

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

10X GENOMICS, INC. and PRESIDENT AND
FELLOWS OF HARVARD COLLEGE,

Plaintiffs,

v.

VIZGEN, INC.,

Defendant.

C.A. No. 22-595-MFK

REDACTED - PUBLIC VERSION
(Filed November 12, 2024)

VIZGEN, INC.,

Counterclaim-Plaintiff,

and

PRESIDENT AND FELLOWS OF HARVARD
COLLEGE,

Counterclaim-Plaintiff as to certain
claims,

v.

10X GENOMICS, INC.,

Counterclaim-Defendant as to certain
claims,

and

PRESIDENT AND FELLOWS OF HARVARD
COLLEGE,

Counterclaim-Defendant as to certain
claims.

**VIZGEN, INC.’S OPENING BRIEF IN SUPPORT OF ITS MOTIONS FOR SUMMARY
JUDGMENT AND TO EXCLUDE EXPERT TESTIMONY UNDER *DAUBERT***

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I. INTRODUCTION AND SUMMARY OF ARGUMENT

Defendant Vizgen, Inc. (“Vizgen”) respectfully moves for summary judgment of: (1) no foreign damages based on Vizgen’s sales of the MERSCOPE® platform outside the U.S.; (2) no direct or indirect infringement, and thus no damages, based on the sales of MERSCOPE® products to non-profits; (3) invalidity of U.S. Patent Nos. 11,021,737 (the “’737 Patent”), 11,293,051 (the “’051 Patent”), 11,293,052, and 11,549,136 (the “’136 Patent”) (collectively, the “TOSS Patents”) for lack of enablement and written description under 35 U.S.C. § 112.

Vizgen also moves to exclude: (1) the opinions of 10x Genomics, Inc.’s (“10x”) technical expert, Dr. John Quackenbush, and damages expert, Julie Davis, relating to damages that are based on arbitrary methodology and lack scientific reasoning; and (2) the opinions of President and Fellows of Harvard College’s (“Harvard”) expert, Rebecca Eisenberg, which are based on improper legal conclusions, rather than appropriate factual or technical analysis.

II. VIZGEN’S MOTIONS FOR SUMMARY JUDGMENT

Vizgen respectfully requests summary judgment on patent damages and invalidity issues.

A. 10x is not Entitled to Damages for Vizgen’s Foreign Sales

10x’s attempt to include Vizgen’s foreign sales in its damages theory should be rejected as a matter of law. 10x contends its royalty base should include revenue from non-infringing sales of the MERSCOPE® platform to distributors and customers outside the United States because “Vizgen’s domestic infringement enables Vizgen’s profits from conduct of its distributors and customers abroad.” SOF ¶ 1. To support this theory, 10x’s damages expert Julie Davis offers conclusory statements about Vizgen’s testing of MERSCOPE® and performance of “Proof of Principle” (“PoP”) studies in the United States. SOF ¶¶ 2-3; *see also* Ex. 2 (Davis Op. Rep.) at 24. At no point, however, does Ms. Davis establish causation between Vizgen’s testing or PoP studies in the United States and foreign sales of MERSCOPE®. *See id.* [REDACTED]

[REDACTED]

In *Brumfield v. IBG LLC*, the Federal Circuit recently clarified the “minimum requirement for a patentee seeking reasonable-royalty damages based on foreign conduct that is not independently infringing.” 97 F.4th 854, 877 (Fed. Cir. 2024). The Court explained:

If the patentee seeks to increase that amount by pointing to foreign conduct that is not itself infringing, the patentee must, at the least, show why that foreign conduct increases the value of the domestic infringement itself—because, *e.g.*, the domestic infringement enables and is needed to enable otherwise-unavailable profits from conduct abroad—while respecting the apportionment limit that excludes values beyond that of practicing the patent. This kind of causal connection, framed in terms of the agreement-to-pay aspect of a hypothetical negotiation, is a necessary beginning—we need not here say it is sufficient—for a foreign-conduct analysis in a reasonable-royalty case.

Id. *Brumfield* affirmed the exclusion of a damages opinion that had “no focused, coherent explanation of the required causal connection to domestic infringement.” *Id.* at 880-81.

