

**United States Court of Appeals
for the Federal Circuit**

BIO-RAD LABORATORIES, INC.,
Appellant

v.

INTERNATIONAL TRADE COMMISSION,
Appellee

10X GENOMICS INC.,
Intervenor

10X GENOMICS INC.,
Appellant

v.

INTERNATIONAL TRADE COMMISSION,
Appellee

BIO-RAD LABORATORIES, INC.,
Intervenor

2020-1475, 2020-1605

Appeals from the United States International Trade
Commission in Investigation No. 337-TA-1068.

Decided: May 28, 2021

BRIAN C. CANNON, Quinn Emanuel Urquhart & Sullivan, LLP, Redwood Shores, CA, argued for Bio-Rad Laboratories, Inc. Also represented by KEVIN P.B. JOHNSON; DAVID LEON BILSKER, ANDREW EDWARD NARAVAGE, NATHAN SUN, San Francisco, CA; SEAN GLOTH, II, New York, NY; S. ALEX LASHER, Washington, DC.

RONALD TRAUD, Office of the General Counsel, United States International Trade Commission, Washington, DC, argued for International Trade Commission. Also represented by DOMINIC L. BIANCHI, WAYNE W. HERRINGTON.

NICHOLAS P. GROOMBRIDGE, Paul, Weiss, Rifkind, Wharton & Garrison LLP, New York, NY, argued for 10X Genomics Inc. Also represented by JENNIFER DENEALT, JENNIFER H. WU, JOSEPHINE YOUNG; SAURABH GUPTA, Washington, DC.

Before NEWMAN, LOURIE, and DYK, *Circuit Judges*.

Lourie, *Circuit Judge*.

In this consolidated appeal, Bio-Rad Laboratories, Inc. (“Bio-Rad”) and 10X Genomics, Inc. (“10X”) each challenge a portion of a decision by the United States International Trade Commission (“Commission”) regarding Bio-Rad’s allegations that 10X violated section 337 of the Tariff Act of 1930, 19 U.S.C. § 1337, by importing into the United States certain microfluidic chips. *See* Comm’n Opinion, *In the Matter of Certain Microfluidic Devices*, USITC Inv. No. 337-TA-1068, 2020 WL 225020 (Jan. 10, 2020) (“*Commission Opinion*”). Specifically, Bio-Rad challenges the Commission’s determination that 10X did not infringe the claims of U.S. Patent 9,500,664 (the “664 patent”) by importing its “Chip GB.” 10X challenges the Commission’s

determination that it infringes the claims of the '664 patent as well as U.S. Patents 9,636,682 (the "682 patent") and 9,649,635 (the "635 patent") by importing its "GEM Chips." For the reasons discussed below, we affirm the Commission's decision with respect to both appeals.

BACKGROUND

I. Background of the Patented Technology

The '664, '682, and '635 patents (collectively, the "asserted patents") relate generally to the field of microfluidics, and specifically to the generation of microscopic droplets. A microscopic droplet is a contiguous amount of one type of fluid that is encapsulated within a different fluid. Typically, the inner fluid is aqueous or water-based, while the outer fluid is oil. The two fluids—which make up the two phases of the droplet—are immiscible. In the context of the disclosed inventions in this case, the asserted patents refer to the aqueous fluid in the droplet as the "sample-containing fluid." In contrast, the non-aqueous fluid is referred to as the "background fluid."¹

The use of aqueous droplets in oil allows isolation of materials because each droplet is partitioned from others, and thus chemical reactions can be conducted within each droplet. For example, as indicated by the '664 patent, each droplet acts as a mini-test tube in which a fluid can be subjected to chemical reactions. *See, e.g.*, '664 patent col. 4 l. 52–col. 5 l. 2. An emulsion, which is a collection of droplets,

¹ In this opinion, we will refer to the oil phase of the droplet as the "background fluid," which is the term used in the '664 patent. The '682 and '635 patents use the term "continuous-phase fluid" to describe the oil phase. It appears to be undisputed that, within the context of the asserted patents, there is no meaningful difference between the two terms.

provides the ability to perform a high volume of chemical reactions in parallel. Microfluidic technology has applications in numerous fields of research, including life sciences.

The asserted patents are directed to systems and methods for generating microscopic droplets by using a microfluidic device commonly referred to as a “chip.” A chip typically consists of a monolithic piece of substrate having a number of input and output wells connected by microfluidic channels, which are hair-width pathways through which fluids flow. *See, e.g., Bio-Rad Labs., Inc. v. 10X Genomics Inc.*, 967 F.3d 1353, 1360 (Fed. Cir. 2020). The use of chips to generate microscopic droplets by intersecting microfluidic channels was known before the priority dates of the asserted patents. *See id.* (describing use of microfluidic chips in connection with patents claiming priority from applications filed as early as 2002). The asserted patents in this case, however, are directed to specific chip architectures that, for example, allow for “improved techniques for the generation, mixing, incubation, splitting, sorting, and detection of droplets.” ’664 patent col. 2 ll. 25–27.

The chips used in the systems and methods of the patents comprise input wells, including a “sample well” to hold the sample-containing fluid and a “background fluid well” to hold the background fluid.² The wells are connected to microfluidic channels, which intersect each other at a “droplet-generation region,” where the droplets are formed.

For purposes of this consolidated appeal, claim 1 of the ’664 patent is representative of the asserted claims of that patent, and the same is true for claim 14 of the ’682 patent and claim 1 of the ’635 patent, respectively. The representative claims read as follows:

² As indicated above, the ’682 and ’635 patents refer to this well as a “continuous-phase well.”

