

# U.S. Customs and Border Protection



## QUARTERLY IRS INTEREST RATES USED IN CALCULATING INTEREST ON OVERDUE ACCOUNTS AND REFUNDS ON CUSTOMS DUTIES

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

**ACTION:** General notice.

**SUMMARY:** This notice advises the public that the quarterly Internal Revenue Service interest rates used to calculate interest on overdue accounts (underpayments) and refunds (overpayments) of customs duties will remain the same from the previous quarter. For the calendar quarter beginning April 1, 2021, the interest rates for overpayments will be 2 percent for corporations and 3 percent for non-corporations, and the interest rate for underpayments will be 3 percent for both corporations and non-corporations. This notice is published for the convenience of the importing public and U.S. Customs and Border Protection personnel.

**DATES:** The rates announced in this notice are applicable as of April 1, 2021.

**FOR FURTHER INFORMATION CONTACT:** Bruce Ingalls, Revenue Division, Collection Refunds & Analysis Branch, 6650 Telecom Drive, Suite #100, Indianapolis, Indiana 46278; telephone (317) 298-1107.

### SUPPLEMENTARY INFORMATION:

#### Background

Pursuant to 19 U.S.C. 1505 and Treasury Decision 85-93, published in the **Federal Register** on May 29, 1985 (50 FR 21832), the interest rate paid on applicable overpayments or underpayments of customs duties must be in accordance with the Internal Revenue Code rate established under 26 U.S.C. 6621 and 6622. Section 6621 provides different interest rates applicable to overpayments: one for corporations and one for non-corporations.

The interest rates are based on the Federal short-term rate and determined by the Internal Revenue Service (IRS) on behalf of the

Secretary of the Treasury on a quarterly basis. The rates effective for a quarter are determined during the first-month period of the previous quarter.

In Revenue Ruling 2021–06, the IRS determined the rates of interest for the calendar quarter beginning April 1, 2021, and ending on June 30, 2021. The interest rate paid to the Treasury for underpayments will be the Federal short-term rate (0%) plus three percentage points (3%) for a total of three percent (3%) for both corporations and non-corporations. For corporate overpayments, the rate is the Federal short-term rate (0%) plus two percentage points (2%) for a total of two percent (2%). For overpayments made by non-corporations, the rate is the Federal short-term rate (0%) plus three percentage points (3%) for a total of three percent (3%). These interest rates used to calculate interest on overdue accounts (underpayments) and refunds (overpayments) of customs duties remain the same from the previous quarter. These interest rates are subject to change for the calendar quarter beginning July 1, 2021, and ending on September 30, 2021.

For the convenience of the importing public and U.S. Customs and Border Protection personnel, the following list of IRS interest rates used, covering the period from July of 1974 to date, to calculate interest on overdue accounts and refunds of customs duties, is published in summary format.

Beginning date	Ending date	Underpayments (percent)	Overpayments (percent)	Corporate overpayments (eff. 1–1–99) (percent)
070174.....	063075 .....	6	6	.....
070175.....	013176 .....	9	9	.....
020176.....	013178 .....	7	7	.....
020178.....	013180 .....	6	6	.....
020180.....	013182 .....	12	12	.....
020182.....	123182 .....	20	20	.....
010183.....	063083 .....	16	16	.....
070183.....	123184 .....	11	11	.....
010185.....	063085 .....	13	13	.....
070185.....	123185 .....	11	11	.....
010186.....	063086 .....	10	10	.....
070186.....	123186 .....	9	9	.....
010187.....	093087 .....	9	8	.....
100187.....	123187 .....	10	9	.....
010188.....	033188 .....	11	10	.....
040188.....	093088 .....	10	9	.....

Beginning date	Ending date	Under-payments (percent)	Over-payments (percent)	Corporate overpay-ments (eff. 1-1-99) (percent)
100188.....	033189 .....	11	10	.....
040189.....	093089 .....	12	11	.....
100189.....	033191 .....	11	10	.....
040191.....	123191 .....	10	9	.....
010192.....	033192 .....	9	8	.....
040192.....	093092 .....	8	7	.....
100192.....	063094 .....	7	6	.....
070194.....	093094 .....	8	7	.....
100194.....	033195 .....	9	8	.....
040195.....	063095 .....	10	9	.....
070195.....	033196 .....	9	8	.....
040196.....	063096 .....	8	7	.....
070196.....	033198 .....	9	8	.....
040198.....	123198 .....	8	7	.....
010199.....	033199 .....	7	7	6
040199.....	033100 .....	8	8	7
040100.....	033101 .....	9	9	8
040101.....	063001 .....	8	8	7
070101.....	123101 .....	7	7	6
010102.....	123102 .....	6	6	5
010103.....	093003 .....	5	5	4
100103.....	033104 .....	4	4	3
040104.....	063004 .....	5	5	4
070104.....	093004 .....	4	4	3
100104.....	033105 .....	5	5	4
040105.....	093005 .....	6	6	5
100105.....	063006 .....	7	7	6
070106.....	123107 .....	8	8	7
010108.....	033108 .....	7	7	6
040108.....	063008 .....	6	6	5
070108.....	093008 .....	5	5	4
100108.....	123108 .....	6	6	5
010109.....	033109 .....	5	5	4
040109.....	123110.....	4	4	3
010111.....	033111.....	3	3	2
040111.....	093011.....	4	4	3
100111.....	033116.....	3	3	2
040116.....	033118.....	4	4	3
040118.....	123118.....	5	5	4

Beginning date	Ending date	Under-payments (percent)	Over-payments (percent)	Corporate overpayments (eff. 1-1-99) (percent)
010119 .....	063019 .....	6	6	5
070119 .....	063020 .....	5	5	4
070120 .....	063021 .....	3	3	2

Dated: April 19, 2021.

