DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The invention listed below is owned by an agency of the U.S. Government and is available for licensing to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

FOR FURTHER INFORMATION CONTACT: Licensing information and copies of the U.S. patent application listed below may be obtained by communicating with the indicated licensing contact at the Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases, 5601 Fishers Lane, Rockville, MD 20852; tel. 301–496–2644. A signed Confidential Disclosure Agreement will be required to receive copies of unpublished patent applications.

SUPPLEMENTARY INFORMATION: Technology description follows.

Zika Virus Vaccines

Description of Technology

Zika virus (ZIKV) is a flavivirus transmitted by mosquitoes that is strongly linked to neurological complications including Guillain-Barré syndrome, meningoencephalitis, and microcephaly. The association between active ZIKV infection during pregnancy and microcephaly and intrauterine growth retardation in the fetus has been confirmed in murine models of ZIKV infection.

Scientists at NIAID have developed nucleic acid-based vaccine candidates to prevent ZIKV infection in humans. The current lead candidate vaccine is a plasmid DNA vaccine demonstrated to accord protection in preclinical models and is undergoing clinical trial evaluation. Nucleic acid-based vaccines have been developed previously for West Nile virus, another flavivirus similar to Zika (J.E. Ledgerwood, et al. J. Infect. Dis. (2011) 203 (10): 1396– 1404). Immunization with the nucleic acid ZIKV vaccine candidate results in production of noninfectious virus like particles (VLPs) made of ZIKV proteins. These ZIKV VLPs elicit an immune response which includes neutralizing antibodies to ZIKV.

Other preclinical ZIKV vaccine candidates include mRNA, protein, and noninfectious VLPs. NIAID is continuing development of these vaccine candidates. The DNA-based ZIKV vaccine candidate is currently in clinical trials. Consequently, for some fields of use, NIAID will evaluate a license applicant’s capabilities and experience in advancing similar technologies through the regulatory process.

This technology is available for licensing for commercial development in accordance with 35 U.S.C. 209 and 37 CFR part 404, as well as for further development and evaluation under a research collaboration. This technology is not eligible for NIH’s start up license.

Potential Commercial Applications:

- Prevention of Zika virus infection
- Competitive Advantages:
  - There is currently no licensed Zika virus vaccine
- Development Stage:
  - Currently, DNA-based vaccine candidate in Phase I clinical trial
  - Phase II clinical trial planned for early 2017 for DNA-based vaccine candidate
  - Other candidates are in pre-clinical development

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Collaborative Research Opportunity: The National Institute of Allergy and Infectious Diseases is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize Zika virus vaccine technologies. For collaboration opportunities, please contact Dr. Amy Petrik, 240–627–3721; amy.petrik@nih.gov.

Dated: December 6, 2016.

Suzanne Frisbie, Deputy Director, Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases.

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test program, this notice announces the time at which CBP considers a PMS as paid when filers use the Automated Clearing House (ACH) debit process. Except to the extent expressly announced or modified by this document, all aspects, rules, terms and conditions announced in previous notices regarding the tests remain in effect.

DATES: The changes made by this notice are effective January 14, 2017.

ADDRESSES: Comments concerning these test programs may be submitted via email to Monica Crockett at ESARinfoinbox@dhs.gov with a subject line identifier reading, “Post-Summary Corrections Processing.”

FOR FURTHER INFORMATION CONTACT: For policy-related questions, contact John Everett via email at oentrysummary@cbp.dhs.gov. For technical questions related to ABI transmissions, contact your assigned client representative. Interested parties without an assigned client representative should direct their questions to the Client Representative Branch at (703) 650–3500.

SUPPLEMENTARY INFORMATION:

I. Background

Post-Summary Correction (PSC) and Periodic Monthly Statement (PMS) Test Programs

The National Customs Automation Program (NCAP) was established by Subtitle B of Title VI—Customs Modernization in the North American Free Trade Agreement (NAFTA) Implementation Act (Customs Modernization Act) (Pub. L. 103–182, 107 Stat. 2057, 2170, December 8, 1993) (19 U.S.C. 1411). Through NCAP, the thrust of customs modernization was on trade compliance and the development of the Automated Commercial Environment (ACE), the planned successor to the Automated Commercial System (ACS) as the CBP-authorized electronic data interchange (EDI) system. ACE is an automated and electronic system for commercial trade processing which is intended to streamline business processes, facilitate growth in trade, ensure cargo security, and foster participation in global commerce, while ensuring compliance with U.S. laws and regulations and reducing costs for CBP and all of its communities of interest. The ability to meet these objectives depends on successfully modernizing CBP’s business functions and the information technology that supports those functions. CBP’s modernization efforts are accomplished through phased releases of ACE component