1. A system for forming a plurality of **sample**-containing droplets suspended in a background fluid, comprising:
 - a substrate having a bottom surface and a top surface;
 - a **sample** well, a background fluid well, and a droplet well each having an upper region protruding from the top surface of the substrate;
 - a network of channels formed in the bottom surface of the substrate and fluidically interconnecting the **sample** well, the background fluid well, and the droplet well; and
 - a **droplet generation region** defined by the network of channels and configured to generate **sample**-containing droplets suspended in the background fluid;wherein the **droplet generation region** is defined by the intersection of a first channel, a second channel, and a third channel;
wherein the first channel is configured to transport **sample**-containing fluid from the **sample** well to the droplet generation region, the second channel is configured to transport background fluid from the background fluid well to the droplet generation region, and the third channel is configured to transport **sample**-containing droplets from the **droplet generation region** to the droplet well; and
wherein the substrate and the upper region of each well are injection molded as a single piece.

'664 patent col. 43 l. 55–col. 44 l. 13 (emphases added).

14. A system for generating droplets, comprising:

a device including a row of sample wells each configured to receive sample-containing fluid, a row of continuous-phase wells each configured to receive continuous-phase fluid, and a row of droplet wells, the device also including a corresponding channel network for each sample well, the channel network including a **droplet-generation region** and fluidically connecting the sample well to one of the continuous-phase wells and one of the droplet wells;

a holder for the device;

a gasket configured to be attached directly to the holder, such that the gasket extends over each sample well, each continuous-phase well, and each droplet well; and

an instrument configured to

(a) receive an assembly including the device, the holder, and the gasket,

(b) engage the gasket with a manifold, and

(c) apply positive pressure and/or negative pressure to the device via the manifold, such that sample-containing fluid flows from each sample well to the corresponding **droplet-generation region**, continuous-phase fluid flows from each continuous-phase well to the corresponding **droplet-generation region**, and sample-containing droplets flow from each **droplet-generation region** to the corresponding droplet well.

'682 patent col. 34 ll. 20–45 (emphases added).

1. A system to form and concentrate an emulsion, comprising:
 - a device including a sample well configured to receive sample-containing fluid, a continuous-phase well configured to receive continuous-phase fluid, and a droplet well, the device also including a channel network having a first channel, a second channel, and third channel that meet one another in a ***droplet-generation region***; and
 - an instrument configured to operatively receive the device and to create
 - (a) a first pressure differential to drive sample-containing fluid from the sample well to the ***droplet-generation region*** via the first channel, continuous-phase fluid from the continuous-phase well to the ***droplet-generation region*** via the second channel, and sample-containing droplets from the ***droplet-generation region*** to the droplet well via the third channel, such that the droplet well collects an emulsion including sample-containing droplets disposed in continuous-phase fluid, and
 - (b) a second pressure differential to decrease a volume fraction of continuous-phase fluid in the emulsion, after the emulsion has been collected in the droplet well, by selectively driving continuous-phase fluid, relative to sample-containing droplets, from the droplet well via the third channel.

'635 patent col. 33 ll. 29–55 (emphases added). The parties appear to agree that the terms “sample” and “droplet-generation region” have consistent meanings throughout the claims of the '664, '682 and '635 patents.

II. The Parties

The parties in this case have a long history together, which we have discussed in prior opinions. *See Bio-Rad Labs., Inc. v. 10X Genomics Inc.*, 967 F.3d 1353 (Fed. Cir. 2020); *Bio-Rad Labs., Inc. v. ITC*, --- F.3d ---, No. 2020-1785, 2021 WL 1680268 (Fed. Cir. Apr. 29, 2021). Here, we briefly include the portions of that history most relevant to this appeal.

The asserted patents arise out of research conducted by inventors at a company called QuantaLife, Inc. Three of the inventors—Drs. Kevin Ness, Donald Masquelier, and Benjamin Hindson³—were among the founders of QuantaLife in 2008. In 2011, Bio-Rad purchased QuantaLife for approximately \$160 million. *See* Order No. 15: Initial Determination Granting Complainants’ Motion for Summary Determination that the Doctrine of Assignor Estoppel Precludes Respondent from Challenging the Validity of the Asserted Patents, *In the Matter of Certain Microfluidic Devices*, USITC Inv. No. 337-TA-1068, 2018 WL 2003443, at *4 (Mar. 5, 2018) (“*Assignor Estoppel Opinion*”). With the purchase, Bio-Rad acquired QuantaLife’s patent rights, *see id.*, presumably including QuantaLife’s rights to provisional patent applications from which the ’664, ’682, and ’635 patents claim priority. *See* J.A. 422, 475, 512. At the time of the purchase, Drs. Ness, Masquelier, and Hindson became employees of Bio-Rad, and over the following two years they executed assignments to Bio-Rad of their rights to the applications that later issued as the ’664, ’682, and ’635 patents. *Assignor Estoppel Opinion*, 2018 WL 2003443, at *5–6.

³ Drs. Ness and Masquelier are named inventors on all three of the asserted patents. Dr. Hindson is a named inventor on the ’682 and ’635 patents.

Not long after Bio-Rad acquired QuantaLife, Drs. Hindson and Ness left Bio-Rad to start 10X, and Dr. Masquelier joined 10X shortly thereafter as its fifth employee. *Id.* at *7. 10X has developed technology and products in the field of microfluidics that are designed for use with commercial next-generation sequencing platforms, with the goal of achieving DNA and RNA sequencing at the single cell level. Drs. Hindson, Ness, and Masquelier were all “extensively involved with the design, implementation, and/or manufacture” of 10X’s products. *Id.*

