

the United States did not result in a change in the medicinal use of the finished product and the active ingredient. The active ingredient retained its chemical and physical properties and was merely put into dosage form and packaged for sale. The active ingredient did not undergo a change in name, character or use. Therefore, CBP held that no substantial transformation occurred in United States, and Acyclovir tablets were considered a product of the country in which the active ingredient was produced.

HQ H215656, dated January 11, 2013, concerned the country of origin of Rybix ODT, a pharmaceutical product used for the management of moderate to moderately severe pain in adults. The API, tramadol hydrochloride, manufactured in India, was shipped to France where it underwent four processes of manufacturing consisting of the preparation of the API, preparation of the tablet blend, tablet compression, and packaging in blister packs. CBP determined that the processing in France did not result in a change in the medicinal use of the finished product, and the API retained its chemical and physical properties and was merely put into dosage form and packaged. Accordingly, CBP held that no substantial transformation occurred in France.

HQ H233356, dated December 26, 2012, concerned the country of origin of Ponstel, a pharmaceutical product used for the relief of mild to moderate pain caused by primary dysmenorrhea. Mefenamic acid, which is the API in Ponstel, was manufactured in India, and imported into the United States, where it was blended with inactive ingredients and packaged into dosage form. CBP determined that this process did not substantially transform the mefenamic acid because its chemical character remained the same and, therefore, CBP found that the country of origin of the Ponstel capsules was India.

You state that the FDA requires that a unique National Drug Code (“NDC”) be assigned to every drug product such as Donepezil Hydrochloride tablets, but prohibits that same NDC from being associated with any API, such as Donepezil Hydrochloride, that has not been demonstrated to be safe and effective and cannot be sold for the treatment of any human disease condition. You also state that the FDA requires the name of the drug product (Donepezil Hydrochloride tablet) to appear on every drug product label and prohibits use of that name on the label for the API. Further, you state that Donepezil Hydrochloride is intended only for use by producers for further processing or for research since it is unstable and not fit for medical use and may not be sold to consumers. Additionally, you state that the API is poisonous and has poor flow properties. For these reasons, you claim that extensive additional processing of the API, sourced in India, with other ingredients must occur to change the API’s properties and make it into a stable drug product.

This office consulted with CBP’s Laboratories and Scientific Services Directorate concerning the instant case, which informed us that the imported API, Donepezil Hydrochloride, retains its chemical and physical properties upon

processing in the United States. Increasing the stability of the API and standardizing its concentration do not change the API. Further, the processing performed in the United States does not affect the medicinal use of the API. Based on the information presented, the API does not undergo a change in name, character or use. Therefore, in accordance with the rulings cited, we find that no substantial transformation occurs in United States, and the Donepezil Hydrochloride tablets would be considered a product of India, where the API was produced, for purposes of U.S. government procurement.

In addition, you asked whether the Donepezil Hydrochloride tablets are “manufactured in the United States” within the meaning of the term “U.S.-made end products”, as set forth in Section 25.003 of the Federal Acquisition Regulations System, Title 48, Code of Federal Regulations (48 C.F.R. § 25.003), and implemented in 48 C.F.R. § 52.225–5. As stated in 19 C.F.R. § 177.21, subpart B is intended to be applied consistent with the Federal Acquisition Regulations (48 C.F.R. chapter 1). The definition of country of origin in subpart B, 19 C.F.R. § 177.22(a) has two rules (see above) as does 48 C.F.R. § 25.003. The term “manufactured in the United States” in 48 C.F.R. § 25.003 correlates to the first rule of 19 C.F.R. § 177.22(a) which provides that an article is a product of a country or instrumentality if “it is wholly the growth, product, or manufacture of that country or instrumentality”. Since the production of Donepezil Hydrochloride tablets partially occurs in India, we do not find that they are manufactured in the United States.

HOLDING:

The country of origin of the Donepezil Hydrochloride tablets for U.S. Government procurement purposes is India.

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 after 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. 2018–02245 Filed 2–2–18; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Notice of Issuance of Final Determination Concerning Certain Ethernet Switch Products

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 certain ethernet switch products known as Nyquist Ethernet Switches. Based upon the facts presented, CBP has concluded that the country of origin of the Nyquist Ethernet Switches is Mexico for purposes of U.S. Government procurement.

