monoclonal neutralizing antibodies for treatment and prevention of Ebola Zaire disease. The monoclonal antibodies (mAbs) bind to different regions of the Ebola glycoprotein that are unique for these two mAbs. Alone or in combination, the mAbs prevent or reverse Ebola Zaire virus disease in non-human primates. Nonclinical studies have demonstrated complete protection against disease with a single antibody and complete protection against viremia by addition of a second antibody. The current nonclinical pharmacology demonstrates a favorable pharmacokinetic profile and there is a first-in-time human clinical trial projected for 2017. The anticipated indications for this technology include pre-and post-symptomatic treatment, and pre-and post-exposure prophylaxis.

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.

Potential Commercial Applications

- Therapeutics
- Diagnostics

Competitive Advantages

- Favorable pharmacokinetic profile
- Favorable manufacturing
- Complete protection against disease with a single unique mAb
- Complete protection with fewer administrations and/or lower doses than any other mAb
- Complete protection against viremia with two antibodies

Development Stage

- In vivo data available (animal)
- Entering first-in-time human clinical trial (2017)

Inventors: Nancy J. Sullivan (NIAID); Barney S. Graham (NIAID); Julie Ledgerwood (NIAID); Daphne A. Stanley (NIAID); Antonio Lanzavecchia (IRB) Davide Corti (IRB); John Trefry (USAMRIID/WR)

Publications

Corti D, et al., Protective monotherapy against lethal Ebola virus infection by a potently neutralizing antibody. Science. 2016 Mar 18;351:1339–42. [PMID: 26917593]

Misasi J, et al., Structural and molecular basis for Ebola virus neutralization by protective human antibodies. Science. 2016 Mar 18;3511343–6. [PMID: 26917592].

Intellectual Property

HHS Reference No. E–045–2015—U.S. Provisional Application No. 62/087,087, filed December 3, 2014; PCT Application No. PCT/US2015/060733, filed November 13, 2015 HHS Reference No. E–278–2016- U.S. Provisional Application No.62,080,094, filed November 14, 2014; PCT Application No. PCT/IB2015/002342, filed November 13, 2015

Licensing Contact: Dr. Dianca Finch, 240–669–5503; *dianca.finch@nih.gov.*

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 products for treatment and prevention of Ebola Zaire disease. For collaboration opportunities, please contact Dr. Dianca Finch, 240–669–5503; *dianca.finch@nih.gov.*

Dated: May 9, 2017.

Suzanne Frisbie,

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

[FR Doc. 2017–10156 Filed 5–18–17; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Notice of Issuance of Final Determination Concerning a Certain Visitor Management System

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of final determination.

SUMMARY: This document provides notice that U.S. Customs and Border Protection (''CBP'') has issued a final determination concerning the country of origin of a certain visitor management system known as the Raptor Basic System. Based upon the facts presented for purposes of U.S. Government procurement, CBP has concluded that China is the country of origin of the identification scanner and printer components of the Raptor Basic System, that the United States is the country of origin of the label component of the Raptor Basic System, and that Taiwan is the country of origin of the barcode scanner that is compatible with the Raptor Basic System.

DATES: The final determination was issued on May 08, 2017. A copy of the final determination is attached. Any party-at-interest, as defined in 19 CFR 177.22(d), may seek judicial review of this final determination within June 19, 2017.

FOR FURTHER INFORMATION CONTACT: Robert Dinerstein, Valuation and Special Programs Branch, Regulations and Rulings, Office of Trade, at (202) 325–0132.

SUPPLEMENTARY INFORMATION: Notice is hereby given that on May 08, 2017, pursuant to subpart B of Part 177, U.S. Customs and Border Protection Regulations (19 CFR part 177, subpart B), CBP issued a final determination concerning the country of origin of a certain visitor management system known as the Raptor Basic System, which may be offered to the U.S. Government under an undesignated government procurement contract. This final determination, HQ H277116, was issued under procedures set forth at 19 CFR part 177, subpart B, which implements Title III of the Trade Agreements Act of 1979, as amended (19 U.S.C. 2511–18). In the final determination, CBP concluded that the identification scanner and printer components of the Raptor Basic System were not substantially transformed in the United States, and thus remain products of China. Additionally, CBP concluded that the label component of the Raptor Basic System was a product of the United States and that the barcode scanner that is compatible with the Raptor Basic System was a product of Taiwan. Therefore, for purposes of U.S. Government procurement, China is the country of origin of the identification scanner and printer components of the Raptor Basic System, the United States is the country of origin of the label component of the Raptor Basic System, and Taiwan is the country of origin of the barcode scanner that is compatible with the Raptor Basic System.

