IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

10X GENOMICS, INC. and THE BOARD OF TRUSTEES OF THE LELAND STANFORD JUNIOR UNIVERSITY, Plaintiffs, v. PARSE BIOSCIENCES, INC., Defendant.	CIVIL ACTION NO. 22-1117

OPINION

Slomsky, J. **February 12, 2025**

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I. INTRODUCTION

Plaintiff 10x Genomics, Inc. ("Plaintiff" or "10x") and the Board of Trustees of the Leland Stanford Junior University ("Stanford University") as a nominal defendant filed a Complaint alleging patent infringement by Defendant Parse Biosciences, Inc. ("Defendant" or "Parse").[1] (Doc. No. 1.) Six patents covering genomic technologies are alleged to have been infringed and can be separated into two categories of patents. First, the Giresi Patents: United States Patent No. 10,150,995 ("the '995 patent"); United States Patent No. 10,619,207 ("the '207 patent"); United States Patent No. 10,738,357 ("the '357 patent"). Second, the Brenner Patents: United States Patent No. 10,155,981 ("the '981 patent"); United States Patent No. 10,697,013 ("the '013 patent"); and United States Patent No. 10,240,197 ("the '197 patent").

On September 13, 2024, Defendant filed a Motion for Summary Judgment.[2] (Doc. Nos. 259, 260.) In the Motion, Defendant asserts first that it has not directly or indirectly infringed the Giresi Patents. As to the Brenner Patents, it contends that they should be found invalid because their written specification does not correlate with the claims of the patents. Plaintiffs filed a Response in Opposition to the Motion, asserting that Defendant has directly infringed the Giresi patents by using Plaintiffs' data and protocols in its own products and experiments, and indirectly infringed the same patents by advertising and potentially selling such products. (Doc. No. 271.) They further maintain that the Brenner patents are valid because their specification and claims do correlate as they both discuss the "dual tagging" method, despite the patents also referring to the "reflex" method. (Id.)

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[1] On October 7, 2022, Stanford University was realigned as a Plaintiff. (See Doc. No. 9.)

[2] Attached to Defendant's Motion for Summary Judgment is a Daubert Motion to Preclude Plaintiff's Damages Expert's Report and Testimony. (Doc. No. 260 at 24.) This Motion will be decided separately by the Court.

For the reasons set forth below, Defendant's Motion for Summary Judgment (Doc. Nos. 259, 260) will be denied.

II. FACTUAL BACKGROUND[3]

Generally, the Giresi and Brenner patents are directed to compositions and laboratory methods used to uncover genetic information that can then be used to better understand the genetic underpinnings of human life and disease. See the three (3) Brenner patents: '981 Patent, Claim 1 ("A method of analyzing nucleic acids from a plurality of single cells . . ."); '013 Patent, Claim 1 ("A method for multiplexed analysis of nucleic acids from single cells . . ."); '197 Patent, Claim 1 ("A method of counting nucleic acids in a sample . . ."); see also the three (3) Giresi patents: '995 Patent, Claim 1 ("A method for analyzing a biologic sample . . ."); '207 Patent, Claim 1 ("A method for generating a sequencing library from a plurality of cells . . ."); '357 Patent, Claim 1 ("A composition comprising: a permeabilized cell nucleus[4] comprising . . . an insertional enzyme complex . . ."). The science relevant to each group of patents will be discussed below.

A. Scientific Background

A basic overview of the relevant scientific principles is necessary to understand the patent terms at issue in this case. To begin, every cell in the human body contains chromosomes that encode genetic information. The genetic information encoded in chromosomes is comprised of deoxyribonucleic acids, or "DNA." (See '995 Patent at 8:63–9:14, 13:29–35.) DNA is a type of molecule known as a "nucleic acid" that can store genetic information. (See Defs. Slide 10.)

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[3] The Factual Background discussed in Subsection A has been adopted from this Court's prior Opinion on Claim Construction. (Doc. No. 209.)

[4] Permeabilization is the act or process of making something, such as a cell nucleus, permeable—often through use of surfactants so the cell's contents are accessible. frontiers https://www.frontiersin.org/articles/10.3389/fchem.2019.00588/full. Surfactants are substances that decrease the surface tension of a cell to make its content.

Nucleic acids such as DNA are made up of chains of smaller building blocks called nucleotides. Nat'l Human Genome Rsch. Inst. https://www.genome.gov/about-genomics/fact-sheets/Deoxyribonucleic-Acid-Fact-Sheet. A chain of nucleic acid also is referred to as a polynucleotide.[5] Each nucleotide in a polynucleotide contains one of four nitrogen bases (also known as nucleobases): 1) adenine (A); 2) thymine (T); 3) guanine (G); and 4) cytosine (C).[6] (See Defs. Slide 10.) Another type of polynucleotides is oligonucleotides, which, put simply, are small polynucleotides.[7] Stedman's Medical Dictionary 980 (24th ed. 1982).

In this case, the patents are focused on compositions and methods to differentiate between polynucleotides (such as DNA) within a large population of cells (the Brenner patents) (see Doc. No. 33 at 17; see e.g., '981 Patent at 6:33–7:22, 15:36–50) and to determine epigenetic[8] features in cells (the Giresi patents), (see Doc. No. 33 at 17; see, e.g., '995 Patent at 21:16–40).

1. The Brenner Patents

The Brenner patents refer to a group of three patents that Plaintiffs assert were infringed by Defendant: 1) the '981 patent; 2) the '013 patent; and 3) the '197 patent. The Brenner patents

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[5] All DNA strands are polynucleotides, but not all polynucleotides are DNA. Polynucleotides can also be RNA or other molecules. (See Defs. Slide 10.)

[6] In general, a polynucleotide is identified based on a sequence of the nucleobases. For example, the first letter of each base would create a sequence in a specific order. "A" would stand for adenine, "T" for thymine, "G" for guanine and "C" for cytosine. A sequence might look like the following: AATTGCCAAT etc. Given the number of polynucleotides in DNA, the number of different sequences is vast.

[7] Oligonucleotides are described as "small" polynucleotides because they contain less chains of nucleotides than other polynucleotides. See Pieczenik v. Dyax Corp., 76 F. App'x 293, 296-97 (Fed. Cir. 2003).

