

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

TAKEDA VACCINES, INC.,
Petitioner

v.

VALNEVA AUSTRIA GMBH,
Patent Owner

Case IPR2023-00354
U.S. Patent No. 11,219,681

PETITIONER TAKEDA VACCINES, INC.'S UPDATED EXHIBIT LIST

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Petitioner Takeda Vaccines, Inc., files this Updated Exhibit List to accompany filing of Exhibit 1210, the transcript of a teleconference held between the Board and parties on April 19, 2023.

<i>Exhibit #</i>	<i>Description</i>
1001	Barbero Calzado, J., et al., U.S. Patent No. 11,219,681, “Zika Virus Vaccine” (filed March 10, 2020; issued Jan. 11, 2022)
1002	Declaration of Dan H. Barouch, M.D., Ph.D.
1003	<i>Curriculum Vitae</i> of Dan H. Barouch, M.D., Ph.D.
1004	File History of U.S. Patent No. 11,219,681
1005	Yoshii, K., et al., “A Conserved Region in the prM Protein Is a Critical Determinant in the Assembly of Flavivirus Particles,” <i>J. General Virology</i> , 93: 27–38 (2012)
1006	Larocca, R.A., et al., “Vaccine Protection Against Zika Virus from Brazil,” <i>Nature</i> , 536: 474–478 (2016)
1007	Halloway, T., “WRAIR Technology Helps Create Japanese Encephalitis Vaccine,” <i>available at</i> : https://web.archive.org/web/20150920175227/http://www.army.mil/article/19643/WRAIR_Technology_helps_create_Japanese_Encephalitis_Vaccine/ (last accessed November 9, 2022)
1008	Barbero Calzado, J., et al., International Patent Appl. Publ. No. WO 2017/109225 A1, “Zika Virus Vaccine” (filed Dec. 23, 2016; published June 29, 2017)
1009	BLAST alignment of SEQ ID NO: 47 to SEQ ID NO: 73
1010	<i>Intentionally Left Blank</i>
1011	<i>Intentionally Left Blank</i>
1012	<i>Intentionally Left Blank</i>
1013	<i>Intentionally Left Blank</i>
1014	European Patent Appl. No. 15202585.4 (filed Dec. 23, 2015)
1015	European Patent Appl. No. 16161068.8 (filed Mar. 18, 2016)

<i>Exhibit #</i>	<i>Description</i>
1016	European Patent Appl. No. 16176025.1 (filed June 23, 2016)
1017	European Patent Appl. No. 16176049.1 (filed June 23, 2016)
1018	European Patent Appl. No. 16182845.4 (filed Aug. 4, 2016)
1019	GenBank: KJ776791.1, “Zika Virus Strain H/PF/2013 Polyprotein Gene, complete CDs,” <i>available at</i> : https://www.ncbi.nlm.nih.gov/nuccore/KJ776791.1 (last modified June 13, 2014) (last accessed November 9, 2022)
1020	BLAST alignment of KJ776791.1 to SEQ ID NO: 72
1021	Watanaveeradej, V., et al., “Safety and Immunogenicity of a Rederived, Live-Attenuated Dengue Virus Vaccine in Healthy Adults Living in Thailand: A Randomized Trial,” <i>Am. J. Trop. Med. Hyg.</i> , 91(1): 119–128 (2014)
1022	Orenstein, W.A., et al., “Global Vaccination Recommendations and Thimerosal,” <i>Pediatrics</i> , 131(1): 149–151 (2012)
1023	Eckels, K.H., et al., “Japanese Encephalitis Virus Live-Attenuated Vaccine, Chinese Strain SA14-14-2; Adaptation to Primary Canine Kidney Cell Cultures and Preparation of a Vaccine for Human Use,” <i>Vaccine</i> , 6(6): 513–518 (1988)
1024	Martinez, L.J., et al., “Safety and Immunogenicity of a Dengue Virus Serotype-1 Purified-Inactivated Vaccine: Results of a Phase 1 Clinical Trial,” <i>Am. J. Trop. Med. Hyg.</i> , 93(3): 454–460 (2015)
1025	WHO Director-General Summarizes the Outcome of the Emergency Committee Regarding Clusters of Microcephaly and Guillain-Barré Syndrome, World Health Organization, (Feb. 1, 2016), <i>available at</i> : https://web.archive.org/web/20160204040311/http://www.who.int/mediacentre/news/statements/2016/emergency-committee-zika-microcephaly/en/ (last accessed November 9, 2022)
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1027	Li, X-F, et al., “Complete Genome Sequence of a Chikungunya Virus Isolated in Guangdong, China,” <i>J. Virology</i> , 86(16): 8904–8905.

