IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

BIO-RAD LABORATORIES, INC., THE UNIVERSITY OF CHICAGO, LAWRENCE LIVERMORE NATIONAL SECURITY, LLC, AND PRESIDENT AND FELLOWS OF HARVARD COLLEGE,

Plaintiffs,

v.

STILLA TECHNOLOGIES, INC. AND STILLA TECHNOLOGIES,

Defendants.

Civil Action No. 1:19-cv-11587-WGY

STILLA'S TRIAL BRIEF

TABLE OF CONTENTS

I.	CONTESTED ISSUES OF FACT				
	A.	Invalidity or Unenforceability of the Asserted Patents			
		1.	'933 Patent Is Invalid in Light of the Prior Art and Lack of Written Description		
		2.	'933 Patent Is Unenforceable In Light of Inequitable Conduct		
		3.	'780 Patent Is Invalid in Light of the Prior Art		
		4.	^{'444} Patent Is Invalid in Light of the Prior Art, Lack of Written Description, and Lack of Enablement		
		5.	'310 Patent Is Invalid in Light of the Prior Art and Lack of Written Description		
	B.	Alleged Infringement of the Asserted Patents			
		1.	Plaintiffs Have Not Alleged Willfulness Against Stilla, Nor Should They Be Allowed to Amend Their Pleadings on the Eve of Trial		
		2.	No Direct Infringement of the Asserted Patents		
		3.	No Indirect Infringement5		
		4.	No Evidence of Infringement of Stilla's Opal Chip6		
		5.	Plaintiffs' Doctrine of Equivalents Arguments Should Be Limited to the Arguments Raised in Expert Reports		
		6.	Stilla's Naica® System Does Not Meet Limitations of '933 Patent7		
		7.	Stilla's Naica® System Does Not Meet Limitations of '780 Patent 8		
		8.	Stilla's Naica® System Does Not Meet Limitations of '444 Patent 11		
		9.	Stilla's Naica® System Does Not Meet Limitations of '310 Patent 12		
	C.	Requ §§ 28	est for Damages Under 35 U.S.C. § 284, and Impact of 35 U.S.C. 35, 286, 287, 288 on Any Potential Award		
II.	QUE	ESTIONS RAISED BY PENDING MOTIONS			
III.	OTH	THER ISSUES OF LAW 16			

Case 1:19-cv-11587-WGY Document 257 Filed 06/23/21 Page 3 of 25

	А.	Claim Construction	16
IV.	ADDITIONAL MATTERS TO AID IN THE DISPOSITION OF TRIAL		16
	А.	Deposition Designations of Rustem Ismagilov	16
	B.	Remote, Live Testimony by Witnesses Outside of the U.S	17
	C.	Stilla's Trade Secret Information	17
	D.	GDPR Compliance	18
	E.	Fact Witness Testimony	18
	F.	Use of Exhibit Binders	19
	G.	Objections to Witnesses, Demonstratives, and Exhibits	19
	Н.	Stilla's Patent Misuse Defense	20
	I.	Objections to Expert Testimony	20
	J.	Fact Witnesses	20
	K.	Exhibits Must Come In Through a Sponsoring Witness	20

Case 1:19-cv-11587-WGY Document 257 Filed 06/23/21 Page 4 of 25

Stilla Technologies is a Paris-based biotechnology company founded in 2013. Stilla provides unique solutions its customers can use to run certain types of digital PCR (also called "dPCR") experiments. Digital PCR is used in the industry to refer to a process where the test solution is separated into tiny micro-compartments (such as droplets or micro-wells), each of which functions as its own microscopic test tube. Depending on the contents of each micro-compartment, a polymerase chain reaction (PCR) may occur in some of the micro-compartments. The process is "digital" because it is possible to count how many micro-compartments are "positive" (where a reaction occurred) and how many are negative (no reaction). Different forms of digital PCR have been in use since the 1990s. Stilla's technical expert has opined that all of the limitations of all of the asserted claims of the Asserted Patents were issued in light of very narrow alleged improvements over the prior art. Examination of additional prior art references establishes that all of the claims of the Asserted Patents are either anticipated or obvious.

Stilla's technology does not infringe any claim of any Asserted Patent. Plaintiffs (or its licensors) did not invent digital PCR. The patents-in-suit claim very specific approaches to digital PCR using droplets. For example, the '933 patent requires that droplets are formed by using two fluid flows. The '780 patent requires the use of an "injection orifice" and "carrier fluid." The '444 patent requires that droplets are created using a specific type of narrow "microfluidic" channel (and defines the dimensions in the specification) and that the droplets contact each other but do not fuse. And the '310 patent (which has a much later priority date) is limited to a particular application, with specific requirements for what must be (and what cannot be) in the droplets.

