Filed on behalf of Foundation Medicine, Inc.

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Foundation Medicine, Inc.
Petitioner

v.

Caris MPI, Inc.
Patent Owner

Case IPR2019-00166
U.S. Patent No. 9,292,660

PETITIONER'S MOTION FOR ADMISSION *PRO HAC VICE* OF SHIRLEY X. LI CANTIN

I. Statement of Precise Relief Requested

Pursuant to 37 C.F.R. § 42.10(c) and Paper No. 6 authorizing the parties to file motions for *pro hac vice* admission under 37 C.F.R. § 42.10(c), Petitioner Foundation Medicine, Inc. ("FMI") requests that the Patent Trial and Appeal Board (the "Board") admit Shirley X. Li Cantin *pro hac vice* in this proceeding, IPR2019-00166. Patent Owner Caris MPI, Inc. does not oppose this motion.

II. Statement of Facts Showing Good Cause for the Board to Recognize Counsel *Pro Hac Vice* During the Proceeding

In accordance with 37 C.F.R. § 42.10(c), the Board may recognize counsel *pro hac vice* during a proceeding upon a showing of good cause, subject to the condition that lead counsel be a registered practitioner and to any other conditions the Board may impose. Section 42.10(c) indicates that, "where lead counsel is a registered practitioner, a motion to appear *pro hac vice* by counsel who is not a registered practitioner may be granted upon a showing that counsel is an experienced litigating attorney and has an established familiarity with the subject matter at issue in the proceeding." The facts here establish good cause for the Board to recognize Ms. Cantin *pro hac vice* in this proceeding.

Lead counsel, David L. Cavanagh, is a registered practitioner. Back-up counsel, William Kim and Kevin M. Yurkerwich, are also registered practitioners.

Ms. Cantin is an experienced litigator who has an established familiarity with the subject matter at issue in the proceeding. Accompanying this motion as Exhibit 1115 is the Declaration of Shirley X. Li Cantin in Support of this Motion for Admission *Pro Hac Vice* ("Cantin Decl."). In her declaration, Ms. Cantin asserts:

> I am a member in good standing of the Bars of Massachusetts and New York and am admitted to practice before the U.S. District Court for the District of Massachusetts and the U.S. District Court for the Western District of Texas. I am admitted to practice before the U.S. Courts of Appeal for the Federal Circuit and the First Circuit. I am also admitted to practice before the U.S. Tax Court.

Cantin Decl. ¶ 3 (Ex. 1115). Ms. Cantin states that she has an established relationship with Petitioner FMI. *Id.* ¶¶ 11-12 (Ex. 1115). Ms. Cantin further demonstrates that she has a detailed working knowledge of the relevant subject matter through her participation in other proceedings involving U.S. Patent No. 9,292,660 and FMI's diagnostic products. Ms. Cantin also has significant experience with litigation involving pharmaceutical drug products, including cancer therapies, as a result of her participation as counsel in pharmaceutical-related patent cases. *Id.* ¶ 12 (Ex. 1115).

In her declaration, Ms. Cantin also attests to each of the listed items required by the Order – Authorizing Motion for Pro Hac Vice Admission – 37 C.F.R. §

42.10 in IPR2013-00639, Paper 7. *See id.* ¶¶ 1-13 (Ex. 1115). Ms. Cantin attests that she has read and will comply with the Office Patent Trial Practice Guide and the Board's Rules of Practice for Trials set forth in 37 C.F.R. § 42. *Id.* ¶ 8 (Ex. 1115). Ms. Cantin further attests that she agrees to be subject to the United States Patent and Trademark Office's Rules of Professional Conduct as set forth in 37 C.F.R. §§ 11.101 *et seq.* and disciplinary jurisdiction under 37 C.F.R. § 11.19(a). *Id.* ¶ 9 (Ex. 1115).

III. Conclusion

For the foregoing reasons, FMI respectfully requests that the Board admit Ms. Cantin *pro hac vice* in this proceeding.