Section 177.29, CBP Regulations (19 CFR 177.29), provides that a notice of final determination shall be published in the **Federal Register** within 60 days of the date the final determination is issued. Section 177.30, CBP Regulations (19 CFR 177.30), provides that any party-at-interest, as defined in 19 CFR 177.22(d), may seek judicial review of a final determination within 30 days of publication of such determination in the **Federal Register**.

Dated: May 08, 2017.

Alice A. Kipel,

Executive Director, Regulations and Rulings, Office of Trade.

HQ H277116

May 08, 2017

OT:RR:CTF:VS H277116 AJR

Ms. Heather Mims
Centre Law and Consulting LLC
8330 Boone Boulevard, Suite 300

Tysons, VA 22182

RE: U.S. Government Procurement; Country of Origin of a Visitor Management System

Dear Ms. Mims:

This is in response to your letter, dated June 15, 2016, requesting a final determination on behalf of Raptor Technologies, LLC (''Raptor''), pursuant to subpart B of Part 177 of the U.S. Customs and Border Protection (''CBP'') Regulations (19 C.F.R. Part 177). Under these regulations, which implement Title III of the Trade Agreements Act of 1979 (''TAA''), as amended (19 U.S.C. § 2511 *et seq.*), CBP issues country of origin advisory rulings and final determinations as to whether an article is or would be a product of a designated country or instrumentality for the purposes of granting waivers of certain ''Buy American'' restrictions in U.S. law or practice for products offered for sale to the U.S. Government.

This final determination concerns the country of origin of the Raptor Basic System (''RBS''). We note that Raptor is a party-at-interest within the meaning of 19 C.F.R. § 177.22(d)(1) and is entitled to request this final determination.

FACTS:

Raptor provides security and safety products to schools across the United States, and plans to sell its RBS product to the U.S. Government. The RBS is a visitor management system that is typically installed in elementary schools and used as a screening tool. The RBS is comprised of a scanner, a printer, the Raptor software, and labels. Installation of the RBS requires the use of a customer provided computer, where the software is installed. Once the RBS is installed and ready for use, users are able to scan the identification cards of individuals visiting the school in order to obtain personal/public information pertaining to the visitor. Based on the information received, the user prints out a color coded visitor tag which signifies the access or identity type of the visiting person.

Specifically, the RBS consists of the Raptor software, one roll of Blanco labels, one Acuant Duplex ID scanner (''ID scanner''), and one Dymo printer. Along with the cost for these items, the software updates, database set-up, and shipping fee are integrated into the RBS price. Additional ID scanners, printers, and labels can be purchased for use with the RBS, along with barcode scanners that are also compatible with the system. According to Raptor, the RBS and its compatible products are produced for sale in the United States as follows:

(1) **Raptor Software:** Raptor developed the software for the RBS in the United States. Additionally, Raptor's engineers write the source code for the software in the United States, and Raptor will install the software to customer specifications onto the RBS in the United States. The software is a critical component because it controls the entire system enabling it to manage, report, send, alert, and track all visitors entering public or private premises, along with notifying the Raptor technical support team about any potential issues. The software connects and communicates with the printers, scanners, and customer-provided computers within the system. The software accounts for 30 percent of the RBS price. Additionally, the software makes the RBS operational by automatically updating and permitting access to various databases, including the RBS database, which is also located in the United States. Raptor spends approximately two hours setting up the database, and training its customers how to use the system, which accounts for 21.86 percent of the RBS price. Together the cost of the software, database set-up, and training for the RBS system account for 51.86 percent of the RBS price.

(2) **Blanco Labels:** Blanco, Inc. develops and manufactures the labels in the United States, and the labels are printed with the Raptor logo in the United States. The RBS only uses these labels for the temporary badges and passes that it prints. The labels account for 6.25 percent of the RBS price.