Stilla's solution, called the Naica® System, takes a unique approach to partitioning, processing, and detecting digital PCR. Stilla's technology is rooted in novel microfluidics research

1

Case 1:19-cv-11587-WGY Document 257 Filed 06/23/21 Page 5 of 25

done at the École Polytechnique between 2009 and 2012. Rémi Dangla, current CTO and former CEO of Stilla Technologies, is one of the key inventors of this novel technology. Dr. Dangla developed a brand new method of droplet formation that had never been done before. Dr. Dangla's inventions use a specific wedge-shaped architecture (also called a confinement gradient) formed inside a plastic chip, called the Sapphire Chip. When the sample fluid flows through the chip, the physical wedge geometry will cause the sample fluid to partition into tens of thousands of droplets, which form an array of droplets or a "droplet crystal." Stilla's droplet formation approach is different from any other process previously used for digital PCR and offers unique benefits compared to the alleged inventions in the Asserted Patents. Stilla's Naica® System also includes a standard thermocycler to perform the PCR and a standard microscope to detect the results—neither of which implement any technology Plaintiffs claim to have invented.

I. CONTESTED ISSUES OF FACT

A. Invalidity or Unenforceability of the Asserted Patents

1. '933 Patent Is Invalid in Light of the Prior Art and Lack of Written Description

The evidence will show that claims 1-10 of the '933 patent are invalid as obvious in light of the disclosure of i) Quake '332 alone or in combination with Klein and/or Wittwer; and/or ii) Quake '332 alone or in combination with Kojima, and Klein and/or Wittwer. The evidence will show that a person of ordinary skill in the art would have been motivated to combine the droplet formation and device of Quake '332 and/or Kojima with the multiplex PCR of Wittwer and/or Klein and would have had a reasonable expectation of success in such combination. Additionally, the evidence will show that claim 9 of the '933 patent is also invalid for failing to meet the written description requirement for patentability.

2. '933 Patent Is Unenforceable In Light of Inequitable Conduct

Further, the claims of the '933 patent are unenforceable due to the inequitable conduct of the named inventors and the prosecuting attorney for the '933 patent, which is an issue that will not be tried to the jury.

3. '780 Patent Is Invalid in Light of the Prior Art

The evidence will show that claims 1-3 and 9-13 of the '780 patent are invalid as obvious in light of the disclosure of i) Quake '332 in combination with Nakano and/or Wittwer; ii) Nisisako in combination with Nakano and/or Wittwer; and/or iii) Curcio in combination with Nakano and/or Wittwer. The evidence will show that a person of ordinary skill in the art would have been motivated to combine the droplet formation and device of Quake '332, Nisisako, and/or Curcio with the multiplex PCR of Wittwer and/or Nakano and would have had a reasonable expectation of success in such combination.

4. '444 Patent Is Invalid in Light of the Prior Art, Lack of Written Description, and Lack of Enablement

The evidence will show that claims 1-5 and 8 of the '444 patent are invalid as anticipated and/or obvious in light of the disclosure of Quake '332 alone and/or in combination with Riess '933, Sugiura, Mizuno, and/or Sadtler. The evidence will also show that a person of ordinary skill in the art would have been motivated to modify and/or combine Quake '332 and/or Riess '933 and/or Sugiura and/or Mizuno and/or Sadtler so as to arrive at all the limitations of claims 1-5 and 8 of the '444 patent and would have had a reasonable expectation of success in doing so. Additionally, the evidence will show that claims 1-5 and 8 of the '444 patent are also invalid for failing to meet the written description and/or enablement requirements for patentability.

5. '310 Patent Is Invalid in Light of the Prior Art and Lack of Written Description

The evidence will show that claims 1-5, and 8-9 of the '310 patent are invalid as anticipated and/or obvious in light of the disclosure of i) Lo alone and/or in combination with Mathies, Kiss, and/or Zeng; ii) Mathies alone and/or in combination with Lo, Kiss, and/or Zeng; iii) Kiss alone and/or in combination with Beer; and/or iv) Mathies alone and/or in combination with Beer. The evidence will also show that a person of ordinary skill in the art would have been motivated to modify and/or combine Lo and/or Mathies and/or Kiss and/or Beer and/or Zeng so as to arrive at all the limitations of claims 1-5 and 8-9 of the '310 patent, rendering them invalid as obvious, and would have had a reasonable expectation of success in doing so. Additionally, the evidence will show that claim 4 of the '310 patent is also invalid for failing to meet the written description requirement for patentability.

B. Alleged Infringement of the Asserted Patents

1. Plaintiffs Have Not Alleged Willfulness Against Stilla, Nor Should They Be Allowed to Amend Their Pleadings on the Eve of Trial

Plaintiffs did not plead willfulness in their complaint. Nor did Plaintiffs ever seek leave from the Court to amend their complaint to add a willful infringement claim. And in the nearly two years this case has been pending, Plaintiffs made no claim or allegation of willfulness by Stilla. Plaintiffs did not inform Stilla that they planned to ask to amend their pleadings until less than a month prior to trial, and did not provide any justification for the undue delay. To date, Plaintiffs have still not moved to amend their complaint. Previously, during discovery, Plaintiffs' position was that no party should be allowed to amend their pleadings.¹ At this late stage, to allow Plaintiffs

¹ When the parties were negotiating their amended pre-trial schedule, Plaintiffs did not agree to a proposed April 2, 2021 deadline to amend pleadings without leave of the Court. *See* ECF No. 174 at 2 n.2.