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1028	Putnak, R., et al. “Development of a Purified, Inactivated, Dengue-2 Virus Vaccine Prototype in Vero Cells: Immunogenicity and Protection in Mice and Rhesus Monkeys,” <i>J. Infectious Diseases</i> , 174: 1176–1184 (1996)
1029	Musso, D., et al., “Potential Sexual Transmission of Zika Virus,” <i>Emerging Infectious Diseases</i> , 21(2): 359–361
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1031	Duffy, M.R., “Zika Virus Outbreak on Yap Island, Federated States of Micronesia,” <i>New England J. of Med.</i> , 360(24): 2536–2543
1032	Cao-Lormeau, V. and Musso, D., “Emerging Arboviruses in the Pacific,” <i>The Lancet</i> , 384: 1571–1572 (2014)
1033	Zika Virus Microcephaly and Guillain-Barré Syndrome, Situation Report, World Health Organization, <i>available at</i> : https://web.archive.org/web/20160320210243/http://apps.who.int/iris/bitstream/10665/204633/1/zikasitrep_17Mar2016_eng.pdf?ua=1 (Mar. 17, 2016) (last accessed November 9, 2022)
1034	Maurice, J., “WHO Reveals its Shopping List for Weapons Against Zika,” <i>The Lancet</i> 387: 733 (2016)
1035	Besnard, M., et al., “Evidence of perinatal transmission of Zika virus, French Polynesia, December 2013 and February 2014,” 19(13): pii=20751 (2014)
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1037	Rasmussen, S.A., “Vaccines and Pregnancy: Past, Present, and Future,” <i>Seminars in Fetal & Neonatal Med.</i> , 19: 161–169 (2014)
1038	Plotkin, S.A. and Plotkin, S.L., “The Development of Vaccines: How the Past Led to the Future,” <i>Nature Reviews Microbiology</i> 9: 889–893 (2011)
1039	Heinz, F.X. and Stiasny, K., “Flaviviruses and Flavivirus Vaccines,” <i>Vaccine</i> 30: 4301–4306 (2012)

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1041	Ishikawa, T., et al., “A Review of Successful Flavivirus Vaccines and the Problems with Those Flaviviruses for Which Vaccines are Not Yet Available,” <i>Vaccine</i> , 32: 1326–1337 (2014)
1042	Burton, D.R., “Antibodies, Viruses and Vaccines,” <i>Nature Review Immunology</i> 2: 706–713 (2002)
1043	Roehrig, J.T., et al., “Guidelines for Plaque-Reduction Neutralization Testing of Human Antibodies to Dengue Viruses,” <i>Viral Immunology</i> , 21(2): 123–132 (2008)
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1046	Bauer, K., “A Phase II, Randomized, Safety and Immunogenicity Trial of a Re-Derived, Live-Attenuated Dengue Virus Vaccine in Healthy Children and Adults Living in Puerto Rico,” <i>Am. J. Trop. Med. Hyg.</i> , 93(3): 441–453 (2015)
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1050	Brinton, M.A. and Basu, M., “Functions of the 3’ and 5’ Genome RNA Regions of Members of the Genus Flavivirus,” <i>Virus Research</i> 206: 108–119 (2015)
1051	Okada, K., et al., “Safety and Immunogenicity of a Freeze-Dried, Cell Culture-Derived Japanese Encephalitis Vaccine (Inactivated) (JEBIK [®] V) in Children,” <i>Vaccine</i> ,
1052	Cohen, J., “The Race for a Zika Vaccine Is On,” <i>Science</i> 351(6273): 543–544 (2016)
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1056	Zhang, X., et al., “Genetic and Biochemical Characterizations of Zika Virus NS2A Protein,” <i>Emerging Microbes & Infections</i> , 8(1): 585–602 (2019)
1057	Sample GenBank Record <i>available at</i> : https://www.ncbi.nlm.nih.gov/genbank/samplerecord/#ModificationDateB (last accessed November 9, 2022)
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1060	Schuller, E., et al., “Long-term Immunogenicity of the New Vero Cell-Derived, Inactivated Japanese Encephalitis Virus Vaccine IC51 Six and 12 Month Results of a Multicenter Follow-Up Phase 3 Study,” <i>Vaccine</i> , 26: 4382–4386 (2008)
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1067	Annunziato, F., et al., “The 3 Major Types of Innate and Adaptive Cell-Mediated Effector Immunity,” <i>J. Allergy & Clinical Immunology</i> , 135(3): 626–635 (2014)
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1069	Benson, D.A., et al., “GenBank,” <i>Nucleic Acids Research</i> , 41: D36–D42 (2012)

