

UNITED STATES PATENT AND TRADEMARK OFFICE

---

BEFORE THE PATENT TRIAL AND APPEAL BOARD

---

JUBILANT DRAXIMAGE INC.,  
Petitioner,

v.

BRACCO DIAGNOSTICS INC.,  
Patent Owner.

---

Case IPR2018-01449  
Patent 9,299,467 B2

---

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

MARSCHALL, *Administrative Patent Judge.*

DECISION TO INSTITUTE  
*35 U.S.C. § 314(a)*

## I. INTRODUCTION

Jubilant DraxImage Inc. (“Petitioner”) filed a Petition (Paper 1, “Pet.”) requesting institution of an *inter partes* review of claims 1–4, 6–16, and 18–22 of U.S. Patent No. 9,299,467 B2 (Ex. 1001, “the ’467 patent”). Bracco Diagnostics Inc. (“Patent Owner”) filed a Preliminary Response (Paper 6, “Prelim. Resp.”). Under 35 U.S.C. § 314, an *inter partes* review may not be instituted “unless . . . there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.”

Upon consideration of the Petition and Preliminary Response and for the reasons explained below, we determine that Petitioner has shown that there is a reasonable likelihood that it would prevail with respect to at least one of the challenged claims. As such, we institute an *inter partes* review of all challenged claims on all presented challenges, and thus, institute an *inter partes* review of claims 1–4, 6–16, and 18–22 of the ’467 patent.

## II. BACKGROUND

### A. *Related Proceedings*

The parties indicate that the ’467 patent has been asserted in *Bracco Diagnostics Inc. v. Jubilant DraxImage Inc.*, Case No. 3-18-cv-04422 (D.N.J.). Pet. 2; Paper 4, 2; Exs. 1002, 1004. A related patent, U.S. Patent No. 9,299,468 B2, claims priority to applications in common with the ’467 patent, and is the subject of challenges in Cases IPR2018-01448 and IPR2018-01450. Pet. 2; Paper 4, 2.

### B. *The ’467 Patent (Ex. 1001)*

The ’467 patent issued March 29, 2016, from an application filed August 8, 2014, which is a continuation of an application filed June 11,

2009, which, in turn, is a continuation of four applications filed June 11, 2008. Ex. 1001, [22], [45], [63], 1:8–19.

The '467 patent relates to “systems that generate and infuse radiopharmaceuticals.” *Id.* at 1:23–24. Figure 1D of the '467 patent is reproduced below.

