Keywords: **Assignment, inventorship (general), ownership, 19 USC §1337(a)(1)(B), infringement**

General: **A court considering a co-ownership claim of a past employer on a new invention of a past employee will refer to employment agreement language as well as whether or not the past employer's claim to contribution was publically available when an application to cover the new invention is filed.**

Bio-Rad Laboratories, Inc. v. International Trade Commission
Appeal no. 2020-1785
Fed. Cir. April 29, 2021

I. Facts

Appellant, Bio-Rad Laboratories, Inc. ("Bio-Rad") appealed findings from a US International Trade Commission ("ITC") investigation into allegations of patent infringement filed by intervenor, 10X Genomics Inc. ("10X"). At its core, this is an employer-inventor patent dispute over patents transferred to Bio-Rad at the purchase of a startup, QuantaLife, in October 2011 that employed Dr. Serge Saxonov and Dr. Ben Hindson.

When their employment began with QuantaLife, Hindson and Saxonov signed agreements that stated, "Employee shall assign to the Company . . .Employee's entire right to any IP described in the preceding subsection, . . . whether or not patentable." When Bio-Rad bought QuantaLife, Hindson and Saxonov signed new agreements "All inventions (including new contributions, improvements, designs, developments, ideas, discoveries, copyrightable material, or trade secrets) which I may solely or jointly conceive, develop or reduce to practice during the period of my employment by Bio-Rad shall be assigned to Bio-Rad).

In April 2012, both Saxonov and Hindson left Bio-Rad. By July 2012, both Saxonov and Hindson formed 10X as a competitor of Bio-Rad. 10X filed its first round of patent applications in August 2013, which includes US Patent Nos 9,689,024, 9,695,468, and 9,856,530 ("the 10X patents") in question. The 10X patents include methods for molecule barcoding, which describe that a microcapsule may be a gel bead with analytes or reagents coupled to the interior or outer surface of the gel bead. These analytes or reagents are released when triggered by chemical agents, enzymes, light, heat, or magnetic fields. Two of the 10X patents share a specification and list Saxonov, Hindson, and four other inventors. It is undisputed that the conception date for the claims is no earlier than January 2013.

After 10X began selling its products, including two called GemCode and Chromium, Bio-Rad released its own ddSEQ™ system, which used oligonucleotide molecules attached to a gel bead that release in response to an enzyme complex cleaving the gel bead.

10X filed a complaint against Bio-Rad with the ITC for patent infringement of the 10X patents, targeting the ddSEQ™ system under the Tariff Act of 1930, 19 USC §1337(a)(1)(B) which bars on importation and sale "of articles that...infringe a valid and enforceable United States Patent." During this hearing, Bio-Rad asserted an affirmative defense claiming co-ownership of the 10X patents under the employment agreements even though the inventions claimed were not made until after the employment ended with Bio-Rad. At the conclusion of the review, the Administrative Law Judge ("ALJ") determined that Bio-Rad had infringed the 10X patents and, thus, was barred from importing and selling the ddSEQ™ system under the Tariff Act. The ALJ also rejected Bio-Rad's defense that it co-owned the 10X patents.

The ITC reviewed the decision in part after Bio-Rad petitioned the negative ruling. First, the ITC determined the identified "ideas" that Saxonov and Hindson worked on while at QuantaLife and Bio-Rad did not include specifics required by the 10X patent claims at issue and focused on a different delivery vehicle means than a gel bead as claimed by the 10X patents. Second, the ITC determined that Bio-Rad failed to show any of the ideas that Saxonov and Hindson worked on when with Bio-Rad or QuantaLife remained outside the published prior art by the conception date for the patents at issue. Thirdly, the ITC clarified that the ALJ's use of the term "inventive concept" to mean "the specific arrangement of elements claimed in the asserted patents," reasoning that the inventive concept here was the combination of several elements resulting in gel beads that deliver barcodes into the droplets with nucleic acid samples, in which the barcodes are releasably attached to the gel beads. The ITC affirmed the ALJ's finding on all grounds, including the ownership issue. Bio-Rad appealed.

II. Issue

1. Did the ITC err in finding that Bio-Rad's ddSEQ™ system infringed the claims of the 10X patents?

2. Did the ITC err in finding that 10X's domestic products practice the asserted claims of one of the 10X patents (e.g., '530 patent)?

3. Did the ITC err in rejecting Bio-Rad's indefiniteness challenge to the asserted claims of one of the 10X patents (e.g., '530 patent)?

