserted patents were valid.

B. Economic Prong

Staff and Jubilant contend Bracco's investments in its Model 1700 system cannot satisfy the domestic industry requirement because the Model 1700 device has not been approved by the FDA and is not commercially available. CIB at 38-45; RRB at 5-15; SRB at 1-6. Staff and Jubilant also challenge some of the investments relied upon Bracco to prove up its industry.

Whether the Bracco Model 1700 is an article protected by the asserted patents under section 337(a)(3) "is not determined by a rigid formula, but by an examination of the facts in each investigation, the article of commerce, and realities of the marketplace." *Certain Batteries & Electrochemical Devices Containing Composite Separators, Components Thereof, & Prod. Containing Same,* Inv. No. 337-TA-1087, Notice of Comm'n Decision (Sept. 7, 2018). I examine the relevant facts in this investigation below.

1. The History of Bracco's Rubidium Infusion Systems

The story begins with the Bracco CardioGen-82 Model 510, which was approved by the FDA in 1989. Tr. at 589:18-590:3. The Model 510 remains the only Bracco rubidium infusion system commercially available in the United States to date. *Id.* It is undisputed that the Model 510 does not practice any asserted patent claim because all of the asserted claims require a dose calibrator on-board the cart and a computer configured to perform a strontium breakthrough test. The Model 510 does not have either of those features. JX-112C at .0003 (Model 510 system

controlled by instrument panel), .0009 (Model 510 had manual breakthrough testing); Tr. at 1069:4-20 (Model 510 lacks computer).

Around [redacted], Bracco began developing a new product called the CardioGen-82 NextGen ("NextGen"). JX-0137C.038. The NextGen had a [redacted] and could [redacted] features the Model 510 [redacted]. Tr. at 205:16-206:6; *see generally* JX-112C (internal Bracco comparison of Model 510 and NextGen). But the NextGen design still did not have a [redacted] and did not use a [redacted]. Tr. at 171:11-14, 174:10-176:2; CX-0515C.004; RX-408C; JX-112C at .0009. It therefore did not practice any asserted patent claim. By [redacted], Bracco had paid a contractor to build [redacted] units of the NextGen design. Tr. at 168:22-169:7, 172:16-21. Bracco and its witnesses often call those [redacted] units "prototypes," but the record shows that the devices were finished articles ready for sale to customers [redacted]. *Id*.; *see also id*. at 193:8-22. Bracco [redacted] of the NextGen system in [redacted]. JX-0105C ([redacted] NextGen product). The [redacted] the NextGen [redacted] in [redacted]. JX-0111C.

After the [redacted], the record shows that Bracco received reports from the field about patients receiving excess radiation from the original Bracco Model 510. Tr. at 210:11-25. Bracco initiated a voluntary recall of the Model 510 in 2011. *Id*. Bracco's senior director of regulatory affairs Patrice Marchildon testified that these events caused Bracco to "put on hold" its design efforts and its efforts to [redacted] for the NextGen model. *Id*.; *see also id*. at 255:3-10. By [redacted], Bracco had [redacted] for the NextGen product. JX-0137C.039; Tr. at 210:11-25, 252:3-6, 253:14-23, 255:3-10.

Years after [redacted] the NextGen, Bracco set to work on another design, which it designated the CardioGen-82 Model 1700. The first concrete fact relating to the Model 1700

design occurred in late [redacted], when Bracco hired a firm called [redacted] to analyze the NextGen model and make a proposal for a new design. Tr. at 149:2-4; 176:3-20; CX-0515C.016 (referring to non-disclosure agreement signed [redacted]). [redacted] concluded that the only components of the NextGen system that [redacted]. CX-0515C.004; Tr. at 179:11-180:8. Bracco contracted with [redacted] to overhaul the design. CX-0515.003. The overhaul included "major design improvements" over the NextGen model, including [redacted] and, in [redacted], [redacted]. Tr. at 261:4-23; 184:8-12. [redacted] worked with another contractor called [redacted] to build [redacted] units of the Model 1700. Tr. at 166:17-167:3, 192:25-193:7; CX-0515.003 ("[redacted] will oversee the manufacture . . . ."), -.007 ("[redacted] will build the units"). Although Bracco again calls the [redacted] units of the Model 1700 made under the contract "prototypes," the record shows that the devices are finished articles ready for sale to customers. JX-0162C.005 (showing [redacted] under the contract was to build [redacted] of the [redacted] units); Tr. at 194:4-195:7. The record evidence shows Bracco made payments for the manufacture of [redacted] units of the Model 1700 starting in [redacted]. *See* JX-0162C.001 (showing line items for "[redacted]" and "[redacted]" under "Less: Cost of Prototype Units").

Bracco applied to the FDA in [redacted] seeking approval for the Model 1700. JX-0137C. The FDA initially set a goal date of [redacted], for providing a final determination on the application. JX-0181C; Tr. at 264:1-8, 271:19-22.

After Bracco submitted its FDA application for the Model 1700, two adverse events occurred in the field at facilities using Bracco's original Model 510. First, in December 2018, eight patients were injected with high levels of strontium from a Bracco Model 510 system, apparently because a technician erroneously used Ringer's lactate as an eluate instead of saline.

Tr. at 437:10-11, 440:2-44:19; RX-0534C.000009. Then in March 2019, four more patients at a different facility were injected with high levels of strontium when a Bracco Model 510 system was again incorrectly used with Ringer's lactate. Tr. at 446:12-447:12; RX-0531C; RX-0534C.000013.

In response to these incidents, the FDA mandated a new warning be placed on rubidium generators instructing technicians of the importance of using saline. Tr. at 909:1-910:22; *see also* RX-0528C; CX-0788; RX-524C. The record also reflects that the 2018 and 2019 strontium breakthrough events likely have had an [redacted]. Tr. at 277:9-21; 293:21-24; RX-0526C.0004 ([redacted]). The FDA did not approve the Model 1700 by the [redacted] goal date, and to date the FDA still has not approved the Model 1700 for sale or use with patients. Tr. at 264:9-12.

2. Whether FDA Approval Is Required for a Domestic Industry

Jubilant contends that without FDA approval for the Model 1700 Bracco cannot prove a domestic industry. RRB at 5-6. For that proposition, Bracco relies on *Certain Minoxidil Powders, Salts, and Compositions for Use in Hair Treatment*, Inv. No. 337-TA-267, Comm'n Op. at 1-2 (Sept. 23, 1988) ("*Minoxidil*") and *Certain Monoclonal Antibodies Used for Therapeutically Treating Humans Having Gram Negative Bacterial Infections*, Inv. No. 337-TA-323, Comm'n Op., 1991 WL 788550, at *2 n.6 (June 28, 1991) ("*Monoclonal Antibodies*"). But those Commission opinions do not stand for the rule Bracco advances.

To understand the Commission's opinion in *Minoxidil,* some background is in order. The *Minoxidil* investigation occurred concurrently with efforts to amend the domestic industry requirements of section 337 in 1988. The administrative law judge ("ALJ") in *Minoxidil* issued the initial determination before the amendments were passed and while FDA approval for

minoxidil was pending. *Minoxidil*, Comm'n Op. at 1-2. The ALJ found that a domestic industry in minoxidil did exist, even though FDA approval had not been granted. *Minoxidil*, Final Initial Determination (February 26, 1988), at 59-62. The ALJ further determined that infringing imports would have a tendency to injure that industry, and would in fact injure the industry when FDA approval was granted. *Id.* at 62-68. The Commission investigative staff sought Commission review of the ALJ's initial determination, arguing that the finding of a violation of section 337 found by the ALJ was too speculative. *Id.*, Comm'n Op. at 1. In the alternative, the Commission investigative staff sought a stay pending FDA approval. *Id.* The Commission then determined to review the ID and issued a series of stays, eventually suspending the investigation until the FDA made its determination. *Id.* at 1-2.

While the investigation was suspended, the 1988 amendments to section 337 took effect and the FDA granted approval of minoxidil. *Id.* at 2. The Commission then resumed the investigation and affirmed the ALJ's initial determination on domestic industry in part, noting much of the analysis had become moot due to the change in law and FDA approval. *Id.* at 3-4. The Commission vacated the ALJ's findings about injury to the domestic industry because the statute had been amended to eliminate any injury requirement and broaden the criteria for the industry requirement for investigations based on patent infringement. *Id.* at 4. But the Commission affirmed the ALJ's finding that a domestic industry existed based on evidence of plant and equipment expenditures. *Id.* at 5-6. Those expenditures of record were necessarily prior to FDA approval. *Minoxidil*, Comm'n Op. at 2 (Rogaine approved by FDA on August 17, 1988); *id.*, Final Initial Determination at 60 ("Upjohn's Rogaine business is already active. . . . The formulation, bottling, and packaging plant was started up this year and has been run on a commercial scale in order to build up the inventory necessary to meet the projected initial demand

. . . following FDA approval"), *id.*, Final Initial Determination at 61 ("The domestic industry for Rogaine has not yet reached the point of commercial sales. Sales can begin only after approval by the FDA"). *See also Scanning Multiple-Beam Equalization Sys. for Chest Radiography & Components Thereof*, Inv. No. 337-TA-326, Order No. 21 (Aug. 2, 1991) (in *Minoxidil* "[t]he Commission did not have reason to address the question presented here: whether the requirement of an industry in the process of being established would be satisfied under the amended statute if the complainant needed FDA approval before the product could be marketed, and the product was not ready to submit to FDA for approval"). The Commission never stated in *Minoxidil* that FDA approval is required for a domestic industry based on a pharmaceutical or medical device.

As for *Monoclonal Antibodies*, the other opinion cited by Bracco, that opinion disposed of a request for a stay in favor of concurrent district court litigation. It merely cited *Minoxidil* as an illustration of a circumstance for which the Commission has stayed an investigation. *Monoclonal Antibodies*, 1991 WL 788550, at *2 (citing *Minoxidil* in footnote 6 for proposition that "the Commission has suspended investigations where an imminent decision by an agency was expected to have an important impact on the Commission's investigation"). It did not lay down a rule for when a domestic industry is established.

Other Commission decisions illustrate that commercial availability of a patented article in the United States is not necessary to show either that a domestic industry exists or that an industry in the process of being established. For example, in *Certain Non-Volatile Memory Devices*, Inv. No. 337-TA-1046 (October 26, 2018) ("*Memory Devices*"), the Commission considered whether investments to develop and produce a certain type of semiconductor wafer should be considered in a domestic industry analysis when the wafer had not been incorporated into a commercial product. *Memory Devices*, Comm'n Op. at 40-45. The Commission found that the complainant

had invested in a large research team and dedicated facilities in New York and Vermont to develop and manufacture the wafer. *Memory Devices*, Comm'n Op. at 40. The Commission determined those investments contributed to a domestic industry in "articles protected by the patent," as recited in section 337(a)(2). *Id.* at 41. The Commission explained that the text of the statute, the legislative history, and past Commission practice demonstrate that the term "article" in section 337(a)(2) "is sufficiently capacious to embrace pre-commercial or non-commercial items." *Id*. The Commission ultimately found that the complainant in *Memory Devices* had proved a domestic industry in the process of being established. *Id.* at 44.