Here, Ms. Davis’s opening report contains two conclusory paragraphs regarding inclusion of foreign MERSCOPE® sales in the royalty base. Ex. 2 (Davis Op. Rep.) at 24-25. The first of the two paragraphs states:

[REDACTED]

Id. at 24. When asked about this conclusion and the materials cited in support, Ms. Davis disclaimed the statement as her opinion and stated she was referring to [REDACTED]

[REDACTED] Ex. 3 (Davis Tr.) at 100:17-101:11; 99:17-100:16. And when asked about the PoP studies discussed in the second paragraph, Ms. Davis conceded that [REDACTED]

[REDACTED] *Id.* at 102:1-24.

[REDACTED] Despite this, Ms. Davis did not demonstrate that foreign sales in her royalty base were connected to any PoP studies

performed in the United States and that the PoP studies were necessary for foreign sales. Because 10x has failed to establish any causal link between foreign and domestic activity, summary judgment excluding foreign sales from 10x's royalty base should be granted.

Moreover, to the extent the Court grants Vizgen's motion for summary judgment that 10x has failed to prove it is entitled to foreign damages under *Brumfield*, Ms. Davis's opinions relating to foreign damages should also be excluded.

B. Vizgen Sales to Academic and Non-Profit Customers are Noninfringing and Thus Should be Excluded From Damages

[REDACTED]

[REDACTED] Accordingly, academic and non-profit users of Vizgen's accused MERSCOPE® products cannot be direct infringers, and Vizgen cannot be liable for sales to those customers. [REDACTED]

[REDACTED]

10x contends that Vizgen's customers, users, and service providers directly infringe the Asserted Claims by using MERSCOPE® as instructed, and that Vizgen is liable for induced or contributory infringement under 35 U.S.C. §§ 271(b) and 271(c). SOF ¶ 5. This assertion is wrong because [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

constitute direct infringement because *sales* of products capable of performing the patented methods do not constitute *direct* infringement of method claims. *See Joy Techs., Inc. v. Flakt, Inc.*, 6 F.3d 770, 773, 774-75 (Fed. Cir. 1993); *Packet Intel. LLC v. NetScout Sys., Inc.*, 965 F.3d 1299, 1314 (Fed. Cir. 2020). Moreover, Vizgen’s sales of MERSCOPE® products to non-profits do not constitute *indirect* infringement because [REDACTED]

[REDACTED]—as a matter of law—the use of a patented method pursuant to a license does not constitute direct infringement. *See Carnegie Mellon*, 890 F. Supp. 2d at 608; *Met-Coil*, 803 F.2d at 687. There is no basis for liability or damages for MERSCOPE® sales to non-profits.

C. The TOSS Patents Asserted Claims are Invalid Under 35 U.S.C. § 112

The TOSS Patents Asserted Claims¹ are invalid for lack of enablement and written description because their shared specification (“Common Specification”) does not provide support for and/or adequately describe the full scope of the claims, including failing to disclose *in situ*, multiplexed detection of the full range of claimed analytes.

1. The TOSS Patents Asserted Claims Lack Enablement

A patent’s specification must describe the invention and “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 . . . to make and use the same.” 35 U.S.C. § 112. The Supreme Court reaffirmed in *Amgen Inc. v. Sanofi* that “the specification must enable the full scope of the invention as defined by its claims[,]” allowing for “a reasonable amount of experimentation.” 598 U.S. 594, 610-12 (2023). “Enablement is a question of law based on underlying factual findings,” which courts can resolve on summary judgment. *Baxalta Inc. v. Genentech, Inc.*, 81 F.4th 1362,

¹ Claims 18, 21, 23, 47 and 48 of U.S. Patent No. 11,021,737; claims 3, 26, 38, 67, 77, 85 and 96 of U.S. Patent No. 11,293,051; claims 26, 35, 60, and 73 of U.S. Patent No. 11,293,052; and claims 7 and 28 of U.S. Patent No. 11,549,136. SOF ¶ 15.

1365, 1367 (Fed. Cir. 2023) (affirming summary judgment of no enablement).²

Here, the Asserted Claims broadly cover analysis of a wide range of molecular analytes in samples. All of the TOSS Patents Asserted Claims recite identifying an “analyte” in a “cell or tissue sample.” SOF ¶ 16. The Court construed “analyte” to mean “the molecule detected, identified or measured by binding of a detection reagent whose probe reagent(s) recognize it (i.e., are specific binding partners thereto).” D.I. 327 at 23. The Common Specification further states that an “analyte” can be a “nucleic acid, peptide, a polypeptide/protein . . . a lipid, a carbohydrate, a glycoprotein, a glycolipid, a small molecule, or organic monomer, sugar, peptidoglycan, a cell, a virus or a drug.” SOF ¶ 17. The Court did not otherwise narrow the scope of “analyte” or construe “cell or tissue sample” during claim construction. *See generally* D.I. 327.