4. Did the ITC err in finding that Bio-Rad has no ownership in the 10X patents under the employment agreements with Hindson and Saxonov?

III. Discussion

1. No. The court agreed with the ITC that the claims of the 10X patents are infringed by Bio-Rad's ddSEQ™ system, finding that the ITC cited sufficient evidence to support its findings against Bio-Rad's three main arguments, one for each of the 10X patents.

'024 patent. Bio-Rad disputed the alleged infringement based on how the ddSEQ™ system's enzyme removes a portion of the oligonucleotide molecule and not some part of the gel material as referred to in the '024 patent specification. The court rejected this argument and found instead that the claim language merely required "applying a stimulus to said porous gel bead to release said oligonucleotide molecules," where "said" molecules

having only to consist of oligonucleotides that contain barcoding sequences (which may be less than the entirety of an oligonucleotide molecule). The court found that the ITC cited sufficient evidence to support its findings.

'468 patent. Bio-Rad disputed alleged infringement based on how ddSEQ™ system's nucleic-acid sample solution and reagent solution do not mix until droplets are formed. Claim 1 of the '468 patent requires both the oligonucleotide and nucleic-acid samples to be in an aqueous phase that meets at a first junction to form an aqueous mixture. On its appeal to the ITC, Bio-Rad relied on a grainy image to prove that their oligonucleotide and nucleic-acid samples mix later at a second junction to form an aqueous mixture, but the court rejected this argument, siding instead with credible testimony from 10X's expert witness. The court noted that Bio-Rad failed to produce evidence fully explaining the grainy image, and thus the court found that the ITC cited sufficient evidence to support its findings.

'530 patent. Bio-Rad argued at appeal that because barcoding begins immediately after a first droplet is formed, 10X has not proven their infringement. The court rejects this argument due to undisputed claim construction interpreting the relevant claim language to only require that, after 1,000 droplets are formed, the required barcode detachment/generation occur in each of them. As long as that occurs, the fact that barcoding of other polynucleotides also happened before 1,000 droplets were generated is irrelevant. The court found that the ITC cited sufficient evidence to support its findings.

2. No. Bio-Rad contested at appeal the ITC's determination that 10X's product comes within the asserted claims of the '530 patent and thereby satisfies the domestic-industry requirement of the Tariff Act, 19 USC §1337(2). The standard used here is essentially the same as an infringement analysis. *Alloc, Inc. v. Int'l Trade Comm'n*, 342 F.3d 1361, 1375 (Fed. Cir. 2003). The court agreed with the ITC that the claims of the 10X patents are practiced by 10X's product. The court also rejected Bio-Rad's attempts to discount evidence, such as using 10x's investor slides from 2013 as evidence of product operation in 2015 and 2016 because the investor slides had enough references to the 10X products of 2015 and 2016 to qualify. The court found the ITC cited sufficient evidence to support its findings in support of 10X practicing the 10X patents and thereby satisfies the domestic-industry requirement of the Tariff Act, 19 USC §1337(2).

3. No. Bio-Rad contested the ITC's previous rejection of its indefiniteness challenge to the asserted claims of one of the 10X patents (e.g., '530 patent). The court found that the ITC had sufficient evidence to support its rejection of the indefiniteness challenge, reminding Bio-Rad in the process that a modification of a claim construction does not imply or presumptively suggest indefiniteness and is more routine during litigation.

4. No. Bio-Rad contested at appeal the ITC's rejection of its co-ownership affirmative defense against the 10X patents. If Bio-Rad is found to be a co-owner, then it cannot also be an infringer. Bio-Rad argued its co-ownership on two grounds: 1) Bio-Rad asserted that, if Saxonov and Hindson, while working at Bio-Rad, had ideas that contributed to the post-employment inventions at issue, then the assignment provisions required assignment of their co-ownership interest to Bio-Rad; and 2) Bio-Rad asserted that Saxonov and Hindson did have co-inventorship-qualifying idea while employed at Bio-Rad (e.g., while working for QuantaLife).

The court first notes that the assignment provisions of the agreement signed by Saxonov and Hindson while working at QuantaLife suggested that the subject of the required assignment must be "intellectual property," whether or not the right is a patent, trademark, trade secret, copyright, or other form of intellectual property. Secondly, the court notes that the assignment provisions are limited temporally and to IP "that Employee conceives, develops or creates alone or with the aid of others during the term of Employee's employment with the Company." The court interpreted this as that the assignment duty of Saxonov and Hindson is limited to subject matter that itself could be protected as intellectual property before the termination of employment (even if any formal government grants needed for protection may not have been acquired).