Dated: July 3, 2019

Respectfully submitted,

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Petitioner's Exhibit List

Exhibit	Exhibit Name
1001	U.S. Patent No. 9,292,660 (the "'660 patent")
1002	Declaration of Paul T. Spellman, Ph.D.
1003	File History Excerpt
1004	PCT Publication No. WO 03/017038 (published Feb. 27, 2003) ("Lu")
1005	Illumina® Gene Expression Profiling, Technical Bulletin, RNA Profiling with the DASL® Assay (2005) ("Illumina")
1006	U.S. Patent Publication No. 2002/0150966 ("Muraca")
1007	Amy L. McDoniels-Silvers et al., *Differential Expression of Critical Cellular Genes in Human Lung Adenocarcinomas and Squamous Cell Carcinomas in Comparison to Normal Lung Tissues*, 4 Neoplasia 141 (2002)
1008	Robert Langreth & Michael Waldholz, *New Era of Personalized Medicine Targeting Drugs For Each Unique Genetic Profile*, 4 The Oncologist 426 (1999)
1009	Charles Sawyers, *Targeted cancer therapy*, 432 Nature 294 (2004)
1010	*NHGRI Seeks Next Generation of Sequencing Technologies* (Oct. 14, 2004), https://www.genome.gov/12513210/2004-release-nhgri-seeks-next-generation-of-sequencing-technologies/
1011	Genomics and Personalized Medicine Act of 2006, S. 3822, 109th Cong.
1012	Jackson B. Gibbs, *Anticancer drug targets: growth factors and growth factor signaling*, 105 J. Clinical Investigation 9 (2000)
1013	Nida Iqbal & Naveed Iqbal, Imatinib: A Breakthrough of Targeted Therapy in Cancer, Chemotherapy Research & Practice 1 (2014)
1014	Gleevec™ (imatinib mesylate) Prescribing Information (Jan. 22, 2002)
1015	Herceptin® (trastuzumab) Prescribing Information (Sept. 1998)

Exhibit	Exhibit Name
1016	S. Scholl, *Targeting HER2 in Other Tumor Types*, 12 Annals Oncology S81 (2001)
1017	Iressa™ (gefitinib) Prescribing Information (May 2, 2003)
1018	Tarceva™ (erlotinib) Prescribing Information (Nov. 18, 2004)
1019	James Moyer et al., *Induction of Apoptosis and Cell Cycle Arrest by CP-358,774, an Inhibitor of Epidermal Growth Factor Receptor Tyrosine Kinase*, 57 Cancer Research 4838 (1997)
1020	ClinicalTrials.gov, Study of TARCEVA (Erlotinib) as Adjuvant Treatment for Locally Advanced Head and Neck Squamous Cell Carcinoma, available at https://clinicaltrials.gov/ct2/show/NCT01515137
1021	NCI Drug Dictionary, https://www.cancer.gov/publications/dictionaries/cancer-drug/def/cetuximab
1022	Henry Q. Xiong & James L. Abbruzzese, Epidermal growth factor receptor-targeted therapy for pancreatic cancer, 29 Seminars in Oncology 31 (2002)
1023	Erbitux™ (cetuximab) Prescribing Information (Feb. 12, 2004)
1024	Affidavit of Christopher Butler (Nov. 5, 2018)
1025	Erbitux™ (cetuximab) Prescribing Information (Mar. 1, 2006)
1026	Jane E. Staunton et al., *Chemosensitivity prediction by transcriptional profiling*, 98 PNAS 10787 (2001)
1027	Atul J. Butte et al., *Discovering functional relationships between RNA expression and chemotherapeutic susceptibility using relevance networks*, 97 PNAS 12182 (2000)
1028	Thomas M. Daly et al., *Precision Profiling and Components of Variability Analysis for Affymetrix Microarray Assays Run in a Clinical Context*, 7 J. Molecular Diagnostics 404 (2005)
1029	Thomas Jarvie, *Next generation sequencing technologies*, 2 Drug Discovery Today: Technologies 255 (2005)
1030	Daniel R. Rhodes et al., *Oncomine: A Cancer Microarray Database*