This breadth—the fact that the TOSS Patents claim the detection of a vast number of molecular “analytes” in a cell or tissue sample—is not enabled for the simple reason that the TOSS Patents do not disclose *how* that detection occurs. The Common Specification contains only one example corresponding to an actual experiment, “Example 1: Exemplary Hybridization-Based Detection Methods of Detection Reagents.” SOF ¶ 24. Example 1 involves analyzing “a sample comprising *C. albicans*” (a species of yeast) in a solution. SOF ¶ 25 (listing *Candida albicans* among “[f]ungal infectious agents which can be detected”). The TOSS Patents simply have no discussion to enable the *full scope* of “analytes,” which as explained above includes any

² There are eight *Wands* factors related to assessing enablement: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988). *Amgen* did not require a factor-by-factor analysis under *Wands*, and the Federal Circuit has confirmed that “[w]e do not interpret *Amgen* to have disturbed our prior enablement case law, including *Wands* and its factors.” *Baxalta*, 81 F.4th at 1367.

“molecule” corresponding to broad categories ranging from nucleic acids to carbohydrates, cells, or viruses. This is because Example 1 identifies only one analyte: [REDACTED]

[REDACTED] Ex. 16 (Satija Rep.) ¶ 265. “If a patent claims an entire class of processes, machines, manufactures, or compositions of matter, the patent’s specification must enable a person skilled in the art to make and use the entire class.” *Amgen*, 598 U.S. at 610. For that reason, the Supreme Court confirmed that a patent enabling only 26 antibodies failed to enable “a ‘vast’ number of additional antibodies.” *Id.* at 613; *see also Baxalta*, 81 F.4th at 1366 (affirming lack of enablement for “*millions* of potential candidate antibodies”). The same situation exists here: the patents claim a broad scope of an “analyte,” but (at best) enable only one. Because the full scope of the claims is not enabled, the TOSS Patents Asserted Claims are invalid.

Dr. Satija, 10x’s expert, asserts that “the specification teaches specific types of probes that can be used to detect each type of analyte.” SOF ¶ 26. However, that disclosure does not overcome the enablement issue because it merely recites a laundry list of potential probes, and one of ordinary skill in the art would need “to pick and choose” the appropriate probe for a given analyte without any guidance. *See* Ex. 18 (Metzker Reply Rep.) ¶ 245. 10x’s expert also states that enablement occurs because the number of “predetermined subsequences” needed to design the proper probes “is a function of the degree of multiplexing and available colors.” SOF ¶ 27. Again, this broad statement does not enable the claims. The Common Specification states that “the nucleic acid label or nucleic acid tag can comprise **any number** of pre-determined subsequences”—up to 70 “or more”—which again provides no guidance for how the number of probes relates to the number of nucleic acid labels. Ex. 13 (’051 Patent) at 37:23-25, 37:34-36 (emphases added).

Moreover, the TOSS Patents Asserted Claims are not enabled because they fail to teach the required methods *in* a cell or tissue sample. Example 1 only involves “[a] solution suspension

of streptavidin-coated Dynabeads” to detect an antigen *on* the surface of yeast cells—not *in* the cell or tissue sample, as the claims require. Ex. 12 (’737 Patent) at 80:52-58. 10x’s expert claims (without support) that [REDACTED]

[REDACTED] Ex. 16 (Satija Rep.) at p. 106, ¶ 267. But this is merely a conclusory and incorrect summary that does not explain how the example enables the claimed “in a cell or tissue sample.”

In addition, 10x’s expert attempts to show enablement by re-defining and narrowing the term “in a cell or tissue sample” to [REDACTED]

[REDACTED] SOF ¶ 21. This argument is flawed and contradicted by his own admission that *in situ* that requires preserving an analyte’s [REDACTED]

[REDACTED] For example, Dr. Satija now opines that [REDACTED]

[REDACTED]

SOF ¶¶ 19-20 (defining “*in situ*” as “at the physical location where those analytes exist within a cell or tissue sample”) (emphasis added). During claim construction, no party requested construction of “cell or tissue sample,” and the Court’s claim construction order lacks any such definition. *See generally* D.I. 327. These new definitions are also incorrect because the Asserted Claims do not recite “*in situ*” and are not limited to such applications. However, even under Dr. Satija’s re-defined criteria, Example 1 is not an *in situ* experiment, and therefore would not enable the claims.