DATES: The final determination was issued on January 30, 2018. 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 March 7, 2018.

FOR FURTHER INFORMATION CONTACT: Yuliya A. Gulis, Valuation and Special Programs Branch, Regulations and Rulings, Office of Trade, at (202) 325–0042.

SUPPLEMENTARY INFORMATION: Notice is hereby given that on January 30, 2018 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 certain ethernet switch products known as Nyquist Ethernet Switches, which may be offered to the U.S. Government under an undesignated government procurement contract. This final determination, HQ H282390, 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 last substantial transformation took place in Mexico. Therefore, the country of origin of the Nyquist Ethernet Switches is Mexico for purposes of U.S. Government procurement.

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: January 30, 2018.

Alice A. Kipel,

*Executive Director, Regulations and Rulings,
Office of Trade.*

HQ H282390

January 30, 2018

OT:RR:CTF:VS H282390 YAG

CATEGORY: Origin

Ms. Carolyn Muhlstein
Senior Manager, Global Customs
Cisco Systems, Inc.
170 West Tasman Drive
San Jose, CA 95134

RE: U.S. Government Procurement; Country of Origin of Ethernet Switch; Substantial Transformation

Dear Ms. Muhlstein:

This is in response to your letter, dated May 6, 2016, on behalf of Cisco Systems, Inc. ("Cisco"), requesting a final determination concerning the country of origin of Cisco's Nyquist Ethernet Switch ("NES"), pursuant to subpart B of Part 177, U.S. Customs and Border Protection ("CBP") Regulations (19 CFR § 177.21, *et seq.*). As a domestic importer of merchandise, Cisco is a party-at-interest within the meaning of 19 CFR § 177.22(d)(1) and is entitled to request this final determination. In addition, we have reviewed and grant the request for confidentiality pursuant to 19 CFR § 177.2(b)(7), with respect to certain information submitted.

FACTS:

Cisco plans to import the NES from Mexico. The NES is designed to interconnect devices on a computer network, while offering new capabilities, such as enabling new applications, differentiated security, dense wireless, and simplified and diverse network architecture. Each NES consists of one or more printed circuit board assemblies ("PCBA"), two power supplies, an uplink module, a protective metal housing, and ancillary devices to support additional features. The NES is configured with Cisco's configuration data. The configuration data programs the logic gates of the hardware components on the PCBA, which imparts physical changes to the patterns of interconnections in the hardware circuitry, defining the behavior of each component. The NES operates using Cisco's Polaris Operating System Software ("Polaris OS").

In China, PCBAs are manufactured using: application specific integrated circuit ("ASIC") components, which are assembled to final form in Korea incorporating materials from Taiwan and Japan in a process that takes between 12 and 25 weeks; central processing unit ("CPU") components from Taiwan; synchronous dynamic random access memory ("SDRAM") components from Taiwan or Korea; and, flash components from Korea and China. The PCBAs are tested to ensure that the PCBA components can properly interact with one another, and they are packaged and shipped to Mexico.

In Mexico, the following operations take place:

1. One or more PCBAs are installed into the NES chassis.
2. Two power supplies are installed in the NES chassis.
3. One uplink module is installed in the NES chassis.
4. Ancillary devices that support additional NES features are installed into the chassis.
5. A metal housing is added to complete the NES chassis assembly.
6. The power-on and bootloader initialization take place to activate the power system and fan modules of the NES, followed by the activation and preliminary testing of the CPU, ASIC, and ancillary devices.
7. The Polaris OS and configuration data developed in the United States are loaded onto a non-volatile flash memory, and then pushed out to the components of the PCBA.
8. The NES is tested to ensure the product functions as designed.

Cisco states that the Polaris OS and configuration data are downloaded onto the NES using in-circuit programming. According to Cisco, traditionally, each component of a PCBA (*e.g.*, ASICs) is completely programmed at or prior to assembly onto the PCBA; however, with in-circuit programming the hardware components are designed to be programmed after the PCBA is completely assembled. Cisco states that while the Polaris OS and configuration data are simultaneously downloaded onto the NES through the in-circuit programming, the Polaris OS and configuration data have different purposes and affect the NES differently and in sequence. Cisco explains that the configuration data does not operate on the hardware in the manner that the Polaris OS does. Rather, the configuration data completes the hardware programming, and the Polaris OS runs on the completed hardware.