III. The Accused Products

There are two accused products in this appeal. The first accused product is 10X’s commercial GEM Chips, which 10X imports and sells to the public. Bio-Rad accused the GEM Chips of infringing the following claims: claims 1, 2, 14, and 15 of the ’664 patent; claims 14, 16, and 17 of the ’682 patent; and claims 1, 13, 14, 16, and 21 of the ’635 patent. *See* J.A. 2. The GEM Chips have input wells for three different materials—gel beads, sample, and oil—and one output well to collect droplets. *See* J.A. 2309–10. The microfluidic channels on the GEM Chips intersect each other such that the gel bead and sample fluid are mixed at a first intersection, the resulting mixture enters into a microfluidic channel referred to as a “singulation channel,” and the mixture then mixes with the oil at a second intersection. *See* J.A. 2409. The GEM Chips are used in conjunction with sequencing platforms called the “Chromium™ Controller” and “Chromium™ Single Cell Controller” (collectively, “Chromium Controllers”) to prepare sample-containing droplets for DNA sequencing or other analysis. *See* Initial Determination on Violation of Section 337, *In the Matter of Certain Microfluidic Devices*, USITC Inv. No. 337-TA-1068, 2018 WL 5279172, at *26 (Sept. 20, 2018) (“*ALJ Initial Determination*”).

The second accused product is 10X’s Chip GB, which 10X imports and uses in its internal manufacturing process

but does not sell to end-user customers. Bio-Rad accused the Chip GB of infringing claims 1 and 14 of the '664 patent. *See* J.A. 46, 167. 10X utilizes the Chip GB to generate droplets that are used to make the gel beads that are packaged with the GEM Chips and sold to customers. The Chip GB contains one input well that holds an aqueous monomer solution, a second input well that holds oil, and channels from each of the wells that intersect each other to allow for the formation of droplets that are collected in a droplet well. *See* J.A. 10149. Over time, the monomers within each droplet polymerize, and the droplet becomes a gel bead. J.A. 869.

IV. Procedural History at the Commission

Bio-Rad filed its complaint on July 31, 2017, and the Commission instituted Investigation No. 337-TA-1068. On March 5, 2018, the Administrative Law Judge (“ALJ”) granted Bio-Rad’s motion for summary determination that the doctrine of assignor estoppel precluded 10X from challenging the validity of the asserted patents. *See Assignor Estoppel Opinion*, 2018 WL 2003443. The Commission determined not to review that decision. *See* Notice of Commission Determination, *In the Matter of Certain Microfluidic Devices*, USITC Inv. No. 337-TA-1068, 2018 WL 1756706 (Apr. 9, 2018).

On April 4, 2018, the ALJ issued a claim construction order. *See* J.A. 669–707. Relevant to this appeal, the order included an agreed-upon definition for “sample” as “a compound, composition, and/or mixture of interest, from any suitable source(s).” *See* J.A. 704. Also relevant to this appeal, the ALJ construed the term “droplet-generation region” to mean “the intersection of (1) a sample-containing dispersed phase fluid inlet channel, (2) a continuous phase fluid inlet channel, and (3) a droplet outlet channel.” J.A. 682.

On September 20, 2018, the ALJ issued an initial determination on Bio-Rad’s infringement allegations. *See*

ALJ Initial Determination, 2018 WL 5279172. With respect to the GEM Chips, the ALJ determined that: the GEM Chips directly infringe the asserted claims of the '664 patent, *see id.* at *46–51; the use of the GEM Chips with the Chromium Controllers directly infringes the asserted claims of the '682 and '635 patents, *see id.* at *53–68; 10X induces and contributes to its customers' direct infringement of the '682 and '635 patents, *see id.* at *70–82; and Bio-Rad met the domestic injury requirement, *see id.* at *82–87. With respect to the Chip GB, however, the ALJ held that 10X's Chip GB does not infringe claims 1 and 14 of the '664 patent (the only claims asserted against the Chip GB) because the monomer solution used by 10X in the Chip GB is not a “sample” under the parties' agreed upon construction. *See id.* at *51; J.A. 180–81.

The Commission issued its final determination on January 10, 2020. *See Commission Opinion*, 2020 WL 225020. Relevant to this appeal, the Commission reviewed the ALJ's findings regarding whether 10X indirectly infringes the '682 and '635 patents with respect to the GEM Chips, including whether 10X had the requisite knowledge for indirect infringement. *Id.* at *9. The Commission found that direct and circumstantial evidence showed that “10X had knowledge of the '682 and '635 patents at least by the filing of the complaint on July 31, 2017,” and that 10X knew or should have known that its activities would induce and/or contribute to its customers' infringement. *Id.* Also relevant to this appeal, the Commission reviewed the ALJ's findings regarding whether 10X's Chip GB infringes claims 1 and 14 of the '664 patent. *Id.* at *10–11. In all respects relevant to this appeal, the Commission adopted the ALJ's initial determination that the Chip GB does not infringe the asserted claims of the '664 patent because the monomer solution used by 10X is not a “sample.” *Id.*

After the Presidential Review Period, Bio-Rad appealed from the Commission's final determination that the Chip GB does not infringe the '664 patent. 10X appealed

from the Commission's final determination that its GEM Chips directly infringe the asserted patents and that it induces and/or contributes to its customers' infringement of the '682 and '635 patents. We consolidated the appeals in the nature of cross-appeals. We have jurisdiction under 19 U.S.C. § 1337(c) and 28 U.S.C. § 1295(a)(6).

DISCUSSION

"We review the Commission's final determinations under the standards of the Administrative Procedure Act." *Guangdong Alison Hi-Tech Co. v. ITC*, 936 F.3d 1353, 1358–59 (Fed. Cir. 2019); *see also* 19 U.S.C. § 1337(c); 5 U.S.C. § 706. The Commission's legal determinations are reviewed de novo, while its factual findings, including the factual findings it adopts from the ALJ, are reviewed for substantial evidence. *Guangdong*, 936 F.3d at 1358–59. "A finding is supported by substantial evidence if a reasonable mind might accept the evidence as adequate to support the finding." *Henny Penny Corp. v. Frymaster LLC*, 938 F.3d 1324, 1330 (Fed. Cir. 2019).