[8] Epigenetics is the study of "modifications to a chromosome that impact what genes are transcribed to mRNA (which can then be expressed as proteins) without changing the chromosome's DNA sequence." (Doc. No. 104 at 9.)

cover "methods for analyzing nucleic acids from single cells" through "tagging." (See '981 patent, '013 patent, '197 patent.) "Tags," which are also referred to as "molecular tags," also would have a sequence of nucleobases. Tags can then be used to identify a polynucleotide.[9] The method in the Brenner patents allows scientists to apply two "tags" to one polynucleotide. One tag would indicate the "source"[10] or, for example, the specific cell the polynucleotide is from, and the other tag would identify the polynucleotide itself. (Pl. Slide 7.) The inventors refer to both a single tag and a combination of tags attached to a polynucleotide as a "MID."[11] (See Doc. No. 104 at 16.)

Using such methods, it is possible to differentiate between vast numbers of otherwise indistinguishable polynucleotides in a sample in order to analyze it and to count the number of different polynucleotides in each cell. (Id.)

2. The Giresi Patents

As noted above, the Giresi patents refer to the other three patents that Plaintiffs allege were infringed by Defendant. This group of patents includes: 1) the '995 patent; 2) the '207 patent; and 3) the '357 patent. The Giresi patents largely improve on conventional methods used to

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[9] For example, a tag could have the sequence "ATTG," which means it is comprised of the nitrogen bases adenine, thymine, thymine and guanine.

[10] According to the '981 patent's specification, a polynucleotide's "source" could be the cell, tissue, or individual that the polynucleotide was isolated from. (See '981 patent at 6:40-44.) The '981 patent's specification states:

> For example, a nucleic acid sample may be a pool of polynucleotides derived from different sources, e.g., polynucleotides derived from different individuals, different tissues or cells, or polynucleotides isolated at different time points.

(Id.)

[11] The parties agree to the construction of "multiplex identifier (MID) sequence" as "a tag or combination of tags associated with a polynucleotide whose identity (e.g., the tag DNA sequence) can be used to differentiate polynucleotides in a sample." (Doc. No. 104 at 16.)

analyze open chromatin regions of DNA. (See, e.g., Doc. No. 1 at ¶¶ 17, 40.) Open chromatin contains regions of nucleosomes that allow access to DNA. By contrast, closed chromatin contains regions of nucleosomes where the DNA is wrapped tightly around histones[12] and is not accessible for analysis using a MID. ('995 patent at 1:26-31, 12:54-60, 17:15-17.) Thus, scientists are interested in methods to identify and use open chromatin, rather than closed chromatin.

The Giresi patents seek to "solve[] problems associated with determining what areas of the genome are available for transcription and translation into proteins—namely regions of open chromatin." (Doc. No. 33 at 18; Tr. at 104:14–105:6.) Prior methods of analyzing areas of open chromatin required a 44-step process that few people could reproduce, a large sample size and extensive time to complete. (Doc. No. 33 at 18; Tr. at 103:12–104:13.) The inventors of the Giresi patents determined that an engineered insertional enzyme, known as a "transposase," could be introduced into a cell nucleus and used to tagment[13] (i.e., cleaved and tagged in the same reaction) only the areas of open chromatin. (See Doc. No. 33 at 18; Tr. at 107:11–108:1; Tr. at 103:12–104:13.) This had never been done before and reduced the 44-step process to a two-step process. (Id.)

In the Giresi patents, the inventors introduced an engineered enzyme referred to as "Tn5 transposase" that can be inserted into cell nuclei to perform tagmentation inside the cell nucleus, that is, to tag a polynucleotide. (Tr. at 106:25–107:3; 106:8–107:20.) Previously, tagmentation could only be performed on DNA that had already been removed from the nucleus and stripped from its chromatin complex. (Tr. at 76:5–20 & Parse Slide 53.) The claims in two of the Giresi

[12] Histones are a basic form of protein found in cells.

[13] "Tagmentation" is a prior art process that cleaves and tags in the same reaction "using an insertional enzyme such as Tn5 or MuA that cleaves the genomic DNA in open regions in the chromatin and adds adaptors to both ends of the fragments." (Doc. No. 104 at 66.)

patents, the '995 and the '207 patents, are directed to new applications of the insertional enzyme complex, transposase, by inserting it into a cell nucleus to tagment DNA found in open chromatin to create tagged DNA fragments. (Doc. No. 33 at 20.) The claims in the third patent, the '357 patent, are directed toward a composition consisting of a man-made insertional enzyme complex (the transposase) and tagged nucleic acid fragments derived from regions of open chromatin located inside the nucleus of a cell. (Doc. No. 33 at 22; '357 patent, Claim 16.)

B. Procedural History

On December 7, 2023, the parties submitted a Joint Claim Construction Brief that outlined eight (8) agreed upon claim terms and five (5) disputed claim terms with the parties' proposed constructions. (Doc. Nos. 104, 105.) On March 1, 2024, the Court held a Markman hearing on the disputed terms. On May 3, 2024, this Court construed the five (5) disputed claim terms in its Opinion Resolving Claim Construction Disputes as follows:

Claim Term	**Court's Construction**
"combinational tagging"	"approach in which one MID is attached by ligation and a second MID is attached by primer extension"
"wherein at least 90 percent of said plurality of sample polynucleotides is associated with a unique second tag sequence"	"wherein at least 90 percent of said plurality of sample polynucleotides of said cell is associated with a unique second tag sequence"
"random sequences"	Plain and ordinary meaning, which is "sequences having random bases"
"digital count"	Plain and ordinary meaning, which is "a numerical count"
"adapter sequence"	Plain and ordinary meaning, which is "sequence of an adapter"

(Doc. No. 209 at 36-37.)

C. Defendant's Motion for Summary Judgment

On September 13, 2024, Defendant filed a Motion for Summary Judgment.[14] (Doc. Nos. 259, 260.) First, regarding the Giresi patents, Defendant argues that Plaintiffs have no evidence of indirect infringement because they have failed to identify any third-party that has used or performed any infringing ATAC-seq method, nor has Defendant sold any ATAC-seq product.[15] (Doc. No. 260 at 8.) Second, Defendant contends that Plaintiffs also have no evidence of direct infringement. (Id.) To this point, it asserts that although Plaintiffs reference a poster presented at the American Society of Human Genetics ("ASHG") conference showcasing Defendant's research and development work, the poster did not reveal the protocol that was used, nor was Plaintiffs' technical expert able to identify whether Defendant was using an ATAC-seq protocol.[16] (Id. at 10.) And it maintains that even if Plaintiff could prove that Defendant infringed one time in its ASHG presentation, this is still insufficient as de minimis infringement. (Id.)

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[14] The citations referenced in this Opinion utilize the ECF docket page numbers.