Case 1:19-cv-11587-WGY Document 257 Filed 06/23/21 Page 8 of 25

to now argue that Stilla was allegedly willful would be unfairly prejudicial to Stilla, as Stilla was not on notice of this alleged claim and there was no discovery (including possible defensive discovery) into any alleged willful infringement. *See, e.g., Euro-Pro Operating LLC v. Dyson Inc.*, 164 F. Supp. 3d 235, 240 (D. Mass. 2016) (denying request to amend the pleading after close of fact discovery because "allowing an amendment at this stage of proceedings would be unduly prejudicial as it would require the reopening of fact discovery and the taking of additional depositions in support of a legal theory that Plaintiff did not attempt to advance until far too late in the life of this case"); *Resnick v. Copyright Clearance Ctr., Inc.*, 422 F. Supp. 2d 252, 256 (D. Mass. 2006) (denying motion for leave to amend the pleading based on undue delay and futility).

2. No Direct Infringement of the Asserted Patents

Plaintiffs cannot sustain their allegations of infringement against Stilla for any of the asserted claims of the patents-in-suit (which are all method claims, except claims 1-3 of the '780 patent, which require "a sample") because (1) they have no evidence (and their experts have not opined) that all uses of the Naica® System necessarily infringe the asserted claims; and (2) their experts have not identified any specific act(s) of alleged direct infringement by Stilla or anyone else in the U.S. As described below, Plaintiffs cannot meet their burden to establish that every single use of Stilla's Naica® System necessarily performs every step of each asserted claim. Further, Plaintiffs have no evidence that Stilla or some third party used the accused Naica® System to perform each step of each asserted claim in the United States.

3. No Indirect Infringement

Plaintiffs cannot sustain their allegations of indirect infringement against Stilla for any of the asserted claims of the patents-in-suit. The trial will show: 1) there is no evidence that Stilla acted with intent to cause acts by users of the Naica® System that would constitute direct infringement; 2) there is no evidence that Stilla knew that the actions of the users of the Naica®

Case 1:19-cv-11587-WGY Document 257 Filed 06/23/21 Page 9 of 25

System would infringe at least one of the asserted claims or that the Naica® System is especially adapted to infringe any asserted claim; 3) there is no evidence that Stilla was willfully blind to such knowledge; 4) there is no evidence that the users of the Naica® System infringed at least one of the asserted claims; 5) there is no evidence that the Naica® System is a material component of any asserted claim; and 6) there is no evidence of no substantially non-infringing uses of the Naica® System.

4. No Evidence of Infringement of Stilla's Opal Chip

The trial will demonstrate that there is no evidence in the record to support an infringement allegation against Stilla's Opal Chip for any asserted claim. Plaintiffs' experts failed to analyze any technical documentation for the Opal Chip, and they have simply asserted—without evidentiary support—that there are no substantive differences between the Opal Chip and the Sapphire Chip.

5. Plaintiffs' Doctrine of Equivalents Arguments Should Be Limited to the Arguments Raised in Expert Reports

In their expert reports, Plaintiffs' experts alleged that Stilla infringes claim 1 of the '933 patent, claims 10 and 12 of the '780 patent, and claim 1 of the '444 patent under the doctrine of equivalents ("DOE"). During drafting of the parties' pre-trial memorandum, Plaintiffs would not agree to language limiting the question of whether Stilla infringes under DOE to only these claims. Instead, Plaintiffs asked the Court to decide if Plaintiffs were "permitted to assert infringement under the doctrine of equivalents for [any asserted claim of any asserted patent]." Jt. PTM (Dkt. 234) at 8-10. This is not the first time that Plaintiffs have tried to expand their case beyond their allegations in their contentions or their experts' reports. *See* Stilla's MIL No. 4 (Dkts. 216, 217) (requesting Court preclude technical experts from offering testimony not disclosed in their expert reports). While Stilla was not aware of Plaintiffs' position regarding their DOE allegations at the

Case 1:19-cv-11587-WGY Document 257 Filed 06/23/21 Page 10 of 25

time of the MIL deadline, Stilla's request to preclude Plaintiffs from offering expert testimony outside of their expert reports is equally applicable to this situation. Plaintiffs' experts' reports only include DOE analysis for claim 1 of the '933 patent, claims 10 and 12 of the '780 patent, and claim 1 of the '444 patent. Plaintiffs' experts should not be permitted to offer any opinions regarding any alleged infringement under DOE for any other asserted claim.

