

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NANOSTRING TECHNOLOGIES, INC.,
Petitioner,

v.

PRESIDENT AND FELLOWS OF HARVARD COLLEGE,
Patent Owner

Case IPR2024-00526
Patent 11,542,554

PETITIONER'S REPLY TO PATENT OWNER'S PRELIMINARY RESPONSE

TABLE OF CONTENTS

	Page
I. BANKRUPTCY PROCEEDING AND DISTRICT COURT STAY	1
II. IMPACT ON THE FINTECH FACTORS	2
A. Factor 1: Likelihood of a Stay	2
B. Factor 2: Proximity of Trial Date to Final Written Decision.....	3
C. Factor 3: Investment in Parallel Proceeding	5

TABLE OF AUTHORITIES

	Page
Cases	
<i>Apple Inc. v. Fintiv, Inc.</i> , IPR2020-00019, Paper 11 (PTAB Mar. 20, 2020)	1, 2, 5
<i>CyWee Grp. Ltd. v. Samsung Elecs. Co. Ltd.</i> , No. 2:17-cv-00140-WCB-RSP, 2019 WL 11023976 (E.D. Tex. Feb. 14, 2019).....	5
<i>IOENGINE, LLC v. PayPal Holdings, Inc.</i> , 2019 U.S. Dist. LEXIS 141545 (D. Del. Aug. 21, 2019)	2
<i>Micron Tech., Inc. v. Godo Kaisha IP Bridge 1</i> , IPR2020-01008, Paper 10 (PTAB Dec. 7, 2020).....	3
<i>NTP, Inc. v. Rsch. In Motion, Ltd.</i> , 418 F.3d 1282 (Fed. Cir. 2005).....	2
<i>Oticon Med. AB v. Cochlear Ltd.</i> , IPR2019-00975, Paper 15 (PTAB Oct. 16, 2019)	3
<i>Sand Revolution II, LLC v. Cont’l Intermodal Group – Trucking LLC</i> , IPR2019-01393, Paper 24 (PTAB June 16, 2020).....	5
<i>Tesla, Inc. v. Charge Fusion Technologies, LLC</i> , IPR2023-00062, Paper 13 (PTAB May 11, 2023).....	4, 5
<i>ThreatModeler Software Inc. v. IriusRisk, Inc.</i> , 1-22-cv-00912 (D. Del. Nov. 20, 2023).....	3

PETITIONER’S EXHIBIT LIST

Exhibit #	Description
EX1001	U.S. Patent No. 11,542,554 (“the ’554 Patent”)
EX1002	Declaration of Dr. Kirk Czymmek, Ph.D. under 37 C.F.R. § 1.68
EX1003	Kok Hao Chen et al., <i>Spatially resolved, highly multiplexed RNA profiling in single cells</i> , 348(6233) Science 412 (Research Article Summary) – aaa6090-1 - aaa6090-14 (2015) (“Zhuang”)
EX1004	U.S. Patent No. 10,457,980 to Long Cai et al. (“Cai”)
EX1005	Olympus Lifescience, <i>Instructions IX71/IX51 Inverted Research Microscope/Inverted Basic Microscope</i> , (2005) at https://www.ucc.ie/en/media/academic/anatomy/imagingcentre/icdocuments/OLYMPUSIX71_manual.pdf (“Olympus Manual”)
EX1006	Biopetechs, <i>FCS2 (Focht Live-Cell Chamber System) Instructions</i> , 1-6 (2007) at http://www.biopetechs.com/Instructions/FCS2_i/fcs2-3_i.htm (“FCS2 Instructions”)
EX1007	Sivaraj Sivaramakrishnan et al., <i>Shear Stress Induced Reorganization of the Keratin Intermediate Filament Network Requires Phosphorylation by Protein Kinase Cζ</i> , 20 Molecular Biology of the Cell 2755-2765 (2009) (“Sivaramakrishnan”)
EX1008	Chatarina Larsson et al., <i>In situ detection and genotyping of individual mRNA molecules</i> , 7 Nature Methods 395-397 (2010) (“Larsson”)
EX1009	Emmanuelle Querido and Pascal Chartrand, “Chapter 12 Using Fluorescent Proteins to Study mRNA Trafficking in Living Cells,” 85 <i>Methods In Cell Biology</i> , Elsevier Inc. 273-292 (2008) (“Querido”)
EX1010	Andrea M. Femino et al., “[13] Visualization of Single Molecules of mRNA in Situ,” 361 <i>Methods in Enzymology</i> , Elsevier Science (USA) 245-304 (2003) (“Femino”)
EX1011	Evan P. Perillo et al., <i>Enhanced 3D localization of individual RNA transcripts via astigmatic imaging</i> , 8950 SPIE 895003-1-895003-11 (2014) downloaded from https://www.researchgate.net/publication/263033754_Enhanced_3D_localization_of_individual_RNA_transcripts_via_astigmatic_imaging (“Perillo”)
EX1012	Alison J. North, <i>Seeing is believing? A beginners’ guide to practical pitfalls in image acquisition</i> , 172 The Journal of Cell Biology 9-18 (2006) (“North”)
EX1013	US Patent Application Publication No. US 2015/0267251 A1 to Long Cai et al. (“Cai reference”)
EX1014	Paul James, <i>Water Objectives A personal exploration.....all is not what it seems</i> , Microscopy UK 1-8 (2004) at www.microscopy-uk.org.uk/mag/indexmag.html?http://www.microscopy-uk.org.uk/mag/artoct04/pjwater.html (“James”)
EX1015	David L. Spector et al., “[75] Observation of Live Cells in the Light Microscope,” <i>Cells A Laboratory Manual Volume 2: Light Microscopy and Cell Structure</i> , Cold Spring Harbor Laboratory Press, 75.1-75.13 (1998) (“Spector”)