[15] As stated in the Complaint:

> "ATAC" is an acronym that stands for assay for transposase-accessible chromatin, and was invented by Stanford University researchers to identify transposase-accessible chromatin in a way that allowed for the simultaneous, high-throughput identification of open chromatin regions, nucleosome positioning, and regulatory motifs using sequencing technology.

(Doc. No. 1 at 6.) Plaintiffs claim that Defendants have used the ATAC-seq protocol described in the Giresi patents in their own research, experiments, and even advertised an ATAC-seq product to be placed in the marketplace.

[16] According to its website, the ASHG is an annual conference held once a year and is the "largest human genetics and genomics meeting and exposition in the world." ASHG Annual Meeting, ASHG, https://www.ashg.org/meetings/.

Regarding the Brenner patents, Defendant argues that the patents do not describe the claimed inventions as a whole, in violation of 35 U.S.C. § 112(a).[17] (Id. at 12.) Specifically, Defendant takes the position that the specification in the Brenner patents describe the "reflex" method, whereas the claims in the same patents describe the "dual tagging" method. (Id.) It supports this theory with testimony of the original inventors, Dr. Gi Mikawa and Dr. Robert Osborne, who said that their original 2009 patent application described the "reflex" method and that the specification was not about "single cell analysis or dual tagging." (Id. at 18.)

Lastly, Defendant contends that the Brenner patents are invalid for failing to claim what the inventors "regarded as" their invention, in violation of 35 U.S.C. §112(b).[18] (Id. at 21-22.) Again, Defendant argues that the Brenner patents specification and claims are different because their specification describes the "reflex" method, while their claims describe the "dual tagging" method. (Id. at 22.) Defendant reiterates that the original inventors of the patents described tagging as a prior art in their specifications, not as their own invention. (Id. at 23.)

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[17] 35 U.S.C. § 112(a) states:

> **(a) IN GENERAL.—**
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> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention.

[18] 35 U.S.C. § 112(b) states:

> **(b) CONCLUSION.—**
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> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.

D. Plaintiffs' Opposition to Defendant's Motion for Summary Judgment

On September 27, 2024, Plaintiffs filed their Opposition to Defendant's Motion for Summary Judgment. (Doc. No. 271.)

First, Plaintiffs argue that Defendant has directly infringed the Giresi patents in violation of 35 U.S.C. § 271(a).[19] Specifically, they assert that Defendant's employees testified that the data portrayed on Defendant's poster at the ASHG conference was generated using Tn5, the insertional enzyme complex used in the Giresi patents, and that this testimony shows direct infringement. (Id. at 12.) Further, Plaintiffs submit that 10x's technical expert, Dr. John Quackenbush, opined that based on the content of the poster and internal protocols he reviewed, the data was generated through an ATAC-seq protocol, thus directly infringing on the Giresi patents. (Id.) Moreover, Defendant announced in an online article its intention to launch an ATAC-seq product to directly compete with 10x Genomics. (Id. (quoting Doc. No. 273-2 (Ex. 2)).)

Second, Plaintiffs argue that Defendant indirectly infringed the Giresi patents because Defendant has not promised Plaintiffs that it would not sell the ATAC-seq product that was already advertised to the public, and that this shows an intent to infringe Plaintiffs' patents. (Id. at 18.)

Regarding the Brenner patents, Plaintiffs argue that the original patent application disclosed both the "reflex" method and the "dual tagging" method as their inventions, which are the subject of the claims in the Brenner patents. (Id. at 21-23.) Further, Plaintiffs point out that

[19] 35 U.S.C. § 271(a) states:

> (a) Except as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent.

the parties' technical experts dispute what the specifications state about the "dual tagging" method. (Id.)

Lastly, Plaintiffs contest Defendant's argument that the claims in the Brenner patents are invalid under 35 U.S.C. § 112(b) based on the "regarded as" doctrine. (Id. at 26.) Plaintiffs aver that "there is a battle of the experts over whether a person of skill in the art would understand from the specification of the Brenner patents whether the inventors were also in possession of the dual tagging invention." (Id. at 26-27.)

E. Defendant's Reply in Support of its Motion for Summary Judgment

On October 4, 2024, Defendant filed a Reply in Support of its Motion for Summary Judgment. (Doc. No. 281.) First, regarding indirect infringement of the Giresi patents, Defendant argues that Plaintiffs admit that Defendant has never sold any ATAC-seq product and merely argues that it may do so in the future. (Id. at 5-6.) It also argues that Defendant's Chief Executive Officer ("CEO") Alexander Rosenberg has stated that they did not have plans to release the ATAC-seq product, and Plaintiff has never disputed this concession. (Id.) And regarding direct infringement of the Giresi patents, Defendant argues that Plaintiffs cannot identify the data used in the ASHG poster and only speculate that the experiments infringed the patents. (Id. at 7.)

As to the Brenner patents, Defendant contends that Plaintiffs have failed to show that the "dual tagging" method for single cells is what the inventors "regarded as" their invention, because the testimony of Plaintiffs' own expert shows that tagging was not the invention of the Brenner patents but rather what the patents describe as a prior art. (Id. at 13.)

III. STANDARD OF REVIEW

Granting summary judgment is an extraordinary remedy. Summary judgment is appropriate "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). In reaching this decision,

the court must determine whether "the pleadings, depositions, answers to interrogatories, admissions, and affidavits show there is no genuine issue of material fact and that the moving party is entitled to judgment as a matter of law." Favata v. Seidel, 511 F. App'x 155, 158 (3d Cir. 2013) (quoting Azur v. Chase Bank, USA, Nat'l Ass'n, 601 F.3d 212, 216 (3d Cir. 2010)). A disputed issue is "genuine" only if there is a sufficient evidentiary basis on which a reasonable jury could find for the non-moving party. Kaucher v. Cty. of Bucks, 455 F.3d 418, 423 (3d Cir. 2006) (citing Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986)). For a fact to be considered "material," it "must have the potential to alter the outcome of the case." Favata, 511 F. App'x at 158. Once the proponent of summary judgment "points to evidence demonstrating no issue of material fact exists, the non-moving party has the duty to set forth specific facts showing that a genuine issue of material fact exists and that a reasonable factfinder could rule in its favor." Id. (quoting Azur, 601 F.3d at 216).