6. Stilla's Naica® System Does Not Meet Limitations of '933 Patent

The evidence will show that Stilla's Naica® System does not infringe independent claim 1, and as a result does not infringe any asserted dependent claims (claims 4-10) of the '933 patent. Stilla's Sapphire Chip, which forms droplets, lacks the limitation of claim 1 of "forming a plurality of droplets of the aqueous fluid in the immiscible carrier fluid at the outlet of the microchannel based, at least in part, on the flow of the aqueous fluid and surface tension of the aqueous fluid relative to the carrier fluid at the outlet . . ." for multiple reasons. Further, the Sapphire Chip does not infringe claim 1 under the doctrine of equivalents. Because Stilla's Sapphire Chip does not infringe claim 1, the Sapphire Chip also does not infringe claims 4-10, which depend from claim 1. Additionally, Stilla's Sapphire Chip does not infringe claim 9 because the Sapphire Chip lacks the limitation "wherein each of the plurality of droplets comprises a target molecule."

Stilla's Sapphire Chip does not form a plurality of droplets of the aqueous fluid in the immiscible carrier fluid as required by the Court's claim construction: "forming a plurality of droplets of the aqueous fluid by introducing a stream of the aqueous fluid into a flow of an immiscible carrier fluid." The Sapphire Chip does not include "a flow of an immiscible carrier fluid," and droplets do not form "by introducing a stream of the aqueous fluid into a flow of an immiscible carrier fluid." The evidence will show, to the extent there is any movement of the oil within the Sapphire Chip, this movement is merely a local and approximately reciprocal (i.e., no net flow) displacement of the local oil resulting from droplet formation. The movement of oil

Case 1:19-cv-11587-WGY Document 257 Filed 06/23/21 Page 11 of 25

phase is not used to form the droplets. Also, the oil phase does not flow from one place to another and therefore does not serve as a carrier fluid.

The Sapphire Chip does not infringe claim 1 under the doctrine of equivalents because the droplet formation method of the Sapphire Chip is substantially different from that claimed in the '933 patent. While the '933 patent describes only droplet formation resulting from two flows of two immiscible fluids, the Stilla droplet formation occurs as a result of the flow of a single sample fluid (an aqueous phase) entering a chamber that has a fixed geometry and which is pre-filled with a second quiescent fluid.

Further, the evidence will show that Stilla's Sapphire Chip does not infringe claim 1 because droplet formation does not occur "at the outlet of the microchannel," as required by claim 1. Rather, the droplets are formed in the chamber of the Sapphire Chip.

Further, the evidence will show that Stilla's Sapphire Chip does not infringe claim 9 of the '933 patent because each of the droplets generated in the Sapphire Chip does not include one target molecule as required by claim 9. The distribution of target molecules in the droplets in the Naica® System follows a Poisson distribution, where some droplets contain no molecules, other droplets contain one target molecule, and still other droplets contain more than one target molecule.

7. Stilla's Naica® System Does Not Meet Limitations of '780 Patent

The evidence will show that Stilla's Naica® System does not infringe independent claims 1 and 10, and as a result does not infringe any asserted dependent claims (claims 2, 3, 9, and 11-13) of the '780 patent. Stilla's Naica® System lacks at least the following limitations of claim 1: "means for partitioning said sample into partitioned sections, wherein said means for partitioning said sample into partition orifice" and "means for performing PCR on said partitioned sections of said sample." Because Stilla's Naica® System does not infringe claim 1, the Naica® System also does not infringe claims 2-3 and 9, which depend from

Case 1:19-cv-11587-WGY Document 257 Filed 06/23/21 Page 12 of 25

claim 1. Stilla's Naica® System additionally does not infringe claims 2 and 3 because the Naica® System lacks the limitations "wherein said injection orifice is an injection orifice that produces microdroplets" (claim 2) and "wherein said injection orifice is an injection orifice that injects said sample and a PCR reagent" (claim 3). Stilla's Naica® System also lacks the limitation "partitioning said sample into partitioned sections, wherein said step of partitioning said sample into partitioned sections, wherein said step of partition orifice into an immiscible carrier fluid" in claim 10. Further, the Naica® System does not infringe claim 10 under the doctrine of equivalents.

The evidence will show that Stilla's Sapphire Chip does not include the structure identified in the '780 patent that performs the function of "partitioning said sample into partitioned sections," as required by claim 1. The '780 patent identifies the structure for this function as "a small orifice or microjet that forces the PCR mix (sample and reagent) into an immiscible carrier fluid in a channel or tube, such as the structure depicted in Figure 3 or equivalents thereof." First, the evidence will show that Stilla's Sapphire Chip does not have a carrier fluid. The aqueous sample fluid in the Sapphire Chip exits the microchannel into an oil-filled chamber. Rather than being formed by being forced into and then carried away by a flow of carrier fluid, the droplets in the Sapphire Chip are formed because of the flow of the aqueous liquid and the geometry. Second, the evidence will show that Stilla's Sapphire Chip does not have an injection orifice. The opening at the end of the aqueous sample microfluidic channel in the Sapphire Chip is not an "injection orifice." An injection orifice is a region of rapid contraction and acceleration, while the Stilla flow feature is a region of a gradual expansion and deceleration. Also, the pressure gradients along the lengths of the channel drive flow through the channel, but do not force PCR solution through any orifice, as described in the '780 patent. For similar reasons, the evidence will also show that the

Case 1:19-cv-11587-WGY Document 257 Filed 06/23/21 Page 13 of 25

Sapphire Chip does not have an "injection orifice that produces microdroplets," as required by claim 2. And, similarly, the evidence will show that the orifice of the Sapphire Chip does not "inject[]" said sample and a PCR reagent, as required by claim 3, because any flow of the PCR solution is driven by a pressure gradient, not an injection of PCR solution.