Both parties' appeals relate to patent infringement, which is a two-step analysis. *Packet Intelligence LLC v. NetScout Sys.*, 965 F.3d 1299, 1306 (Fed. Cir. 2020) (citing *Clare v. Chrysler Grp. LLC*, 819 F.3d 1323, 1326 (Fed. Cir. 2016)). The first step of the infringement analysis is claim construction, *id.*, which is an issue of law that we review de novo. *Linear Tech. Corp. v. ITC*, 566 F.3d 1049, 1054 (Fed. Cir. 2009). The second step of the infringement analysis involves a comparison of the accused product to the construed claims, which is an issue of fact that we review for substantial evidence. *See Packet Intelligence*, 965 F.3d at 1305–06. We address the parties' respective appeals in turn.

I. Bio-Rad's Appeal

We first address Bio-Rad's appeal of the Commission's determination that 10X's Chip GB does not infringe

claims 1 and 14 of the '664 patent. Bio-Rad makes two arguments. The first argument relates to the ALJ's determination that because the Chip GB does not involve a "sample," it "does not include a 'sample well,' a sample channel, sample-containing droplets, or the claimed 'droplet generation region.'" See J.A. 180. Bio-Rad's second argument is that, because the claims recite structural limitations (*e.g.*, wells and channels), infringement of the claims cannot depend on the substances inside those wells and channels. We address each argument below.

A

Turning first to the "sample" issue, the ALJ's claim construction order adopted the parties' agreed-upon construction for the term "sample," which was taken directly from the specification of the '664 patent to mean "a compound, composition, and/or mixture of interest, from any suitable source(s)." See J.A. 704; *see also* '664 patent col. 8 ll. 36–37. In applying the claim construction to the question of infringement, the ALJ found credible witness testimony demonstrating that 10X's Chip GB is used to encapsulate certain monomers within oil, and those "monomers are not a 'sample' but 'an input for a **reagent** production process.'" J.A. 179 (emphasis in original). The ALJ quoted testimony distinguishing the monomers, which "are of no interest," from a sample, which is "something that the customer cares about and wants to analyze." *Id.* The ALJ further found that this testimony was "consistent with the distinction the '664 patent makes between a 'sample' and a 'reagent.'" *Id.* The ALJ focused on the '664 patent's identification of "clinical samples such as blood and plasma, and research samples such as cultured [sic] cells or bacteria" as compared to the patent's definition of "reagent" as "a compound [sic], set of compounds, and/or composition that is **combined with a sample** in order to perform a particular test(s) on the sample." J.A. 179–80 (emphasis in original).

Bio-Rad argues that the ALJ erred as a matter of law by imposing additional implied limitations that the “sample” must be biological and that it must be “of interest” to end-user customers. According to Bio-Rad, the term “sample” in the patent is deliberately broad and not limited to biological samples or any other source, the patent is agnostic as to who must be interested in the sample, and the term “of interest” in the construction is intended only to distinguish the sample fluid (which is of interest) from the background fluid (which is not of interest). Bio-Rad contends that the ALJ’s distinction between a “sample” and a “reagent” was incorrect because the ’664 patent indicates that the same compound can be both a reagent and a sample. *See* Bio-Rad Br. at 28–29 (citing the overlap between the list of reagents and the list of analytes in the specification of the ’664 patent).

Bio-Rad also argues that the ALJ erred as a factual matter in finding that the monomer input for the Chip GB is not a sample. Bio-Rad contends that the monomer solution is “of interest” to 10X because it leads to the formation of gel beads that 10X later tests and evaluates before selling to customers. As further evidence that the monomer solution is of interest to 10X, Bio-Rad argues that 10X carefully designed the monomer solution with particular concentrations of ingredients to serve as a gel bead precursor solution. And Bio-Rad points to prior art monomer solutions used in the formation of droplets that would meet the definition of “sample” in the ’664 patent.

10X and the Commission respond that the ALJ applied the exact construction of “sample” to which the parties agreed, and that Bio-Rad’s challenge is really directed at the ALJ’s factual application of that construction to the Chip GB. 10X and the Commission argue that substantial evidence, including fact and expert testimony, supports the ALJ’s factual finding that the monomer input for the Chip GB is not a sample, but rather a reagent. 10X notes that the distinction between samples and reagents is supported

in the '664 patent, which defines a reagent as something that is “combined with a sample in order to perform a particular test(s) on the sample.” *See* '664 patent col. 9 ll. 19–21. And, 10X argues, while a particular compound could conceivably be a sample or analyte in one context and a reagent in another context, the specification does not teach that the same compound can simultaneously be both a sample and a reagent.

10X further argues that the “hallmark” of a sample in the context of the '664 patent is that there is something within it that is tested and analyzed. *See* 10X Br. at 27 (citing the '664 patent’s definition of “analyte,” which is “a component(s) or potential component(s) of a sample that is analyzed in a test”). While 10X concedes that it performs quality control testing on a small subset of droplets, it argues that the monomers are not tested or analyzed in such a way as to make them samples because “they are an already-known starting material for an already-known polymerization reaction.” *See* 10X Br. at 30. Moreover, 10X argues, because the monomer solution was carefully designed with particular concentrations of ingredients to form gel beads, the composition is known and does not need to be tested.

Under substantial evidence review, we “must affirm a Commission determination if it is reasonable and supported by the record as a whole, even if some evidence detracts from the Commission’s conclusion.” *Spansion, Inc. v. ITC*, 629 F.3d 1331, 1344 (Fed. Cir. 2010). Here, BioRad bore the burden of proving that the Chip GB contains every element of the claimed invention, including the “sample well” and other claim elements that reference a “sample.” *See Uniloc USA, Inc. v. Microsoft Corp.*, 632 F.3d 1292, 1301 (Fed. Cir. 2011). Under the applicable standard of review, we find that substantial evidence supports the ALJ’s finding, which the Commission adopted, that BioRad failed to meet its burden of showing that the monomer solution in the Chip GB is a “sample.”