Exhibit #	Description
EX1016	Hamilton, <i>HVXM 8-5 Valve Laboratory Products</i> , (November 7, 2023) at https://www.hamiltoncompany.com/laboratory-products/valves/36766 (“Hamilton website”)
EX1017	Clare O’Connor, <i>Fluorescence In Situ Hybridization (FISH)</i> , 1(1):171 Nature Education (2008) at https://www.nature.com/scitable/topicpage/fluorescence-in-situ-hybridization-fish-327/ (“O’Connor”)
EX1018	Derek Toomre and Joerg Bewersdorf, <i>A New Wave of Cellular Imaging</i> , 26 Annu. Rev. Cell Dev. Biol. 285-287 (2010) (“Toomre”)
EX1019	Robert S. Fischer et al., <i>Microscopy in 3D: a biologist’s toolbox</i> , 21(12) Trends Cell Biol. 682-691 (2011) at https://pubmed.ncbi.nlm.nih.gov/22047760/ (“Fischer”)
EX1020	Sheel Shah et al., <i>Dynamics and spatial genomics of the nascent transcriptome by intron seqFISH</i> , 174(2) Cell 363-376 (2018) at https://pubmed.ncbi.nlm.nih.gov/29887381/ (“Shah”)
EX1021	Jeffrey R. Moffitt and Xiaowei Zhuang, <i>RNA Imaging with Multiplexed Error Robust Fluorescence in situ Hybridization</i> , 572 Methods Enzymol 1-49 (2016) at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5023431/ (“Moffitt”)
EX1022	Steven M. Chirieleison et al., <i>Automated Live Cell Imaging Systems Reveal Dynamic Cell Behavior</i> , 27 Biotech. Prog. 913-924 (2011) (“Chirieleison”)
EX1023	Michael D. Abràmoff et al., <i>Image Processing with ImageJ</i> , Biophotonics Int’l. 1-7 (2004) (“ImageJ”)
EX1024	Erlend Hodneland et al., <i>CellSegm – a MATLAB toolbox for high-throughput 3D cell segmentation</i> , 8:16 Source Code for Biology and Medicine 1-24 (2013) (“Hodneland”)
EX1025	Emilie A. Delaune et al., <i>Single-Cell-Resolution Imaging of the Impact of Notch Signaling and Mitosis on Segmentation Clock Dynamics</i> , 23 Developmental Cell, Elsevier Inc. 995-1005 (2012) (“Delaune”)
EX1026	Duy Anh Bui and Peter C. Hauser, <i>Analytical devices based on light-emitting diodes – a review of the state-of-the-art</i> , 853 Analytica Chimica Acta 46-58 (2014) (“Bui”)
EX1027	Jie Xiao, “Single-Molecule Imaging in Live Cells,” <i>Handbook of Single-Molecule Biophysics</i> , Springer 43-93 (2009) (“Xiao”)
EX1028	Allen Ehrlicher et al., “Chapter 21 Optical Neuronal Guidance,” 83 <i>Methods in Cell Biology</i> , Elsevier Inc. 495-520 (2007) (“Ehrlicher”)
EX1029	Christopher Fang-Yen et al., <i>Video-rate tomographic phase microscopy</i> , 16(1) Journal of Biomedical Optics 011005-1 – 011005-5 (2011) (“Fang-Yen”)
EX1030	Marc J.P. Richard et al., <i>Cellular mechanisms by which lipoic acid confers protection during the early stages of cerebral ischemia: A possible role for calcium</i> , 69 Neuroscience Research 299-307 (2011) (“Richard”)
EX1031	Harvard Apparatus, <i>PHD 22/2000 Syringe Pump Series User’s Manual</i> , (1996) at https://www.harvardapparatus.com/media/harvard/pdf/702000_Syringe_Pumps_Manual.pdf (“Harvard Apparatus Manual”)
EX1032	Feimo Shen et al., “[32] Digital Autofocus Methods for Automated Microscopy,” 414 <i>Methods in Enzymology</i> , Elsevier Inc. 620-632 (2006) (“Shen”)