The TOSS Patents Asserted Claims also are not enabled because the Common Specification fails to teach high multiplexed detection of analytes in a cell or tissue sample, including at the level achieved by Vizgen’s MERSCOPE® platform as accused by 10x. As

explained above, Example 1 identifies only one analyte: “an extracellular analyte of a yeast cell.” Ex. 16 (Satija Rep.) ¶ 265. 10x’s expert did not, and could not, identify a working example of multiplexed detection of analytes in a cell or tissue sample in the Common Specification.

2. The TOSS Patents Asserted Claims Lack Written Description

The written description requirement is separate and distinct from enablement and depends on “whether the disclosure of the application relied upon reasonably conveys 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) (en banc). The Federal Circuit has explained that “an adequate written description” of a genus “requires a precise definition, such as by structure, formula, chemical name, physical properties, or other properties, of species falling within the genus sufficient to distinguish the genus from other materials.” *Id.* at 1350. Patent claims reciting a large functional genus require sufficiently representative description. *See Juno Therapeutics, Inc. v. Kite Pharma, Inc.*, 10 F.4th 1330, 1336 (Fed. Cir. 2021) (granting JMOL of invalidity where claims “cover an enormous number (millions of billions) of scFv candidates” and the patent “discloses neither representative species nor common structural features of the claimed scFv genus to identify which scFvs would function as claimed”).

Here, as explained above, the TOSS Patents Asserted Claims are broadly directed to a functional genus: identification of an “analyte” based on its binding to a “detection reagent.” *E.g.*, Ex. 12 (’737 Patent) cl. 18. A “sufficient description of a genus,” such as the claimed “detection reagent,” “requires the disclosure of either a representative number of species falling within the scope of the genus or structural features common to the members of the genus.” *Ariad*, 598 F.3d at 1350. Therefore, the inventors needed to convey in the Common Specification that they possessed the claimed invention, encompassing all detection reagents to bind all analytes as claimed, with a way to distinguish which detection reagents bind to which analytes.

Summary judgment is appropriate because the Common Specification simply lacks the required disclosure. The Court construed “detection reagent” to have a “plain and ordinary meaning,” noting that it comprises “a probe targeting an analyte, and a nucleic acid label.” D.I. 327 at 14. The Common Specification discloses the probe reagent “can be any targeting molecule of interest” that “interacts with or binds to a target molecule or an analyte for the analysis of the target or the analyte” and provides numerous examples: “a nucleic acid, an antibody or a portion thereof, an antibody-like molecule, an enzyme, a cell, a virus, an antigen, a small molecule, a protein, a peptide, a peptidomimetic, a sugar, a lipid, a glycoprotein, a peptidoglycan, an aptamer, and any combinations thereof.” Ex. 12 (’737 Patent) at 7:15-22, 30:61-66. The target probe portion of the detection reagent is defined functionally (by the ability to bind an analyte), but the Asserted Claims provide no structural features that satisfy those functional elements. *See* Ex. 18 (Metzker Reply Rep.) ¶ 293. The Common Specification also lacks description of any binding partners (a probe and an analyte), apart from the few non-specific species in the Figures. It also fails to provide any examples of specific probe reagents other than a few nucleic acid sequences in Table 3 and a commercially available antibody in Example 1. This closely mirrors the situation in *Juno*, where the claims covered potentially “millions of billions” of biological candidates, and the specification failed to show possession of those candidates or representative species, and thus “no means of distinguishing which scFvs will bind to which targets.” 10 F.4th at 1338.

Realizing these deficiencies, 10x tries to recharacterize the claims as limited to (1) highly multiplexed (2) *in situ* analysis (3) providing spatial location. *Id.* ¶ 59. However, as explained above in connection with enablement, the Common Specification reveals that the inventors lacked disclosures for even this embodiment. Example 1 (the sole working example) does not describe any of these three characteristics, as it involves *ex situ* analysis of one yeast species. Similarly, for

claims to determining location of analytes in a cell or tissue sample, the Common Specification describes only the general concept of using a “distinguishable feature in each image” to align images from each detection cycle, without identifying that distinguishable feature. The inventors merely state that “the spatial movement of an analyte in a sample can be less than 100 μm , including less than 50 μm , less than 25 μm , less than 10 μm , less than 1 μm or smaller, over a time period, during which a temporal detection of the detection reagents occurs[,]” Ex. 12 (’737 Patent) at 6:33-39, but do not describe how to determine any analyte’s location. Accordingly, the TOSS Patents Asserted Claims fail both the written description and enablement requirements.