In deciding a motion for summary judgment, "[t]he evidence of the nonmovant is to be believed, and all justifiable inferences are to be drawn in his favor." Id. (alteration in original) (quoting Chambers ex rel. Chambers v. Sch. Dist. of Phila. Bd. of Educ., 587 F.3d 176, 181 (3d Cir. 2009)). The Court's task is not to resolve disputed issues of fact, but to determine whether there exist any factual issues to be tried. Anderson, 477 U.S. at 247-49. Whenever a factual issue arises which cannot be resolved without a credibility determination, at this stage the court must credit the nonmoving party's evidence over that presented by the moving party. Id. at 255. If there is no factual issue, and if only one reasonable conclusion could arise from the record regarding the potential outcome under the governing law, summary judgment must be awarded in favor of the moving party. Id. at 250.

IV. ANALYSIS

A. Direct Infringement of the Giresi Patents Claim

First, Defendant contends that there is no genuine dispute of material fact that Defendant did not directly infringe on the Giresi patents, in violation of 35 U.S.C. § 271. (Doc. No. 260 at 9.)

A patent is infringed when a person "without authority makes, uses or sells any patented invention, within the United States . . . during the term of the patent." 35 U.S.C. § 271(a). Plaintiff has the burden of proving infringement by a preponderance of the evidence. SmithKline Diagnostics, Inc. v. Helena Lab. Corp., 859 F.2d 878, 889 (Fed. Cir. 1988) (internal citations omitted). Generally, a patentee may prove infringement either by direct or indirect infringement. To establish liability for direct infringement, the plaintiff must show that "each and every step of the method or process was performed." Aristocrat Techs. Australia Pty Ltd. v. Int'l Game Tech., 709 F.3d 1348, 1362 (Fed. Cir. 2013). They also must be able to identify specific instances of direct infringement or show that the accused method or product necessarily infringes the patent. ACCO Brands, Inc. v. ABA Locks Mfrs. Co., 501 F.3d 1307, 1313 (Fed. Cir. 2007). Direct infringement is a strict liability offense. Commil USA, LLC v. Cisco Sys., Inc., 575 U.S. 632, 639 (2015).

Here, a genuine issue of material fact exists as to whether Defendant directly infringed on the Giresi patents. Plaintiff argues that Defendant's employees testified that the data from the American Society of Human Genetics ("ASHG") poster was generated with an insertional enzyme complex Tn5, which was used in the Giresi patents. Specifically, Plaintiffs refer to the testimony of Zeynap Sayar, a senior scientist working for Defendant, who stated that she worked on a Tn5 transposase. (See Doc. No. 271 at 12; Doc. No. 273-3 at 10:1-5.) Further, Alexander Rosenberg, Defendant's CEO, also testified that the poster derived from work that used a Tn5 transpose. (Doc.

No. 273-4 at 207:10-25, 208:1.) Plaintiffs' technical expert, Dr. Quackenbush, also testified at his deposition that Defendant was using Plaintiffs' ATAC-seq protocol in the poster. (Doc. No. 271 at 15.)

Defendant counters this evidence, arguing that the poster never disclosed the protocol that was used to generate its data. Moreover, Zeynap Sayar, the senior scientist working for Defendant, testified that she was unsure of the protocols used in generating the poster:

> To answer that question absolutely accurately, I would need to go back to each experiment that we performed in this poster and look at the protocol associated with them. As research and development goes, you make a lot of changes to protocols, so I can't tell you if we did every step exactly as it's outlined. . . .

(Doc. No. 273-3 at 34:6-12.)

Viewing these facts in a light most favorable to Plaintiffs, there is a genuine issue of material fact as to whether Defendant was using Plaintiffs' ATAC-seq protocol that was presented on the ASHG poster, thus infringing on the Giresi patents. At the summary judgment stage, the testimony provided by Defendant's scientists and its CEO does not conclusively show that it did not use the Giresi patents ATAC-seq method in its data presented at the ASHG conference. Rather, it only demonstrates that its employees were unable to confirm what method was used without reviewing the experiments and associated protocols.

Second, Plaintiffs argue that the number of times Defendant has infringed is disputed because the testimony from its CEO revealed that its employees worked on an ATAC-seq protocol through the fall 2023 and that Defendant also received inquiries from potential customers about a Parse ATAC-seq product. (Doc. No. 273-4 at 169:17-24.) Moreover, Plaintiffs assert that their expert testimony reveals Defendant's documents identified ATAC-seq protocols and experiments that would infringe the Giresi patents. But Defendant counters that Plaintiffs' expert has only speculated that an ATAC-seq protocol and work allegedly using Tn5 infringed on the Giresi

patents. Taking this evidence together, there remains a genuine dispute of material fact as to whether Defendant was directly infringing on the Giresi patents.

Alternatively, Defendant argues that if any infringement is found, it should be considered de minimis. (Doc. No. 281 at 8-9.) Courts have construed this exception narrowly and held that infringement cannot be de minimis, even if only performed for experimental purposes, where the use has "definite, cognizable and not insubstantial commercial purposes." Roche Prods., Inc. v. Bolar Pharm. Co., 733 F.2d 858, 863 (Fed. Cir. 1984); Embrex, Inc. v. Serv. Eng'g Corp., 216 F.3d 1343, 1349 (Fed. Cir. 2000). As noted by the Federal Circuit in Roche, when experimental use is used for business reasons and "not for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry," the de minimis exception is inapplicable. Roche Prods, Inc., 733 F.2d at 863.

Here, as noted above, there is a genuine dispute of material fact as to whether Defendant was using an infringing ATAC-seq protocol in the poster presented at the ASHG conference. While Defendant contends that its ASHG presentation should be considered an instance of singular infringement, a genuine dispute of material fact exists regarding if Defendant used an ATAC-seq method, created an ATAC-seq product and advertised that product to potential customers in the marketplace. Therefore, its conduct cannot fall within the narrowly construed de minimis exception at this summary judgment stage.

For these reasons, summary judgment will be denied as to Defendant's direct infringement of the Giresi patents.

B. Indirect Infringement of the Giresi Patents Claim

The Court will also deny summary judgment on Defendant's claim that there was no indirect infringement of the Giresi patents.

Liability for indirect infringement arises through the existence of direct infringement. Dynacore Holdings Corp. v. U.S. Philips Corp., 363 F.3d 1263, 1272 (Fed. Cir. 2004). To establish indirect infringement, a patent owner has available two theories: active inducement of infringement and contributory infringement. See 35 U.S.C. § 271(b)-(c).

i. Active Inducement of Infringement

Pursuant to 35 U.S.C. § 271(b), "whoever actively induces infringement of a patent shall be liable as an infringer." To show induced infringement, the patentee must establish both direct infringement and that the infringer "knowingly induced infringement and possessed specific intent to encourage . . . infringement." Toshiba Corp. v. Imation Corp., 681 F.3d 1358, 1363 (Fed. Cir. 2012) (internal quotations omitted).