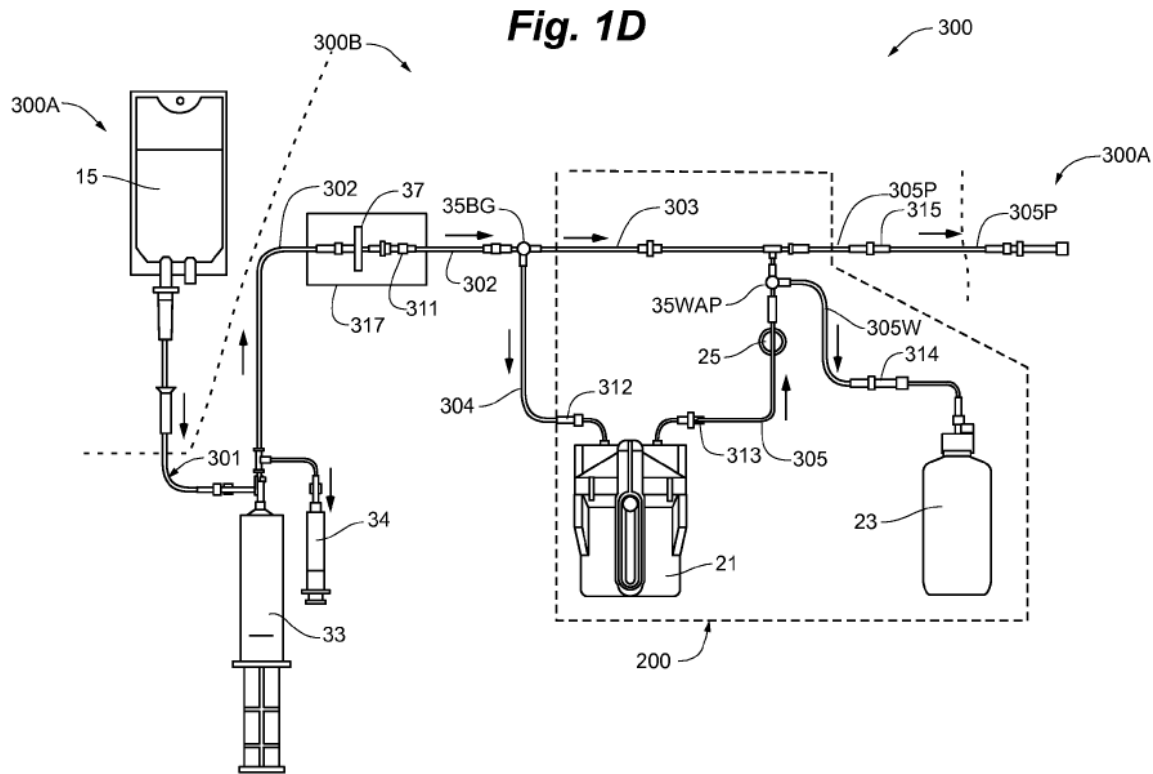


Figure 1D is “a schematic of an infusion circuit.” *Id.* at 2:8–9. Infusion system 10 can be mobile and may incorporate infusion circuit 300, a part of which is contained within shielding assembly 200. *Id.* at 3:46–50, 4:47–56, Fig. 1A. Infusion circuit 300 includes eluant reservoir 15 that contains saline as the eluant, syringe pump 33 that pumps eluant from reservoir 15, radioisotope generator 21 through which eluant is pumped to create a radioactive eluant, and activity detector 25 that measures the activity of the eluant from generator 21. *Id.* at 4:59–5:5. Activity detector 25 also

provides feedback for directing the eluant via divergence valve 35WP<sup>1</sup> to either waste bottle 23 or patient line 305*p*. *Id.* at 5:4–8. Divergence valve 35BG directs eluant to either tubing line 304 to generator 21 or to by-pass tubing line 303 and patient line 305*p*. *Id.* at 5:35–39.

“[A]ccording to alternate embodiments, system 10 includes an ‘on board’ dose calibrator for quality control tests, and circuit 300 is expanded to include elements for an automated collection of eluate samples for activity measurements, via the on board dose calibrator,” such as “downstream of divergence valve 35WP and in communication with tubing line 305P.” *Id.* at 7:64–8:5; *see also id.* at 18:48–52 (stating “some alternate embodiments . . . include an on board dose calibrator so that the entire sequence of sample collection and calculation steps . . . for the quality control procedures, may be automated”).

Also, in some embodiments, “computer 17 is coupled to a controller of system 10” and “monitor 172 of computer 17 not only displays indications of system operation for a user of system 10, but also serves as a device for user input (e.g. touch screen input).” *Id.* at 3:22–27. The user can interact with menus on computer 17 to perform breakthrough testing. *Id.* at 16:48–51. Computer 17 may calculate and display the breakthrough test results and may also display the allowable limits for those test results. *Id.* at 17:50–54. “[S]ystem 10 will not allow an infusion if the results exceed the acceptable limits.” *Id.* at 17:57–58.

---

<sup>1</sup> The “Detailed Description” of the ’467 patent describes valve 35WP; however, Figure 1D labels the valve as “35WAP.”

*C. Illustrative Claim*

The '467 patent has 22 claims, of which Petitioner challenges claims 1–4, 6–16, and 18–22 in this proceeding. Of those, claims 1 and 13 are independent. Claim 1 is reproduced below.

1. A system comprising:

a shielding assembly configured to contain a radioisotope generator that generates radioactive eluate via elution;

a computer carried by the shielding assembly, wherein the computer is configured to receive a user input and, responsive to receiving the user input, control the radioisotope generator to generate a sample of eluate via elution during breakthrough testing; and

a dose calibrator electronically coupled to the computer and configured to measure an activity of the sample of eluate generated during breakthrough testing,

wherein the computer carried by the shielding assembly is configured to receive the activity data from the dose calibrator and calculate breakthrough test results, and

the computer is further configured to prevent a patient infusion procedure if a breakthrough test result exceeds an allowable limit.

Ex. 1001, 23:48–64.

*D. Evidence Relied Upon by Petitioner*

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

# Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

## Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

## Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

## Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

## API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

## LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

## FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

## E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.