Exhibit	Exhibit Name
	and Integrated Data-Mining Platform, 6 Neoplasia 1, 1 (2004)
1031	Daniel R. Rhodes et al., *Large-scale meta-analysis of cancer microarray data identifies common transcriptional profiles of neoplastic transformation and progression*, 25 PNAS 9309 (2004)
1032	Daniel R. Rhodes et al., *Oncomine 3.0: Genes, Pathways, and Networks in a Collection of 18,000 Cancer Gene Expression Profiles*, 9 Neoplasia 166 (2007)
1033	H. Parkinson, *ArrayExpress—a public repository for microarray gene expression data at the EBI*, 33 Nucleic Acids Research D553 (2005)
1034	Jeremy Gollub et al., *The Stanford Microarray Database: data access and quality assessment tools*, 31 Nucleic Acids Research 94 (2003)
1035	Alexander Statnikov et al., *GEMS: A System for Automated Cancer Diagnosis and Biomarker Discovery from Microarray Gene Expression Data*, 74 Int'l J. Med. Informatics 491 (2005)
1036	C.J. Zheng et al., *TRMP: a database of therapeutically relevant multiple pathways*, 20 Bioinformatics 2236 (2004)
1037	X. Chen et al., *TTD: Therapeutic Target Database*, 30 Nucleic Acids Research 412 (2002)
1038	S. Forbes et al., *COSMIC 2005*, 94 British J. Cancer 318 (2006)
1039	Justin Lamb et al., *The Connectivity Map: Using Gene-Expression Signatures to Connect Small Molecules, Genes, and Disease*, 313 Science 1929 (2006)
1040	Timothy R. Hughes et al., *Functional Discovery via a Compendium of Expression Profiles*, 102 Cell 109 (2000)
1041	U.S. Provisional Patent Application No. 60/747,645
1042	Oxford Dictionary of Biochemistry and Molecular Biology (Oxford University Press, 2d ed. 2006)
1043	Xiaojun Zhao et al., *Homozygous Deletions and Chromosome Amplifications in Human Lung Carcinomas Revealed by Single Nucleotide Polymorphism Array Analysis*, 65 Cancer Research 5561

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	(2005)
1044	HUGO Gene Nomenclature Committee Symbol Report: EGFR, available at https://www.genenames.org/cgi-bin/gene_symbol_report?hgnc_id=HGNC:3236
1045	HUGO Gene Nomenclature Committee Symbol Report: ERBB2, available at https://www.genenames.org/cgi-bin/gene_symbol_report?hgnc_id=HGNC:3430
1046	Business Wire, *Illumina Launches DASL Assay and Cancer Panel for Gene Expression Profiling of Paraffin-Embedded Samples* (Jan. 13, 2005)
1047	Marina Bibikova et al., *Gene Expression Profiles in Formalin-Fixed, Paraffin-Embedded Tissues Obtained with a Novel Assay for Microarray Analysis*, 50 Clinical Chemistry 2384 (2004)
1048	Marina Bibikova et al., *Quantitative Gene Expression Profiling in Formalin-Fixed, Paraffin-Embedded Tissues Using Universal Bead Arrays*, 165 American J. Pathology 1799 (2004)
1049	Jian-Bing Fan et al., *A Versatile Assay for High-Throughput Gene Expression Profiling on Universal Array Matrices*, 14 Genome Research 878 (2004)
1050	Jeffrey S. Ross & Geoffrey S. Ginsburg, *The Integration of Molecular Diagnostics with Therapeutics: Implications for Drug Development and Pathology Practice*, 119 Am. J. Clinical Pathology 26 (2003) ("Ross")
1051	Masuko Katoh & Masaru Katoh, *Bioinformatics for Cancer Management in the Post-Genome Era*, 5 Technology in Cancer Research & Treatment 169 (2006)
1052	David Stipp, *Gene Chip Breakthrough*, Fortune Magazine, Mar. 31, 1997, at 56
1053	Jian-Bing Fan et al., *BeadArray™-based solutions for enabling the promise of pharmacogenomics*, 39 BioTechniques 583 (2005)
1054	U.S. Patent No. 9,092,392 (the "'392 patent")
1055	David S. Wishart et al, *DrugBank: a comprehensive resource for* in

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	silico *drug discovery and exploration*, 34 Nucleic Acids Research D668 (2006)
1056	Timothy K. Egan, *Monitoring Patients Undergoing Cancer Therapy*, 31 Lab. Med. 666 (2000)
1057	G. William Moore et al., *A Prototype Internet Autopsy Database: 1625 Consecutive Fetal and Neonatal Autopsy Facesheets Spanning Twenty Years*, 120 Archives Pathology Lab. Med. 782 (1996)
1058	HUGO Gene Nomenclature Committee Symbol Report: CASP8, available at https://www.genenames.org/cgi-bin/gene_symbol_report?hgnc_id=HGNC:1509
1059	Phillip G. Febbo & Geoffrey S. Ginsburg, *Personalized diagnostic and therapeutic strategies in oncology*, 2 Personalized Medicine 97 (2005)
1060	HUGO Gene Nomenclature Committee Symbol Report: ESR1, available at https://www.genenames.org/cgi-bin/gene_symbol_report?hgnc_id=HGNC:3467
1061	NIH National Cancer Institute, *How Imatinib Transformed Leukemia Treatment and Cancer Research*, (updated Apr. 11, 2018) https://www.cancer.gov/research/progress/discovery/gleevec
1062	Claudia Dreifus, *Researcher Behind the Drug Gleevec*, N.Y. Times (Nov. 2, 2009), at D4
1063	Dan L. Longo, *Imatinib Changed Everything*, 376 New England J. Med. 982 (2017)
1064	Federico Cappuzzo et al., *Clinical experience with gefitinib: An update*, 58 Critical Reviews in Oncology/Hematology 31 (2006)
1065	Complaint for Patent Infringement
1066	[Reserved]
1067	Yardena Samuels et al., *High Frequency of Mutations of the PIK3CA Gene in Human Cancers*, 304 Science 554 (2004)
1068	Hong-Guang Xie & Felix W. Frueh, *Pharmacogenomics steps toward personalized medicine*, 2 Personalized Medicine 325 (2005)
1069	Andreas Gnirke et al., *Solution hybrid selection with ultra-long*

