

United States Court of Appeals for the Federal Circuit

BIO-RAD LABORATORIES, INC.,
Appellant

v.

INTERNATIONAL TRADE COMMISSION,
Appellee

10X GENOMICS INC.,
Intervenor

2020-1785

Appeal from the United States International Trade
Commission in Investigation No. 337-TA-1100.

Decided: April 29, 2021

BRIAN C. CANNON, Quinn Emanuel Urquhart & Sullivan, LLP, Redwood Shores, CA, argued for appellant. 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.

BENJAMIN S. RICHARDS, Office of the General Counsel, United States International Trade Commission, Washington, DC, argued for appellee. Also represented by

DOMINIC L. BIANCHI, WAYNE W. HERRINGTON, SIDNEY A. ROSENZWEIG.

MATTHEW D. POWERS, Tensegrity Law Group, LLP, Redwood Shores, CA, argued for intervenor. Also represented by PAUL EHRLICH, ROBERT LEWIS GERRITY, UTSAV GUPTA, DANIEL RADKE, JENNIFER ROBINSON, STEFANI SMITH; AZRA HADZIMEHMEDOVIC, SAMANTHA A. JAMESON, AARON MATTHEW NATHAN, McLean, VA.

Before TARANTO, CHEN, and STOLL, *Circuit Judges*.

TARANTO, *Circuit Judge*.

10X Genomics Inc. filed a complaint against Bio-Rad Laboratories, Inc. with the International Trade Commission, alleging that Bio-Rad's importation and sale of microfluidic systems and components used for gene sequencing or related analyses violated section 337 of the Tariff Act of 1930, 19 U.S.C. § 1337. Invoking the statute's bar on importation and sale "of articles that . . . (i) infringe a valid and enforceable United States patent," 19 U.S.C. § 1337(a)(1)(B), 10X alleged that Bio-Rad infringed certain claims of several of 10X's patents, including U.S. Patent Nos. 9,689,024, 9,695,468, and 9,856,530. The Administrative Law Judge (ALJ) determined that Bio-Rad violated the statute with respect to all three patents. Specifically, the ALJ found that Bio-Rad infringed the patent claims now at issue and also that 10X practiced the claims, the latter fact satisfying the requirement of a domestic industry "relating to the articles protected by the patent," *id.* § 1337(a)(2). In addition, the ALJ rejected Bio-Rad's defense that it could not be liable for infringement because it co-owned the asserted 10X patents under assignment provisions that two of the named inventors signed when they were employees of Bio-Rad (and its predecessor), even though the inventions claimed were not made until after the employment. The

Commission affirmed the ALJ's determinations, though it modified some of the ALJ's reasoning. We affirm.

I

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The first two of the three patents at issue on appeal, *i.e.*, the '024 patent and '468 patent, share a specification.¹ Both patents are entitled “Methods for Droplet-Based Sample Preparation.” And both list Benjamin Hindson, Serge Saxonov, and Michael Schnall-Levin as the co-inventors. On the record and arguments before us, we take as a given that the conception date for the claims at issue was no earlier than in January 2013.

The shared specification describes methods of preparing samples that can include “fragmenting molecules, isolating molecules, and/or attaching unique identifiers to particular fragments of molecules.” '024 patent, col. 1, lines 34–37. The material of interest (analyte)—which may be polynucleotides (*e.g.*, DNA segments), cells, or other material—can be subdivided into “an assembly of partitions (*e.g.*, microwells, droplets) that are loaded with microcapsules.” *Id.*, col. 4, lines 24–27. Each partition, or a microcapsule in it, may contain a sample of the analyte and a reagent, the latter of which may be a unique identifier that enables tracking partition content in further processing. *Id.*, col. 4, lines 29–44.

In one embodiment, of central importance to the present matter, “a microcapsule may be a gel bead.” *Id.*, col. 9, lines 28–34. Analytes or reagents may be coupled to the interior or to the outer surface of the gel bead. *See id.*,

¹ Before the Commission, 10X also alleged infringement of a fourth patent, U.S. Patent No. 9,644,204, but the ALJ rejected the allegation, the Commission affirmed, and 10X has not appealed that ruling.

col. 9, lines 35–42. The analytes or reagents may then be released from the microcapsule via a stimulus, or “trigger,” which take the form of, *e.g.*, chemical agents, enzymes, light, heat, or magnetic fields. *Id.*, col. 22, lines 4–21.

One example of a reagent is a “molecular barcode” that can serve as a unique identifier. *See id.*, col. 12, lines 9–14. Molecular barcodes can be used to identify and track individual molecules of (say) the nucleic acid segments. *See id.* For example, if multiple samples are analyzed simultaneously by pooling them, *see id.*, col. 12, lines 31–39, and the analytes from each sample are tagged with a barcode, analytes from different samples can be identified and tracked in the pooled sample, *id.*, col. 12, lines 36–39. “Oligonucleotide barcodes . . . may be particularly useful in nucleic acid sequencing.” *Id.*, col. 12, lines 43–44.

10X asserted independent claim 1 and dependent claims 5, 17, 19, and 22 of the '024 patent against BioRad. Claim 1 recites:

1. A method for sample preparation, comprising:
 - a) providing a droplet comprising a porous gel bead and a target nucleic acid analyte, wherein said porous gel bead comprises at least 1,000,000 oligonucleotide molecules comprising barcode sequences, wherein said oligonucleotide molecules are releasably attached to said porous gel bead, wherein said barcode sequences are the same sequence for said oligonucleotide molecules;
 - b) applying a stimulus to said porous gel bead to release said oligonucleotide molecules from said porous gel bead into said droplet, wherein upon release from said porous gel bead, a given oligonucleotide molecule from said oligonucleotide mole-

cules attaches to said target nucleic acid analyte;
and

c) subjecting said given oligonucleotide molecule attached to said target nucleic acid analyte to nucleic acid amplification to yield a barcoded target nucleic acid analyte.

Id., col. 33, line 56, through col. 34, line 7.

With respect to the '468 patent, 10X asserted independent claim 1 and dependent claims 6, 7, 9, and 21 against Bio-Rad. Claim 1 recites:

1. A method for droplet generation, comprising:

(a) providing at least 1,000,000 oligonucleotide molecules comprising barcode sequences, wherein said barcode sequences are the same sequence for said at least 1,000,000 oligonucleotide molecules, wherein said at least 1,000,000 oligonucleotide molecules are releasably attached to a bead, wherein said bead is porous;

(b) combining said at least 1,000,000 oligonucleotide molecules and a sample comprising a nucleic acid analyte each in an aqueous phase at a first junction of two or more channels of a microfluidic device to form an aqueous mixture comprising said at least 1,000,000 oligonucleotide molecules attached to said bead and said sample; and

(c) generating a droplet comprising said at least 1,000,000 oligonucleotide molecules attached to said bead and said sample comprising said nucleic acid analyte by contacting said aqueous mixture with an immiscible continuous phase at a second junction of two or more channels of said microfluidic device.

'468 patent, col. 33, line 56, through col. 34, line 9.

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