The evidence will also show that Stilla's Naica® System does not include the structure identified in the '780 patent that performs the function of "performing PCR on said partitioned sections of said sample," as required by claim 1. The '780 patent identifies the structure for this function as "a pump to move partitioned sections in a continuous channel or tube that passes through a heating element and a cooling element, such as the structure depicted in Figure 3 or equivalents thereof." PCR in the Naica® System is completely different. The Geode instrument performs PCR by subjecting the entire chip to cyclic temperature changes. The entire Sapphire Chip is heated and cooled many times, while the droplets remain essentially static in the Sapphire Chip chamber.

Further, the evidence will show that the Naica® System does not infringe claim 10, at least because, as discussed above, the Sapphire Chip does not have a "carrier fluid," nor does it have an "injection orifice," both of which are required for claim 10. Further, the evidence will show that the Sapphire Chip produces droplets in a fundamentally different way than the methods described in the '780 patent, and therefore does not infringe claim 10 under the doctrine of equivalents. The PCR solution in the Sapphire Chip travels through the distribution channel of the Sapphire Chip from the inlet to the end of the microchannel (not an injection orifice) and droplets are formed as the solution passes through the confinement gradient portion of the oil-filled chamber. It is not PCR solution being injected into a carrier fluid that causes droplet formation.

8. Stilla's Naica® System Does Not Meet Limitations of '444 Patent

The evidence will show that Stilla's Naica® System does not infringe independent claim 1, and as a result does not infringe any asserted dependent claims (claims 2-5 and 8), of the '444 patent. Stilla's Sapphire Chip, where droplets are formed, lacks at least the following limitations of claim 1: "providing a droplet generator to produce, under microfluidic control, a plurality of aqueous microcapsules surrounded by an immiscible continuous phase . . ." and "pooling the microcapsules into one or more common compartments such that a portion of the plurality of microcapsules contact each other but do not fuse with each other due to the presence of the surfactant." Further, the Sapphire Chip does not infringe claim 1 under the doctrine of equivalents. Because Stilla's Sapphire Chip does not infringe claim 1, the Sapphire Chip also does not infringe claims 2-5 and 8, which depend from claim 1.

The evidence will show that the Sapphire Chip does not "provid[e] a droplet generator to produce, under microfluidic control, a plurality of aqueous microcapsules." The evidence, including the parties' agreed upon claim constructions, will show that this term requires that the plurality of aqueous droplets are produced (i.e., formed) in "a channel having a largest cross-sectional dimension (measured perpendicular to the direction of fluid flow) of no more than 1 mm and ratio of its length to its largest cross-sectional dimension of at least 3:1." Stilla's Sapphire Chip does not meet this requirement of the '444 patent. *First*, the droplets in the Sapphire Chip based on the confinement gradient of the chamber. *Second*, the chamber of the Sapphire Chip does not meet the geometric limitations of claim 1 of the '444 patent.

Further, the evidence will show that the droplets in Stilla's Sapphire Chip are not "surrounded by an immiscible continuous phase" as required by claim 1 of the '444 patent. The evidence will show that the droplets in the Stilla Sapphire Chip would only meet this limitation if

Case 1:19-cv-11587-WGY Document 257 Filed 06/23/21 Page 15 of 25

they contact each other, but at that point, the droplets would no longer be "surrounded by an immiscible continuous phase" based on the alleged inventors' express definitions in the specification of the '444 patent and as required by claim 1 of the '444 patent, and therefore this limitation is not met. Similarly, the evidence will show that Stilla's Sapphire Chip does not "pool[] the microcapsules into one or more common compartments such that a portion of the plurality of microcapsules contact each other but do not fuse with each other due to the presence of the surfactant." The "droplets"—as defined by the specification and claims of the '444 patent—in Stilla's Sapphire Chip do not physically contact each other because each pair of droplets is separated by two layers of surfactant and a layer of immiscible oil. Therefore, the droplets in the Sapphire Chip do not satisfy this limitation of claim 1 of the '444 patent. Additionally, the evidence will show that the Sapphire Chip does not infringe under the doctrine of equivalents because there is no contact between two droplets in the Sapphire Chip (and no fusing), and that is not equivalent to droplets that contact each other and do not fuse, as required by claim 1 of the '444 patent. Droplets that contact each other are not substantially the same as droplets that do not contact each other.

9. Stilla's Naica® System Does Not Meet Limitations of '310 Patent

The evidence will show that Stilla's Naica® System does not infringe independent claim 1, and as a result does not infringe any asserted dependent claims (claims 2-5 and 8-9), of the '310 patent. Stilla's Sapphire Chip lacks several limitations of claim 1, including "providing a plurality of [droplets] each comprising a nucleic acid molecule," "a plurality of different primer types each specific to amplify a different target sequence," and "a plurality of optically labeled probe types each specific for a different target sequence." Because Stilla's Sapphire Chip does not infringe claim 1, the Sapphire Chip also does not infringe claims 2-5 and 8-9, which depend from claim 1.