According to Cisco, the PCBAs will have no commercial functionality when exported from China to Mexico because without the configuration data and the Polaris OS, the NES cannot function as intended. Cisco states that the NES will have large quantities of configurable elements, which require the configuration data to provide the firmware, modes and configuration settings, timing parameters, and physical properties for the components to function in the NES. Cisco states that the Polaris OS will provide I/O processor, route processor, and forwarding processor capabilities to the hardware, allowing the components to communicate with each other. Cisco notes that approximately 95 percent of the configuration data and 70 to 80 percent of the software code that will be loaded onto the NES in Mexico will be completely new and tailored based on customer needs and specifications.

ISSUE:

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

LAW AND ANALYSIS:

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, pursuant to subpart B of Part 177, 19 CFR § 177.21 *et seq.*, which implements Title III of the Trade Agreements Act of 1979, as amended (19 U.S.C. § 2511 *et seq.*).

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 CFR § 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.

In *Data General v. United States*, 4 C.I.T. 182 (1982), the court determined that the programming of a foreign PROM ("Programmable Read-Only Memory" chip) in the United States substantially transformed the PROM into a U.S. article. In the United States, the programming bestowed upon each integrated circuit its electronic function, that is, its "memory" which could be retrieved. A distinct physical change was effected in the PROM by the opening or closing of the fuses, depending on the method of programming. The essence of the article, its interconnections or stored memory, was established by programming. *See also, Texas Instruments v. United States*, 681 F.2d 778, 782 (CCPA 1982) (stating the substantial transformation issue is a "mixed question of technology and customs law").

Accordingly, the programming of a device that defines its use generally constitutes substantial transformation. *See* Headquarters Ruling ("HQ") HQ 735027, dated September 7, 1993 (programming blank media (EEPROM) with instructions that allow it to perform certain functions that prevent piracy of software constitutes a substantial transformation); *but see* HQ 734518, dated June 28, 1993 (motherboards are not substantially transformed by the implanting of the central processing unit on the board because, whereas in *Data General* use was being assigned to the PROM, the use of the motherboard had already been determined when the importer imported it).

Cisco argues that the country of origin of the NES will be Mexico because the final assembly of the NES and installation of the Polaris OS and configuration data onto the NES in Mexico will substantially transform the PCBA into the NES. While the configuration data is specific to the NES,

Cisco notes that the ASIC is not, and can be used in other Cisco products with different configuration data. Additionally, Cisco states that the Polaris OS allows the NES to switch and route packets, which is the critical functional element of the NES. Cisco states that the configuration data physically changes the electrical values of the logic gates present in the ASICs and other components, by connecting the gates in combinations that tell the components how to function and communicate within the system. Cisco argues that the configuration data installed on the NES should be distinguished from software installations because the configuration data completes the hardware programming, physically changing the hardware itself. Cisco states the software's incorporation onto the NES is different because it runs on the completed hardware as opposed to being a part of the hardware itself.

Cisco cites HQ 563012, dated May 4, 2004, in support of its position. In HQ 563012, CBP held that the PCBA and casing that were manufactured for a switch in China, were substantially transformed in the United States or Hong Kong, where U.S.-origin software was loaded, and the PCBA was further assembled with a power supply, fans, and an A/C filter of various origins to form the final fabric switch. CBP noted that in addition to the actual assembly, the configuration and software download operations performed in either Hong Kong or in the United States transformed the switch from a non-functional device into a fabric switch that was capable of performing various storage network functions.