The Commission has also applied the reasoning in *Memory Devices* to an existing industry. In *Certain Road Construction Machines and Components Thereof,* Inv. No. 337-TA-1088 ("*Road Construction Machines*"), the Commission addressed whether the complainant must prove that domestic industry articles were on sale in the United States as of the time of the complaint. *Road Construction Machines,* ID at 74 (Feb. 14, 2019). Four prototypes of the patented machines were being used in the United States when the complaint was filed. *Id*. at 71. Examining the statute and prior Commission decisions, the ALJ determined that there is no requirement that articles be commercialized to satisfy the domestic industry requirement. *Id*. at 74-75. The ALJ found that the complainant's investment included "labor on the claimed technology" that resulted in "a complete machine incorporating the features of the patent." *Id*. The ALJ found that a domestic industry existed at the time of the complaint even without commercial sales of the machines. *Id*. at 75-79. The Commission did not review the relevant part of the ALJ's determination. *Road Construction Machines,* Notice of Comm'n Determination to Review-in-Part a Final Initial Determination (Apr. 12, 2019), at 2.

Here, as in *Road Construction Machines*, it is undisputed that articles exist in the United States that embody the claims of the asserted patents. A subcontractor manufactured at least [redacted] units of the Model 1700 system for Bracco by the time the [redacted], and Bracco [redacted]. Tr. at 154:11-16. Those articles would be "articles protected by" the asserted patents if those patents were valid. This record contains no facts that would preclude those articles from being the subject of an existing domestic industry or a domestic industry in the process of being established under section 337(a)(2).

Bracco presents evidence of the money it spent to bring its Model 1700 into existence. I examine the significance and substantiality of those investments next.

3. Plant and Equipment

Bracco argues it satisfies the economic domestic industry requirement under section 337(a)(3)(A) based on significant investments in plant and equipment. Bracco points to a claimed [redacted] payment to subcontractor [redacted] "to purchase equipment in connection with the manufacture of Model 1700 carts." CIB at 41. Bracco also claims that it "[a]ditionally" invested [redacted] in "prototype units of the Model 1700 system" and "interim models." *Id*. at 42. These statements are misleading, as I explain below, but Staff also raises a threshold problem with Bracco's argument. Staff contends that Bracco claimed only [redacted] dollars in the "plant and equipment" section of its pre-hearing brief. CPB at 378 ¶ 641. Under Ground Rule 11.2, "[a]ny contentions not set forth in detail in the pre-hearing brief" are deemed abandoned or withdrawn, unless the party "is not aware and could not be aware in the exercise of reasonable diligence at the time of filing the pre-hearing brief." Staff argues Bracco has waived claiming any plant and equipment investment over [redacted]. SRB at 2-3.

The "plant and equipment" section of Bracco's pre-hearing brief concludes, "Thus, the evidence will show that between 2009 and 2017 Bracco has invested over [redacted] (USD) into plant and equipment related to the Model 1700, which indisputably practices the [a]sserted [p]atents." CPB at 378 ¶ 641. Bracco did not identify any other amounts as plant and equipment in its pre-hearing brief. Bracco's pre-hearing brief did identify a [redacted] payment to [redacted], but Bracco's pre-hearing brief characterized that payment as engineering, research, and development under section 337(a)(3)(C). CPB at 384, ¶ 656. While it is possible for the same investment to be categorized under multiple subparagraphs of section 337(a)(3), *see Certain Solid State Storage Drives, Stacked Electronics Components, and Products Containing Same*, Inv. No. 337-TA-1097, Comm'n Op. at 8-14 (June 29, 2019), Bracco was still required in its pre-hearing brief to "set forth in detail" how it would characterize investments so that all parties could prepare for trial. *See* Ground Rule 11.2. I find that Bracco did not give adequate notice of the arguments about plant and equipment in its post-hearing brief. Bracco therefore is precluded from relying on more than [redacted] in plant and equipment in this final initial determination. The misleading nature of statements in Bracco's domestic industry briefing make it all the more appropriate to find waiver. I discuss those misleading statements next.

In its post-hearing brief, Bracco claimed [redacted] "to purchase equipment in connection with the manufacture of Model 1700 carts." CIB at 41. But that is misleading; the [redacted] was a purchase of finished NextGen units and Model 1700 units from a subcontractor. *See* JX-0162C.001; Tr. at 144:22-145:8, 161:19-162:2, 168:22-169:7, 172:16-21, 194:4-195:7. Bracco's own witness, Mr. Troger, confirmed that the payment was *no*t for "the actual physical plant" or "special equipment" inside a plant. *See id*. at 190:12-19.

Next, Bracco claims that its [redacted] investment in "prototypes" was made "[a]dditionally" to the [redacted] expenditure. CIB at 42. That statement too is misleading. The record shows the [redacted] figure cited by Bracco *includes* the [redacted] for purported prototypes; it was not spent "[a]dditionally." *Compare* CIB at 42, *with* JX-0162C.001 (labeling the [redacted] figure as "Including Cost of Prototype Units").

Moreover, as I have already explained, Bracco's assertion of investments of [redacted] for "prototype units" is misleading. The testimony of Bracco's own witness under cross-examination is that the so-called "prototypes" were finished, user-ready products produced under a manufacturing contract. Tr. at 168:22-169:7, 172:16-21, 194:4-195:7; *see also* JX-0162C.001; CX-0740C.

I find that the [redacted] investment cited by Bracco in its pre-hearing brief represent fees paid to contractors between 2009 and 2017 for the manufacture of [redacted] units of the NextGen product and [redacted] units of the Model 1700. *Compare* CPB at 378 *with* JX-0162C at .001, .005; Tr. at 161:19-162:2 (Mr. Troger testifying that "this [redacted] reflects [redacted] units"); *see also* 168:22-169:7, 172:16-21, 194:4-195:7; RX-0310C.000005. Payment for the [redacted] finished NextGen units was [redacted] of the [redacted]. *See* JX-0162C at .001, .005. I find that investments to produce the [redacted] NextGen units in 2009 and 2010 are not related to "articles protected by" the asserted patents. While Bracco attempts to cast the NextGen units as "interim prototypes" related to the Model 1700, I reject that characterization for several reasons. First, the NextGen system lacked features of the patented invention, including a [redacted] and a [redacted]. Second, the record shows the NextGen units were not prototypes; they were finished articles that were ready to be sold to customers [redacted]. Tr. at 168:22-169:7, 172:16-21, 194:4-195:7. Third, the record

does not show a continuum of development between the NextGen system and the Model 1700. Bracco put its design process "on hold" in 2011 and [redacted] for the NextGen system at the same time. Tr. at 210:11-25, 252:3-6, 253:14-23, 255:3-10; JX-0137C.039. The record reflects no concrete design effort by Bracco or any subcontractor from [redacted] to [redacted]. Tr. at 176:3-20; CX-0515C.016 (referring to non-disclosure agreement signed [redacted]). Moreover, no major components of the NextGen system [redacted]. CX-0515C.004; Tr. at 179:11-180:8. For at least those reasons, I decline to credit [redacted] of the [redacted] claimed by Bracco as an investment in plant and equipment related to manufacturing the Model 1700.

The question remains whether the [redacted] payment from Bracco to [redacted] for [redacted] finished Model 1700 units constitutes an investment in plant and equipment. *See* JX-0162C.001. Staff and Jubilant argue that Bracco failed to establish that those [redacted] units have a nexus to the asserted patents. SRB at 3-4, CRB at 8-9. Staff and Jubilant's argument is understandable, given that Bracco misleadingly characterized those units as "prototypes" in many places. I have found, however, that the [redacted] units in question are in fact finished, commercially ready devices. *See* JX-0162C.005; Tr. at 194:4-195:7. There is no question that [redacted] manufactured the [redacted] Model 1700 units in the United States. Tr. at 155:4-18. Thus, Bracco's [redacted] payment could be considered to be a combination of (1) rent paid to [redacted] for use of [redacted] plant and equipment to manufacture the [redacted] Model 1700 units; (2) payment for the work of [redacted] employees who built the devices (Tr. at 165:2-5); and (3) payment for the materials used to make the devices. Only the first category would be considered plant and equipment, and the record does not indicate what that amount is. Nevertheless, I find it is more likely than not that a significant proportion of the [redacted] payment represents a significant investment in plant and equipment relating to the Model

1700. I need not calculate the amount to the penny. *Certain Stringed Musical Instruments and Components Thereof*, Inv. No. 337-TA-586, USITC Pub. 4120 (December 2009), Comm'n Op. at 25-26 ("A precise accounting is not necessary, as most people do not document their daily affairs in contemplation of possible litigation."); *Certain Optoelectronic Devices for Fiber Optic Communications Thereof, and Products, Containing Same*, Inv. No. 337-TA-860, USITC Pub. 4852 (Nov. 2018), Comm'n Op. at 18-19 ("[W]hether investment activities are significant or substantial 'is not evaluated according to any mathematical formula,' but rather, 'entails an examination of the facts in the investigation, the article of commerce, and the realities of the marketplace.") (quoting *Certain Printing and Imaging Devices and Components Thereof*, Inv. No. 337-TA-690, Comm'n Op. at 27 (Feb. 17, 2011)).

4. Labor and Capital

Bracco argues it satisfies the economic domestic industry requirement under section 337(a)(3)(B) based on significant employment of labor and capital in the United States. CIB at 43-45. Bracco contends in 2016 and 2017 it paid [redacted] in salaries to Bracco employees in the United States for work relating to the Model 1700 system. These employees include engineers and technical personnel and regulatory employees who worked on the FDA approval process. *Id*.

a) *FDA Compliance Expenses*

Staff asserts that FDA approval and compliance related expenses should not be credited toward satisfaction of the domestic industry requirement, likening them to patent prosecution activities and maintenance fees that the Commission has disregarded in past investigations. SIB at 22-23.

Staff's comparison of patent prosecution to FDA compliance is inapt. First, Staff's argument is built on the incorrect premise that patent prosecution categorically cannot be considered in connection with domestic industry investments. To my knowledge the Commission has never stated that rule. The only two authorities that Staff cites certainly do not stand for that proposition. In *Video Game Systems*, a majority of the Commission stated that "patent prosecution activities *alone* would be insufficient to establish the domestic industry requirement under section 337(a)(3)(C)," but a footnote from Commissioner Aranoff makes clear that the Commission majority preserved the option for considering patent prosecution expenses if appropriate circumstances arose in the future. *Certain Video Game Systems and Controllers*, Inv. No. 337-TA-743, Comm'n Op. (Apr. 15, 2011) at 8 n.1. In the other opinion cited by Staff, *Certain Loom Kits for Creating Linked Articles*, Inv. No. 337-TA-923, Comm'n Op. at 6 (May 21, 2015) (EDIS Doc. No. 559662), the Commission set aside without comment the ALJ's statements about patent prosecution fees. That means the Commission took no position on the issue. *Beloit Corp. v. Valmet Oy*, 742 F.2d 1421, 1422 (Fed. Cir. 1984) (it is not appropriate "to assume that the Commission has adopted all findings" of an ALJ when the Commission took no position on an issue).