Case 1:19-cv-11587-WGY Document 257 Filed 06/23/21 Page 16 of 25

Stilla's Sapphire Chip does not "provid[e] a plurality of [droplets] each comprising a nucleic acid molecule." As the evidence will show, the droplets of the alleged invention of the '310 patent are each limited to having no more than a single template molecule per droplet, which are distinguished from prior art systems that used a Poisson distribution and where at least some droplets contain multiple target templates. The distribution of target molecules in the droplets in the Sapphire Chip follows a Poisson distribution, where some droplets contain no target molecule, others contain one target molecule, and yet others contain more than one target molecule.

Further, the evidence will show that Stilla's Sapphire Chip does not "provid[e] a plurality of [droplets] each comprising . . . reagents for an amplification reaction comprising a plurality of different primer types each specific to amplify a different target sequence." The Court construed the claim term "plurality of different primer types" to mean "more than one set of different primers or primer pairs, each set." Because certain assays, such as single-plex assays for rare mutation detection, performed on the Sapphire Chip use only one primer pair, in these situations the droplets of the Sapphire Chip will not contain "more than one set of primers or primer pairs." For similar reasons, the evidence will show that Stilla's Sapphire Chip does not "provid[e] a plurality of [droplets] each comprising . . . a plurality of optically labeled probe types each specific for a different target sequence." The evidence will show that a "plurality of optically labeled probe types" requires the use of two or more different types of probes. The Sapphire Chip does not infringe claim 1 (or any of the dependent claims either).

C. Request for Damages Under 35 U.S.C. § 284, and Impact of 35 U.S.C. §§ 285, 286, 287, 288 on Any Potential Award

In the event the jury finds the Asserted Patents valid and infringed, Plaintiffs are entitled to no more than a reasonable royalty for any alleged infringement from October 2016 through

13

Case 1:19-cv-11587-WGY Document 257 Filed 06/23/21 Page 17 of 25

2020. The reasonable royalty should be calculated based on a hypothetical negotiation on the eve of the first alleged infringement. In this case, the date of the hypothetical negotiation is different for the '933 patent, which issued after Stilla's first sales in the United States. But Plaintiffs' damages expert, Mr. Malackowski, assumes a single hypothetical negotiation date that is a year and a half prior to the issuance of the '933 patent. Stilla could not have infringed a patent that did not yet exist. Further, the evidence will show that Mr. Malackowski's analysis of existing licenses is flawed and that there are substantial differences between his cherry-picked licenses, with rates up to 15%, and the license that would result from the hypothetical negotiation. Other licenses in the record confirm that Plaintiffs and Stilla would have agreed to a reasonable royalty rate of 5% or less (depending on which patents are found to be infringed). In addition, Mr. Malackowski did not properly evaluate the footprint of the Asserted Patents when applying the same 15% royalty rate to the Sapphire Chip as to Stilla's standard thermocycler and microscope instruments, which do not use any technology Plaintiffs claim to have invented. The evidence of record confirms that Plaintiffs and Stilla would have agreed to apply the royalty rate only to the Sapphire Chips, consistent with the footprint of the alleged inventions. Moreover, the parties would also have considered the ease of designing around the '444 patent. These differences will be explained to the jury by Stilla's expert, Dr. Maness.

The evidence will show that this case does not qualify as "exceptional," and therefore Plaintiffs are not entitled to an award of attorney fees under 35 U.S.C. § 285, nor are Plaintiffs entitled to costs, as their costs are limited under 35 U.S.C. § 288. To the extent that Plaintiffs seek damages otherwise accruing prior to six years before they filed their First Amended Complaint, such damages are barred by 35 U.S.C. § 286. The relief sought by Plaintiffs based on Defendants' alleged infringement of the '780 patent is further limited by 35 U.S.C. § 287 because the evidence

Case 1:19-cv-11587-WGY Document 257 Filed 06/23/21 Page 18 of 25

will show that the owner(s) of the Asserted Patents, and/or their licensees, failed to mark allegedly practicing products.

II. QUESTIONS RAISED BY PENDING MOTIONS

Both sides filed motions *in limine* in this case (as well as opposition and reply briefs), and those MILs are listed below. While none of the motions have been formally ruled on, the Court did make relevant comments regarding some of these MILs during the pretrial conference. Stilla respectfully requests the Court rule on the pending motions, as described below.

BioRad's MIL No. 1 (Dkts. 222, 223) regarding precluding PTAB proceedings should be denied because it would unfairly preclude Stilla from presenting relevant evidence, including the patent owners' own statements regarding the patents and prior art at issue in this litigation and evidence relevant to the validity of the '780 Patent. *See* Stilla's Opp'n (Dkt. 227).