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	oligonucleotides for massively parallel targeted sequencing, 27 Nature Biotechnology 182 (2009)
1070	Timothy Ley et al., *DNA sequencing of a cytogenetically normal acute myeloid leukemia genome*, 456 Nature 66 (2008)
1071	David J. Sugarbaker et al., *Transcriptome sequencing of malignant pleural mesothelioma tumors*, 105 PNAS 3521 (2008)
1072	Andreas Gnirke et al., *Solution hybrid selection with ultra-long oligonucleotides for massively parallel targeted sequencing*, 27 Nature Biotechnology 182, Supplementary Figures and Tables (2009)
1073	Ashish Gautam et al., *RRM1-induced metastasis suppression through PTEN-regulated pathways*, 22 Oncogene 2135 (2003)
1074	U.S. Patent Publication No. 2008/0014146 ("Von Hoff")
1075	Alberto Bardelli & Victor E. Velculescu, *Mutational analysis of gene families in human cancer*, 15 Current Opinion in Genetics & Development 5 (2005)
1076	ThermoFisher Scientific, Overview of Immunohistochemistry (IHC), available at https://www.thermofisher.com/us/en/home/life-science/protein-biology/protein-biology-learning-center/protein-biology-resource-library/pierce-protein-methods/overview-immunohistochemistry.html
1077	HUGO Gene Nomenclature Committee Symbol Report: PIK3CA, available at https://www.genenames.org/cgi-bin/gene_symbol_report?hgnc_id=HGNC:8975
1078	HUGO Gene Nomenclature Committee Symbol Report: CTNNB1, available at https://www.genenames.org/cgi-bin/gene_symbol_report?hgnc_id=HGNC:2514
1079	U.S. Patent No 8,768,629 (the "'629 patent")
1080	Degeng Wang, *Discrepancy between mRNA and protein abundance: Insight from information retrieval process in computers*, 32 Computational Biology & Chemistry 462 (2008)
1081	Gerold Bepler, *Pharmacogenomics: A reality or still a promise?*, 54 Lung Cancer S3 (2006)
1082	HUGO Gene Nomenclature Committee Symbol Report: BRAF, available at https://www.genenames.org/cgi-bin/gene_symbol_report?hgnc_id=HGNC:1097
1083	HUGO Gene Nomenclature Committee Symbol Report: RAF1,

Exhibit	Exhibit Name
	available at https://www.genenames.org/cgi-bin/gene_symbol_report?hgnc_id=HGNC:9829
1084	U.S. Provisional Application No. 61/217,289
1085	U.S. Provisional Application No. 61/170,565
1086	U.S. Provisional Application No. 61/105,335
1087	Tobias Sjöblom et al., *The Consensus Coding Sequences of Human Breast and Colorectal Cancers*, 314 Science 268 (2006)
1088	Tobias Sjöblom et al., *The Consensus Coding Sequences of Human Breast and Colorectal Cancers*, 314 Science 268, Supporting Material (2006), available at http://science.sciencemag.org/content/suppl/2006/10/24/1133427.DC1
1089	Tobias Sjöblom et al., *The Consensus Coding Sequences of Human Breast and Colorectal Cancers*, 314 Science 268, Table S1 (2006), available at http://science.sciencemag.org/content/suppl/2006/10/24/1133427.DC1
1090	Tobias Sjöblom et al., *The Consensus Coding Sequences of Human Breast and Colorectal Cancers*, 314 Science 268, Tables S2A and S2B (2006), available at http://science.sciencemag.org/content/suppl/2006/10/24/1133427.DC1
1091	Tobias Sjöblom et al., *The Consensus Coding Sequences of Human Breast and Colorectal Cancers*, 314 Science 268, Table S3 (2006), available at http://science.sciencemag.org/content/suppl/2006/10/24/1133427.DC1
1092	Tobias Sjöblom et al., *The Consensus Coding Sequences of Human Breast and Colorectal Cancers*, 314 Science 268, Table S4 (2006), available at http://science.sciencemag.org/content/suppl/2006/10/24/1133427.DC1
1093	Tobias Sjöblom et al., *The Consensus Coding Sequences of Human Breast and Colorectal Cancers*, 314 Science 268, Table S5 (2006), available at http://science.sciencemag.org/content/suppl/2006/10/24/1133427.