Exhibit #	Description
EX1033	Olympus Lifescience, <i>Inverted Research System Microscopes IX71/IX81 IX2 Series Manual Olympus IX-71</i> , (2009) at https://afns-labs.ualberta.ca/wp-content/uploads/sites/58/2018/05/Olympus-IX81-brochure.pdf.pdf
EX1034	Information Disclosure Statement (IDS) dated August 6, 2021, submitted by Applicant during prosecution of U.S. Patent Application No. 17/395,534 before the United States Patent and Trademark Office.
EX1035	Non-Final Rejection issued by the United States Patent and Trademark Office dated March 4, 2022, during prosecution of U.S. Patent Application No. 17/395,534
EX1036	Notice of Allowance issued by the United States Patent and Trademark Office dated June 21, 2022, during prosecution of U.S. Patent Application No. 17/395,534
EX1037	Pending and Amended claims filed by the Applicant on February 14, 2022, during prosecution of U.S. Patent Application No. 17/395,534 before the United States Patent and Trademark Office
EX1038	Applicant's Arguments and Remarks made in an Amendment, Amendment/Request for ReConsideration-After Non-Final Rejection and Claims filed by the Applicant on June 3, 2022, during prosecution of U.S. Patent Application No. 17/395,534 before the United States Patent and Trademark Office
EX1039	Kristen A. Brileya et al., <i>Biofilm growth mode promotes maximum carrying capacity and community stability during product inhibition syntrophy</i> , 5 <i>Frontiers in Microbiology</i> 1-13 (2014) ("Brileya")
EX1040	U.S. Patent Application Publication No. US 2011/0090562 A1 to Jeffrey S. Brooker ("Brooker")
EX1041	U.S. Patent Application Publication No. US 2011/0216953 A1 to Daniel E. Callahan and Bahram Pravin ("Callahan")
EX1042	U.S. Patent Application Publication No. US 2015/0098126 A1 to Phillip Johannes Keller and Raghav Kumar Chhetri ("Keller")
EX1043	Nikon MicroscopyU, <i>Culture Chambers for Live-Cell Imaging</i> (August 2015) at https://web.archive.org/web/20150810165805/http://www.microscopyu.com:80/articles/livecellimaging/culturechambers.html . ("Nikon")
EX1044	Cassandra S. Niman et al., <i>Controlled microfluidic switching in arbitrary time sequences with low drag[†]</i> , 13 <i>Lab Chip</i> 2389-2396 ("Niman")
EX1045	Thermo Fischer Scientific, <i>Fluorescence SpectraViewer</i> , at https://thermofischer.com/order/fluorescence-spectraviewer/#/
EX1046	Gregory B. Sands et al., <i>Automated Imaging of Extended Tissue Volumes Using Confocal Microscopy</i> , 67 <i>Microscopy Research and Technique</i> 227-239 (2005) ("Sands")
EX1047	Caroline A. Schneider et al., <i>NIH Image to Image J: 25 years of Image Analysis</i> , 9(7) <i>Nat. Methods</i> 671-675 (2012) downloaded at https://pubmed.ncbi.nlm.nih.gov/22930834/ ("Schneider")
EX1048	Peder Skafte-Pedersen et al., <i>A self-contained, programmable microfluidic cell culture system with real-time microscopy access</i> , 14 <i>Biomed Microdevices</i> 385-399 (2012) ("Skafte-Pedersen")