Next, Staff has not addressed Commission determinations contrary to the rule it proposes. On at least two occasions the Commission has credited investments to obtain FDA approval as part of the domestic industry. For example, *Certain Salinomycin Biomass and Preparations Containing Same*, Inv. No. 337-TA-370, USITC Pub. 2978 (July 1996), Initial Determination at 128 (not reviewed), concerned a chemical compound regulated by the FDA. *See id*. at 297 (FF H 14), 298 (FF H 23). The Commission supported its finding of a domestic industry in part based on findings that (1) many employees of the patent owner's licensee spent time on "regulatory

activities" (*id*. at 128); (2) the licensee had an FDA-approved plant for making the chemical (*id*. at 299); (3) the complainant had "a consultant in the United States that it uses in connection with FDA matters related to" the chemical (*id*. at 296), and (4) the licensee had "plans to submit elements of the package seeking FDA approval" for use of the chemical in animals (*id.* at 301).

Similarly, *Certain Diltiazem Hydrocholoride and Diltiazem Preparations Containing Same*, Inv. No. 337-TA-348, USITC Pub. 2902 (June 1995), Initial Determination at 120-28 (unreviewed in relevant part), also involved a chemical compound regulated by the FDA. *Id.* at 126, 143, 292. The Commission supported its finding of a domestic industry in part based on findings that the complainant (1) "conducts research and development . . . in order to comply with FDA requirements" (ID at 142, 323, *see also id*. at 144); (2) maintains processes and equipment in accordance with "FDA requirements" (*id*. at 143, 323); (3) spent an amount on the order of at least $1 million "on research and development including FDA approval, clinical trials, formulation research," and other activities (*id*. at 324); (4) employed personnel "responsible for the research and development activities relating to FDA-required clinical testing from development phase 1 through phase 3" (*id*. at 325-26); and (5) employed other personnel responsible for research on "products for which FDA approval is pending (phase 3B) and for those products which have already been approved" (*id*. at 326).

Staff's argument is also somewhat internally contradictory. On the one hand, Staff argues that FDA approval is necessary for Bracco to have a viable domestic industry, but on the other Staff argues that investments to obtain that approval should not be considered as part of the domestic industry analysis. *Compare* SIB at 22-23, *with id*. at 28-29. If FDA approval is necessary for Bracco to exploit its invention, as Staff apparently concedes, it follows that expenditures to obtain that approval contribute to the domestic industry. *Certain Magnetic Tape Cartridges and*

Components Thereof, Inv. No. 337-TA-1058, Comm'n Op. at 53 (Apr. 9, 2019) (The Commission "has defined the domestic industry to include investments necessary to bring to market the patented technology as embodied in the asserted domestic industry products.").

I determine that, if the asserted patents were valid, Bracco's efforts to obtain FDA approval of the Model 1700 would have been central to enabling exploitation of the patented invention. Bracco employs at least [redacted] people at a facility in Melville, New York, who support the regulatory approval activities for the Model 1700 system. RX-0310C.000003. In 2016 and 2017, Bracco invested approximately [redacted] in salaries for those employees. *Id*. at .000005-6. That amount is a significant employment of labor and capital in the United States, consistent with section 337(a)(3)(B).

The record also shows Bracco expended [redacted] in consulting fees to a contractor assisting Bracco with FDA approval. RX-0310C.000005-6. The contractor is located in the [redacted], but has some employees in the United States. *Id*. at .000004; Tr. at 155:16-156:14. The amount Bracco paid its own employees in the United States for their work on FDA compliance is significantly greater that the contract expenditure. I need not rely on this particular contract expenditure in my domestic industry analysis.

b) *Engineering Labor Expenses*

The record demonstrates that in 2016 and 2017 Bracco employed approximately [redacted] to [redacted] engineers and technical personnel in the United States who spent a substantial amount of their time working on development of the Model 1700 system. RX-0310C.000006. The record also indicates that other engineers worked on the project during that same time, but not as extensively. In 2016, Bracco estimates that [redacted] U.S.-based engineering employees worked on some aspect of the development of the Model 1700 system. *Id*. at .000007. In 2017, Bracco estimates that number

was [redacted] engineering employees. *Id*. Pro-rating the time each employee spent on the Model 1700, Bracco paid U.S.-based engineers [redacted] for work exclusive to the Model 1700 device in 2016 and 2017. *Id*. at .000006; Tr. at 164:1-12.

Staff and Jubilant critique the engineering salaries cited by Bracco as lacking foundation and not being sufficiently tied to the Model 1700. RRB at 9-10; SRB at 3-4. Neither objection is valid. First, as to foundation, Bracco's project manager Mr. Troger testified about the salaries in question. Tr. at 136:10-20. Mr. Troger testified that he had personal knowledge of who worked on the Model 1700 and the time they spent because he made project assignments. *Id.* at 188:18-22; RX-0411C at 225:3-11, 227:8-14, 228:2-17. He also corroborated his knowledge by talking to other employees. Tr. at 191:20-192:8; RX-0411C at 225:3-11, 227:8-14, 228:2-17. After Mr. Troger made time estimates, he provided them to the Bracco HR department, who calculated expenditures with salary information corresponding to the employees in question. Tr. at 197:11-17. I find sufficient foundation for Mr. Troger's testimony about engineering salaries paid in 2016 and 2017.

As for the connection of the salaries to the Model 1700, Staff appears to contend that it is possible that the [redacted] cited above was for work related to "prototypes" that did not practice the asserted patents. SRB at 3-4. I have already determined that Bracco [redacted] the non-practicing NextGen system in [redacted], and engineering salaries from that era do not demonstrate a domestic industry in articles practicing the asserted patents. But the pro-rated portion of engineering salaries paid in 2016 and 2017 are reasonably attributed to the Model 1700 system. By that time, the record shows that Bracco was paying a contractor to build Model 1700 units, not "prototypes" that lacked features of the asserted patent claims. *See* Tr. at 194:4-195:7. *See Certain Solid State Storage Drives, Stacked Elecs. Components, & Prods. Containing Same*, Inv. No.

337-TA-1097, Comm'n Op. at 21 (June 29, 2018) ("[A]ll that is required is the use of reasonable allocations for the purposes of establishing the economic prong of the domestic industry requirement.") (citing *Certain NOR and NAND Flash Memory Devices*, Inv. No. 337-TA-560, 2006 WL 3775919, at 2 (Order No. 37) (Nov. 17, 2006) ("*Certain NOR and NAND Flash Memory Devices*"), *not reviewed*, Notice of Comm'n Decision (Dec. 8, 2006)).

Based on the record, I find that Bracco paid at least [redacted] in salary to U.S.-based engineers for work on the Model 1700 in 2016 and 2017. If the asserted patents were valid, that amount would be considered a significant employment of labor and capital in the United States, consistent with section 337(a)(3)(B).

5. Engineering, Research, and Development

Bracco asserts that between 2009 and 2018 Bracco has invested over [redacted] into research and development ("R&D") related to the Model 1700, including over [redacted] in payments to third parties. CIB at 40-41 (citing JX-0162C).[10] Bracco provided an exhibit summarizing expenditures by vendor. JX-0162C.002 (payments to [redacted]); JX-0162C.003 (payments to [redacted]); JX-0162C.004 (payments to [redacted]); JX-0162C.005 (payments to [redacted] and [redacted] for prototype units).

I have explained above why I do not credit Bracco's investments in the non-practicing NextGen system as part of a domestic industry in articles practicing the asserted patents. Setting those investments aside, the record shows that Bracco has worked with [redacted]

[10] Staff asserts that Bracco's pre-hearing brief was limited to a claim of [redacted] in R&D, and according to Ground Rule 11.2 any claim beyond that is waived. *See* SRB at 4. But Bracco's pre-hearing brief asserted, "Quantitatively, the evidence is expected to show that Bracco's Model 1700 investments have surpassed [redacted] (USD)." CPB at 376, ¶ 634. I find Bracco provided adequate notice of the contention.

(“[redacted]”) since at least [redacted] to design, develop, and test the Model 1700 system. Tr. at 176:3-20; CX-0515C.016 (referring to non-disclosure agreement signed [redacted]). [redacted] acted as the program manager for the Model 1700 development program, facilitating design and development and managing various sub-contractors. JX-0116C.003; Tr. at 150:11-22. To this end, [redacted] employed about [redacted] employees in the United States in 2016 and 2017 specifically for the development of Bracco’s Model 1700 system. Tr. at 164:23-165:1; RX-0310C.000007. The record supports the following payments from Bracco to [redacted], by year:

Year	**Amount**
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
Total	[redacted]

JX-0162C.001; RX-0310C.000007-8. The record reflects these outlays to [redacted] were exclusively for the Model 1700 and were made exclusively in the United States. *See* Tr. at 149:2-21, 156:15-158:7; RX-0310C.000007-.000008; JX-0119C. I find that, if the asserted patents were valid, Bracco’s expenditure of at least [redacted] on [redacted] for services to design and develop the Model 1700 would constitute a substantial investment in research and development to exploit the inventions claimed in the asserted patents, consistent with section 337(a)(3)(C). The same [redacted] investment also would constitute a substantial employment of capital, consistent with section 337(a)(3)(B). *See Certain Solid State Storage Drives, Stacked Electronics Components, and Products Containing Same*, Inv. No. 337-TA-1097, Comm’n Op. at

11-12 (June 29, 2018) (noting that the same expenditures may be credited under multiple subsections).[11]

C. Status of the Industry

1. A Domestic Industry Exists

I have found above that Bracco has made a significant investment in plant and equipment and a significant employment of labor and capital for articles protected by the asserted patents. I have also found that Bracco has made a substantial investment in research and development to exploit the inventions claimed in the asserted patents. At least [redacted] of these investments were made as of the time the complaint was filed in this investigation on April 3, 2018. That amount includes at least [redacted] paid to [redacted] in 2014-2017 and the salary Bracco paid to engineers ([redacted]) and regulatory personnel ([redacted]) in its employ in 2016 and 2017. I therefore find that a domestic industry exists under section 337, subparagraphs (a)(2) and (3). *See Certain Video Game Sys. & Controllers*, Inv. No. 337-TA-743, Comm'n Opinion at 5 (Jan. 20, 2012) (normally, "the appropriate date for determining whether a domestic industry exists or is in the process of being established is the date of filing of the complaint"), *affirmed by Motiva, LLC v. Int'l Trade Comm'n*, 716 F.3d 596, 601 n.6 (Fed. Cir. 2013).