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1071	BLAST alignment of translation of KJ776791.1 ORF to SEQ ID NO: 73
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1073	Fauci, A.S. and D.M. Morens, “Zika Virus in the Americas – Yet Another Arbovirus Threat,” <i>The New England Journal of Medicine</i> , 374(7): 601–604 (2016)
1074	Dyer, O., “Zika Vaccine Could Be In Production By Year’s End, Says Maker,” <i>BMJ</i> 352:i630 (2016)
1075	BLAST alignment of PRVABC59 to SEQ ID NO: 72
1076	BLAST alignment of translation of PRVABC59 ORF to SEQ ID NO: 40
1077	Kumar, S., et al., “Metal Ion Leachates and the Physio-Chemical Stability of Biotherapeutic Drug Products,” <i>Current Pharmaceutical Design</i> , 20: 1173–1181 (2014)
1078	Declaration of Scott Bailey, Ph.D.
1079	<i>Curriculum Vitae</i> of Scott Bailey, Ph.D.
1080	Luca, V.C., et al., “Crystal Structure of the Japanese Encephalitis Virus Envelope Protein,” <i>J. Virology</i> , 86(4): 2337–2346 (2012)
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1082	Mukhopadhyay, S., et al., “A Structural Perspective of the <i>Flavivirus</i> Life Cycle,” <i>Nature Review Microbiology</i> , 3: 13–22 (2005)

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1083	Möhlen, M., et al., International Patent Appl. Publ. No. WO 2013/083726 A1, “Aluminum Compounds for Use in Therapeutics and Vaccines” (filed Dec. 6, 2012; published June 13, 2013)
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1091	DiNunno, N.M., et al., “Identification of a Pocket Factor That Is Critical to Zika Virus Assembly,” <i>Nature Communications</i> , 11: 4953 (2020)
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1093	Tan, T.Y., et al., “Capsid Protein Structure in Zika Virus Reveals the Flavivirus Assembly Process,” <i>Nature Communications</i> , 11: 895 (2020)

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1094	Ma, X., et al., “Identification and Characterization of Key Residues in Zika Virus Envelope Protein for Virus Assembly and Entry,” <i>Emerging Microbes & Infections</i> , 11(1): 1604–1620 (2022)
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1096	Barzon, L., et al., “Zika Virus: From Pathogenesis to Disease Control,” <i>FEMS Microbiology Letters</i> , 363(18): 1–17 (2016)
1097	Declaration of Ingrid Hsieh-Yee, Ph.D.
1098	BLAST alignment of KJ776791.2 to SEQ ID NO: 72
1099	Poland, G.A., et al., “Zika Vaccine Development: Current Status,” <i>Mayo Clinic Proceedings</i> , 94(12): 2572–2586 (2019)
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1104	File History of U.S. Patent Application No. 16/063,007
1105	BLAST alignment of SEQ ID NO: 2 and SEQ ID NO: 72
1106	BLAST alignment of SEQ ID NO: 3 and SEQ ID NO: 72
1107	BLAST alignment of SEQ ID NO: 4 and SEQ ID NO: 72
1108	BLAST alignment of SEQ ID NO: 5 and SEQ ID NO: 72
1109	BLAST alignment of SEQ ID NO: 6 and SEQ ID NO: 72
1110	BLAST alignment of SEQ ID NO: 7 and SEQ ID NO: 72