BioRad's MIL No. 2 (Dkts. 220, 221) regarding the term "troll" and similar, unspecified pejorative terms should be denied. *See* Stilla's Opp'n (Dkt. 228). Stilla has agreed not to use the term "troll." *Id*.

BioRad's MIL No. 3 (Dkts. 214, 215) regarding preclusion of 10X's Antitrust Allegations against Bio-Rad, including *any* discussion of anticompetitive effects, should be denied. *See* Stilla's Opp'n (Dkt. 229). Stilla has agreed not to refer to 10X's pending antitrust case against BioRad. *Id*.

BioRad's MIL No. 4 (Dkts. 218, 219) regarding accusations by Mr. Wadler should be denied because the accusations are relevant to damages, as BioRad's own expert acknowledges. *See* Stilla's Opp'n (Dkt. 230).

BioRad's MIL No. 5 (Dkts. 224, 225) regarding Dr. Santiago's non-infringement opinions should be denied. *See* Stilla's Opp'n (Dkt. 231). Based on the Court's comments at the pretrial conference, it appears that the Court agrees that Dr. Santiago should be, and will be, able to discuss

Case 1:19-cv-11587-WGY Document 257 Filed 06/23/21 Page 19 of 25

his opinions regarding the plain and ordinary meaning of claim terms, as disclosed in his expert reports.

Stilla's omnibus motion in limine (Dkts. 216, 217; see also Reply at Dkt. 235) should be

granted, and the Court should preclude:

- 1. The introduction of evidence and arguments regarding the Applera License because it is more prejudicial than probative;
- 2. The introduction of evidence and arguments regarding the Licensing Executives Society survey because it is more prejudicial than probative;
- 3. Testimony by Plaintiffs' fact witnesses regarding license agreements and terms for which they lack personal knowledge or foundation;
- 4. Plaintiffs' technical experts from offering opinions and testimony not disclosed in their expert reports, and from relying on evidence not cited in their expert reports or identified in their lists of materials considered; and
- 5. Arguments that figures and specifications from Stilla's patents represent commercial embodiments of the Sapphire Chip

Again, based on the Court's comments at the pretrial conference, it appears that the Court agrees

that all experts will be limited to opinions disclosed in their expert reports (see Stilla MIL No. 4).

III. OTHER ISSUES OF LAW

A. Claim Construction

As discussed in detail in the Pretrial Memorandum, there are a number of relevant claim terms that have not yet been construed, including means-plus-function terms. Stilla respectfully requests the Court provide guidance on these claim terms. Having the Court's guidance on these terms will allow for a simplification of the presentation of the evidence to the jury.

IV. ADDITIONAL MATTERS TO AID IN THE DISPOSITION OF TRIAL

A. Deposition Designations of Rustem Ismagilov

Stilla objects to Plaintiffs' deposition designation of its own party witnesses, namely their designation of portions of Rustem Ismagilov's December 8, 2020 deposition. Plaintiffs submitted

Case 1:19-cv-11587-WGY Document 257 Filed 06/23/21 Page 20 of 25

deposition designations for Dr. Ismagilov, who was designated as a corporate representative during this litigation for Plaintiff the University of Chicago. Dr. Ismagilov was also an ESI custodian during fact discovery, where Plaintiffs collected and produced his emails and documents. Additionally, Dr. Ismagilov was represented by Weil, Gotshal & Manges LLP, who is also counsel for Plaintiffs Bio-Rad and the University of Chicago. Not only do courts prefer live testimony over deposition testimony, but the fact that Plaintiffs have control over Dr. Ismagilov as their corporate designee raises evidentiary concerns, including concerns regarding hearsay. Therefore, unless Plaintiffs can establish that the witness is unavailable, under the Federal Rules of Civil Procedure, Plaintiffs should not be allowed to play for the jury any deposition testimony of their own witnesses.

B. Remote, Live Testimony by Witnesses Outside of the U.S.

The parties agree that Dr. Rémi Dangla, Stilla (FR)'s co-founder, former CEO, and current CTO, and Dr. Etienne Fradet, Stilla (FR)'s co-founder and VP of R&D, will be allowed to testify live by remote means. In light of the COVID-19 worldwide pandemic, travel to the U.S. from France now requires a visa, and the current requirements for a visa include a National Interest Exception. *See* <u>https://fr.usembassy.gov/visas/</u>. Dr. Dangla may still attend in-person if he is able to travel to Boston.

C. Stilla's Trade Secret Information

As a company involved in developing and commercializing cutting edge technology, Stilla does hold trade secrets regarding the accused products. Some of these trade secrets are tangentially related to the case. Therefore, Stilla will provide a numbered list of its trade secrets, listing each trade secret with particularity, to the Court by Tuesday, June 28. Stilla respectfully requests the Court's guidance on how to refer to these trade secrets during trial, and whether the jury will be provided with the list of trade secrets.