[11] Before I move on from the topic of domestic industry accounting, I observe that this litigation has followed an unfortunate recent trend of losing sight of the domestic industry forest by concentrating on each line item tree. There is no serious dispute that Bracco and its contractors designed and manufactured the Model 1700 system in the United States at great expense, and that the Model 1700 practices the inventions in the asserted patents. Nevertheless, Bracco aggressively identified an over-inclusive bucket of expenses, likely learning from past Commission determinations that line items would be whittled away in litigation. And Staff and Jubilant were no doubt following a well-worn path when challenging individual expenditures asserted by the complainant. This investigation *did* present serious questions about FDA approval, but surely nitpicking line items is not what Congress intended on these facts. Perhaps all concerned about this area of the law can do better in the future.

2. Whether the Domestic Industry Will Persist

Jubilant and Staff contend that, even if Bracco has met its burden of showing that a domestic industry exists, the continued existence of that domestic industry uncertain because it is unknown whether the FDA will approve the Model 1700. SIB at 27-29; RRB at 12-14. Bracco avers it has no intention of abandoning commercialization of the Model 1700. CRB at 7-8.

The future of any industry is speculative. As a general matter, however, "the only activities that are relevant to the determination of whether a domestic industry exists or is in the process of being established are those that occurred before the complaint was filed." *See Certain Video Game Sys. & Controllers*, Inv. No. 337-TA-743, Comm'n Opinion at 5 (Jan. 20, 2012) (citing *Certain Coaxial Cable Connectors*, Inv. No. 337-TA-650, Comm'n Op. at 51 n.17 (April 14, 2010)). In appropriate circumstances, the Commission may consider activities and investments beyond the filing of the complaint, such as when there is evidence that a complainant's domestic industry is dwindling. *See id*. (citing *Certain Electronic Devices, Including Mobile Phones, Portable Music Players, and Computers*, Inv. No. 337-TA-701, Order No. 58, at 6 (Nov. 18, 2010) (unreviewed) and *Certain Electronic Imaging Devices*, Inv. No. 337-TA-726, Order No. 18 (Feb. 7, 2011) (unreviewed)).

Here, the facts indicate that Bracco submitted an application to the FDA in [redacted] seeking approval for the Model 1700. JX-0137C. The FDA initially set a goal date of [redacted], to dispose of the application. JX-0181C; Tr. at 264:1-4. The FDA endeavors to review and act on 90% of applications by their goal dates. Tr. at 264:5-8; 271:19-22. The FDA did not approve the Model 1700 by the [redacted] goal date, and it still has not approved the Model 1700. Tr. at 264:9-12. The record reflects that the 2018 and 2019 strontium breakthrough events likely have had an [redacted]. Tr. at 277:9-21, 293:21-24; RX-0526C.0004 ([redacted]).

The evidence also shows that Bracco's FDA application [redacted]. Tr. at 266:9-267:20.

Even without FDA approval, however, Bracco's industry presently exists, as I have found above. And the industry is not dwindling. To the contrary, after the filing of the complaint Bracco continues to have [redacted]. Tr. at 154:11-16. If the Commission ever issues a remedy in this investigation, I find that any uncertainty relating to the domestic industry's continued existence can be addressed by including a reporting requirement for Bracco in the remedy. *See Variable Speed Wind Turbines*, Comm'n Op. at 18 (imposing reporting requirement and limited exclusion order where record reflected uncertainty concerning continued existence of domestic industry).

VIII. CONCLUSIONS OF LAW

1. The Commission has personal jurisdiction over the parties, subject-matter jurisdiction over the investigation, and *in rem* jurisdiction over the accused products.

2. The importation requirement of section 337 is satisfied with respect to the accused Jubilant RUBY Version 3.1 and 4.0 strontium-rubidium infusion systems, as stated in Order No. 27. *See* Notice of a Comm'n Det. not to Review an Initial Det. Granting Summary Det. as to Certain Patent Infringement Issues (March 12, 2019) (EDIS Doc. ID 669522)

3. The importation requirement of section 337 is satisfied with respect to the accused RUBY-FILL rubidium generator and RUBY Set.

4. The asserted claims of all asserted patents (U.S. Patent No. 9,814,826, U.S. Patent No. 9,750,869, and U.S. Patent No. 9,750,870) are invalid as obvious.

5. No asserted claim of any asserted patent (U.S. Patent No. 9,814,826, U.S. Patent No. 9,750,869, and U.S. Patent No. 9,750,870) has been shown to be invalid as anticipated.

6. The technical prong of the domestic industry requirement for all asserted patents (U.S. Patent No. 9,814,826, U.S. Patent No. 9,750,869, and U.S. Patent No. 9,750,870) would have been satisfied if the patents were not invalid.

7. The economic prong of the domestic industry requirement for all asserted patents (U.S. Patent No. 9,814,826, U.S. Patent No. 9,750,869, and U.S. Patent No. 9,750,870) would have been satisfied if the patents were not invalid.

8. Jubilant induced others to practice every asserted patent claim of all asserted patents (U.S. Patent No. 9,814,826, U.S. Patent No. 9,750,869, and U.S. Patent No. 9,750,870), which actions would have constituted inducement of infringement under 35 U.S.C. § 271(b) if the patents were not invalid.

9. Jubilant contributed to the practice every asserted patent claim of all asserted patents (U.S. Patent No. 9,814,826, U.S. Patent No. 9,750,869, and U.S. Patent No. 9,750,870) by others, which actions would have constituted contributory infringement under 35 U.S.C. § 271(c) if the patents were not invalid.

10. Jubilant is not estopped from asserting a patent invalidity defense under the doctrine of assignor estoppel, as Jubilant is not in privity with any of the named inventors who assigned their inventions.

11. No violation of section 337 has occurred based on the importation or sale of articles alleged to infringe the asserted claims of U.S. Patent No. 9,814,826.

12. No violation of section 337 has occurred based on the importation or sale of articles alleged to infringe the asserted claims of U.S. Patent No. 9,750,869.

13. No violation of section 337 has occurred based on the importation or sale of articles alleged to infringe the asserted claims of U.S. Patent No. 9,750,870.

IX. RECOMMENDED DETERMINATION ON REMEDY & BOND

The Commission's Rules provide that the administrative law judge shall issue a recommended determination concerning the appropriate remedy in the event that the Commission finds a violation of section 337, and the amount of bond to be posted by respondents during Presidential review of the Commission action under section 337(j). *See* 19 C.F.R. § 210.42(a)(l)(ii).

In connection with this Recommended Determination, and pursuant to Commission Rule 210.50(b)(1), 19 C.F.R. § 210.50(b)(1), the Commission directed me to take evidence concerning the public interest pursuant to section 337(d)(1), (f)(1), and (g)(1). *See* 83 Fed. Reg. 19112 (May 1, 2018).

Before issuing a remedy for a violation of section 337, the Commission must consider the effect of the remedy on the following public interest factors: (1) the public health and welfare;

(2) competitive conditions in the United States economy; (3) the production in the United States of articles that are like or directly competitive with those that are the subject of the investigation; and (4) United States consumers. *See* 19 U.S.C. §§ 1337(d)(1), (f)(1). The Commission begins this analysis with the understanding that the public interest favors the protection of intellectual property rights by excluding infringing products. *See, e.g., Certain Two-Handle Centerset Faucets & Escutcheons & Components Thereof*, Inc. No. 337-TA-422, Comm'n Op. at 9 (July 21, 2000). Only in rare circumstances will the Commission to determine that the public interest considerations outweigh the patent holder's rights. *See Spansion*, 629 F.3d at 1360. The Commission can, however, tailor the remedy to minimize the impact on the public interest. *See e.g., Certain Personal Data and Mobile Commc'ns Devices & Related Software*, Inv. No. 337-TA-710, Comm'n Op. at 83 (delaying the effective date of an exclusion order based on competitive conditions in the United States economy).

Pursuant to that mandate, I make the following factual determinations relevant to the four statutory public interest factors. My final initial determination relays some of the facts below, but I repeat them here for clarity and convenience.

A. Background Facts

Coronary artery disease ("CAD") is a major public health issue in the United States, affecting millions of Americans. RX-0351. It is the leading cause of death in the United States in both men and women. RX-0419.0007. For decades, nuclear molecular imaging has been a leading medical tool for diagnosing diseases like CAD. JX-0096.0011. Positron emission tomography, also called PET imaging or a PET scan, is one type of nuclear medicine imaging. JX-0096.0003; RX-0392; RX-0400; RX-0403. In PET imaging, a radioactive isotope or "tracer" is introduced into a patient's blood stream intravenously. As the tracer decays, it emits radiation (positrons),

which can be detected by a scanner and converted into images by software. RX-0106.0014. Physicians then use these images to determine if the patient's heart is functioning properly.

In this investigation, it is important to note that neither the alleged Bracco domestic industry device nor the accused Jubilant infusion system can perform PET on its own. The systems at issue only inject the patient with radioactive eluate; they do not capture images and they do not process image data. A clinic uses the Bracco or Jubilant infusion system with a scanner and image software of the clinic's choice to perform PET. *See* Tr. at 452:21-453:3, 458:17-459:7, 471:13-25, 484:20-485:17, 564:24-10, 577:21-25.

There are many factors that contribute to the usefulness of a PET image independent of the infusion system used. Tr. at 543:15-544:4, 566:17-567:8. One major factor is the scanner or camera used to detect the positrons emitted from the tracer. JX-0186.003-4. Different types of scanners have different sensitivities to positron emissions. *Id*.; JX-0096.003; Tr. at 507:17-508:8, 544:5-545:7. Radiation dosage also plays a role. JX-0186.012. Higher radioactivity can cause detector saturation on some scanners, resulting in inaccurate readings. JX-0096.003, .006-7; Tr. at 413:16-23. Patient idiosyncrasies also have an effect. JX-0186.020. Imaging of larger patients may require higher doses of radioactive tracer. JX-0186.009. An image may also be influenced by the time at which it is captured compared to the time of elution injection. JX-0186.012-14. Another important factor is the software used to process the data gathered by the scanner's detectors. JX-0186.020; JX-0096.008, .017-18; Tr. at 458:17-459:7.

All of the factors above combine to yield PET images. Physicians may visually inspect PET images of the heart and observe relative differences in radiotracer uptake in different regions of the heart tissue or differences in uptake at different times. JX-0186.009, .018; JX-0096.002; Tr. at 405:25-406:4. Differences in myocardial uptake, or "perfusion," can indicate disease.

JX-0186.018-19; JX-0096.002. Some conditions may not be detected by visual inspection of images. For example, if a patient has equally balanced reduction in blood flow in all three vascular territories of heart, also termed "balanced ischemia," a visual interpretation of a perfusion study may not detect the condition because no difference between regions is noticeable. JX-0186.011, .016; Tr. at 408:8-409:19.

Physicians may also use software that analyzes PET data to quantify myocardial blood flow ("MBF"). JX-0186.020; Tr. at 923:16-924:1. Measuring MBF in absolute terms—milliliters per gram of tissue per minute—is called quantitative MBF analysis. JX-0186.001. Quantitative MBF analysis is inherently more reproducible than visual analysis and can improve diagnostic and prognostic accuracy over visual interpretation of perfusion images alone. JX-0186.020; JX-0096.010-11; Tr. at 407:15-19, 483:12-484:12. For example, quantitative MBF studies can detect balanced ischemia. JX-0186.011; Tr. at 408:8-409:19. MBF studies are also the only non-invasive approach to reliably identify cardiac allograft vasculopathy, a common form of rejection in heart transplant patients and a leading cause of death for such patients. *Id.* at 627:9-528:1; JX-0096.0014 (MBF data allows identification of allograft vasculopathy); JX-0186.0021; JX-0173.0001 (MBF data provides advantages over invasive coronary angiography for identifying early stage allograft vasculopathy); *see also* Tr. at 528:2-529:18 (invasive coronary angiography procedures have attendant risks not present in PET studies).