The compelling factor here is the distinction between “samples” and “reagents.” The ’664 patent consistently makes clear that a sample is not a reagent, beginning with the opening sentences of the introduction section. See ’664 patent col. 1 ll. 26–31 (“Many biomedical applications rely on high-throughput assays of **samples** combined with **reagents**. For example, in research and clinical applications, high-throughput genetic tests using target-specific **reagents** can provide high-quality information about **samples**” (emphases added)). The patent goes on to list definitions that lead to the unavoidable conclusion that a compound cannot simultaneously be a sample and a reagent. For example, within the definition of “sample,” the patent states that “[a] sample is the general subject of interest for a test that analyzes an aspect of the sample, such as an aspect related to at least one analyte that may be present in the sample.” *Id.* at col. 8 ll. 37–40. Similarly, the term “analyte” is defined as “a component(s) or potential component(s) of a sample that is analyzed in a test.” *Id.* at col. 9 ll. 1–2. And the term “test” is defined as “a procedure(s) and/or reaction(s) used to characterize a sample, and any signal(s), value(s), data, and/or result(s) obtained from the procedure(s) and/or reaction(s).” *Id.* at col. 8 ll. 7–9. Thus, the patent describes a relationship between a sample, the analyte(s) it contains, and the test(s) performed to analyze it.

In contrast, the patent defines a “reagent” as “a compound, set of compounds, and/or composition that is **combined with a sample** in order to perform a particular test(s) on the sample.” *Id.* at col. 9 ll. 19–21 (emphasis added). Thus, a reagent is not a part of a sample, nor is it the same thing as a sample in the context of the patent. The ALJ’s findings reflect a correct determination that, while the term “sample” is defined broadly in the patent, the definition of “sample” is not so broad as to include reagents within its scope.

Bio-Rad is essentially asking us to broaden the term “sample” to mean any compound. But even Bio-Rad cannot dispute that the agreed-upon construction is more limited than that. Bio-Rad insists that the term “of interest” in the construction is simply to distinguish the aqueous fluid from the background fluid. But, if that were true, there are a number of broader terms in the patent that the claim could have used, including “aqueous fluid.” The actual term that the claim uses—“sample”—is undoubtedly narrower. *See, e.g., id.* at col. 14 ll. 43–46 (“‘Sample-containing’ means that the *aqueous fluid* from which the droplets are formed *contains sample* material to be analyzed for the presence of one or more target molecules.” (emphases added)). We cannot rewrite the claims to remove that narrowing limitation.

We do not believe the ALJ improperly treated the term “of interest” subjectively by requiring that the sample be of interest to any particular person (*e.g.*, an end-user customer). Rather, the ALJ applied the term “of interest” in a reasonable objective manner, consistent with the ’664 patent and as it would be understood by a person of ordinary skill in the art within the field of microfluidics. The ’664 patent discusses the value of microscopic droplets in allowing chemical reactions to be conducted and sample to be tested and analyzed within each droplet. *See id.* at col. 15 ll. 51–65. The patent further states that “[a] sample is the general subject *of interest for a test that analyzes* an aspect of the sample.” *Id.* at col. 8 ll. 37–40 (emphasis added). Thus, despite the inclusion of the phrase “of interest” in the claim construction, we find no problem of unclear subjectivity in the ALJ’s infringement analysis, which properly focused on testing that analyzes aspects of the sample.

Because we find no error in the claim construction, what remains is the second step of the infringement analysis, which turns on whether the monomer solution in the Chip GB is properly characterized as a sample or as a

reagent. We review that fact question for substantial evidence. *See Packet Intelligence*, 965 F.3d at 1305–06. The Commission adopted the reasoning of the ALJ, which relied on testimony from multiple witnesses that the monomer is a reagent and not a sample. Those witnesses focused on the fact that 10X does not analyze the monomers, but rather uses them to make the gel beads that go into reagent kits. *See* J.A. 179 (citing testimony from multiple fact and expert witnesses). We also agree with 10X that quality control testing is not the type of testing described in the patent, and it does not change the nature of the monomer. We therefore conclude that substantial evidence supports the ALJ’s finding that the monomer in the Chip GB is not a sample. Accordingly, Bio-Rad has failed to persuade us to overturn the Commission’s finding that the Chip GB does not infringe claims 1 and 14 of the ’664 patent.

B

For its second argument, Bio-Rad contends that, regardless whether the monomer solution in the Chip GB is a “sample,” the claims recite structural limitations all of which are included in the Chip GB. Bio-Rad suggests that the physical object in the claims is “a chip with three wells and interconnecting channels,” and there is no dispute that the Chip GB has those structural elements. *See* Bio-Rad Br. at 30. This argument fails for a number of reasons.

First, it is not clear that Bio-Rad raised this argument before the Commission. At its core, the argument pertains to the construction of claim terms that characterize the wells and channels that make up the structure of the chip, including the terms “sample well” and “background fluid well.” Bio-Rad was required to have presented this argument to the ALJ and is precluded from raising it for the first time on appeal. *See Interactive Gift Express, Inc. v. CompuServe Inc.*, 256 F.3d 1323, 1346 (Fed. Cir. 2001) (“As it relates to claim construction, the doctrine [of waiver] has

been applied to preclude a party from adopting a new claim construction position on appeal.”).