(3) **Acuant Duplex ID Scanner:** The ID scanner consists of a hardware component made in China and a software component developed by Acuant (''Acuant software'') in the United States. The Acuant software is loaded onto the hardware component in the United States, and permits the ID scanner to communicate with the Raptor software. Raptor states that without the Raptor software, the ID scanner would not be an integral part of the RBS. The ID scanner accounts for 30.93 percent of the RBS price.

(4) **Dymo Printer:** Dymo designs and engineers the printer in the United States and manufactures the printer in China. The printer communicates with the Raptor software, and Raptor states that without this software, the printer would not print the specific visitor badges or passes. The printer accounts for 8.68 percent of the RBS price.

(5) **Barcode Scanner:** The barcode scanner is not required for the RBS, but is compatible with the system. Scan Technology Inc. manufactures the barcode scanner in Taiwan with parts that are also from Taiwan. The barcode scanners are also inspected and tested in Taiwan before they are shipped to the United States. While the barcode scanners are not part of the RBS, and will not be included within the RBS price, the purchase price for one barcode scanner comes to approximately 10 percent of the RBS price.

The final assembly of the RBS occurs in the United States. According to Raptor, this process is complex and uses skilled technicians to complete it. This assembly takes approximately one hour per system and sometimes there are several systems installed in one school. The final testing of the RBS printers, scanners, and software also occurs in the United States. According to Raptor, it takes approximately one hour to test a system with a skilled technician, but some locations require testing multiple systems. Additionally, Raptor technicians train the users on how to use the system in the United States, and this training takes approximately one hour.

ISSUE:

What is the country of origin of the RBS for purposes of U.S. Government procurement?

LAW AND ANALYSIS:

Pursuant to subpart B of Part 177, 19 C.F.R. § 177.21 *et seq.,* which implements Title III of the TAA, as amended (19 U.S.C. § 2511 *et seq.*), CBP issues country of origin advisory rulings and final determinations as to whether an article is or would be a product of a designated country or instrumentality for the purposes of granting waivers of certain ''Buy American'' restrictions in U.S. law or practice for products offered for sale to the U.S. Government.

Under the rule of origin set forth under 19 U.S.C. § 2518(4)(B):

An article is a product of a country or instrumentality only if (i) it is wholly the growth, product, or manufacture of that country or instrumentality, or (ii) in the case of an article which consists in whole or in part of materials from another country or instrumentality, it has been substantially transformed into a new and different article of commerce with a name, character, or use distinct from that of the article or articles from which it was so transformed.

See also 19 C.F.R. § 177.22(a).

In order to determine whether a substantial transformation occurs when the components of various origins are assembled to form completed articles, CBP considers the totality of the circumstances and makes decisions on a

case-by-case basis. The country of origin of the article's components, the extent of the processing that occurs within a given country, and whether such processing renders a product with a new name, character, and use are primary considerations in such cases. Here, the determination will be a ''mixed question of technology and customs law, mostly the latter.'' *Texas Instruments v. United States*, 681 F.2d 778, 782 (CCPA 1982).

In this case, Raptor acquires scanners and printers that were manufactured outside of the United States and installs onto them the Raptor software that was developed in the United States. The installation of the Raptor software takes place in the United States, and Raptor further customizes these devices with the software for each of its customers in the United States, as well as trains its customers on how to use the system. This package of hardware components, software components, and services are integrated together by Raptor as the RBS, which is the product being sold to the U.S. Government.

Raptor believes that the country of origin of the RBS is the United States reasoning that the printers, scanners, labels, and software are substantially transformed into the RBS in the United States by installing critical software in the United States. Raptor also believes that the software, ID scanner, printer, and label components of the RBS are individually products of the United States, and that the RBS-compatible Barcode scanner is a product of Taiwan.

With regard to the Raptor software, Raptor argues that software is substantially transformed into a new article of commerce where the software build takes place, citing to HRL H268858, dated February 12, 2016.[1] However, while HRL H268858 took into account the development of the software as a factor in substantial transformation, it did not state that the intangible software itself was a product of a particular origin. Rather, it decided that the intangible software, partially developed in the United States, and tangible U.S.-origin blank discs, when combined by loading the software onto the discs, resulted in one product of the United States.