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1094	Tobias Sjöblom et al., *The Consensus Coding Sequences of Human Breast and Colorectal Cancers*, 314 Science 268, Table S6 (2006), available at http://science.sciencemag.org/content/suppl/2006/10/24/1133427.DC1
1095	Olena Morozova & Marco A. Marra, *Applications of next-generation sequencing technologies in functional genomics*, 92 Genomics 255 (2008)
1096	HUGO Gene Nomenclature Committee Symbol Report: KIT, available at https://www.genenames.org/cgi-bin/gene_symbol_report?hgnc_id=HGNC:6342.
1097	HUGO Gene Nomenclature Committee Symbol Report: KRAS, available at https://www.genenames.org/cgi-bin/gene_symbol_report?hgnc_id=HGNC:6407
1098	Affidavit of Christopher Butler (May 10, 2019)
1099	Declaration of Mark Abramovitz (June 3, 2019)
1100	Mark Abramovitz & Brian Leyland-Jones, *A Systems Approach to Clinical Oncology: Focus on Breast Cancer*, 4 Proteome Sci. (2006)
1101	Jian-Bing Fan et al., *Multiplexed RNA Profiling of Paraffin Samples – Assay Tutorial: Reproducible Gene Expression from Degraded RNAs Using the DASL Assay*, 25 Genetic Eng'g News 28 (2005)
1102	Fixed on Expression, 4 Bio-IT World 22 (2005)
1103	Seminar Notice, Sunnybrook Research Institute, *Applying Genomic and Proteomic Platforms Towards the Individualization of Treatment for Breast Cancer Patients* (Oct. 25, 2006)
1104	Illumina Seminar Series Notice, University of Florida, *From Whole-Genome to Whole-Solution, Disease Analysis Tools for the Next Generation* (Feb. 15, 2007)
1105	Declaration of George Yu (June 3, 2019)
1106	*Affymetrix, Inc. v. Illumina, Inc.*, No. 1:04-cv-00901-JJF, D.I. 140 (D. Del. Dec. 22, 2005)
1107	*Affymetrix, Inc. v. Illumina, Inc.*, No. 1:04-cv-00901-JJF, D.I. 209

Exhibit	Exhibit Name
	(D. Del. Feb. 9, 2006)
1108	*Affymetrix, Inc. v. Illumina, Inc.*, No. 1:04-cv-00901-JJF, D.I. 357 (D. Del. Feb. 5, 2007)
1109	Declaration of Sylvia Hall-Ellis (May 31, 2019)
1110	Andrew C. Haller et al., *Transcriptional Profiling of Degraded RNA in Cryopreserved and Fixed Tissue Samples Obtained at Autopsy*, 6:9 BMC Clinical Pathology (2006)
1111	Marina Bibikova et al., *Quantitative Expression Profiling of RNA from Formalin-Fixed, Paraffin-Embedded Tissues Using Randomly Assembled Bead Arrays*, in Genomics Protocols (Mike Starkey & Ramnath Elaswarapu eds., 2d ed. 2008)
1112	A. Mitra et al., *Melanoma Sentinel Node Biopsy and Prediction Models for Relapse and Overall Survival*, 103 Brit. J. Cancer 1229 (2010)
1113	Natalie Stickle and Neil Winegarden, *Toward the Realization of the Promise of Microarrays in Oncology*, Genomics and Pharmacogenomics, in Anticancer Drug Development and Clinical Response (Federico Innocenti ed., 2008)
1114	Declaration of David B. Bassett in Support of Motion for Admission *Pro Hac Vice*
1115	Declaration of Shirley X. Li Cantin in Support of Motion for Admission *Pro Hac Vice*

CERTIFICATE OF SERVICE

I hereby certify that on July 3, 2019, I caused true and correct copies of the following materials:

- Petitioner's Motion for Admission *Pro Hac Vice* of Shirley X. Li Cantin
- Exhibit 1115, Declaration of Shirley X. Li Cantin in Support of Motion for Admission *Pro Hac Vice*; and
- Petitioner's Exhibit List

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