functionality designed to replace specific legacy ACS functions and add new functionality. Section 101.9(b) of title 19 of the Code of Federal Regulations (19 CFR 101.9(b)) provides for the testing of NCAP components. See T.D. 95–21, 60 FR 14211 (March 16, 1995). A list of ACE tests is provided in Section III below.

1. PSC Test Program

On June 24, 2011, CBP published a notice in the Federal Register (76 FR 37136) that announced a plan to conduct an NCAP test concerning new ACE capabilities which allow importers to file a PSC for certain entry summaries using the Automated Broker Interface (ABI). Importers and other brokers are also allowed to use ABI to file a PSC to those pre-liquidation ACE entry summaries that were accepted by CBP, fully paid, and under CBP control. On November 19, 2013, CBP published a notice in the Federal Register modifying and clarifying the terms and conditions of the PSC test. See 78 FR 69434.

2. PMS Test Program

On February 4, 2004, CBP published a notice in the Federal Register (69 FR 5362) that announced a plan to conduct an NCAP test concerning PMS which allows importers to deposit estimated duties, fees and taxes on a monthly basis. CBP modified and clarified the PMS test in seven subsequent Federal Register notices published on:

- September 8, 2004 (69 FR 54302); February 1, 2005 (70 FR 5199);
- August 8, 2005 (70 FR 45736); September 22, 2005 (70 FR 55623);
- January 20, 2006 (71 FR 3315); June 2, 2006 (71 FR 32114);
- and October 17, 2008 (73 FR 61991).

II. Test Modifications and Clarifications

This document announces numerous modifications and clarifications to the PSC and PMS tests. Each modification and clarification is discussed separately below. Except to the extent expressly announced or modified by this document, all aspects, rules, terms, requirements, obligations and conditions announced in previous notices regarding the PSC and PMS tests remain in effect.

A. Modifications and Clarifications of the PSC Test

1. Expansion of Entry Types

This document announces that CBP is expanding the type of entries that may be corrected by filing a PSC, in addition to the current entry types 01 (Consumption—Free and Dutiable) and 03 (Consumption—Antidumping/Countervailing Duty). The additional entry types are as follows:

- 04—Consumption—Quota/Visa
- 05—Consumption—Foreign Trade Zone (FTZ)
- 07—Consumption—Antidumping/Countervailing Duty and Quota/Visa Combination
- 21—Warehouse
- 22—Re-Warehouse
- 23—Temporary Importation Bond (TIB)
- 31—Warehouse Withdrawal—Consumption
- 32—Warehouse Withdrawal—Quota
- 34—Warehouse Withdrawal—Antidumping/Countervailing Duty
- 36—Warehouse Withdrawal—Antidumping/Countervailing Duty & Quota/Visa Combination
- 51—Defense Contract Administration Service Region (DCASR)
- 52—Government—Dutiable

2. Merchandise Subject to Quota

When filing a PSC for an entry of merchandise subject to quota, the date and time of submission will be considered the date and time of presentation of the merchandise to CBP. If a PSC is filed on an entry with merchandise subject to quota, and the quota is full or nearly full at threshold, the PSC filer must do two things. The filer must follow the Entry Summary Business Rules and Process Document on www.cbp.gov and also, within 24 hours of making the correction, contact Headquarters Quota Branch: (202) 663–6560 (public phone number), email address: HQQuote@cbp.dhs.gov, regardless of whether the correction concerns merchandise subject to quota.

3. Deposit of Duties, Fees and Taxes With PSC Showing Increase in Liability

This document announces that if a PSC is filed that increases the importer’s liability for duties, fees or taxes, the importer must deposit those additional duties, fees and taxes within three business days of submitting the PSC. No additional PSCs can be filed until those duties, fees and taxes are deposited.