Exhibit #	Description
EX1049	Leïla Tirichine et al., <i>3D fluorescent in situ hybridization using Arabidopsis leaf cryosections and isolated nuclei</i> , 5:11 Plant Methods 1-7 (2009) (“Tirichine”)
EX1050	Johannes T. Wessels et al., <i>Light-Emitting Diodes in Modern Microscopy—From David to Goliath?</i> , 81A Cytometry Part A 188-197 (2012) downloaded at https://onlinelibrary.wiley.com/doi/10.1002/cyto.a.22023 (“Wessels”)
EX1051	Michael H. Winer et al., <i>Application of a three-dimensional (3D) particle tracking method to microfluidic particle focusing</i> , 14 Lab Chip 1443-1451 (2014) (“Winer”)
EX1052	Patrick JM Zessin et al., <i>A hydrophilic gel matrix for single-molecule super-resolution microscopy</i> , 2:4 Optical Nanoscopy 1-8 (2013) (“Zessin”)
EX1053	Olympus Lifescience, <i>Research Inverted System Microscope IX71/IX81 IX2 Series</i> , (2005) at https://www.olympus-lifescience.com/data/olympusmicro/brochures/pdfs/ix71.pdf?rev=EABE
EX1054	Ilja Gerhardt et al., <i>Detection of Single Molecules Illuminated by a Light-Emitting Diode</i> , 11 Sensors 905-916 (2011) (“Gerhardt”)
EX1055	Akifumi Hattori et al., <i>Single-molecule Imaging with an Inexpensive UV-LED Light Source</i> , 38 Chemistry Letters 234-235 (2009) (“Hattori”)
EX1056	Jason S. Kuo et al., <i>High-power blue/UV light-emitting diodes as excitation sources for sensitive detection</i> , 25 Electrophoresis 3796-3804 (2004) (“Kuo”)
EX1057	Thermo Fischer Scientific, <i>FluoSpheres™ Carboxylate-Modified Microspheres</i> , (January 9, 2024) at https://www.thermofisher.com/order/catalog/product/F8809
EX1058	Metadata for Ex.1005
EX1059	Metadata for Ex.1033
EX1060	Metadata for Ex.1053
EX1061	Stipulation and Order Amending Scheduling Order, <i>10X Genomics, Inc. and President And Fellows of Harvard College v. Nanostring Technologies Inc.</i> , C.A. No. 22-261-MFK (December 20, 2023 D. Del.) (No. 231)
EX1062	Plaintiffs, 10x Genomics, Inc. and President and Fellows of Harvard College’s Complaint, <i>10X Genomics, Inc. and President And Fellows of Harvard College v. Nanostring Technologies Inc.</i> , C.A. No. 22-261-MFK (February 28, 2022 D. Del.) (No. 1)
EX1063	Plaintiffs, 10x Genomics, Inc. and President and Fellows of Harvard College’s Second Amended Complaint, <i>10X Genomics, Inc. and President And Fellows of Harvard College v. Nanostring Technologies Inc.</i> , C.A. No. 22-261-MFK (March 1, 2023 D. Del.) (No. 92)
EX1064	Defendant, NanoString Technologies, Inc.’s First Amended Answer, Affirmative Defenses, and Counterclaims to 10x and Harvard’s Second Amended Complaint, <i>10X Genomics, Inc. and President And Fellows of Harvard College v. Nanostring Technologies Inc.</i> , C.A. No. 22-261-MFK (July 18, 2023 D. Del.) (No. 157)
EX1065	Curriculum Vitae of Kirk J. Czymmek
EX1066	Defendant, NanoString Technologies, Inc.’s Status Report Regarding Bankruptcy-Related Developments, <i>10X Genomics, Inc. and President And Fellows of Harvard College v. Nanostring Technologies Inc.</i> , C.A. No. 22-261-MFK (February 22, 2024 D. Del.) (No. 275)