Unlike HRL H268858, where CBP determined the country of origin of a tangible product, here we have no indication that the Raptor software by itself is a tangible product prior to its integration with the scanners and printers of the RBS. In rendering final determinations for purposes of U.S. Government procurement, CBP recognizes that the Federal Acquisition Regulation (''FAR'') restricts the U.S. Government's purchase of products to U.S.-made or designated country end products for acquisitions subject to the TAA, which excludes automatic data processing (''ADP'') telecommunications and transmission services, and related services. *See* 19 C.F.R. § 177.21; and, subpart 25.4, FAR (48 C.F.R. Subpart 25.4). *See also* General Note 3(e), Harmonized Tariff Schedule of the United States (''HTSUS'') (stating that that telecommunication transmissions are not goods subject to the provisions of the tariff schedule, and as such would not require a country of origin marking). To the extent the Raptor software is an intangible product developed in the United States and transmitted via intangible signals, the Raptor software, by itself, is not subject to the country of origin determinations issued by CBP for purposes of U.S. Government procurement.

However, the ID scanner and printer, which are tangible products imported into the United States are subject to the country of origin determination issued by CBP. In this regard, CBP may look at the process of loading U.S.-developed software onto these products in the United States when considering the extent of processing that occurs within the United States under the substantial transformation test. While Raptor argues that this process will transform the ID scanner and printer into products of the United States, we disagree as explained below.

Here, both the development and loading of the software take place in the United States. However, the ID scanners and printers in this case serve as scanners and printers, even before software is loaded onto them in the United States. While the Acuant software gives the ID scanner the particular features of an Acuant branded scanner, and while the Raptor software gives the ID scanner and printer the ability to function within the RBS, this does not change the fact that these products have a predetermined use prior to having software installed onto them in the United States. *See* HRL H215657, dated April 29, 2013 (holding that the process of developing and installing software onto foreign flashlights in the United States did not change the basic operations of the flashlight). Likewise, the process of customizing the RBS to work with multiple devices and multiple databases, or the process of training the customer how to use the system, will not transform the scanner into something other than a scanner or the printer into something other than a printer. *See generally National Hand Tool Corp. v. United States*, 16 Ct. Int'l Trade 308, 311 (1992) (holding that processing in the United States did not substantially transform tools already shaped for a predetermined use prior to importation into the United States).

Raptor also cites to HRL H039856, dated August 12, 2009, to argue that the RBS is a product of the United States. In HRL H039856, various components of foreign origin, including a printer control unit and laser scanning unit, were imported into Japan and assembled into multifunction printers (''MFP(s)''). CBP has considered similar MFP cases on various occasions. In these cases, various components, including printer unit and scanner unit subassemblies, are physically integrated together to create an MFP capable of printing, scanning, and similar operations. Prior to this assembly, these subassemblies lack these capabilities. *See* HRL H263561, dated December 23, 2015; HRL H025106, dated June 11, 2008; and, HRL 562936, dated March 17, 2004. Unlike these MPF cases, the scanner and printer in this case do not require integration into the RBS to function as scanners and printers. Moreover, integrating the scanner and printer components into the RBS does not result in a printer and scanner that are physically assembled together. That is, after integration into the system, the scanner will look like the same scanner, and the printer like the same printer, both still without permanent physical attachments to other tangible products. *See Uniroyal, Inc. v. United States,* 3 CIT 220, 542 F. Supp. 1026 (1982), *aff'd* 702 F. 2d 1022 (Fed. Cir. 1983) (noting that if the manufacturing or combining process is a minor one which leaves the identity of the article intact, a substantial transformation has not occurred).

We also disagree with Raptor's argument that the various hardware component parts of the RBS cannot function as a visitor management system without the Raptor software, citing to HRL H090115, dated August 2, 2010, and HRL H21555, dated July 13, 2012. The software installation process in HRL H090115 was only part of the 16 day process that rendered a substantial transformation, and thus is distinguished from this case which only involves a one to three hour process per system, mainly focusing on the software installation. Similarly we distinguish HRL H21555 because that case involved microcomputer devices which could not function without the proprietary software, whereas this case involves printers and scanners that are functional without the Raptor software.

[1] Raptor also cites to HRL H192146, dated June 8, 2012, which is a non-binding advisory ruling.

Additionally, we note that the ID scanner and printer are products that can be individually purchased and used outside of the system without the Raptor software. Thus, whether these products are substantially transformed into the RBS is really a question of whether the software development and loading are sufficient to transform these individual products into a different article of commerce, the RBS. As indicated above, regardless of the software installed onto the ID scanner and printer, the ID scanner and printer already have their respective functions as scanners and printers prior to their incorporation into the system. They function as scanners and printers when they are manufactured in China, their basic functions in this regard do not change once imported into the United States, and their physical appearance will remain the same even after integrated into the RBS. Accordingly, the ID scanner and printer remain products of China for purposes of U.S. Government procurement.