Even assuming Example 1 sufficiently describes to one of skill in the art that the inventors had possession of the claimed invention with respect to one species of yeast, nothing in the Common Specification demonstrates the inventors had possession of other any other analytes. As described above under the Common Specification an “analyte” is broadly defined and can include for example “a drug.” *E.g.*, Ex. 13 (’051 Patent) at 59:44-52. There is no description of how to convert the process of Example 1 to identify a drug in a cell or tissue sample. Nor is there any description of how the components of the claimed method could be adjusted to account for the characteristics of a drug or other analytes. *See Ariad*, 598 F.3d at 1351.

III. VIZGEN’S MOTIONS TO EXCLUDE EXPERT OPINIONS

Vizgen respectfully moves to exclude certain opinions from Dr. John Quackenbush (10x’s infringement expert), Julie Davis (10x’s damages expert), and Professor Rebecca Eisenberg (Harvard’s expert on NIH grants).

A. Dr. Quackenbush and Ms. Davis’s Opinions on Damages Should be Excluded

10x’s damages expert uses a 10x-ReadCoor acquisition valuation as the basis for implying a reasonable royalty. Ms. Davis, as she must do, attempts to apportion the valuation of the entirety of the technology (including patents and patent “families”) in the acquisition to the Asserted

Patents. Ms. Davis’s apportionment theory is flawed and should be excluded, because it simply asserts (and allegedly accepts) asserted values for the various acquired patents chosen arbitrarily by 10x’s technical expert, Dr. Quackenbush. Any apportionment analysis must account for the technical comparability of the asserted patents to that technology being used as a basis for determining a reasonable royalty. *Omega Pats., LLC v. CalAmp Corp.*, 13 F.4th 1361, 1379 (Fed. Cir. 2021).

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] This random assignation of value by Ms. Davis—an economist with no technical training—is improper and should be disregarded under *Daubert*. Ms. Davis purportedly relied on Dr. Quackenbush for technical comparability, [REDACTED]

[REDACTED]

[REDACTED]

Recognizing that their initial expert reports were insufficient to establish the “value” used to apportion down to a reasonable royalty, the 10x experts attempted to correct their deficiencies in their reply reports. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] But the fact remains that nowhere in Dr. Quackenbush's opening expert report was this "scale" disclosed. Because the material was not originally disclosed by the experts, their *ex post facto* attempts to "fix" the errors through their reply reports should be disregarded.

In addition, the alleged "fixes" in Dr. Quackenbush's reply report do not provide any reasonable measure of technical comparability among the obtained patents and patent families to the Asserted Patents. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

to the five Asserted Patents. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Indeed,

proving or tending to prove an established royalty.” *Georgia-Pac. Corp. v. U.S. Plywood Corp.*, 318 F. Supp. 1116, 1120 (S.D.N.Y. 1970) (emphasis added). [REDACTED]

[REDACTED] Ms. Davis offers no justification for valuing the entire patent families when “[t]he hypothetical negotiation can only concern the patents currently at issue.” See *Ronald Katz Tech. Licensing, LP v. Time Warner Cable Inc.*, 712 F. Supp. 2d 1080, 1108 (C.D. Cal. 2010). [REDACTED]

[REDACTED] Accordingly, Ms. Davis’s “implied royalty rate” under the ReadCoor/10x merger should be excluded for this additional reason.

B. Professor Eisenberg’s Testimony Should be Excluded

Vizgen respectfully moves to exclude the report of Harvard’s expert, law professor Dr. Rebecca S. Eisenberg, who has apparently been retained to opine on the meaning and scope of the Bayh-Dole Act and the Grant Application submitted by Harvard to the NIH in this case. Her opinions on the former effectively instruct the jury on what the law is—a role exclusively reserved for this Court. As for the latter, Professor Eisenberg repeatedly purports to opine on what Harvard

or the NIH “would have understood” (*i.e.* what they believed) about their respective legal obligations and the language in the contracts and documents at issue in this case, despite that such testimony is lay testimony improper for “expert” opinion. Each of these problems requires excluding the respective opinions from trial.