Exhibit #	Description
EX1067	Oral Order Staying Case, <i>10X Genomics, Inc. and President And Fellows of Harvard College v. Nanostring Technologies Inc.</i> , C.A. No. 22-261-MFK (March 14, 2024 D. Del.) (No. 279)
EX1068	Stipulation and Order Lifting Stay, <i>10X Genomics, Inc. and President And Fellows of Harvard College v. Nanostring Technologies Inc.</i> , C.A. No. 22-261-MFK (June 14, 2024 D. Del.) (No. 286)
EX1069	Joint Status Report, <i>10X Genomics, Inc. and President And Fellows of Harvard College v. Nanostring Technologies Inc.</i> , C.A. No. 22-261-MFK (June 28, 2024 D. Del.) (No. 298)
EX1070	Joint Status Report Attachment A – Proposed Schedules for the 261 and 1375 Cases, <i>10X Genomics, Inc. and President And Fellows of Harvard College v. Nanostring Technologies Inc.</i> , C.A. No. 22-261-MFK (June 28, 2024 D. Del.) (No. 298-1)
EX1071	Oral Order Advancing Trial Date to September 16, 2024, <i>10X Genomics, Inc. and President And Fellows of Harvard College v. Nanostring Technologies Inc.</i> , C.A. No. 22-261-MFK (December 13, 2023 D. Del.) (No. 227)
EX1072	United States District Courts — National Judicial Caseload Profile (https://www.uscourts.gov/sites/default/files/fcms_na_distprofile1231.2023_0.pdf) last visited on June 30, 2024.

The Petition explained how the parallel district court proceeding did not justify discretionary denial under *Fintiv*. Pet. 68-73. All the arguments made still apply, including that Petitioner was barred from filing the IPR petition until 9 months after the '554 patent issued, which was already roughly 19 months after the ongoing parallel district court case was filed. *Id.*

Relevant facts and circumstances relating to the *Fintiv* factors, however, have since changed and they now weigh even more strongly against discretionary denial. Petitioner underwent a Chapter 11 bankruptcy proceeding, during which the district court proceeding was stayed and the dates for discovery, dispositive motions, and trial were vacated. Petitioner accordingly requested authorization on June 20, 2024, to file a Reply to Patent Owner's Preliminary Response to address changes in circumstances relating to the *Fintiv* factors, which was granted on June 24, 2024. *See* EX3001. As authorized, Petitioner addresses below the bankruptcy proceedings, the stay of the parallel district court litigation, and their impact vis-à-vis *Fintiv*.

I. BANKRUPTCY PROCEEDING AND DISTRICT COURT STAY

Petitioner filed for Chapter 11 bankruptcy on February 4, 2024. EX1066.001-.002. The parallel district court proceeding (Case No. 22-cv-00261) was then stayed, and the trial date vacated, on March 14, 2024. EX1067.

On June 14, 2024, the district court lifted the bankruptcy stay and substituted Bruker Spatial Biology, Inc. and Bruker Nano, Inc. for NanoString as defendants.

EX1068. The parties are working to reach an agreement as to trial schedules for the parallel district court litigation and related patent litigation not involving the '554 patent. EX1069.001-002. Patent Owner has proposed a trial date for the parallel district court litigation in late June or early July, however, no agreement has been reached. *Id.*; EX1070. Thus, there is currently no trial schedule and no trial date, although the district court may enter a schedule shortly.

II. IMPACT ON THE *FINTIV* FACTORS

A. Factor 1: Likelihood of a Stay

When the Petition was filed, the then-scheduled district court trial date was September 16, 2024. EX1071. That was well before the expected date of August 2025 for the final written decision to issue if an IPR were to be instituted. Paper 7. Following the bankruptcy stay, however, the scheduled district court trial date was vacated and has not yet been rescheduled. EX1069.001.

This factor now weighs more in favor of institution. *See, e.g., IOENGINE, LLC v. PayPal Holdings, Inc.*, 2019 U.S. Dist. LEXIS 141545, at *10-11 (D. Del. Aug. 21, 2019) (liberal stay policy applies to IPR proceedings, including where less than all asserted patents and claims are subject to IPR). While five additional patents are asserted in the parallel district court litigation, there are strong non-infringement defenses for each because their claims are method claims that are not performed entirely within the United States. *See NTP, Inc. v. Rsch. In Motion, Ltd.*, 418 F.3d

1282, 1318 (Fed. Cir. 2005) (“[U]se of a patented method does not infringe unless ‘each of the steps is performed within this country.’”). Further, the parallel district court litigation is at a relatively early stage, as discussed for Factor 3 below, making a stay realistic. *See, e.g., ThreatModeler Software Inc. v. IriusRisk, Inc.*, 1-22-cv-00912 (D. Del. Nov. 20, 2023) (“a stay pending final resolution of...IPR proceedings is in the best interest of the parties and promotes judicial economy because discovery is in its early stages”). This factor now favors institution.