Rubidium-82 has been used as a radiation source for cardiac PET imaging for many decades, well before the invention in the patents at issue. *See, e.g.*, RX-0207 (CardioGen-82 Model 510 user manual); Tr. at 137:15-24, 589:18-590:8. Rubidium-82 is generated in portable generators by passing .9% NaCl saline over strontium-82 (Sr-82). RX-106.000018. The saline picks up rubidium atoms generated by the strontium as it decays and the resulting eluate is injected

into the patient's vein. As the generator ages, strontium eventually starts to detach from the column and contaminate the eluate, posing a risk to patient health. *Id.* Such an occurrence is known as strontium "breakthrough." *Id.* Strontium breakthrough can also be caused by a user putting the wrong solution into the generator. Tr. at 451:9-452:1. To prevent inadvertent patient exposure to strontium resulting from strontium breakthrough, operators must perform daily quality-control checks on the generator. RX-106 at .0019-.0020.

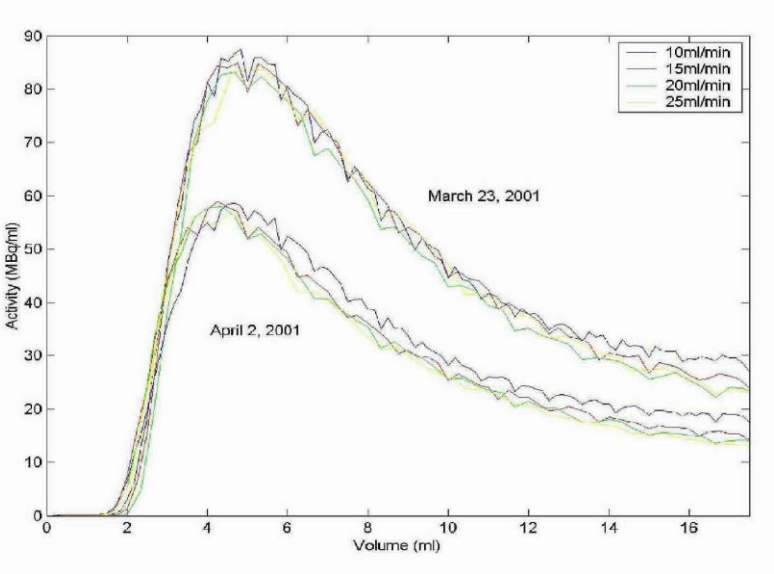
As with any exposure of humans to radioactive materials, physicians performing PET diagnostics adhere to the principle of "ALARA," namely, exposure of patients and operators to radioactivity should be "as low as reasonably achievable." *See* RX-0318.0001; RX-0419.0091; see also RX-0422; Tr. at 504:7-505:1.

1. The CardioGen-82 Model 510

The Bracco CardioGen-82 Model 510 has been on the market since 1989. Tr. at 589:18-24. The record shows that there are roughly [redacted] units of the Model 510 currently in use in the United States, constituting over [redacted] of the rubidium infusion market. RX-413C.084, .113.

The FDA-approved dose of radiation using the Model 510 is from 30 mCi to 60 mCi, with a recommended dose of 40 mCi. RX-0257. The Model 510 does not control the profile of the

rubidium dose's radioactivity, resulting in a "bolus" profile having an initial sharp spike in radioactivity followed by a long tapering:



RX-0106.000021; Tr. at 413:10-13.

Because calibration of the Model 510 requires recalibration after each dosage change, dosing is generally set for the day regardless of patient weight in clinical settings. Tr. at 505:19-507:2.

The Model 510 does not automate breakthrough testing. While the FDA requires operators to complete a daily safety protocol before using the Model 510, the system has no mechanism to ensure user compliance with the protocol. Tr. at 214:12-16, 215:7-19; *see also* RX-0257.000001. Breakthrough tests for the Model 510 are performed manually using stopwatches and complex worksheets. Tr. at 590:21-591:15, 933:8-12; RX-216.

The Model 510 has been involved in at least six incidents involving patients being dosed with unsafe elutions tainted by strontium breakthrough. Tr. at 436:3-447:12. In 2011, a number of patients at two different facilities in the United States were injected with high levels of strontium due to technicians failing to perform proper daily quality control procedures. Tr. at 436:3-437:5. This triggered Bracco to issue a voluntary recall on all strontium-rubidium generators in the United

States. Tr. at 433:25-434:11, 436:3-437:5. Four years later, in 2016, a technician mistakenly used Ringer's lactate instead of saline as an eluent, triggering a strontium breakthrough and infusing patients with high levels of strontium. Tr. at 444:20-446:11; RX-0534C; RX-0530C. In December 2018, a routine radiation sweep of a facility in Colorado uncovered another breakthrough. A technician had again used Ringer's lactate with the Model 510 and eight patients were injected with [redacted] high levels of strontium over a [redacted], [redacted]. Tr. at 437:10-11, 440:2-444:19, 515:10-517:17; RX-530-C; RX-0534C. Compounding the erroneous use of Ringer's lactate, the technicians at the Colorado facility had failed to properly perform the required daily quality control procedures which would have detected the resulting breakthrough. Tr. at 440:9-444:19. On March 21st of this year, four patients were injected with high levels of strontium at a facility in Kentucky. *Id.* at 446:12-447:12; RX-0531C; RX-0534C. Subsequent investigation revealed that this event was also caused by the use of Ringer's lactate. Tr. at 446:12-447:12.

In response to some of these incidents, the FDA mandated a new "boxed warning" for rubidium generators instructing technicians about the importance of using saline. Tr. at 909:1-910:22; *see also* RX-0528C; CX-0788; RX-524C.

The foregoing breakthrough incidents notwithstanding, the Model 510 has administered millions of doses to patients during its 30 years on the market, and it continues to be considered safe and effective. *See* RX-0410C; Tr. at 227:2-8, 908:23-25.

Many clinicians use the Model 510 to perform quantitative MBF studies, a technique that has been known since at least the 1990s. *See* Tr. at 921:20-922:20, RX-0076. On the other hand, there is evidence that a minority of Model 510 users do not have the proper camera and software technology to perform quantitative MBF studies. *See* Tr. at 485:3-17.

2. The RUBY Version 3 System

In September 2016, the FDA approved Jubilant's RUBY Version 3 system. Tr. at 318:16-17, 328:4-6. The record shows that there are ■ units of the RUBY Version 3 currently in use in the United States, less than 10% of the rubidium infusion market. Tr. 328:4-6; *see* RX-413C.113.

Whereas the Bracco Model 510 is largely manual, the RUBY Version 3 includes computerized calculations, computer-controlled functions, and automated safety features. Each day, the RUBY system software prevents patient infusions until an automated breakthrough test is performed with satisfactory results. JX-0007.037; JX-0027.0043. The user interface walks the operator through the steps for performing an automated strontium breakthrough test. JX-0007.037-44; JX-0027.0043-49; Tr. at 522:1-18. The technician must acknowledge each step of the process to go on to the next screen. *Id.*; RX-0083C.0007-8. The RUBY system also has automatic lock-outs that prevent patient elutions from occurring if strontium breakthrough is detected, or if the generator is past its expiration limits. JX-0027.0043-49; RX-0083C.0007-8.

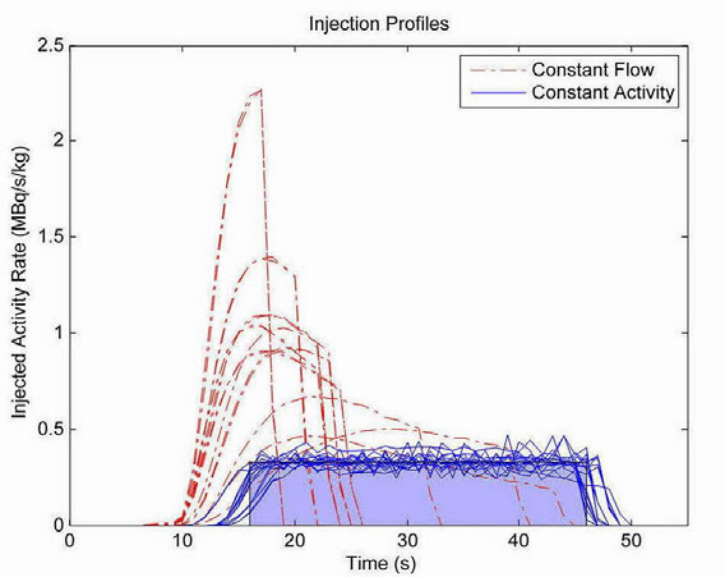
The automated system in the RUBY Version 3 will ensure breakthrough events are caught within 24 hours. The breakthrough would not be detected until an operator runs the safety protocol the next day after the breakthrough event, however. Tr. at 462:5-15. The same lag in breakthrough detection exists in the manual calculation protocol prescribed for Bracco's Model 510. *Id.* Thus, in both systems, patients injected later the same day as the breakthrough event will be exposed to high levels of strontium.

Also like the Model 510, the RUBY Version 3 system instructs users to only use saline with the generator. Tr. at 423:4-12. Several warnings appear on the screen of the RUBY system reminding technicians to use saline. *Id.* Although these warnings are designed to deter user error,

the RUBY system has no feature to physically prevent a technician from using Ringer's lactate instead of saline. Tr. at 521:3-522:18.

To date, there are no documented cases of patients treated with a RUBY Version 3 being injected with high levels of strontium. Tr. at 935:2-15.

Unlike the bolus injection profile of CardioGen Model 510's, the RUBY Version 3 can perform elutions with a more even "constant activity" profile. To achieve the constant activity profile, the RUBY Version 3 monitors eluate radioactivity in real time and makes adjustments to the eluate flow to provide a consistent average level of radioactivity throughout the injection. Tr. at 415:19-416:2; JX-0007.0046. The image below compares a bolus injection profile with a constant activity profile:



RX-0360.000006.

The RUBY Version 3 system allows a broader range of dosing, and lower dosing, than the Model 510. The FDA has approved the RUBY Version 3 for doses between 10 mCi and 60 mCi, compared with the Model 510 range of 30 mCi to 60 mCi. *Compare* CX-0007.001-002, *with* RX-0257.001. With constant activity infusions and lower approved dosing ranges, at least one

physician reported he was able to more reliably obtain MBF data than with the Model 510. Tr. at 414:19-416:19, 526:14-21.