1. Professor Eisenberg Cannot Instruct the Jury on the Law

An expert witness cannot render a legal opinion because it would “usurp the District Court’s pivotal role in explaining the law to the jury.” *Berckley Inv. Grp., Ltd. v. Colkitt*, 455 F.3d 195, 217 (3d Cir. 2006). Courts in this Circuit and District routinely exclude expert testimony as to legal conclusions. *See, e.g., Salas by Salas v. Wang*, 846 F.2d 897, 905 n.5 (3d Cir. 1988); *Transportes Aereos Pegaso, S.A. de C.V. v. Bell Helicopter Textron, Inc.*, 623 F. Supp. 2d 518, 533 (D. Del. 2009) (excluding expert testimony regarding the question of the existence or non-existence of a contract because the “Federal Rules do not permit experts to testify as to legal conclusions”); *Watkins v. New Castle Cnty.*, 374 F. Supp. 2d 379, 393 (D. Del. 2005) (granting motion to exclude expert testimony to extent expert offers legal opinion). Professor Eisenberg’s report improperly invades the province of this Court by offering legal opinions concerning the Bayh-Dole Act, the meaning and scope of the NIH Grant Application and Notice of Award, and the legal effect of [REDACTED]

a. Professor Eisenberg Impermissibly Intends to Tell the Jury How to (Incorrectly) Interpret the Bayh-Dole Act

Professor Eisenberg's report and testimony largely focus on her interpretation of the Bayh-Dole Act and implementing regulations, policy statements, guidance, and practice. *See* Ex. 23 (Eisenberg Rep.) § V. Professor Eisenberg offers a legal opinion that in order for the NIH to limit Harvard's ability to exclusively license the subject inventions arising from the NIH Grant, the NIH would have had to make and defend a "determination of exceptional circumstances" (or "DEC") in accordance with Bayh-Dole. *Id.* ¶ 133 ([REDACTED]); *see also id.* at ¶¶ 43-96. That is clearly an impermissible opinion on the law. This alone is basis for exclusion.

Indeed, compounding the problems here is that Professor Eisenberg's conclusions are not only based on an improper interpretation of 35 U.S.C. § 202(a), but an incorrect one as well. That statute speaks to the restriction or elimination of the right to retain title.⁵ Nowhere does the statute provide that an agency must make a determination of exceptional circumstances to restrict a grantee's ability to exclusively license a patent where the penalty for breaching the restriction is something short of the government's taking title to the invention. Professor Eisenberg cites to no independent authority, such as a publication or NIH policy, for her interpretation of § 202(a) and

⁵ The statute provides that "[e]ach nonprofit organization or small business firm may, within a reasonable time after disclosure as required by paragraph (c)(1) of this section, elect to retain title to any subject invention: *Provided, however,* That a funding agreement may provide otherwise...(ii) in exceptional circumstances when it is determined by the agency that restriction or elimination of the right to retain title to any subject invention will better promote the policy and objectives of this chapter." 35 U.S.C. § 202(a) (emphasis added).

cites examples, not based on her experience, but that she recently found online.⁶ By Professor Eisenberg's own admission, these examples of agency DEC's all involve circumstances where the government sought to restrict a university's retention of title or eliminate the University's ability to take title to an invention.⁷ Thus, even if it were proper for a law professor to instruct the jury on the meaning of a statute, she does so as an advocate applying a plainly incorrect and unsupported interpretation, requiring exclusion of these opinions on an independent basis. *Rupert v. Ford Motor Co.*, 640 F. App'x 205, 207-08 (3d Cir. 2016) (affirming exclusion where testimony lacked sufficient grounds and expert was unable to articulate a bases for opinion).

b. Professor Eisenberg Impermissibly Intends to Tell the Jury How to Interpret the Grant Application and the Notice of Award's Legal Effects

Subject to certain exceptions that are not applicable here, experts are prohibited from testifying as to "legal duties, standards or ramifications arising from a contract." *Allscripts Healthcare, LLC v. Andor Health, LLC*, 2022 WL 3021560, at *26 (D. Del. July 29, 2022). Nevertheless, Professor Eisenberg dedicates nearly twenty pages of her report to parsing the contractual language of the NIH Grant Application and Notice of Award before concluding that

⁶ Ex. 26 (Eisenberg Tr.) at 190:11-21 (Q: "[REDACTED]

66:14-21 (stating that she [REDACTED]).