Similar to the scenario in HQ 563012, where Hong Kong was found to be the origin, in this case, the major components of the NES, particularly the PCBA comprised of the ASIC, CPU, SDRAM, and flash components, will be manufactured in China, and then shipped to another country where the final assembly (adding the casing, power supply, uplink modules, and ancillary devices to the PCBA), software loading, configuration, and testing take place. Here, the other country is Mexico, which is different from the country where the U.S.-origin software is developed. While CBP has normally focused on where the origin of the software and where the programming took place, applying CBP's precedent in HQ 563012 to Cisco's manufacturing operations in Mexico, we find that the PCBAs from China will be substantially transformed by the final assembly, software loading, configuration, and testing operations in Mexico, and thus the country of origin for purposes of U.S. Government procurement will be Mexico.¹

¹ See HQ H175415, dated October 4, 2011 (CBP held that imported Ethernet switches underwent a substantial transformation after U.S.-origin software was downloaded onto the devices' flash memory in the United States, which allowed the devices to function); see also HQ H052325, dated March 31, 2009 (holding that imported network devices underwent a substantial transformation in the United States after U.S.-origin software was downloaded onto the devices in the United States, which gave the devices their functionality); and, HQ H034843, dated May 5, 2009 (holding that Chinese USB flash drives underwent a substantial

HOLDING:

Based on the facts provided, the PCBAs from China will be substantially transformed into the NES by the processes that take place in Mexico. As such, the NES will be considered a product of Mexico for purposes of U.S. Government procurement.

Notice of this final determination will be given in the **Federal Register**, as required by 19 CFR 177.29. Any party-at-interest other than the party which requested this final determination may request, pursuant to 19 CFR 177.31, that CBP reexamine the matter anew and issue a new final determination. Pursuant to 19 CFR 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. 2018-02244 Filed 2-2-18; 8:45 am]

BILLING CODE 9111-14-P

INTERNATIONAL TRADE COMMISSION

[USITC SE-18-007]

Government in the Sunshine Act Meeting Notice

AGENCY HOLDING THE MEETING: United States International Trade Commission.

TIME AND DATE: February 9, 2018 at 11:00 a.m.

PLACE: Room 101, 500 E Street SW, Washington, DC 20436, Telephone: (202) 205-2000.

STATUS: Open to the public.

MATTERS TO BE CONSIDERED:

1. *Agendas for future meetings:* None.
 2. Minutes.
 3. Ratification List.
 4. Vote in Inv. Nos. 701-TA-592 and 731-TA-1400 (Preliminary) (Plastic Decorative Ribbons from China). The Commission is currently scheduled to complete and file its determinations on February 12, 2018; views of the Commission are currently scheduled to be completed and filed on February 20, 2018.
 5. *Outstanding action jackets:* None.
- In accordance with Commission policy, subject matter listed above, not

transformation in Israel when Israeli-origin software was loaded onto the devices, which made the devices functional). CBP has also held that when software is programmed in one country, and loaded onto a switch in different countries, the process of loading the software is not a sufficient operation by itself to result in a substantial transformation. See HQ H241177, dated December 3, 2013; and, HQ H240199, dated March 10, 2015.

disposed of at the scheduled meeting, may be carried over to the agenda of the following meeting.

By order of the Commission:

Issued: January 31, 2018.

William R. Bishop,

Supervisory Hearings and Information Officer.

[FR Doc. 2018-02280 Filed 2-1-18; 11:15 am]

BILLING CODE 7020-02-P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337-TA-1099]

Certain Graphics Processors and Products Containing the Same Institution of Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that a complaint was filed with the U.S. International Trade Commission on December 29, 2017, under section 337 of the Tariff Act of 1930, as amended, on behalf of ZiiLabs Inc., Ltd. of Bermuda. The complaint alleges violations of section 337 based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain graphics processors and products containing the same by reason of infringement of certain claims of U.S. Patent No. 6,181,355 ("the '355 Patent"); U.S. Patent No. 6,900,800 ("the '800 Patent"); U.S. Patent No. 8,144,156 ("the '156 Patent"); and U.S. Patent No. 8,643,659 ("the '659 Patent"). The complaint further alleges that an industry in the United States exists as required by the applicable Federal Statute.

The complainant requests that the Commission institute an investigation and, after the investigation, issue a limited exclusion order and cease and desist orders.

ADDRESSES: The complaint, except for any confidential information contained therein, is available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW, Room 112, Washington, DC 20436, telephone (202) 205-2000. Hearing impaired individuals are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205-1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at (202) 205-