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1111	BLAST alignment of SEQ ID NO: 8 and SEQ ID NO: 72
1112	BLAST alignment of SEQ ID NO: 9 and SEQ ID NO: 72
1113	BLAST alignment of SEQ ID NO: 10 and SEQ ID NO: 72
1114	BLAST alignment of SEQ ID NO: 11 and SEQ ID NO: 72
1115	BLAST alignment of SEQ ID NO: 12 and SEQ ID NO: 72
1116	BLAST alignment of SEQ ID NO: 13 and SEQ ID NO: 72
1117	BLAST alignment of SEQ ID NO: 11 and SEQ ID NO: 12
1118	Nema, S. and Brendel, R.J., “Excipients and Their Role in Approved Injectable Products: Current Usage and Future Directions,” <i>PDA J. Pharmaceutical Science & Technology</i> , 65(3): 287–332 (2011)
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1120	Manikandan, S., “Measures of Central Tendency: The Mean,” <i>J. Pharmacology & Pharmacotherapeutics</i> , 2(2): 140–142 (2011)
1121	COLLEGE PHYSICS 790 (Franklin Miller, Jr. ed., 4th ed. 1977)
1122	Bayat, A., “Bioinformatics,” <i>BMJ</i> , 324: 1018–1022 (2002)
1123	Ekmekci, B., et al., “An Introduction to Programming for Bioscientists: A Python-Based Primer,” <i>PLoS Computational Biology</i> , 12(6): e1004867 (2016)
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1125	Venners, B., “The Making of Python A Conversation with Guido van Rossum, Part I,” <i>available at: https://www.artima.com/articles/the-making-of-python</i>
1126	Adams, P.D., et al., “PHENIX: A Comprehensive Python-Based System for Macromolecular Structure Solution,” <i>Acta Crystallographica Section D</i> , D66: 213–221 (2010)
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<i>Exhibit #</i>	<i>Description</i>
1128	BLAST: Basic Local Alignment Search Tool, <i>available at:</i> https://blast.ncbi.nlm.nih.gov/Blast.cgi
1129	Mount, D.W., “Using the Basic Local Alignment Search Tool (BLAST),” <i>Cold Spring Harbor Protocols</i> (2007), <i>available at:</i> http://cshprotocols.cshlp.org/content/2007/7/pdb.top17.full
1130	Chen, H., et al., “Cut Site Selection by the Two Nuclease Domains of the Cas9 RNA-guided Endonuclease,” <i>J. Biological Chemistry</i> , 289(19): 13284–13294 (2014)
1131	INTRODUCTORY STATISTICS (Prem S. Mann ed., 7th ed. 2010)
1132	Summation Notation, <i>available at:</i> http://www.columbia.edu/itc/sipa/math/summation.html)
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1138	Enfissi, A., et al., “Zika Virus Genome from the Americas,” <i>The Lancet</i> , 387: 227–228 (2016)
1139	PubMed metadata record for <i>Baronti</i> , <i>available at:</i> https://pubmed.ncbi.nlm.nih.gov/24903869/ , accessed and obtained on November 10, 2022