The RUBY Version 3 has features absent from the Model 510 to reduce patient and operator radiation exposure and increase image quality. Tr. at 913:2-16; RX-0318. One such feature is simplified weight-based dosing. Weight-based dosing allows a technician to use lower amounts of radiation when appropriate based on a patient's weight. Tr. at 505:8-506:8; JX-0096, Public Interest Statement of University of Ottawa, EDIS Doc. ID 641744, at 2. Both the RUBY Version 3 and the Model 510 allow weight-based dosing, but the Model 510 system often requires a technician to recalibrate the system after each dose change. *Id.*; *cf.* JX-097. The RUBY system does not need to be recalibrated for each dose change because it performs an automated saline flush at the end of each infusion. The flush pushes any residual radioactivity out of the system that might otherwise cause the system to require recalibration. Tr. at 508:9-15.

The post-elution flush in the RUBY Version 3 also contributes to better image quality. The flush is performed while the patient is connected to system. That ensures that all generated rubidium is pushed out of the IV line, through the patient's arm vein, and into the patient's heart. Without the flush, radioactive tracer can linger or "pool" in the IV line and the patient's arm. Positron emissions from those areas can degrade the image of the heart. Tr. at 508:9-509:18; RX-0418; Public Interest Comment of Statement of University of Ottawa, EDIS Doc. ID 641744, at 2.

Additionally, the RUBY system flush pushes residual radioactivity away from any medical staff, reducing staff exposure. Tr. at 508:25-509:2 509:9-18. Operator exposure is also reduced by on-board breakthrough testing that does not require a technician to transport radioactive eluate samples.

B. The Public Interest Factors

1. Public Health and Welfare

Currently, the only FDA approved rubidium infusion systems available in the United States are the Model 510 and the RUBY Version 3 system. Tr. at 502:15-25, 574:19-24. Jubilant claims that the RUBY Version 3 system is significantly superior to the Model 510 with respect to both safety and diagnostic accuracy. RIB at 140. Bracco counters that there are no peer-reviewed scientific studies supporting Jubilant's claims. CIB at 50. For the reasons set forth below, I find that, although the RUBY Version 3 offers some safety improvements over the Model 510 and the potential for easier quantification of MBF, those improvements are not substantial or definite enough to militate against entry of a remedy. I find that the effect of a remedy on the public health and welfare does not weigh against entry of a remedy.

a) *Relative Radiation Exposure*

Jubilant claims its RUBY Version 3 is safer for both patients and operators. RIB at 141-142. While the RUBY Version 3 has features that logically would appear to make that system at least marginally safer than the Model 510, I find there is no dispute that the FDA—the agency with expertise on this matter—still considers the Model 510 to be safe and effective when used properly. The record evidence in this investigation does not show otherwise.

First, while the RUBY Version 3 offers automation and lock-out features, it has not been demonstrated that those features substantially reduce patient exposure to strontium when compared to proper use of the Model 510. Exposure to strontium from the Model 510 has occurred at least six times, but each time due to a technician using the wrong eluent. Tr. at 436:3-447:12. Neither the RUBY Version 3 nor the Model 510 prevent breakthrough caused by the use of the wrong eluent. Tr. at 462:5-15. Additionally, the RUBY Version 3 system will detect breakthrough no

sooner than the Model 510; the protocols of both systems discover the problem the next day. *Id.* Though the RUBY system eliminates the chance of user error in daily calibration calculations, the record reflects at most three instances where daily quality controls failed to catch breakthrough. *See* Tr. at 437:10-11, 440:2-44:19; RX-0534C. Given that the Model 510 has been used consistently for nearly thirty years across millions of injections, Jubilant's argument, RIB at 157, that the manual quality control process of the Model 510 is less safe than the automated RUBY Version 3 process is not supported by the record. I find that any safety improvements from automation of the breakthrough test in the RUBY Version 3 system have not been shown to have a statistically significant reduction in patient exposure to strontium.

Nor do differences in ordinary use radiation exposure tip the scale. Although weight-based dosing is easier with the RUBY Version 3 because it does not require recalibration with each dose change, the Model 510 is still capable of performing weight-based dosing. *Compare* Tr. at 508:9-509:2, *with id*. at 555:19-23. There is even evidence that weight-based dosages can be implemented with the Model 510 without recalibration, depending on the range of the dose. *See* JX-0097; Tr. at 549:15-551:6. Weight-based dosing may marginally reduce radiation exposure to some patients and medical staff, but even without it Model 510 dosing is still within limits determined by the FDA to be safe. Tr. at 505:19-506:8, 542:20-543:13, 911:11-913:1; JX-0096. Moreover, the record indicates that physicians only rarely performed weight-based dosing during the decades when the Model 510 was the only available rubidium PET infusion device on the market, which tends to support a conclusion physicians do not view weight-based dosing to be a priority for public health. Tr. at 506:9-20; JX-0097; *see* Public Interest Statement by Howard Lewin, MD of Cardiac Imaging Nuclear Associates (Apr. 11, 2018) (EDIS Doc. No. 641725).

Next, the different infusion profile of each system (bolus versus constant activity) does not make one safer than the other. Both systems expose patients to roughly the same amount of total radioactivity through their injections. Tr. at 416:3-4. And even though the FDA has approved the RUBY Version 3 for a lower range of doses (10 mCi to 60 mCi) than the Model 510 (30 mCi to 60 mCi), there is evidence that various clinics consistently use dosages higher than the minimal dosage approved by the FDA for all patients. *See* Tr. at 548:14-23.

Finally, although the on-board breakthrough test and saline flush of the RUBY Version 3 would seem to reduce radiation exposure for medical staff at least nominally when compared with the Model 510, nothing in the record quantifies that effect. Again, the FDA considers operator exposure with the Model 510 to be within safe limits.

These facts fall short of prior Commission determinations rejecting a remedy after finding a violation of section 337. For instance, in *Certain Fluidized Supporting Apparatus,* Inv. No. 337-TA-182/188 ("*Burn Beds*"), the Commission denied relief on the basis of the public interest where exclusion would reduce supply below that of demand for specialized beds for burn patients to the point that burn victims would, with *certainty,* be forced to use ordinary hospital beds unconducive to recovery and certain to cause pain. *See, e.g.*, *Burn Beds*, Inv. No. 337-TA-182/188, USITC Pub. 1667 (1984), Comm'n Op. at 23-25. Here, exclusion of the generators used in RUBY Version 3 systems and transfer of RUBY patients to the Model 510 would, at most, maintain patient and technician radiation exposure to levels considered by the FDA to be safe for the last

thirty years. I find that the evidence of reduced radiation exposure when using the RUBY Version 3 infusion system is insufficient to weigh against entry of a remedy in this investigation.[12]

b) *Relative Diagnostic Capacities*

Jubilant also argues the RUBY Version 3 system provides physicians more accurate quantitative MBF data, which leads to more accurate diagnoses and prognoses. RIB at 141-142. However, as described in the background section above, neither the RUBY Version 3 nor the Model 510 calculate MBF data. A clinic uses the Bracco or Jubilant infusion system with a scanner and image software of the clinic's choice to obtain quantitative MBF data. *See* Tr. at 452:21-453:3, 458:17-459:7, 471:13-25, 484:20-485:17, 564:24-10, 577:21-25.

The record demonstrates that many factors beyond the choice of infusion system contribute to the calculation of MBF data. Tr. at 543:15-544:4, 566:17-567:8. One major factor is the scanner or camera used to detect the positrons emitted from the tracer. JX-0186.003-4. Different types of scanners have different sensitivities to positron emissions. *Id*.; JX-0096.003; Tr. at 507:17-508:8, 544:5-545:7. Radiation dosage also plays a role. JX-0186.012. Higher radioactivity can cause detector saturation on some scanners, resulting in inaccurate readings. JX-0096.003, .006-7; Tr. at 413:16-23. The software used to process the data gathered by the scanner's detectors also affects MBF results. JX-0186.020; JX-0096.008, .017-18; Tr. at 458:17-459:7. All of this means that the Model 510 might produce more accurate MBF data in one set of circumstances, while the RUBY Version 3 might produce more accurate MBF data in another.

[12] If the CardioGen-82 Model 1700, RUBY Version 3.1, or RUBY Version 4.0 are approved before the entry of a remedy in this case, the Commission should conduct additional fact-finding about the relative risks and benefits of those systems.

For instance, although Jubilant's expert Dr. Lewin testified he was unable to consistently achieve MBF data with the Model 510, he admitted that was because he used an inferior PET imaging camera compared to more advanced cameras available on the market. *See, e.g.*, Tr. at 471:18-19. He further acknowledged that physicians using other imaging equipment were able to get accurate results with the Model 510, and that only 40% of the market use the inferior camera equipment. Tr. at 470:2-471:25.

In fact, Jubilant's other expert, Dr. Murthy, testified that he used the Model 510 to obtain quantitative MBF data from 117 heart transplant patients. Tr. at 556:12-557:18. His published findings state that quantitative MBF data was computed with commercially available software and previously validated methods. JX-0173.003. Dr. Murthy's publication also states quantitative MBF is "routinely measured during PET imaging." *Id*. at .002.[13] Dr. Murthy also did not dispute that another physician he knew, Dr. Gould, obtained quantitative MBF data for 5,800 different patients using the Model 510. Tr. at 562:1-11.

Further in contrast to Dr. Lewin's experience, one hospital in the United Kingdom reported impressive MBF results using the Model 510. With a cohort of 271 consecutive patients, the hospital was able to achieve accurate MBF quantification in 85% of patients using a 40 mCi dose. RX-0076.000001-2. After lowering the dose to 30 mCi dose to correct for some scanner saturation, the clinic achieved accurate MBF quantification in 99% of a second cohort of 159 patients. RX-0076.000001-2.

[13] The article states that myocardial flow reserve ("MFR") is "a well-validated evaluation of abnormal coronary vasodilatory capacity that is now routinely measured during PET imaging." JX-0173.002. The article explains that MFR is "ratio of stress to rest myocardial blood flow (MBF)." *Id*. Thus, Dr. Murthy's article concedes that quantitative MBF is "routinely measured during PET imaging," including the imaging he performed using the Model 510, and is valid. *See id*.

Jubilant points to the bolus infusion profile of the Model 510 (which, as discussed, delivers a higher radioactive peak than the RUBY Version 3's constant activity infusion) as the cause of the Model 510's supposed diagnostic inferiority. Jubilant contends the bolus spike in radioactivity at the beginning of a Model 510 infusion saturates the sensors in certain cameras, preventing successful MBF imaging. *See* Tr. at 413:3-414:11, 525:3-15; RX-0360. The record shows, however, that using different cameras or different dosing mitigates that concern. *See* Tr. at 469:5-471:25, 472:14-473:24, 484:13-485:17; RX-0076. The record also shows that the correct MBF software model can account for the bolus profile. *See* RX-0360.000009 ("In theory, the quantitative MBF results should not depend on the shape of the input function, because the compartment model is formulated to predict the myocardial tissue response curve for any arbitrary shape of input."). In fact, Jubilant's expert Dr. Murthy used bolus profile injections from the Model 510 and obtained quantitative MBF studies using validated methods. JX-0173.002, .003; Tr. at 556:12-557:18.