Here, Defendant avers that Plaintiffs have not identified any third party who has used a Parse ATAC-seq product or performed an ATAC-seq protocol. (Doc. No. 260 at 8-9.) And it further maintains that no Parse ATAC-seq product has ever existed and its CEO has stated that Defendant has no plans to release an ATAC-seq product. (Id.; see also Doc. No. 281 at 6.) On the other hand, Plaintiff argues that Defendant has advertised an ATAC-seq product to the public, namely in the ASHG poster publishing data with an ATAC-seq method and has continued the development of an ATAC-seq product through the fall of 2023. (Doc. No. 271 at 14-18.)

Defendant's summary judgment claim as to indirect infringement will be denied because it has not met its burden of establishing that no genuine dispute of material fact exists as to whether it directly and knowingly infringed the Giresi patents. For example, a question of fact remains as to whether Defendant used infringing ATAC-seq methods in its research and presentation at the ASHG conference. From the poster, the inference arises that when a company elects to display its

data at a nationwide conference, it intends to promote its most compelling research in order to attract potential customers.

Additionally, Plaintiffs point to an article posted on April 14, 2022 on genomeweb.com, which states that Defendant planned to launch a single-cell ATAC-seq kit in the second half of 2022.[20] (Doc. No. 273-2 at 2.) The article also states these products "will help Parse compete with 10x Genomics, which already offers solutions for all of the applications Parse is pursing" and that "the ATAC-seq assay is a priority for the company and that there's already 'a lot of demand' for it." (Id.) Thus, Plaintiff has established that Defendant was aware of 10x's patented methods and that they intended to place an ATAC-seq product in the marketplace.

Defendant also argues, apparently in the alternative, that Plaintiffs' claims fail because they have only alleged that it "might indirectly infringe at some point in the future." (Doc. No. 281 at 6 (emphasis in original).) But an intent to infringe in the future as reflected, for example, in the ASHG poster and Defendant's potential ATAC-seq product, is sufficient to show active inducement. See Takeda Chem. Indus., Ltd. v. Watson Pharms., Inc., 329 F. Supp. 2d 394, 402 (S.D.N.Y. 2004) ("What is necessary is that concrete steps have been taken 'with the intent to conduct activity' that would induce infringement.") (quoting Fina Rsch., S.A. v. Baroid Ltd., 141 F.3d 1479, 1485 (Fed. Cir. 1998)).

Therefore, Plaintiffs have established that there is a genuine dispute of material fact as to whether Defendant actively induced infringement, in violation of 35 U.S.C. § 271(b).

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[20] According to its website, genomeweb.com is an independent online news organization that covers the "scientific and economic ecosystem spurred by the advent of high-throughput genome sequencing." About Us, GENOMEWEB, https://www.genomeweb.com/about-us. The specific article noted above can be found here: https://www.genomeweb.com/sequencing/parse-biosciences-expands-single-cell-product-line-global-reach.

ii. Contributory Infringement

Plaintiffs have also alleged contributory infringement. A patentee may claim contributory infringement to establish indirect infringement under 35 U.S.C. § 271(c), which provides as follows:

> Whoever offers to sell or sells within the United States or imports into the United States a component of a patented machine, manufacture, combination or composition, or a material or apparatus for use in practicing a patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use, shall be liable as a contributory infringer.

35 U.S.C. 271(c). Said differently, a patentee must show: "1) that there is direct infringement, 2) that the accused infringer had knowledge of the patent, 3) that the [method] has no substantial non-infringing uses, and 4) that the [method] is a material part of the invention." Fujitsu Ltd. v. Netgear Inc., 620 F.3d 1321, 1326 (Fed. Cir. 2010). Defendant must know its method or process was both patented and infringing. Aro Mfg. Co. v. Convertible Top Replacement Co., 377 U.S. 476, 488 (1964).

For reasons similar to those stated above, Plaintiffs' indirect infringement claim under a contributory inducement theory will survive Defendant's Motion for summary judgment. First, there remains a genuine dispute of material fact as to whether it directly infringed on the Giresi patents. Second, Defendant was aware of Plaintiffs' ATAC-seq method patent and apparently used it during its research, as noted in the genomeweb.com article, and its products were advertised to compete with 10x Genomics products. Third, Plaintiff maintains that Defendant's alleged ATAC-seq method and/or products were used to generate the same data and research as their own patented products. Lastly, the ATAC-seq is a material part of the Giresi patents and is the central dispute

between the parties. Consequently, Defendant's claim that there was no indirect inducement of the Giresi patents will be denied.

C. The Specification of the Brenner Patents

Next, Defendant contends that this Court should find the Brenner patents (the '981, '013 and '197 patents) invalid because their written specification does not describe the claimed inventions "as a[n] [integrated] whole," in violation of 35 U.S.C. § 112(a). (Doc. No. 260 at 12.) Specifically, it maintains that the Brenner patents' specification describes the "reflex" method as the invention, but their claims describe the method of "dual tagging." (Id.) Defendant further argues that this method of "dual tagging" is not what the original inventors "regarded as" the invention of the Brenner patents, in violation of 35 U.SC. § 112(b). (Id. at 22.)

Pursuant to 35 U.S.C. § 112, a patent must have a written specification that includes the following:

> (a) **IN GENERAL.**—The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention.

35 U.S.C. § 112(a).

The purpose of Section 112(a) is to allow persons of ordinary skill in the art to be able to identify what an inventor has claimed as their invention and to "ensure that the scope of the right to exclude, as set forth in the claims, does not overreach the scope of the inventor's contribution to the field of art as described in the patent specification." Reiffin v. Microsoft Corp., 214 F.3d 1342, 1346 (Fed. Cir. 2000). Therefore, to determine whether a specification contained within a patent is sufficient, "the disclosure of the application relied upon [must] reasonably convey[] to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing

date." Ariad Pharms., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1351 (Fed. Cir. 2010). This is an objective test that looks to "the four corners of the specification from the perspective of a person of ordinary skill in the art." Id.