<i>Exhibit #</i>	<i>Description</i>
1140	Wayback Machine response page indicating that the old URL of “Current Zika product pipeline” at https://web.archive.org/web/20160309222523/http://www.who.int/entity/csr/research-and-development/zika-rd-pipeline.pdf?ua=1 was not archived by the Internet Archive. The Wayback Machine response page was accessed and obtained on December 15, 2022
1141	Table of contents of vol. 2, no. 3 (2014) of <i>Genome Announcements</i> that contains <i>Baronti</i> , archived on June 29, 2014 by the Internet Archive, <i>available at</i> : https://web.archive.org/web/20140629173328/http://genomea.asm.org/content/2/3.toc , accessed and obtained on November 11, 2022
1142	Citations to <i>Baronti</i> , obtained from Google Scholar
1143	Copy of <i>Zika Pipeline</i> archived on March 11, 2016 by the Internet Archive, <i>available at</i> : https://web.archive.org/web/20160311113550/http://www.who.int/csr/research-and-development/zika-rd-pipeline.pdf , accessed and obtained on November 10, 2022
1144	“WHO and Experts Prioritize Vaccines, Diagnostics and Innovative Vector Control Tools for Zika R&D,” a March 9, 2016 WHO Note for media, archived on March 9, 2016 by the Internet Archive, <i>available at</i> : https://web.archive.org/web/20160309222523/http://www.who.int/mediacentre/news/notes/2016/research-development-zika/en/ , accessed and obtained on December 5, 2022
1145	<i>Sifferlin-TIME</i> archived on January 22, 2016 by the Internet Archive, <i>available at</i> : https://web.archive.org/web/20160122154151/http://time.com/4188973/zika-virus-vaccine-nih/ , accessed and obtained on December 5, 2022
1146	Copy of <i>Srivastava</i> obtained from the University of Wisconsin-Madison Steenbock Library
1147	Bibliographic and MARC record for <i>Vaccine</i> that contains <i>Srivastava</i> , <i>available at</i> : https://search.library.wisc.edu/catalog/999552122802121 , from the online catalog of the University of Wisconsin-Madison Library System, accessed and obtained on November 11, 2022

<i>Exhibit #</i>	<i>Description</i>
1148	PubMed metadata record for <i>Srivastava</i> , available at: https://pubmed.ncbi.nlm.nih.gov/11483284/ , accessed and obtained on November 10, 2022
1149	<i>Vaccine</i> website archived by the Internet Archive on October 3, 2002, available at: https://web.archive.org/web/20021003015903/http://www.elsevier.com:80/locate/vaccine , from the Internet Archive, accessed and obtained on November 26, 2022
1150	Citations to <i>Srivastava</i> obtained from Google Scholar
1151	Copy of <i>Thomas</i> obtained from the National Library of Medicine
1152	Bibliographic and MARC record of <i>The American Journal of Tropical Medicine and Hygiene</i> that contains <i>Thomas</i> , available at: https://catalog.nlm.nih.gov/permalink/01NLM_INST/1o1phhn/alma991179293406676 , from the online catalog of the National Library of Medicine, accessed and obtained on November 15, 2022
1153	PubMed metadata record for <i>Thomas</i> , available at: https://pubmed.ncbi.nlm.nih.gov/23208878/ , accessed and obtained on November 10, 2022
1154	Citations to <i>Thomas</i> , obtained from Google Scholar
1155	<i>Intentionally Left Blank</i>
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<i>Exhibit #</i>	<i>Description</i>
1162	Sifferlin, A., “U.S. Launches ‘Full-Court Press’ for a Zika Vaccine,” <i>TIME</i> (Jan. 21, 2016, 3:24 PM), <i>available at</i> : https://time.com/4188973/zika-virus-vaccine-nih/
1163	Srivastava, A. K., Putnak, J. R., Lee, S. H., Hong, S. P., Moon, S. B., Barvir, D. A., ... & Eckels, K. H., (14 August 2001, available online 30 July 2001), “A Purified Inactivated Japanese Encephalitis Virus Vaccine Made in Vero cells,” <i>Vaccine</i> , vol. 19, no. 3, pp. 4557-4565
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1165	<i>Intentionally Left Blank</i>
1166	Declaration of Mr. Nathaniel E. Frank-White of the Internet Archive
1167	<i>Curriculum Vitae</i> of Ingrid Hsieh-Yee, Ph.D.
1168	“Understanding MARC Bibliographic: Machine-Readable Cataloging,” Library of Congress, Parts VII to X
1169	“Stop Codon,” excerpt from G. Davies et al., <i>Molecular Therapies for Cystic Fibrosis</i> , in <i>Kendig’s Disorders of the Respiratory Tract in Children</i> (9th ed., 2019), <i>available at</i> : https://www.sciencedirect.com/topics/neuroscience/stop-codon#:~:text=Premature%20stop%20codons%20are%20those,as%20truncated)%20protein%20is%20formed
1170	Shiver, J. et al., “Scientific Notation and Order of Magnitude,” VisionLearning, <i>available at</i> : https://www.visionlearning.com/en/library/Math-in-Science/62/Scientific-Notation-and-Order-of-Magnitude/250#top
1171	Bailey Declaration Example 1
1172	Bailey Declaration Example 2
1173	Bailey Declaration Python Script 1
1174	Bailey Declaration Python Script 2