With regard to the Blanco labels, Raptor indicates that such will be designed and manufactured in the United States. Similarly, Raptor indicates that the barcode scanner will be manufactured entirely in Taiwan. Raptor provides affidavits signed by the label manufacturer and barcode scanner manufacturer stating that such are products of the United States and Taiwan, respectively. To the extent that the labels and barcode scanner are products from the United States and Taiwan, respectively, each may be individually compliant under the TAA.

While the labels are products that are integrated within the RBS, their country of origin does not change the country of origin of the ID scanner and printer within the RBS. In a number of rulings CBP stated, ''merely packaging parts of a kit together does not constitute a substantial transformation.'' *See* HRL 732498, dated October 3, 1989; and HRL 732897, dated June 6, 1990. As noted from these rulings, packaging the ID scanner and printers with the labels does not substantially transform these products because such are already in their finished forms, not modified or affixed to each other, or combined in a permanent matter. Accordingly, the ID scanner and printers remain products of the country where they will be manufactured, China.

HOLDING:

Based on the facts provided, the integration of the ID scanner, printer, and labels via the Raptor software into the RBS does not substantially transform these individual products into a product of the United States. Rather, for purposes of U.S. Government procurement, the labels are products of the United States, and the ID scanner and printer remain products of China because they are not substantially transformed by the processes that take place in the United States. Moreover, to the extent the RBS-compatible barcode scanner is manufactured in Taiwan, it is a product of Taiwan for purposes of U.S. Government procurement.

Notice of this final determination will be given in the **Federal Register**, as required by 19 C.F.R. § 177.29. Any party-at-interest other than the party which requested this final determination may request, pursuant to 19 C.F.R. § 177.31, that CBP reexamine the matter anew and issue a new final determination. Pursuant to 19 C.F.R. § 177.30, any party-at-interest may, within 30 days of publication of the **Federal Register** Notice referenced above, seek judicial review of this final determination before the Court of International Trade.

Sincerely,

Alice A. Kipel, Executive Director
Regulations and Rulings
Office of Trade

[FR Doc. 2017–10057 Filed 5–18–17; 8:45 am]

BILLING CODE P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2017–0002; Internal Agency Docket No. FEMA–B–1664]

Proposed Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency; DHS.

ACTION: Notice; correction.

SUMMARY: On January 23, 2017, FEMA published in the **Federal Register** a proposed flood hazard determination notice that contained an erroneous table. This notice provides corrections to that table, to be used in lieu of the information published at 82 FR 7849. The table provided here represents the proposed flood hazard determinations and communities affected for Los Angeles County, California, and Incorporated Areas.

DATES: Comments are to be submitted on or before August 17, 2017.

ADDRESSES: The Preliminary Flood Insurance Rate Map (FIRM), and where applicable, the Flood Insurance Study (FIS) report for each community are available for inspection at both the online location and the respective Community Map Repository address listed in the table below. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at *www.msc.fema.gov* for comparison.

You may submit comments, identified by Docket No. FEMA–B–1664, to Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW., Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov.*

FOR FURTHER INFORMATION CONTACT: Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW., Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov;* or visit the FEMA Map Information eXchange (FMIX) online at *www.floodmaps.fema.gov/fhm/fmx_main.html.*

SUPPLEMENTARY INFORMATION: FEMA proposes to make flood hazard determinations for each community listed in the table below, in accordance with Section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR 67.4(a).

These proposed flood hazard determinations, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own, or pursuant to policies established by other Federal, State, or regional entities. These flood hazard determinations are used to meet the floodplain management requirements of the NFIP and are also used to calculate the appropriate flood insurance premium rates for new buildings built after the FIRM and FIS report become effective.

Use of a Scientific Resolution Panel (SRP) is available to communities in support of the appeal resolution process. SRPs are independent panels of experts in hydrology, hydraulics, and other pertinent sciences established to review conflicting scientific and technical data and provide recommendations for resolution. Use of the SRP may only be exercised after FEMA and local communities have been engaged in a collaborative consultation process for at least 60 days without a