Bio-Rad argues that Hindson and Saxonov conceived of key "ideas" of the claimed inventions, if not the entirety of the claims, at QuantaLife/BioRad. These "ideas" were tagging droplets to track a sample-reagent reaction complex, using double-junction microfluidics to combine sample and reagent, and using oligonucleotides as barcodes to tag single cells within droplets. The court considered the ITC's determination that many of these "ideas" are at a level of generality that cannot support joint inventorship or involve nothing more than elements in the already-published prior art. Moreover, the court agreed with the ITC's determination that many of Bio-Rad's "ideas" were already disclosed in a patent of Bio-Rad's and thus were part of the published prior art before the undisputed earliest January 2013 conception date of the 10X patents at issue. Furthermore, the idea of using oligonucleotides as barcodes to tag single cells was affirmatively distinguished over the gel bead methods by the specification in at least one of the 10X patents. Thus, on these grounds, the court affirmed the ITC's finding that Bio-Rad has no co-ownership claim to the 10x patents.

IV. Conclusion

The court affirmed the ITC's ruling that Bio-Rad infringed the 10X patents, violating 19 USC §1337 of the Tariff Act.

V. Appendix

Tariff Act of 1930, 19 USC §1337

(a) Unlawful activities; covered industries; definitions

(1) Subject to paragraph (2), the following are unlawful, and when found by the Commission to exist shall be dealt with, in addition to any other provision of law, as provided in this section:

(B) The importation into the United States, the sale for importation, or the sale within the United States after importation by the owner, importer, or consignee, of articles that—

(i) infringe a valid and enforceable United States patent or a valid and enforceable United States copyright registered under title 17; or

(ii) are made, produced, processed, or mined under, or by means of, a process covered by the claims of a valid and enforceable United States patent.

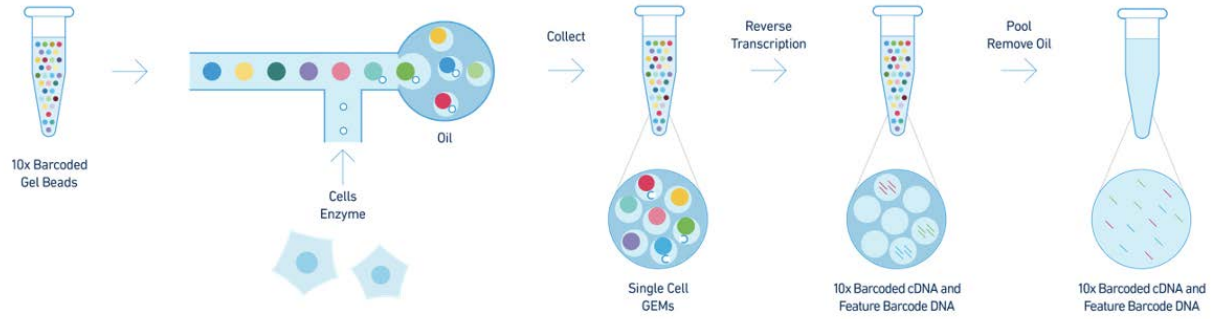
(2) Subparagraphs (B), (C), (D), and (E) of paragraph (1) apply only if an industry in the United States, relating to the articles protected by the patent, copyright, trademark, mask work, or design concerned, exists or is in the process of being established.

(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.



Sample claim from US Patent No. 9,856,530

1. A method for nucleic acid preparation or analysis, comprising:

(a) providing:

(i) at least 1,000 gel beads;

(ii) releasably attached to each of said at least 1,000 gel beads, at least 1,000 barcode molecules comprising identical barcode sequences that are distinct from barcode

sequences of at least 1,000 barcode molecules releasably attached to any other gel bead of said at least 1,000 gel beads; and

(iii) a plurality of cells each comprising a plurality of polynucleotide molecules;

(b) generating a plurality of droplets, wherein at least 1,000 droplets of said plurality of droplets each comprise:

(i) a single gel bead from said at least 1,000 gel beads; and

(ii) a single cell from said plurality of cells; and

(c) in each of said at least 1,000 droplets, using said plurality of polynucleotide molecules from said single cell and barcode molecules of said at least 1,000 barcode molecules from said single gel bead to generate a plurality of barcoded polynucleotide molecules, wherein said barcode molecules become detached from said gel bead.