4. Change of Entry Type When Antidumping and/or Countervailing Duties Are Involved

Previously, a filer under the PSC test could not change a type 03 entry to a type 01 entry. See 76 FR 37136. This document announces that a PSC may declare that a previously filed entry which stated that merchandise covered by that entry was subject to antidumping and/or countervailing duties is not, in fact, subject to such duties. For instance, a PSC may declare that a previously filed 03 entry type is
corrected to indicate it is a 01 entry type.

5. Elimination of CBP’s Policy of Rejecting a PSC When There Is No Deposit of Antidumping and/or Countervailing Duties at Time of Submission of PSC

This notice announces a change in CBP policy which will allow an importer to deposit new or additional antidumping and/or countervailing duties within three business days of submitting the PSC. However, no additional PSCs can be filed until the duties are deposited. Previously, when a PSC declared that an entry was corrected to indicate it was subject to antidumping and/or countervailing duties, or a greater amount of antidumping and/or countervailing duties was owed, and those duties were not deposited at the time of submitting the PSC, CBP would reject the PSC.

6. No Filing of PSC To Make a Post-Importation Claim Under 19 U.S.C. 1520(d)

On June 24, 2011, CBP announced in the Federal Register (76 FR 37136) that one of the data elements that may not be modified via a PSC is the NAFTA indicator. This notice clarifies that such prohibition applies not only to a post-importation NAFTA claim under 19 U.S.C. 1520(d), but also to a claim made under other free trade agreements covered by 19 U.S.C. 1520(d).

7. PSC Submission Within the Time Limitations Authorized by This Test

On November 19, 2013, CBP published a notice in the Federal Register (78 FR 69434) that stated that a PSC cannot be filed when any merchandise covered by the original entry has been conditionally released and its right to admission has not been determined. This restriction was overly broad and prevented importers from filing a PSC because all goods are conditionally released and their admissibility is not legally determined until liquidation. This notice announces that this restriction does not prevent the filing of a PSC within the time periods allowed as long as all other requirements and limitations are met. The time limits authorized by this test are set forth in notices published in the Federal Register on June 24, 2011 (76 FR 37136) and November 19, 2013 (78 FR 69434). This clarification is in line with current practice.

B. Modification to the PMS Test

This notice announces that CBP will consider a PMS as paid, in the event the importer uses the Automated Clearing House (ACH) debit process, when CBP receives confirmation from the Treasury Department that funds are available and transferred to CBP from the financial institution designated by the importer for payment of the ACH debit authorization. Prior to this modification, CBP considered a PMS as paid when CBP transmitted the debit authorization to the designated financial institution. See 69 FR 5362 (February 4, 2004). This change will result in a delay of approximately two working days in the time that CBP uses to consider a PMS as paid. It is important to note that this modification applies only to importers who participate in the test program. For all other importers, the current regulation, 19 CFR 24.25(c)(4), still applies which means CBP will consider a statement as paid upon acceptance of the ACH debit authorization.

III. Development of ACE Prototypes

A chronological listing of Federal Register publications detailing ACE test developments is set forth below.