B. Factor 2: Proximity of Trial Date to Final Written Decision

Prior to the bankruptcy stay, the scheduled trial date of September 16, 2024, fell roughly a year before the expected date for a final written decision of August 2025 if IPR were to be instituted. EX1061.002. Now, however, as discussed above, there is no scheduled trial date. EX1069.001; EX1070.

This fact alone weighs strongly against discretionary denial. *Oticon Med. AB v. Cochlear Ltd.*, IPR2019-00975, Paper 15 at 23–24 (PTAB Oct. 16, 2019) (precedential in relevant part) (lack of trial date weighs against discretionary denial, even when “discovery is ‘well underway’”); *Micron Tech., Inc. v. Godo Kaisha IP Bridge 1*, IPR2020-01008, Paper 10 at 12 (PTAB Dec. 7, 2020) (failure to formally set a trial date and uncertainty as to date weighs against denial).

That being said, the parties are in the process of discussing proposed trial dates, and it is likely that the district court will enter a schedule soon. When this

happens, this factor will still weigh in favor of institution. Indeed, based on the parties' latest correspondence, Patent Owner is not even proposing that trial take place until late June or early July 2025. This is nearly a year away and, if this ends up being the trial date and there is no further delay, it would be less than two months prior to the expected August 2025 date for the final written decision if IPR is instituted. Paper 7; EX1070.

To the extent Patent Owner speculates using median time-to-trial statistics, the Board has recognized that these are not necessarily useful, particularly in circumstances deviating from a typical case. *See, e.g., Tesla, Inc. v. Charge Fusion Technologies, LLC*, IPR2023-00062, Paper 13 at 14 (PTAB May 11, 2023) (declining to speculate as to a trial date based on time-to-trial statistics where a case had been transferred to a different division of district). Here, the circumstances are not those of a typical case, not just for the reasons above but also because the '554 patent was not asserted in the complaint as originally filed on February 28, 2022, but only in a second amended complaint that was not filed until March 1, 2023. EX1062; EX1063. Further, the median time to trial for civil actions in the District of Delaware is now 38 months. EX1072.014. Even if a typical case, with a filing date of February 28, 2022, the projected district court trial date would still not be before April 2025. This factor now favors institution.

C. Factor 3: Investment in Parallel Proceeding

Much effort will remain after the date of the institution decision. EX1070. Based on proposed schedules being discussed by the parties, fact discovery will not close until roughly December 2024 and expert discovery, including expert reports, will not be completed until April or May 2025. *Id.* Further, dispositive motions and responsive briefing will continue into May or June 2025. *Id.*

The investment analysis focuses on work completed “at the time of the institution decision” that concerns “the merits of the invalidity positions.” *Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 11 at 9-10 (PTAB Mar. 20, 2020) (precedential); *Sand Revolution II, LLC v. Cont’l Intermodal Group – Trucking LLC*, IPR2019-01393, Paper 24 at 10 (PTAB June 16, 2020) (informative). Here, where discovery will not be completed and dispositive motions not due until well after the decision on institution, the investment remaining after the institution decision is significant. Further, “the most burdensome parts of the case—filing and responding to pretrial motions, preparing for trial, going through the trial process, and engaging in post-trial motions practice—all lie in the future.” *CyWee Grp. Ltd. v. Samsung Elecs. Co. Ltd.*, No. 2:17-cv-00140-WCB-RSP, 2019 WL 11023976, at *6 (E.D. Tex. Feb. 14, 2019). This factor now favors institution.

Dated: July 1, 2024

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

The undersigned certifies that this brief complies with the type-volume limitations of 37 CFR § 42.24(a)(1)(i). This brief contains no more than 5 pages, as permitted by the Board's email authorization dated June 24, 2024.

Dated: July 1, 2024

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CERTIFICATE OF SERVICE

I hereby certify that on July 1, 2024, copies of the foregoing **PETITIONER'S
REPLY TO PATENT OWNER'S PRELIMINARY RESPONSE** was served via
electronic mail, upon the following:

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