Finally, Jubilant's own experts both confirmed the lack of any studies showing statistically significant difference in outcomes between patients treated with the RUBY Version 3 and those treated with the Model 510. Tr. at 489:19-22, 575:13-19.

These facts do not support a finding that entry of a remedy is against the public interest. As noted above, in *Certain Fluidized Supporting Apparatus*, Inv. No. 337-TA-182/188 the Commission denied relief on the basis of the public interest where exclusion would reduce supply of specialized beds for burn patients to the point that burn victims would, with certainty, be forced to use non-specialized hospital beds and, as a result, caused extreme pain and have reduced recovery prospects. *See, e.g.*, *Burn Beds*, Comm'n Op. at 23-25. Here, exclusion of RUBY generators would require the small portion of the population treated with the nineteen RUBY

Version 3 machines currently in use to switch to a clinic with one of the hundreds of Model 510 units currently in use. *See* Tr. at 328:4-6, 492:5-12. The record shows the Model 510 is widely available. *See* JX-0173.008 (published paper of Jubilant expert Dr. Murthy opining that most transplant centers have access to technology that can obtain quantitative MBF data using the Model 510). It appears that many of those Model 510 units, if not a majority, have been combined with cameras and software that allow accurate quantitative MBF studies. JX-0173.002 (MBF is "routinely measured"). That situation is far short of the certainty of pain and poor recovery for all burn patients west of the Mississippi. *Cf. Burn Beds*, Inv. No. 337-TA-182/188, USITC Pub. 1667 (1984), Comm'n Op. at 23-25.

This investigation is also unlike *Certain Inclined Field Acceleration Tubes,* Inv. No. 337-TA-67, where the Commission declined to order a remedy because the violating articles were "greatly superior," "substantially less expensive," and "indispensable" to fundamental research in nuclear physics. *See Certain Inclined Field Acceleration Tubes*, Inv. No. 337-TA-67, USITC Pub. 1119 (1980), Comm'n Op. at 21-31, 37. Here, the record shows that if the RUBY Version 3 were no longer in use due to excluded generators, hundreds of Model 510 systems would still be available for MBF quantification and other research.

In sum, the effect of an exclusion order or cease and desist order on the public health and welfare factor does not weigh against entry of a remedy.

2. Competitive Conditions in the United States Economy

Jubilant argues that exclusion of their generators will cause a single-supplier market and eliminate all competition in the rubidium PET infusion market. RIB at 169. While the Model 510 would become the only *rubidium* PET infusion system on the market after an exclusion order, multiple noninvasive cardiac imaging tools would remain available, including other forms of PET.

Rubidium-82 is only one of two FDA-approved PET tracers; the other is nitrogen-13-ammonia. Tr. at 574:21-25. Still other PET tracers, such as 15-O water, are in use in Europe and are being investigated for approval in the United States. *Id.* These other options provide competitive pressure for innovation and price. Invasive alternatives like angiography are also available. *See* Tr. at 528:13-17, 489:23-492:23; *see* JX-0173.0001 (comparing cardiac PET imaging and angiography). Given the multiple competing cardiac imaging products on the market, even with Jubilant's exclusion, competition will remain in the marketplace.

The record also indicates that, even if the relevant marketplace is only rubidium PET infusion systems, the market operated for almost thirty years with Bracco as the sole supplier of such systems. Tr. at 885:3-886:1. In that time, consumer satisfaction was "moderate to high." Tr. at 886:2-11; CX-0041C.012. There is no evidence in the record that prices were supra-competitive during Bracco's time as the sole supplier of rubidium infusion systems. In fact, there was no evidence of a change in market prices with the introduction of competition by the RUBY Version 3 system. Even if there were evidence an exclusion order might lead to higher prices, "the Commission has consistently held that the benefit of lower prices to consumers does not outweigh the benefit of providing complainants with an effective remedy for an intellectual property-based section 337 violation." *See Certain Ink Cartridges and Components Thereof*, Inv. No. 337-TA-565 (Consolidated Enforcement Proceeding and Enforcement Proceeding II) ("Ink Cartridges II"), Comm'n Op. at 27 (Aug. 28, 2009) (EDIS Doc. No. 411051).

Jubilant also argues in connection with competitive conditions that a single-supplier market will create the risk of supply disruptions in the market. RIB at 169. That argument appears more relevant to the next factor, but to the extent it is related to competitive conditions I address it here. The record shows that Bracco has never had a supply issue during its nearly thirty years as a single-

supplier. Tr. at 887:17-20. The only supply disruptions in the market have been a voluntary recall in 2011, resulting from consumer misuse rather than production issues, RX-0142C, and *Jubilant's* own supply chain problems. Tr. at 335:12-336:25, 879:4-15. I find that if Bracco were the only supplier, it could adequately supply the market without disruption.

In view of the foregoing, I do not find that the effect of an exclusion order or cease and desist order on competitive conditions in the United States weighs against entry of an exclusion order.

3. Production of Like or Directly Competitive Products in the United States

As mentioned above, Jubilant argues Bracco will be unable to meet demand with domestic supply. The Commission has previously denied a remedy based on demand only when the domestic industry was unable to meet the demand of the United States market. *See, e.g.*, *Certain Automatic Crankpin Grinders*, Inv. No. 337-TA-60, USITC Pub. 1022 (1979), Comm'n Op. at 18-21 (denying remedy where domestic industry could not meet demand of automotive component necessary to meet stated public policy of increased automotive fuel efficiency). The record shows that Bracco has the present capacity to produce [redacted], Tr. at 151:13-23; RX-0412C.153 at 153:22-155:2; *see also* Tr. at 897:13-898:6, and that there are no known supply constraints in producing the Model 510 carts themselves. Tr. at 893:8-9. Bracco also anticipates the [redacted], Tr. at 151:24-152:7, and, with FDA approval, [redacted]. Tr. at 151:18-23. Thus, if Jubilant's generators were excluded, Bracco could and likely would increase its production of like or directly competitive goods in the United States.

The record contains other information relevant to this factor. Kluge, the U.S. contractor who manufactures the RUBY Version 3, submitted public interest comments about production.

Public Interest Statement of Kluge Design Inc., EDIS Doc. ID 641724. Kluge noted that Jubilant sells infusion systems both in the United States and abroad. *Id.*, *see also* Tr. at 318:23-319:3. Kluge speculated that if an exclusion order issues, Jubilant might move manufacture of the RUBY infusion carts from the United States to another country. I find Kluge's comments are speculative and uncorroborated. Indeed, Jubilant itself presented no evidence that it would disrupt its own supply chain to relocate manufacturing abroad.

Viewing the record as a hole, I do not find that the effect of an exclusion order or cease and desist order on competitive conditions in the United States weighs against entry of an exclusion order. *See, e.g.*, *Certain Crystalline Cefadroxil Monohydrate*, Inv. No. 337-TA-293, USITC Pub. 2391 (Mar. 21, 1990), Comm'n Op. at 46-47 (rejecting public interest argument where domestic supply was sufficient to meet demand).

4. United States Consumers

Neither Jubilant nor Bracco nor Staff presented any direct argument concerning the effect that an exclusion order would have on United States consumers. Here, the relevant consumers are physicians and healthcare facilities who purchase and use cardiac imaging systems. As noted above concerning competitive conditions, there is no evidence in the record that an exclusion order will lead to increased prices. And although the small number of facilities with RUBY systems might bear some immediate cost to lease a new infusion systems, the record shows that cost is rather modest compared to other medical devices related to PET imaging. Tr. at 496:15-19 (Cyclotrons cost $25 million), 880:17-24 (monthly lease cost of Model 510 is [redacted] a month); RDX-0006C.000011-12 (compiling system lease price analysis). A small cost to a handful of United States facilities does not outweigh the public interest in the enforcement in patent rights. *See Ink Cartridges II*, Inv. No. 337-TA-565, USITC Pub. 4196 (December 2010), Comm'n Op. at

27 (Aug. 28, 2009) ("The Commission has consistently held that the benefit of lower prices to consumers does not outweigh the benefit of providing complainants with an effective remedy for an intellectual property-based section 337 violation.").

To the extent that consumer choice is relevant to this factor, I have noted above that after an exclusion order medical facilities will still have the choice between Bracco's rubidium infusion system and other cardiac imaging systems.

I find no evidence has been presented showing an exclusion order or a cease and desist order would have a substantial negative impact on United States consumers as a whole. This factor does not weigh against a remedy

5. Conclusion

If an exclusion order or a cease and desist order were to issue in this investigation, I find that the effect of those orders on the four public interest factors would not counsel against issuing a remedy.

C. Limited Exclusion Order

Because I do not find a violation of section 337, I do not recommend that a limited exclusion order should issue. However, if the Commission determines that a violation of section 337 has occurred, I recommend that the Commission issue a limited exclusion order barring entry of articles that directly or indirectly infringe the asserted patent claims. That order would encompass the currently imported RUBY-Fill generators and RUBY sets. As explained above, the effect of an exclusion order on the public interest factors does not counsel against such a remedy.

However, I also recommend that any exclusion order not take immediate effect. The record contains unrebutted comments from members of the public suggesting it may take up to twelve

months for some cardiac imaging clinics to switch from the RUBY Version 3 to the Model 510. Public Interest Statement of Venkatesh L. Murthy, EDIS Doc. ID 641727, at 2 (estimating 6-12 months to revert to use of Bracco system, with patient risk in the interim); Public Interest Statement of April Mann, EDIS Doc. ID 64172, at 2 (estimating 3-6 months, if possible at all, to switch); Public Interest Statement of Howard C. Lewin, EDIS Doc. ID 641725, at 2 (substantial time to switch). Patients served by the dozen or so clinics using the RUBY Version 3 could face delays in obtaining images, potentially leading to undiagnosed and untreated cardiac disease. The risk of such delays is particularly concerning for cardiac transplant patients currently being treated at a facility with a RUBY Version 3 system but without a camera sufficient to produce MBF studies with the Model 510 (such as Dr. Lewin's clinic). If the patient cannot travel to an existing facility with the Model 510 system or another imaging option, that patient might risk more dangerous, invasive procedures or risk having potentially deadly complications from the heart transplant go undetected. *See* Tr. at 527:9-529:18. Bracco does not oppose giving patients and clinics time to transition the Model 510. CIB at 56.

In light of those facts, I find the sudden effect of an exclusion order could be harmful to the public health and welfare. I therefore recommend that effect of any remedy be delayed by a period of at least 12 months to allow sufficient time for facilities with RUBY Version 3 systems to switch to the Model 510 and maintain the standard of care for their current patients without interruption. *See Certain Personal Data and Mobile Communication Devices and Related Software*, Inv. No. 337-TA-710, Comm'n Op. at 83 (Dec. 19, 2011) (EDIS Doc. No. 467457) (delaying the effective date of an exclusion order based on competitive conditions in the United States economy).