- ACE Portal Accounts and Subsequent Revision Notices: 67 FR 21800 (May 1, 2002); 69 FR 5360 and 69 FR 5362 (February 4, 2004); 69 FR 54302 (September 8, 2004); 70 FR 5199 (February 1, 2005).
- Terms/Conditions for Access to the ACE Portal and Subsequent Revisions: 72 FR 27632 (May 16, 2007); 73 FR 38464 (July 7, 2008).
- ACE Non-Portal Accounts and Related Notice: 70 FR 61466 (October 24, 2005); 71 FR 15756 (March 29, 2006).
- ACE Entry Summary, Accounts and Revenue (ESAR I) Capabilities: 72 FR 59105 (October 18, 2007).
- ACE Entry Summary, Accounts and Revenue (ESAR II) Capabilities: 73 FR 50337 (August 26, 2008); 74 FR 9826 (March 6, 2009).
- ACE Entry Summary, Accounts and Revenue (ESAR III) Capabilities: 74 FR 69129 (December 30, 2009).
- ACE Entry Summary, Accounts and Revenue (ESAR IV) Capabilities: 76 FR 37136 (June 24, 2011).
- Post-Entry Amendment (PEA) Processing Test: 76 FR 37136 (June 24, 2011).
- ACE Announcement of a New Start Date for the National Customs Automation Program Test of Automated Manifest Capabilities for Ocean and Rail Carriers: 76 FR 42721 (July 19, 2011).
- ACE Simplified Entry: 76 FR 69755 (November 9, 2011).
- Post-Summary Corrections to Entry Summaries Filed in ACE Pursuant to the ESAR IV Test: Modifications and Clarifications: 78 FR 69434 (November 19, 2013).
- National Customs Automation Program (NCAP) Test Concerning the Submission of Certain Data Required by the Environmental Protection Agency and the Food Safety and Inspection Service Using the Partner Government Agency Message Set Through the Automated Commercial Environment (ACE): 78 FR 75931 (December 13, 2013).
- Modification of National Customs Automation Program (NCAP) Test Concerning Automated Commercial Environment (ACE) Cargo Release to Allow Importers and Brokers to Certify From ACE Entry Summary: 79 FR 24744 (May 1, 2014).
• Announcement of eBond Test: 79 FR 70881 (November 28, 2014).
• eBond Test Modifications and Clarifications: Continuous Bond Executed Prior to or Outside the eBond Test May Be Converted to an eBond by the Surety and Principal, Termination of an eBond by Filing Identification Number, and Email Address Correction: 80 FR 890 (January 7, 2015).
• Modification of National Customs Automation Program (NCAP) Test Concerning the use of Partner Government Agency Message Set through the Automated Commercial Environment (ACE) for the Submission of Certain Data Required by the Environmental Protection Agency (EPA): 80 FR 6098 (February 4, 2015).
• Announcement of Modification of ACE Cargo Release Test to Permit the Combined Filing of Cargo Release and Importer Security Filing (ISF) Data: 80 FR 7487 (February 10, 2015).
• Modification of NCAP Test Concerning ACE Cargo Release for Type 03 Entries and Advanced Capabilities for Truck Carriers: 80 FR 16414 (March 27, 2015).
• Automated Commercial Environment (ACE) Export Manifest for Air Cargo Test: 80 FR 39790 (July 10, 2015).
• Modification of National Customs Automation Program (NCAP) Test Concerning the Submission of Certain Data Required by the Food and Drug Administration (FDA) Using the Partner Government Agency Message Set through the Automated Commercial Environment (ACE): 80 FR 52051 (August 27, 2015).
• Automated Commercial Environment (ACE) Export Manifest for Rail Cargo Test: 80 FR 54305 (September 9, 2015).
• Modification of the National Customs Automation Program (NCAP) Test Concerning the Automated Commercial Environment (ACE) Document Image System (DIS) Regarding Future Updates and New Method of Submission of Accepted Documents: 80 FR 62082 (October 15, 2015).
• Modification of the National Customs Automation Program (NCAP) Test Concerning the Automated Commercial Environment (ACE) Cargo Release for Entry Type 52 and Certain Other Modes of Transportation: 80 FR 63576 (October 20, 2015).
• Modification of the National Customs Automation Program (NCAP) Test Concerning the Automated Commercial Environment (ACE) Entry Summary, Accounts and Revenue (ESAR) Test of Automated Entry Summary Types 51 and 52 and Certain Modes of Transportation: 80 FR 63815 (October 21, 2015).
• Modification of the National Customs Automation Program Test Concerning the Automated Commercial Environment Portal Account to Establish the Exporter Portal Account: 80 FR 63817 (October 21, 2015).
• Notice Announcing the Automated Commercial Environment (ACE) as the Sole CBP-Authorized Electronic Data Interchange (EDI) System for Processing Certain Electronic Entry and Entry Summary Filings Accompanied by Food and Drug Administration (FDA) Data: 81 FR 30320 (May 16, 2016).
• Notice Announcing the Automated Commercial Environment (ACE) as the Sole CBP-Authorized Electronic Data Interchange (EDI) System for Processing Electronic Entry and Entry Summary Filings: 81 FR 32339 (May 23, 2016).
• Modification of the National Customs Automation Program (NCAP) Test Concerning the Automated Commercial Environment (ACE) Portal Accounts to Establish the Protest Filer Account and Clarification that the Terms and Conditions for Account Access Apply to all ACE Portal Accounts: 81 FR 52453 (August 8, 2016).
• National Customs Automation Program (NCAP) Test Concerning Electronic Filing of Protests in the Automated Commercial Environment (ACE): 81 FR 53497 (August 12, 2016).

Dated: December 7, 2016.

Brenda B. Smith,
Executive Assistant Commissioner, Office of Trade.

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