A discussion on the difference between specifications and claims is important here. As recently stated by the Court of Appeals for the Federal Circuit:

> A claim is a numbered paragraph at the end of the patent document that "particularly point[s] out and distinctly claim[s] the subject matter which the inventor or a joint inventor regards as the invention." 35 U.S.C. 112(b); see also Corning Glass Works v. Sumitomo Elec. U.S.A., Inc., 868 F.2d 1251, 1258 (Fed. Cir. 1989). And that invention is what is described in the specification, which "contain[s] a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same." 35 U.S.C. 112(a). When the claims and specification are read together, then, the claims "define the invention to which the patentee is entitled the right to exclude." Phillips v. AWH Corp., 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc) (cleaned up). This is why the claims are "of primary importance, in the effort to ascertain precisely what it is that is patented." Merrill v. Yeomans, 94 U.S. 568, 570, 24 L.Ed. 235 (1876). In short, the claims identify the invention.

Teva Branded Pharm. Prods. R&D, Inc. v. Amneal Pharms. of New York, LLC, 124 F.4th 898, 912 (Fed. Cir. 2024).

When comparing the written specification to the claims of the patent, "the specification must present each claim as an 'integrated whole.'" Flash-Control, LLC v. Intel Corp., No. 2020-2141, 2021 WL 2944592, at *3 (Fed. Cir. July 14, 2021) (quoting Novozymes A/S v. DuPont Nutrition Biosciences APS, 723 F.3d 1336, 1349 (Fed. Cir. 2013)). The Federal Circuit has held that this inquiry is a question of fact. Id.; see also Ralston Purina Co. v. Far-Mar-Co, Inc., 772 F.2d 1570, 1575 (Fed. Cir. 1985) ("Whether the description requirement is met is a question of fact reviewable under the clearly erroneous standard.") Patents are presumed to be valid, and only if

the opposing party can show cause by clear and convincing evidence may a court find a patent invalid. Ariad, 598 F.3d at 1354.

Similarly, 35 U.S.C. § 112(b) involves whether a patent's specification correlates with its claims to present what the inventor intended the invention to be. This is known as the "regarded as" doctrine. Specifically, the statute provides:

> (b) **CONCLUSION.—** The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.

35 U.S.C. § 112(b) (emphasis added).

Under this subsection, "a patent is invalid [] if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention." Nautilus, Inc. v. Biosig Instruments, Inc., 572 U.S. 898, 901 (2014). Like its preceding subsection, § 112(b) is viewed from an objective standpoint. Id. at 908. Moreover, an inventor's subjective belief cannot be used to invalidate a patent under § 112(b). See Solomon v. Kimberly-Clark Corp., 216 F.3d 1372, 1380 (Fed. Cir. 2000) (finding that "inventor testimony, obtained in the context of litigation, should not be used to invalidate issued claims under section 112, paragraph 2").

A review of the Brenner patents' specifications and claims is necessary. First, all three patents are described as a "method for analyzing nucleic acids from single cells." (Doc. No. 1-1 at 2, 33, 65.) In the "Abstract," they are further described as "analyzing nucleic acids from single cells using methods that include using tagged polynucleotides containing multiplex identifier sequences." (Id.)

Next, the "Background of the Invention" states:

> We have previously described methods that enable tagging each of a population of fragmented genomes and then combining them together to create a 'population library' that can be processed and eventually sequenced as a mixture. . . .

(Id. at Ex. 1 at 1:27-30; Ex. 2 at 1:38-41; Ex. 3 at 27-30.)

Then, the "Summary of the Invention" contains the following description:

> Aspects of the present invention are drawn to processes for moving a region of interest in a polynucleotide from a first position to a second position with regard to a domain within the polynucleotide, also referred to as a "reflex method" (or reflex process, reflex sequence process, reflex reaction, and the like). In certain embodiments, the reflex method results in moving a region of interest into functional proximity to specific domain elements present in the polynucleotide (e.g., primer sites and/or MID). Compositions, kits and systems that find use in carrying out the reflex processes described herein are also provided.

(Doc. No. 1-1, Ex. 1 at 1:51-61; Ex. 2 at 63- 67, 1-6; Ex. 3 at 1:52-62.)

This summary is followed by descriptions of the figure drawings of the patents as well as relevant definitions. (See generally the '981, '013 and '197 patents.) After that presentation, there is a "Detailed Description of the Invention," in which the invention is described in relevant part:

> As summarized above, aspects of the present invention are drawn to the use of a 'reflex' sequence present in a polynucleotide (e.g., in an adapter structure of the polynucleotide, in a genomic region of the polynucleotide, or a combination of both) to move a domain of the polynucleotide intra-molecularly from a first location to a second location. The reflex process described herein finds use any number of applications, e.g., placing functional elements of a polynucleotide (e.g., sequencing primer sites and/or MID tags) into proximity to a desired sub-region of interest.

(Id. at Ex. 1 at 13:64-67, 14:1-6; Ex. 2 at 14:5-15; Ex. 3 at 13:64-67, 14:1-6.)

Here, the claims of the Brenner patents are slightly different from one another, but generally describe the method of "dual tagging."[21] (See Ex. 1 at 30:18-48 (the '981 patent); Ex. 2 at 30:38-

[21] For example, the '981 patent claims a method of "generating a plurality of tagged polynucleotides from the plurality of sample polynucleotides, wherein each tagged polynucleotide comprises: (i) a sequence from a sample polynucleotide of the plurality of sample polynucleotides; and (ii) a multiplex identifier (MID) sequence . . ." (Doc. No. 1-1 at 31, Claim 1(b).) The '197 patent is

67, 31:1-9 (the '013 patent); Ex. 3 at 30:15-39 (the '197 patent)). As noted above, the claims refer to both a single tag and a combination of tags attached to a polynucleotide as a multiplex identifier ("MID"). (Id.)

i. Defendant's Motion for Summary Judgment as to the Validity of the Brenner Patents Under 35 U.S.C. § 112(a) Will Be Denied

Defendant contests that the Brenner patents' specification correlates with their claims. Specifically, it argues that the specification describes the "reflex" method, which is a method of breaking up long DNA sequences into smaller segments and then later bringing them together in order to create a longer DNA sequence. (Id.) But Defendant claims the Brenner patents have nothing to do with the "reflex" method, but instead discuss the method of "tagging of nucleic acids from a single cell with two tags, where the first tag tracks the cell the molecule came from, and the second tag distinguishes the molecule from other molecules in the cell." (Doc. No. 260 at 13-14.) It attests that this method, known as "dual tagging," is not contained within the description of the Brenner patents. (Id.) It further argues that tagging is only mentioned as a prior art method in the patents, not as the invention. (Id.) Put differently, Defendant contends that the written descriptions of the Brenner patents only discuss the "reflex" method, whereas their claims discuss the "dual tagging" method.