Even if Bio-Rad’s structural limitations argument were not waived, it fails because it is premised on rewriting the claims in an oversimplified form and removing all limitations that differentiate the recited structures from each other. This is demonstrated by Bio-Rad’s own presentation of the argument in its brief:

What is claimed in the ’664 patent is a physical object (claim 1) as well as the method of manufacturing a physical object (claim 14). . . . The physical object in question is ***a chip with three wells and interconnecting channels***.

Bio-Rad Br. at 30 (emphasis added). Bio-Rad’s summary of the claim is not remotely close to what the claim says. The claim contains more than 25 lines of text that characterize and define the features of the chip (*e.g.*, wells and channels) by differentiating them from each other based on the material (*e.g.*, sample, background fluid, or droplets) that is contained within them. *See* ’664 patent col. 43 l. 55–col. 44 l. 13; *see also* J.A. 689–90.

Inventors are masters of their claims, and the words they use to describe and claim their invention are decisive and binding. The inventors of the ’664 patent did not, as Bio-Rad suggests, seek patent protection for a broad claim to “a chip with three wells and interconnecting channels.” Nor did the inventors choose to differentiate the wells and channels from each other based on physical characteristics (*e.g.*, shape, size, depth, location, etc.). Instead, the inventors chose to characterize the wells and channels based on the material contained within them. Bio-Rad cannot escape that choice by pointing to the general proposition of law that “apparatus claims cover what a device *is*, not what a device *does*.” *See Hewlett-Packard Co. v. Bausch & Lomb, Inc.*, 909 F.2d 1464, 1468 (Fed. Cir. 1990) (emphasis in original). And we reject Bio-Rad’s argument that we should

disregard almost all of the words of the claim simply because the claim limitations are structural.

For the foregoing reasons, we affirm the Commission's determination that Bio-Rad failed to prove that the Chip GB infringes claims 1 and 14 of the '664 patent.

II. 10X's Appeal

We next turn to 10X's appeal of the Commission's determinations with respect to the GEM Chips. 10X raises two challenges. First, 10X challenges the Commission's finding that the accused GEM Chips include the "droplet-generation region" required by all asserted claims. Second, 10X challenges the Commission's findings regarding indirect infringement. We consider each challenge in turn.

A

10X primarily argues that the Commission's error regarding the "droplet-generation region" is one of claim construction. The parties agree that the term has the same meaning in each of the asserted patents. The ALJ construed the term "droplet-generation region" to mean:

the intersection of (1) a sample-containing dispersed phase fluid inlet channel, (2) a continuous phase fluid inlet channel, and (3) a droplet outlet channel.

See J.A. 682. Claim construction is an issue of law that we review de novo. *Linear Tech.*, 566 F.3d at 1054.

10X proposes that the construction of "droplet-generation region" should be:

the intersection of the sample input channel that receives the dispersed phase fluid from the sample well, the oil input channel that receives the continuous-phase or background fluid from the oil well, and the droplet outlet channel that outputs to the droplet well, at which droplets are generated.

See 10X Br. at 39–40. 10X argues that, under its proposed construction, a single channel must extend directly from the sample well to the droplet-generation region. *See id.* 10X contends that such a direct extension is consistent with the patents’ teachings that the fluid arriving at the droplet-generation region is the fluid from the input wells. 10X emphasizes that the patent specifications do not disclose any embodiments or examples in which the fluid that leaves the sample well is mixed with another fluid prior to arriving at the droplet-generation region. And 10X further contends that the ALJ failed to consider its argument that the prior art compels a narrowing construction for the term “droplet-generation region.”

Bio-Rad and the Commission first respond that 10X waived its argument that the claim requires a channel to extend directly from the sample well to the droplet-generation region by failing to propose that requirement in a timely manner before the ALJ. Indeed, Bio-Rad argues that 10X waived that argument three times—first, by failing to propose it in the parties’ Joint Claim Construction Chart; second, by failing to seek review by the Commission of the ALJ’s waiver finding; and third, by failing in its principal brief to ask this court to overturn the ALJ’s waiver finding. On the merits, Bio-Rad and the Commission argue that the intrinsic evidence demonstrates that the channels on the chip must be connected such that sample-containing fluid reaches the droplet-generation region, and that we should reject 10X’s attempt to import an additional unclaimed restriction that the connection between the sample well and the droplet-generation region must be a direct extension. Regarding 10X’s prior art argument, Bio-Rad and the Commission contend that the ALJ expressly stated that all of the arguments provided in the parties’ briefing were considered, and that the ALJ was justified in not elaborating further because 10X failed to put forth a cogent argument that the prior art compelled a narrow construction.

Turning first to the waiver issue, we are not persuaded that 10X waived its claim construction position. The construction that 10X proposes on appeal for the term “droplet-generation region” is identical to the construction it timely proposed in the parties’ Joint Claim Construction Chart. *See* J.A. 3280, 3285. 10X contends, as it did in its claim construction briefing before the ALJ and has maintained throughout the proceedings, that its proposed construction includes a requirement that the channels that intersect at the droplet-generation region must extend directly from the input wells. 10X has consistently argued that such a requirement is embodied by the fact that each channel in the patented chips is defined by what is in it, including the channel that carries the “sample-containing fluid.” Moreover, 10X’s argument is further bolstered by the inclusion in its proposal of a requirement that the channels that intersect at the droplet-generation region must “receive[]” the fluids from the input wells. We find 10X’s current claim construction position to be consistent with that reasonable interpretation of its proposed construction, which 10X has asserted since the beginning of the proceedings in this case.