D. GDPR Compliance

Because Stilla Technologies is a company based in France, it is required to follow the European Union's General Data Protection Regulation (GDPR). As detailed in the Protective Order (Dkt. 137-1), this means information originating from the EU that relates to a Data Subject (an identified or identifiable natural person) must be kept confidential. *Id.* at 2.15. An identifiable person is one who can be identified, directly or indirectly, in particular by reference to an identification number and/or to one or more factors specific to their physical, physiological, mental, economic, cultural, or social identity. *Id.* In light of the PO, identifying information about Data Subjects that were designated as corporate witnesses during discovery are not required to be kept confidential. Id. at 2.16. Other Stilla Technologies or other EU citizens, however, should still be treated as Data Subjects and identifiable information (e.g., name, initials, job title, etc.) should be kept confidential and not revealed in open court. In an attempt to rectify the GDPR confidentiality requirements and the United States' system of providing public access to the justice system and public trials, Stilla proposes that the parties agree to provide aliases for any Data Subject that may be mentioned during the trial. Stilla respectfully requests the Court's guidance on whether the jury should be provided with the list of names for any Data Subject identified by an alias during open court.

E. Fact Witness Testimony

Because the Court has bifurcated the trial into an invalidity phase and a liability phase, Stilla requests that any fact witness testifying at trial be required to limit their direct testimony to issues relevant to the current phase, and that cross-examination will be also limited to the scope of the direct testimony. Plaintiffs have proposed allowing fact witnesses to testify only once, and to give invalidity and liability testimony at the same time. Plaintiffs' proposal would not only result

Case 1:19-cv-11587-WGY Document 257 Filed 06/23/21 Page 22 of 25

in juror confusion, but act as an end run around this Court's order that invalidity be tried first before moving to the infringement/damages phase of the case.

F. Use of Exhibit Binders

Stilla does not agree to Plaintiffs' recent request to provide each juror with a binder that includes *every* exhibit used at trial. In light of the COVID-related protocols limiting the sharing of paper copies, Stilla believes this type of binder system would be unworkable, cumbersome and would serve as a distraction to the jurors. If the Court prefers the jurors to have binders, Stilla requests the binders contain only the asserted patents and the asserted prior art.

Stilla respectfully requests the Court's guidance on whether the Court would like a full set of admitted exhibits, as the trial progresses, and/or if the Court would like a witness binder for each witness that contains all of the exhibits that are planned to be used with each witness on direct and cross.

G. Objections to Witnesses, Demonstratives, and Exhibits

The parties have agreed to a process by which objections to i) witnesses, ii) deposition designations, iii) demonstratives to be used at opening or during direct examination, and iv) exhibits to be used with witnesses are discussed amongst the parties. To the extent the parties cannot resolve the objections, the parties have agreed to raise these issues orally with the Court, outside the presence of the jury, the morning prior to the anticipated witnesses' testimony. The parties have agreed to modify the procedure for deposition designation objection that is outlined in the pretrial memo as follows: Objections to deposition designations will be raised the morning prior to the day the party intends to play the designations (instead of the morning of), in order to give the parties time to edit the deposition video to conform with the Court's guidance on any such objections.

H. Stilla's Patent Misuse Defense

The parties have also agreed that Stilla's patent misuse defense will to go forward as a bench trial (to the extent necessary) after the 10X antitrust trial is completed.

I. Objections to Expert Testimony

The parties agree that the Court should rule at trial on objections to expert testimony as beyond the scope of prior expert disclosures. Any time used to argue and to decide such objections before the jury will be counted against the party who loses the objection or unsuccessfully defends the objection.

J. Fact Witnesses

The parties agree that witnesses will be sequestered during the length of the trial, with the exception of one corporate representative per party who will be allowed in the Courtroom for the duration of the trial. *See* Fed. R. Evid. 615(b). The parties also agree to identify corporate representatives in their Local Rule 43.1(b)(2) witness list notice on June 23, 2021.

K. Exhibits Must Come In Through a Sponsoring Witness

The parties agree that no exhibit will be admitted unless offered into evidence through a witness, who must at least be shown the exhibit. This includes exhibits listed on the parties' number exhibit list.

Dated: June 23, 2021

Respectfully submitted,

/s/ Elizabeth G.H. Ranks

Whitney A. Reichel (BBO #663599) Elizabeth G.H. Ranks (BBO #693679) Qiuyi Wu (BBO #704069) FISH & RICHARDSON P.C. One Marina Park Drive Boston, MA 02210-1878 wreichel@fr.com liz.ranks@fr.com qwu@fr.com (617) 542-5070 Telephone (617) 542-8906 Facsimile

Juanita R. Brooks (*Pro Hac Vice*) Michael A. Amon (*Pro Hac Vice*) K. Nicole Williams (*Pro Hac Vice*) FISH & RICHARDSON P.C. 12860 El Camino Real Suite 400 San Diego, CA 92130 brooks@fr.com (858) 678-5070 Telephone (858) 678-5099 Facsimile

Attorneys for Defendants Stilla Technologies, Inc. and Stilla Technologies

CERTIFICATE OF SERVICE

I hereby certify that this document(s) filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) and paper copies will be sent to those indicated as non-registered participants on this 23rd day of June, 2021.

> <u>/s/ Elizabeth G.H. Ranks</u> Elizabeth G.H. Ranks