⁷ *Id.* at 101:5-8 (Q: "[REDACTED]

117:6-12 (Q: "[REDACTED]

130:24-131:15 (Q: "[REDACTED]

the language in the Grant Application [REDACTED]

[REDACTED] Ex. 25 (Eisenberg Rep.) § IV, ¶¶ 125-61. This is a transparent attempt at instructing the jury as to the scope of the contractual language contained in the Grant Application and Notice of Award—a matter exclusively for this Court. *See Allscripts*, 2022 WL 3021560 at *44 (quoting *Roche Diagnostics Operations, Inc. v. Abbott Diabetes Care*, 756 F. Supp. 2d 598, 606 (D. Del. 2010)) (an expert may not opine as to the legal effect of or scope of a contract).

c. Professor Eisenberg’s Opinion Regarding the Joinder Provision in the ReadCoor License is Inadmissible

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Such testimony is inadmissible because it once again usurps the Court’s role in instructing the jury as to the law and does not assist the trier of fact in understanding the evidence or determining any facts at issue. *See Berckelely*, 455 F.3d at 217.

2. Professor Eisenberg Impermissibly Tries to Provide Lay Witness Testimony by Opining About Harvard and NIH’s State of Mind

“Expert testimony as to intent, motive, or state of mind offers no more than the drawing of an inference from the facts of the case ... and permitting expert testimony on this subject would be merely substituting the expert’s judgment for the jury’s and would not be helpful to the jury.” *Zimmer Surgical, Inc. v. Stryker Corp.*, 365 F. Supp. 3d 466, 497 (D. Del. 2019). Despite this prohibition, Professor Eisenberg opines throughout her report that NIH and Harvard did not intend the language in the Grant Application or Notice of Award to restrict Harvard’s ability to exclusively license the subject inventions arising from the grant because Harvard and NIH would

not have understood the language as a binding commitment.

For example, Professor Eisenberg concludes that “[REDACTED]”
[REDACTED]
[REDACTED]” (*See* Ex. 25 (Eisenberg Rep.) ¶ 160); [REDACTED]
[REDACTED] (*Id.* ¶ 155); [REDACTED]
[REDACTED]
[REDACTED]”
(*Id.* ¶ 171); and “[REDACTED]”
[REDACTED]” (*Id.* ¶ 170). Dr. Eisenberg also concludes that because NIH did not make and defend a DEC in this case, NIH and Harvard must not have believed that NIH was restricting or intended to restrict Harvard’s ability to license the subject inventions from the NIH Grant. *See id.* at ¶¶ 136-37 (the fact that the NIH did not seek a DEC [REDACTED]
[REDACTED]

Harvard cannot simply put up an expert to substitute for testimony from the NIH or Harvard regarding what each side actually understood—indeed, Dr. Eisenberg cites nothing supporting that Harvard was even aware of, or considered the DEC process or the Bayh-Dole Act in making the promises it did in the Grant Application. *Ruiz-Bueno v. Scott*, 2014 WL 576400, at *4 (S.D. Ohio Feb. 12, 2014) (a party cannot develop fact evidence “under the guise of ‘expert discovery’”).

Furthermore, Professor Eisenberg’s failure to consider the record in this case independently renders her opinion unreliable, therefore requiring its exclusion. *See Crowley v. Chait*, 322 F. Supp. 2d 530, 542 (D.N.J. 2004) (“The information upon which an expert bases his testimony must be reliable, and the selective furnishing of information by counsel to an expert runs afoul of Fed.

R. Evid. 703[.]”). Professor Eisenberg repeatedly testified during her deposition that in forming her opinion on what NIH and Harvard “would have understood,” she did not: speak with anyone at NIH or Harvard; review a single deposition transcript of those responsible for the Grant Application; or review any contemporaneous correspondence produced in this case regarding the Grant Application. *See, e.g.,* Ex. 26 (Eisenberg Tr.) at 205:16-24 (Q: [REDACTED])

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] *see also*

Ex. 27 (Eisenberg Materials Considered). This means her “opinion” is just speculation and is therefore inherently unreliable.

IV. CONCLUSION

For the reasons stated above, Vizgen respectfully requests the Court grant Vizgen’s Motions for Summary Judgment and *Daubert* motions.

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