We recognize that the ALJ found that 10X’s argument for a direct extension from the input well was waived because it constituted a “new construction” that “deviates significantly from the construction [10X] set forth in the Joint [Claim Construction] Chart.” *See* J.A. 687–94. And we further note Bio-Rad’s argument that, in petitioning the Commission to review the ALJ’s findings regarding the droplet-generation region, 10X did not explicitly distinguish the waiver finding from the substantive findings on the merits of claim construction. But this is not a case in which 10X is presenting a new construction on appeal that it failed to present below. *See Interactive Gift Express*, 256 F.3d at 1346 (“As it relates to claim construction, the doctrine [of waiver] has been applied to preclude a party from adopting a new claim construction position on appeal.”). Rather,

10X is presenting the exact same claim construction theory that it advanced throughout the entirety of the Commission's investigation. Moreover, 10X has consistently maintained that the ALJ's findings regarding construction of the term "droplet-generation region" are incorrect, including in its petition for Commission review of the ALJ's initial determination, *see* J.A. 2837–51, and in its briefing in this court, *see* 10X Br. at 39–54. Thus, the ALJ's findings regarding that construction, which turn on the implications of 10X's proposed construction, have been repeatedly briefed by the parties, and they remain front and center for our review now. Under these circumstances we do not find that 10X waived its claim construction arguments.

Turning to the merits of the construction of "droplet-generation region," we agree with Bio-Rad and the Commission that the ALJ correctly construed the term. Beginning with the claim language, the various claims indicate that the droplet-generation region is a location on the chip where a network of channels "intersect" or "meet." *See, e.g.*, '664 patent col. 46 ll. 1–5 ("forming a droplet generation region defined by the intersection of a first channel . . . , a second channel . . . , and a third channel"); '682 patent col. 33 ll. 34–37 ("a channel network having a first channel, a second channel, and a third channel that meet one another in a droplet-generation region"). Beyond that, each claim contains limitations regarding wells, channels, fluids, and pressure differentials, none of which justify imposing a requirement that the channels that intersect at the droplet-generation region must extend directly from the input wells.

For example, claim 14 of the '664 patent requires that the channels that intersect at the droplet generation region be "fluidically connected" with the sample well and the background fluid well, respectively. *See* '664 patent col. 46 ll. 1–5. Similarly, claim 1 of the '635 patent requires pressure differentials to drive sample-containing fluid and background fluid from the input wells to the droplet-

generation region “via” the channels. *See* ’635 patent col. 33 ll. 40–55. And claim 14 of the ’682 patent contains no limitation as to how sample-containing fluid flows from a sample well to the droplet-generation region. *See* ’682 patent col. 34 ll. 20–45.

The specifications further support the ALJ’s construction. For example, the ’664 patent states that a channel may “branch” or be “nonlinear,” *see* ’664 patent col. 13 ll. 34–35, indicating that a channel need not extend directly from the sample well to the droplet-generation region. Moreover, notwithstanding any examples disclosed in the patents, the ’664 patent defines “sample-containing” to mean that the “aqueous fluid from which the droplets are formed contains sample material to be analyzed . . . ,” *id.* at col. 14 ll. 43–50, not necessarily that the aqueous fluid from which the droplets are formed is the same fluid that is contained in the sample well. The patent continues by expressly stating that the droplets “may contain additional components other than sample material,” and that “droplet generation may be performed after the sample has been modified by mixing it with one or more reagents.” *Id.* While 10X insists that such “mixing” refers to mixing the sample-containing fluid before it enters the sample well on the chip, the patents do not contain any disclosure to that effect.

10X argues that, in construing the term “droplet-generation region,” the ALJ improperly applied claim differentiation across different patents. But the parties agreed that the term “droplet-generation region” had the same meaning across all of the asserted patents. *See* J.A. 687–88. Having agreed to that premise, 10X cannot now complain that the ALJ arrived at a construction that properly accounts for the different instances in which that term is used in the various claims.

Lastly, we reject 10X’s argument that the ALJ acted contrary to law by failing to consider its arguments based

on the prior art. On appeal, 10X does not challenge the ALJ's application of the doctrine of assignor estoppel to preclude challenges to patent validity. Instead, 10X cites case law that stands for the proposition that assignor estoppel does not limit a defendant's ability to defend itself by arguing for a narrowing claim construction in view of the state of the art. See 10X Br. at 21–23, 39, 47–54 (citing *Westinghouse Elec. & Mfg. Co. v. Formica Insulation Co.*, 266 U.S. 342, 350–51 (1924); *Hologic, Inc. v. Minerva Surgical, Inc.*, 957 F.3d 1256, 1266 (Fed. Cir. 2020)). But, in this case, the ALJ did not preclude 10X from arguing for a narrow construction based on the prior art, nor is there support for 10X's assertion that the ALJ declined to consider those arguments. Rather, the ALJ's claim construction was based on the intrinsic record, including the claims themselves, which are “of primary importance” in claim construction, as well as the specifications of the asserted patents, the specification being the “single best guide to the meaning of a disputed term.” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–15 (Fed. Cir. 2005) (en banc). We therefore do not fault the ALJ for including a statement indicating that, in the interest of brevity, the parties' less relevant arguments—*e.g.*, arguments based on prior art, which necessarily carry less weight in the claim construction analysis—were considered but not specifically addressed in the opinion.

At bottom, the ALJ's construction of the term “droplet-generation region” is consistent with the intrinsic evidence. Like the Commission, we reject 10X's attempt to impose an unclaimed limitation that requires a channel to extend directly from the sample well to the droplet-generation region. Under the ALJ's correct construction, substantial evidence supports the Commission's finding that the use of 10X's GEM chips directly infringes the asserted claims of the '664, '682, and '635 patents.