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similar but instead each tagged polynucleotide comprises of: "(i) a sample sequence from a sample polynucleotide of the plurality of sample polynucleotides; (ii) a first tag sequence distinguishing said sample polynucleotide from sample polynucleotides from other cells; and (iii) a second tag sequence distinguishing said sample polynucleotide from other sample polynucleotides from said cell." (Id. at 94, Claim 1(b).) The '013 patent claims a method of "performing combinatorial tagging to generate a plurality of tagged polynucleotides from said plurality of sample polynucleotides and a plurality of oligonucleotide tags . . . ." (Id. at 62, Claim 1(b).)

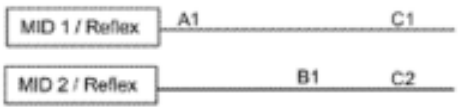
Here, there are genuine disputes of material fact as to whether the written specifications of the Brenner patents describe the "dual tagging" method. Plaintiffs argue in opposition that the Brenner patents' specification discusses not only the "reflex" method, but also the "dual tagging" method. In this regard, Plaintiffs first rely on the testimony of their technical expert, Dr. Quackenbush, who notes that although the "reflex" method is one of the inventions of the Brenner patents, it is not the only one. (Doc. No. 274-2 at ¶ 43.) In his expert report, he opines that the "specification confirms the MID is inventive and was the key aspect to the reflex method," thus supporting the notion that the "dual tagging" method is referred to in the patents' specification. (Doc. No. 274-2 at ¶ 42.) Plaintiffs also reference numerous excerpts from the specification which they argue describe the "dual tagging" method through the use of MIDs. (Id. (referencing columns 6-7, 14-15, and 22-23 of the Brenner patents).) For example, one section of the specification states:

> In one exemplary embodiment, a large collection of sequences is tagged with MID such that each polynucleotide molecule in the sample has a unique MID. In other words, each polynucleotide in the sample (e.g., each individual double stranded or single stranded polynucleotide) is tagged with a MID that is different from every other MID on every other polynucleotide in the sample. In general, to accomplish such molecular tagging the number of distinct MID tags to be used should be many times greater than the actual number of molecules to be analyzed. This will result in the majority of individual nucleic acid molecules being labeled with a unique ID tag (see, e.g., Brenner et al., Proc. Natl. Acad. Sci. USA. 2000 97(4): 1665-70). Any sequences that then result from the reflex process on that particular molecule (e.g., as described above) will thus be labeled with the same unique MID tag and thus inherently linked. Note that once all molecules in a sample are individually tagged, they can be manipulated and amplified as much as needed for processing so long as the MID tag is maintained in the products generated.
>
> For example, we might want to sequence one thousand viral genomes (or a specific genomic region) or one thousand copies of a gene present in somatic cells. After tagging each polynucleotide in the sample with a sequencing primer site, MID and reflex sequence (as shown in the figures and described above), we use the reflex process to break each polynucleotide into lengths appropriate to the sequencing procedure being used, transferring the sequencing primer site and MID to each fragment (as described above). Obtaining sequence information from all of the reflex-processed samples can be used to determine the sequence of each individual polynucleotide in the starting sample, using the MID sequence to defining linkage relationships between sequences from different regions in the polynucleotide being

> sequenced. Using a sequencing platform with longer read lengths can minimize the number of primers to be used (and reflex fragments generated).

(Doc. No. 1-1, Ex. 1 at 22:48-67, 23:1-17; Ex. 2 at 22:57-67, 23:1-27; Ex. 3 at 22:48-67, 23:1-17.)

Second, Plaintiffs assert that Figure 5 in the Brenner patents' specifications describes "dual tagging" as a means to overcome the disadvantages of the prior art. (Doc. No. 271 at 21.) They maintain that Figure 5 shows two MIDs, "one to track the molecule itself and one to track the cellular origin of the molecule," supporting their argument that "dual tagging" is described in the specification. (Id.) And Dr. Quackenbush further opines that this specification correlates with some of the patents' claims that are "routine and conventional, such that persons of skill reading the specification would understand how to integrate those features described in the specification into the disclosed embodiments, including Figure 5, such that no further description was necessary to show possession of the invention." (Id. at 24.) Figure 5 is depicted in relevant part as such:



(See Doc. 1-1 at 8, 39, 71.) Regarding Figure 5, Dr. Quackenbush also stated the following:

> Figure 5 contrasts the prior art methods of analysis against the approach of the disclosed inventions, which uses MIDs and the reflex method, for two nucleic acids originating from two different sources, such as two individual cells. Id. at 1:38-44; 23:18-32; Mikawa Dep. Tr. at 167:17-169:23, 177:7-14 (describing Figure 5 and stating "you can say DNA 1 and DNA 2 are coming from a single cell 1 and 2"); Osborne Dep. Tr. at 195:3-197:18 (describing Figure 5). On the left side of Figure 5, using prior art methods, the two nucleic acids are fragmented, which is required for NGS and then sequenced. '981 Patent at Fig. 5. While the polymorphisms from the two nucleic acids are identified by this approach, there is no way to identify which polymorphism came from which nucleic acid, and whether a single nucleic acid had 1, 2, or 3 of the polymorphisms identified. '981 Patent at Fig. 5. The inventions solved this linkage issue, as demonstrated by the right-hand side of Figure 5 [above]. By tagging the nucleic acids with a MID and then carrying the MID across each nucleic acid fragment using the reflex method, the sequenced fragments can be linked to the nucleic acid from which it was derived. While Figure

> 5 is a simplified depiction, persons of skill reviewing Figure 5 in the context of the disclosures would understand that the MID can include a tag that traces the nucleic acids to their cell of origin, and include a second tag to distinguish among the nucleic acids from that same cell.

(Id.)

And Plaintiffs further argue that because Figure 5 includes the use of MIDs, which has been defined in the specifications as using a "combination of tags," the methodology of "dual tagging" is therefore discussed in the Brenner patents. Specifically, MIDs are defined in the patents as:

> "Multiplex Identifier" (MID) refers to a tag or combination of tags associated with a polynucleotide whose identify (e.g., the tag DNA sequence) can be used to differentiate polynucleotides in a sample. In certain embodiments, the MID on a polynucleotide is used to identify the source from which the polynucleotide is derived. For example, a nucleic acid sample may be a pool of polynucleotides derived from different sources (e.g., polynucleotides derived from different individuals, different tissues or cells, or polynucleotides isolated at different time points), where the polynucleotides from each different source are tagged with a unique MID. As such, a MID provides a correlation between a polynucleotide and its source. In certain embodiments, MIDs are employed to uniquely tag each polynucleotide in a sample.