Staff and Jubilant argue any limited exclusion order should expressly permit users who currently have a RUBY system to continue to receive imported generators and other imported components from Jubilant. SIB at 63, RIB at 173-174. Both argue that clinics and patients currently using the RUBY Version 3 should not be denied access to the purportedly superior attributes of the RUBY system.

I do not find that the record supports the proposed carve-out. Though Jubilant's experts testified they personally preferred the RUBY system and could obtain better results more easily with that system, they both acknowledged there is no statistically significant clinical proof that the RUBY system provides superior patient outcomes to the Model 510. Tr. at 489:19-22, 575:13-19. The record also contains ample evidence that equivalent functionality to the RUBY Version 3 is widely available at facilities using the Model 510. Additionally, I have taken the interests of existing users into account in my recommendation that the effect of any exclusion order be delayed.

One other issue remains. I have noted above that Bracco's alleged domestic industry product has not yet been approved by the FDA. If FDA approval is not granted sometime soon, it is unlikely that Bracco will continue manufacturing the Model 1700. It is even possible that if the FDA denies approval for the Model 1700 that Bracco will abandon that project and go back to the drawing board. I do not consider that outcome to be the most likely scenario, but it is a non-trivial scenario. Accordingly, there remains some degree of uncertainty concerning the continued existence of a domestic industry. In order to ensure that a domestic industry justifying the Commission's remedial order continues to exist, I recommend that Bracco be required to file quarterly reports on the first day of each calendar quarter describing the status of FDA approval of its domestic industry product and its continued manufacturing expenditures for the Model 1700. I

recommend this reporting requirement commence with the first day of the next calendar quarter after the issuance of any remedy and continue for eighteen (18) months after that day.

If Bracco's domestic industry product has not been approved for use in the United States by the expiration of that period or if Bracco has ceased making substantial expenditures to exploit the patents, I recommend the limited exclusion order be rescinded. *See Variable Speed Wind Turbines*, Comm'n Op. at 18. ("If it becomes clear from its reports that complainant has suspended or ceased practice of [a claim from the asserted patents], the Commission [should] consider whether to suspend or revoke the exclusion order, as may be appropriate.").

D. Cease and Desist Order

Because I do not find a violation of section 337, I do not recommend the issuance of a cease and desist order. And even if the Commission determines that a violation of section 337 has occurred, I still do not recommend entry of a cease and desist order, for the reasons discussed below.

Under Commission precedent, "[c]ease and desist orders are generally issued when, with respect to the imported infringing products, respondents maintain commercially significant inventories in the United States or have significant domestic operations that could undercut the remedy provided by an exclusion order." *Certain Air Mattress Systems, Components Thereof, and Methods of Using the Same,* Inv. No. 337-TA-971, Comm'n Op. at 49 (May 17, 2017) (EDIS Doc. No. 614743) (citations and footnote omitted). "A complainant seeking a [cease and desist order] must demonstrate, based on the record, that this remedy is necessary to address the violation found in the investigation so as to not undercut the relief provided by the exclusion order." *Id*. at 50.

The imported articles in question are RUBY-FILL rubidium generators and RUBY Sets. Those articles are presently used with RUBY Version 3 systems, which Jubilant makes

domestically. The evidence shows that Jubilant DraxImage Inc. currently leases out to customers approximately [redacted] installed RUBY Version 3 carts for a list price of [redacted] a month per cart. RX-081C.000007-8; Tr. 323:4-6. Each installed system requires a RUBY generator to operate, and each generator is replaced every 60 days. CX-0569C at 55:6-16. The generators, imported by Jubilant DraxImage Inc., are sold at a list price of [redacted]. RX-081C.000007-8.

Bracco admits that Jubilant does not maintain an inventory of either RUBY-FILL rubidium generators or RUBY Sets; those articles are made to order only when orders are placed by specific customers. CIB at 14-15 (citing Tr. at 320:12-14, CX-0569C at 40:9-19). Nevertheless, Bracco and Staff argue a cease and desist order is appropriate. CIB at 56; SIB at 164. Jubilant, for its part, does not address the question of a cease and desist order separately from its treatment of a potential limited exclusion order. RIB at 172-74. Jubilant only argues that, should a cease and desist order enter, it should be directed only to Jubilant DraxImage Inc. and should not include Jubilant Pharma Limited or Jubilant Life Sciences Limited, as only Jubilant DraxImage Inc. engages in the allegedly infringing conduct. RRB at 55 (citing Tr. at 302:17-22, 303:5-8).

If a limited exclusion order is issued and Jubilant can no longer import RUBY-FILL generators and RUBY Sets, the [redacted] RUBY Version 3 carts Jubilant has installed in the field will no longer be able to be used in a manner that violates section 337. Accordingly, a cease and desist order would no longer be "necessary to address the violation." *See Certain Air Mattress Systems*, Comm'n Op. at 50.

If the Commission nevertheless determines that a cease and desist order is appropriate, the order should be limited to Jubilant DraxImage Inc. The record indicates that Jubilant DraxImage Inc. is the only respondent that performs, induces, or contributes to the practice of the asserted patent claims. Tr. 302:17-22, 303:5-8. I therefore recommend any cease and desist order be issued

solely against Jubilant DraxImage Inc. *See Road Construction Machines*, 337-TA-1088, Comm'n Op. at 51-53 (July 15, 2019) (determining cease and desist order was appropriate only against respondents that record reflected had domestic activities and/or inventory).

Staff recommends that any cease and desist order expressly permit users who currently have a RUBY system to continue to receive imported generators and other imported components from Jubilant. SIB at 164. For the reasons stated above in connection with the limited exclusion order, I do not find that such a carve-out is justified. I do recommend, however, the effect of any cease and desist order be delayed for 12 months, for the same reasons I have explained above in connection with the limited exclusion order.

E. Bond During Presidential Review

In the event that the Commission determines to issue a remedy, the Commission must determine the amount of bond to be required of a respondent during the 60-day Presidential review period. *See* 19 U.S.C. §1337(j)(3). The purpose of the bond is to protect the complainant from any injury. *See* 19 C.F.R. §§ 210.42(a)(1)(ii), 210.50(a)(3).

When reliable price information is available, the Commission has often set the bond by eliminating the differential between the domestic product and the imported, infringing product. *See Microsphere Adhesives, Processes for Making Same, and Prods. Containing Same, Including Self-Stick Repositionable Notes*, Inv. No. 337-TA-366, USITC Pub. 2949 (Dec. 8, 1995), Comm'n Op. at 24. In other cases, the Commission has turned to alternative approaches, especially when the level of a reasonable royalty rate could be ascertained. *See, e.g., Certain Integrated Circuit Telecomm. Chips and Prods. Containing Same, Including Dialing Apparatus*, Inv. No. 337-TA-337, USITC Pub. 2670 (June 22, 1993), Comm'n Op. at 41. A 100 percent bond has been required when no effective alternative existed. *See, e.g., Certain Flash Memory Circuits and*

Prods. Containing Same, Inv. No. 337-TA-382, USITC Pub. 3046 (July 1997), Comm'n. Op. at 26-27 (imposing a 100% bond when price comparison was not practical because the parties sold products at different levels of commerce, and the proposed royalty rate appeared to be *de minimis* and without adequate support in the record).

Bracco seeks a "default bond" of 100%, suggesting that *all* sales of RUBY Systems will be at the expense of Bracco's CardioGen-82. CIB at 57-58. But as Staff and Jubilant point out, SRB at 22-23, RRB at 55-56, Bracco has not even attempted to meet the burden required for a 100% bond. In fact, Bracco contradicts its argument for a 100% bond by elsewhere seeking a 95% bond based on Jubilant's purportedly [redacted]. *Id.* (citing CX-0566C.119; RX-0413C.148). Bracco's admission that a price comparison is possible necessitates rejection of its requested 100% bond. Additionally, Bracco's argument that *all* sales to Jubilant are necessarily lost profits for Bracco is unpersuasive. While it may be true that a site using a Jubilant product is "a sales opportunity that Bracco did not win," Tr. at 884:9-24, the converse does not follow. Bracco supplied no evidence that Bracco would have won that business *but for* Jubilant's presence in the market, and the record reflects there are competing substitute goods. *See* Tr. at 574:19-575:5 (noting existence of at least one competing FDA approved cardiac PET radiotracer to rubidium).[14]

[14] Jubilant argues that, because the domestic industry product is not yet commercially available, it does not compete with the RUBY Version 3 and so causes no injury to sales of that product. That may well be true, but the purpose of the bond is to protect the *complainant* from *any* injury. *See* 19 C.F.R. § 210.50(a)(3). And Bracco certainly competes with Jubilant's RUBY Version 3 with its CardioGen-82 Model 510. Tr. at 875:8-876:2.

I find that Bracco has failed to meet its burden to show a bond is necessary to prevent it from any harm. I thus recommend that, should the Commission find a violation of section 337, a bond of zero percent should be imposed.

X. INITIAL DETERMINATION

I hereby certify to the Commission this Initial Determination and the Recommended Determination.

The Secretary shall serve the confidential version of this Initial Determination upon counsel who are signatories to the Protective Order (Order No. 1) issued in this investigation. A public version will be served at a later date upon all parties of record.

Pursuant to 19 C.F.R. § 210.42(h), this Initial Determination shall become the determination of the Commission unless a party files a petition for review pursuant to 19 C.F.R. § 210.43(a) or the Commission, pursuant to 19 C.F.R. § 210.44, orders on its own motion a review of the Initial Determination or certain issues therein.

Within seven days of the date of this document, the parties must jointly submit a statement to Cheney337@ustic.gov stating whether or not each seeks to have any portion of this document redacted from the public version. Should either or both parties seek to have any portion of this document redacted from the public version thereof, the parties shall attach a copy of a **joint** proposed public version of this document indicating with red brackets any portion asserted to contain confidential business information.[15] To the extent possible, the proposed redactions should

[15] If the parties submit excessive redactions, they may be required to provide an additional written statement, supported by declarations from individuals with personal knowledge, justifying each proposed redaction and specifically explaining why the information sought to be redacted meets the definition for confidential business information set forth in Commission Rule 201.6(a). 19 C.F.R. § 201.6(a).

be made electronically, in a PDF of the issued order, using the "Redact Tool" within Adobe Acrobat, wherein the proposed redactions are submitted as "marked" but not yet "applied." The parties' submission concerning the public version of this document should not be filed with the Commission Secretary.

SO ORDERED.

Clark S. Cheney
Administrative Law Judge

CERTAIN STRONTIUM-RUBIDIUM RADIOISOTOPE INFUSION SYSTEMS, AND COMPONENTS THEREOF INCLUDING GENERATORS **Inv. No. 337-TA-1110**

PUBLIC CERTIFICATE OF SERVICE

I, Lisa R. Barton, hereby certify that the attached **Initial Determination on Violation of Section 337 and Recommended Determination on Remedy and Bond** has been served by hand upon Commission Investigative Attorney, Brian Koo, Esq., and the following parties as indicated, on **August 13, 2019**.

Lisa R. Barton, Secretary
U.S. International Trade Commission
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On Behalf of Complainant Bracco Diagnostics, Inc.:

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