<i>Exhibit #</i>	<i>Description</i>
1175	Bailey Declaration Python Script 3
1176	A. Ramachandran et al., <i>Processing and Integration of Functionally Oriented Prespacers in the Escherichia coli CRISPR System Depends on Bacterial Host Exonucleases</i> , 295 J. BIO. CHEM. 3403, 3412 (2020).
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1179	Souza, M.C.O., et al., “Production of yellow fever virus in microcarrier-based Vero cell cultures,” <i>Vaccine</i> , 27: 6420-6423 (2009)
1180	Pereira, R.C., et al., “An Inactivated Yellow Fever 17DD Vaccine Cultivated in Vero Cell Cultures,” <i>Vaccine</i> , 33: 4261-4268 (2015)
1181	Amended Articles of Incorporation of OCLC, Inc., revised June 23, 2017
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1183	“Discussion Paper No. 2020-DP16: Recording the Mode of Issuance for Manifestations,” Library of Congress, May 29, 2020
1184	<i>Intentionally Left Blank</i>
1185	Publisher’s webpage for <i>Baronti</i> , available at: https://journals.asm.org/doi/full/10.1128/genomeA.00500-14
1186	PubMed Website, available at: https://pubmed.ncbi.nlm.nih.gov/ https://pubmed.ncbi.nlm.nih.gov/%20
1187	List of early citations to <i>Baronti</i>
1188	World Health Organization webpage for <i>Current Zika Pipeline</i> , available at: http://www.who.int/publications/m/item/current-zika-product-pipeline
1189	WorldCat website, available at: https://www.worldcat.org

<i>Exhibit #</i>	<i>Description</i>
1190	BLAST alignment of KU955593.1 to SEQ ID NO: 72
1191	BLAST alignment of FSS13025 NS2A protein and SEQ ID NO: 73 (annotated)
1192	BLAST alignment of MR-766 E protein and SEQ ID NO: 73 (annotated)
1193	Bailey Declaration Example 3
1194	<i>Intentionally Left Blank</i>
1195	Publisher's webpage for <i>Srivastava</i> , available at: https://www.sciencedirect.com/science/article/pii/S0264410X01002080?via%3Dihub
1196	<i>Intentionally Left Blank</i>
1197	Webpage for ScienceDirect, available at: https://www.elsevier.com/solutions/sciencedirect
1198	WorldCat webpage for <i>Vaccine</i> , available at: https://worldcat.org/title/10399916
1199	ScienceDirect webpage for <i>Vaccine</i> , available at: https://www.sciencedirect.com/journal/vaccine
1200	Directory of OCLC Members, available at: https://www.oclc.org/en/contacts/libraries.html
1201	<i>Intentionally Left Blank</i>
1202	National Library of Medicine Classification Schedule, "W General Medicine. Health Professions," available at: https://classification.nlm.nih.gov/schedules/w
1203	<i>Intentionally Left Blank</i>
1204	Publisher's webpage for <i>Thomas</i> , available at: https://www.ajtmh.org/view/journals/tpmd/88/1/article-p73.xml
1205	WorldCat webpage for <i>Thomas</i> , available at: https://worldcat.org/title/1724826
1206	Description of MARC Org Code DNLM, MARC Code List for Organizations

<i>Exhibit #</i>	<i>Description</i>
1207	MEDLINE/PubMed Data Element (Field) Descriptions, <i>available at:</i> https://www.nlm.nih.gov/bsd/mms/medlineelements.html
1208	List of early citations to <i>Thomas</i>
1209	List of early citations to <i>Srivastava</i>
1210	Teleconference Transcript, April 19, 2023

Respectfully submitted,

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CERTIFICATE OF SERVICE (37 C.F.R. § 42.6(e))

I certify that the above-captioned **PETITIONER TAKEDA VACCINES, INC.'S UPDATED EXHIBIT LIST** and **EXHIBIT 1210** were served in their entirety on April 20, 2023, upon the following parties via electronic mail:

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