B

We finally consider the Commission's determination that Bio-Rad proved the elements of induced and contributory infringement of the '682 and '635 patents with respect to the GEM Chips. Induced infringement under 35 U.S.C. § 271(b) requires proof of underlying direct infringement, as well as proof that (1) "the defendant knew of the patent," (2) the defendant knew or should have known that "the induced acts constitute patent infringement," and (3) the defendant "possessed specific intent to encourage another's infringement." *Sanofi, LLC v. Watson Labs. Inc.*, 875 F.3d 643, 643–44 (Fed. Cir. 2017). Contributory infringement under 35 U.S.C. § 271(c) requires proof that (1) the defendant had "knowledge of the patent in suit," (2) the defendant had "knowledge of patent infringement," and (3) the accused product is not a staple article or commodity of commerce suitable for a substantial noninfringing use. *Commil USA, LLC v. Cisco Sys., Inc.*, 135 S. Ct. 1920, 1926 (2015). Because inducement and contributory infringement are issues of fact, *see, e.g., Barry v. Medtronic, Inc.*, 914 F.3d 1310, 1334 (Fed. Cir. 2019), we review the Commission's decisions for substantial evidence. *Guangdong*, 936 F.3d at 1358–59.

With respect to both inducement and contributory infringement, 10X argues that substantial evidence does not support the Commission's findings with respect to the knowledge requirements. 10X contends that the evidence showed that 10X had knowledge of patent applications and not patents, and that the inventors had an objectively reasonable belief that the use of GEM Chips would not infringe the patents. Furthermore, for contributory infringement, 10X argues that it presented evidence that the GEM Chips are suitable for substantial noninfringing uses with design-around systems.

Bio-Rad and the Commission respond that it is undisputed that 10X had knowledge of the '682 and '635 patents

at least by the filing of the complaint in this investigation, which is sufficient for indirect infringement in this case. Bio-Rad and the Commission further argue that substantial evidence supports the Commission's finding that inventors who left Bio-Rad to start 10X knew or should have known that their activities would induce and contribute to infringement of the patents. And Bio-Rad and the Commission argue that 10X's evidence of noninfringing uses relates entirely to hypothetical uses not currently available to customers.

We agree with Bio-Rad and the Commission that substantial evidence supports the Commission's findings regarding indirect infringement. 10X's various arguments attempt to distract from the reality of this case: named inventors of the asserted patents sold their company and patent rights to Bio-Rad, worked for Bio-Rad for a short time, left Bio-Rad to start a new company, and launched new products that have been determined to infringe the patents they assigned to Bio-Rad.

10X's arguments largely attack the ALJ's credibility determinations and weighing of the evidence. For example, 10X points to witness testimony that the inventors subjectively believed that their activities at 10X were different from the patented technology they had sold to Bio-Rad, but the ALJ did not find that testimony credible. The ALJ found that "[p]ertinent and persuasive evidence dating back to 2011 does not support: Dr. Hindson's claim that the ddPCR technology was different that [sic] 10X's products; his description of the technology that QuantaLife transferred to Bio-Rad; or that his subjective belief was valid." *ALJ Initial Determination*, 2018 WL 5279172, at *73. In reaching that finding, the ALJ relied on testimony from two separate witnesses demonstrating that, in response to Bio-Rad's concerns that 10X was using infringing droplet technology, Dr. Hindson repeatedly misled Bio-Rad to believe that 10X was not "using droplets." *See* J.A. 217–18. Although Dr. Hindson offered justifications for his

misleading conduct, the ALJ did not find them credible or persuasive. J.A. 219–21. 10X also points to a 2016 arbitrator’s decision regarding the overlap between QuantaLife’s products and Bio-Rad’s products, but the ALJ found that the arbitration was not germane because it did not involve the asserted patents or their scope. *See* J.A. 222. At the very least, the ALJ found that 10X was willfully blind to the fact that its technology would infringe Bio-Rad’s patents, and continued to import infringing GEM Chips and engage in infringing activities even after Bio-Rad filed its complaint. *ALJ Initial Determination*, 2018 WL 5279172, at *75–76.

Regarding noninfringing uses, the Commission found that each of 10X’s proposed design-arounds is a “hypothetical system that is not yet available to 10X’s customers.” *Commission Opinion*, 2020 WL 225020, at *10. 10X contends that this was legal error because, under the statute, contributory infringement is avoided as long as the accused product is “suitable” for noninfringing use. *See* 35 U.S.C. § 271(c). But, as the Commission noted, 10X’s argument is not consistent with our precedent, which focuses on the real way in which the accused product is made, used, and sold. *See Fujitsu Ltd. v. Netgear Inc.*, 620 F.3d 1321, 1330–31 (Fed. Cir. 2010) (holding that the fact that a user “can turn off the infringing features” does not mean there are substantial noninfringing uses); *Golden Blount, Inc. v. Robert H. Peterson Co.*, 438 F.3d 1354, 1363 (Fed. Cir. 2006) (“[I]t matters not that the assembled device can be manipulated into a non-infringing configuration, because the instructions packaged with each device teach the infringing configuration . . .”). Thus, because 10X failed to point to any real available noninfringing uses, we find no legal error in the Commission’s decision.

It is not within our purview to reweigh the evidence or to question the ALJ’s credibility determinations. *See Norgren Inc. v. ITC*, 699 F.3d 1317, 1326 (Fed. Cir. 2012) (“The responsibility of this court is not to re-weigh de novo the

evidence on close factual questions; it is to review the decision of the Commission for substantial evidence.”); *see also LNP Eng’g Plastics, Inc. v. Miller Waste Mills, Inc.*, 275 F.3d 1347, 1361 (Fed. Cir. 2001) (“This court may not reassess, and indeed is incapable of reassessing, witness credibility and motive issues on review.”). Ultimately, 10X fails to persuade us that there is a lack of substantial evidence to support the ALJ’s findings regarding induced and contributory infringement.

For the foregoing reasons, we affirm the Commission’s determinations with respect to 10X’s indirect infringement of the ’682 and ’635 patents.

CONCLUSION

We have considered the parties’ remaining arguments but we find them unpersuasive. Accordingly, the decision of the Commission is affirmed.

AFFIRMED

COSTS.

No costs.