(Doc. No. 1-1, Ex. 1 at 6:33-47; Ex. 2 at 6:41-55; Ex. 3 at 6:33-47.) MIDs are further stated to be generated in many ways including "by a combination tagging approach in which one MID is attached by ligation and a second MID is attached by primer extension." (Id. at Ex.1 at 7:15-19; Ex. 2 at 7:23-27; Ex. 3 at 15-19.)

Defendant's technical expert, Dr. Gregory Cooper, contests Dr. Quackenbush's findings. Instead, he opines that Figure 5 does not evidence "dual tagging," and only shows an embodiment of the "reflex" method in order to "overcome[] the [patents'] shortcomings in prior art sequencing technologies." (Id. at ¶ 436.) For this reason, Dr. Cooper does not believe the MIDs in Figure 5 relate to the "dual tagging" method but rather describes it as a depiction of the reflex process.

Therefore, to this point, a genuine dispute of material fact remains as to whether the specification, including Figure 5, discusses the method of "dual tagging."

Despite this factual impediment to the Defendant's request for summary judgment, it also posits that Dr. Yoshikazu Gi Mikawa and Dr. Robert Osborne, the original inventors of the Brenner patents, testified that their patent application described the "reflex" method and was not about single cell analysis or "dual tagging." (Id. at 17-18.) Defendant references Dr. Mikawa's testimony where he stated that Figure 5 does not refer to single cells:

> Q: [I]s there any disclosure in any of your 197, 013 or 981 patents that you can remember of how to isolate that material from the single cells for the sequencing?
>
> A: It doesn't say anything, I think.
>
> Q: All right, now finally at the end you were asked about figure 5 of your provisional. Figure 5 of your provisional, that does not refer to single cells; right?
>
> A: No. It's just example.
>
> Q: All right. Thank you.
>
> A: Or maybe you can say DNA 1 and DNA 2 are coming from a single cell 1 and 2.
>
> Q: Okay, well, Figure 5 doesn't say that, does it?
>
> A: No.

(Doc. No. 262-9 at 177:2-17.)

Defendant maintains that after 10x purchased the Brenner patents, it changed the title and abstract of the patents and filed new claims unrelated to the "reflex" method as portrayed by the original inventors and rather focused on a "dual tagging" system. (Doc. No. 271 at 20.) Plaintiffs counter this argument by also citing the original inventors' testimony where they stated that their invention relates to the MID and molecular analysis in single cells. For example, Dr. Mikawa testified:

Q: What would you say is the invention in the 197, 013 and 981 patents?

A: The invention is a reflex mechanism, and together with MID.

Q: And the idea of a MID, was that something that was known in the prior art before the reflex method –

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A: That I don't know.

(Doc. No. 273-16 at 85:14-24.) And again, Plaintiffs dispute the inventor's interpretation of Figure 5 and reiterates that Dr. Quackenbush stated the claimed invention included "dual tagging."

Taking all this evidence together, there are genuine disputes of material fact as to whether the specifications adequately describe the patented claims. While the Brenner patents do describe the "reflex" method, Plaintiffs have presented material facts to show that the patents also describe the "dual tagging" system as the invention, and Plaintiffs' and Defendant's experts even dispute the same. Thus, the Court finds that Defendant has not met its burden at the summary judgment stage to show that there is no genuine dispute of material fact that the Brenner patents are invalid for a lack of written description that coincides with its claims under 35 U.S.C. § 112(a).

Therefore, summary judgment will be denied as to this claim on the Brenner patents.

ii. Defendant's Motion for Summary Judgment as to the Validity of the Brenner Patents Under 35 U.S.C. § 112(b), the "Regarded As" Provision, Will Be Denied

Lastly, Defendant argues that "dual tagging" was not "regarded as" the invention in the Brenner patents' specification, in violation of 35 U.S.C. § 112(b). (Doc. No. 260 at 22.)

On this issue, the parties dispute whether tagging is referenced only as a prior art or included within the invention. Defendant argues that the original inventors stated in the "Background of the Invention" that: "We have previously described methods that enable tagging each of a population of fragmented genomes and then combing them together to create a

'population library' that can be processed and eventually sequenced as a mixture." (Doc. No. 260 at 23-24 (emphasis in original) (quoting Doc. No. 1-1, Ex. 1 at 1:26-29).) It further cites other areas in the specifications where the method of tagging using MIDs is discussed, and maintains that it is solely characterized as a prior art. (Id. at 24.) Further, Defendant argues that Dr. Quackenbush also stated that "the idea of using tags was routine and conventional," which suggests that the method of tagging was not the invention. (Id. (quoting Doc. No. 262-2 at 170:8-16 (Ex. B)).) Thus, Defendant contends that the inventors only regarded the "reflex" method as their invention in the Brenner patents. (Id.)

Plaintiffs, however, dispute this notion and aver that there is a genuine dispute of material fact as to whether a person of skill in the art would understand from the specification whether the inventors regarded "dual tagging" as part of their invention. (Doc. No. 271 at 26-27.) Dr. Quackenbush opined that the specification described the "dual tagging" method as the use of two tag sequences for single cell analysis, which he maintains is the claimed invention. (Id.) And again, Dr. Quackenbush stated in his report that "[w]hen combining the disclosure of Figure 5 with the knowledge of a skilled artisan and the use of routine and conventional method like ligation, a [person of ordinary skill in the art] would have understood that the inventors possessed what they claimed." (Doc. No. 274-2 at ¶ 352.)

For reasons similar to those stated above, there are genuine disputes of material fact as to whether the specification in the Brenner patents adequately describes the patented claims, namely "dual tagging," and whether a person skilled in the art would regard "dual tagging" as part of the invention. Defendant asserts that the patents' specification only describes the method of tagging as a prior art, but Plaintiffs offer countervailing expert testimony that "dual tagging" was part of the invention. Thus, a question of fact remains as to whether a person of skill in the art would

understand whether the inventors regarded "dual tagging" as part of their invention based on the Brenner patents' specification. Accordingly, Defendant has failed to show at the summary judgment stage that the Brenner patents are invalid in this regard.

V. CONCLUSION

For the above-stated reasons, Defendant's Motion for Summary Judgment (Doc. No. 259, 260) will be denied. An appropriate Order follows.