JEFFREY CAINE,  
*Chief Financial Officer,*  
*U.S. Customs and Border Protection.*

[Published in the Federal Register, April 23, 2021 (85 FR 21758)]

**MODIFICATIONS TO THE COLLECTIONS PROCESS FOR DEFERRED TAX PAYMENTS ON CONSUMPTION ENTRIES OF DISTILLED SPIRITS, WINES, AND BEER IMPORTED INTO THE UNITED STATES**

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

**ACTION:** General notice.

**SUMMARY:** This document announces that U.S. Customs and Border Protection (CBP) is modifying the collections process for deferred payments of internal revenue taxes owed on consumption entries of distilled spirits, wines, and beer imported into the United States (other than in bulk containers). The primary modification announced in this notice is the harmonization of the determination of the due date for deferred tax payments with the entry summary date. Another modification is the consolidation of all deferred tax entry bills from all ports of entry for one semi-monthly period into consolidated bill(s) viewable in the Automated Commercial Environment (ACE). CBP is further facilitating deferred tax payments by removing current policy restrictions on the filing of entries with deferred taxes and eliminating the now unnecessary Semi-Monthly Excise Tax Form (Greater than 50) for importers who pay deferred taxes through *Pay.gov*. Lastly, CBP is adding a new payment method for deferred taxes in ACE while also eliminating a current, but lesser-used payment method available through Fedwire.

**DATES:** The modifications to the collections process for deferred taxes that are announced in this notice will become operational on May 1, 2021, except for the elimination of the current payment method using Fedwire. To allow Fedwire users time to convert to a different payment method, CBP is granting a longer transition period through June 30, 2021. As of July 1, 2021, CBP will no longer accept payments of deferred taxes through Fedwire.

**ADDRESSES:** Comments concerning this notice may be submitted at any time via email to the ACE Collections Team, Investment Analysis Office, Office of Finance, U.S. Customs and Border Protection, at *ACECollections@cbp.dhs.gov*, with a subject line identifier reading "Processing of Deferred Tax Payments."

**FOR FURTHER INFORMATION CONTACT:** Steven J. Grayson, Program Manager, Investment Analysis Office, Office of Finance, U.S. Customs and Border Protection, at (202) 579-4400, or *steven.j.grayson@cbp.dhs.gov*.

## **SUPPLEMENTARY INFORMATION:**

### **I. Background Regarding the Ongoing Modernization of the Collections System**

U.S. Customs and Border Protection (CBP) is modernizing its collections system, allowing CBP to eventually retire the Automated Commercial System (ACS) and transfer all collections processes into the Automated Commercial Environment (ACE). This modernization effort, known as ACE Collections, includes the consolidation of the entire collections system into the ACE framework, which will enable CBP to utilize trade data from ACE modules, benefitting both the trade community and CBP. The new collections system in ACE will reduce costs for CBP, create a common framework that aligns with other initiatives to reduce manual collection processes, and provide additional flexibility to allow for future technological enhancements. ACE Collections will also provide the public with more streamlined and better automated payment processes with CBP, including better visibility to data regarding specific transactions.

ACE Collections supports the goals of the Customs Modernization Act (Pub. L. 103–182, 107 Stat. 2057, 2170, December 8, 1993, Title VI of the North American Free Trade Agreement Implementation Act) of modernizing the business processes that are essential to securing U.S. borders, speeding up the flow of legitimate shipments, and targeting illicit goods that require scrutiny. ACE Collections also fulfills the objectives of Executive Order 13659 (79 FR 10655, February 25, 2014) to provide the trade community with an integrated CBP trade system that facilitates trade from entry of goods to receipt of duties, taxes, and fees.

CBP is implementing ACE Collections through phased releases in ACE. Release 1, which was deployed on September 7, 2019, dealt with statements integration, the collections information repository (CIR) framework, and ACH (automated clearinghouse) processing. *See* 84 FR 46749 and 84 FR 46678 (September 5, 2019), and 84 FR 49650 (September 23, 2019). Release 2 was deployed on February 5, 2021, and focused on non-ACH electronic receivables and collections, such as Fedwire, *Pay.gov*, Harbor Maintenance Fee (HMF) and Seized Assets and Case Tracking System (SEACATS) payments, and broker fees. All of the changes in Release 2 were internal to CBP and did not affect the trade community.

As explained more fully below, Release 3 will be deployed on May 1, 2021, and focuses on billing and debt collection. It includes mainly internal, technical changes to the liquidation process, bills, and user fees, and also makes the modifications to the collections process for deferred tax payments that are announced and explained in this

notice. The changes for deferred tax will benefit importers by providing flexibility for how to make their tax payments and access to data regarding which entries are covered by specific bills and payments. Additional releases will follow, and any further changes affecting the trade community will be announced by notice in the **Federal Register**, as needed.

## **II. Modifications to Processing of Deferred Tax Payments for Consumption Entries of Imported Alcoholic Beverages**

The CBP regulations provide an optional method for the payment of estimated import taxes on distilled spirits, wines, and beer imported into the United States (other than in bulk containers) (hereinafter referred to as “alcoholic beverages”). Specifically, an importer, including a transferee of alcoholic beverages in a Customs bonded warehouse, may pay on a semi-monthly basis the estimated import taxes on alcoholic beverages entered, or withdrawn from warehouse, for consumption, subject to the requirements in section 24.4 of title 19 of the Code of Federal Regulations (19 CFR 24.4).

Consistent with 19 CFR 24.4 and other applicable regulations, this notice announces six modifications to the processing of deferred payments of internal revenue tax owed on consumption entries of alcoholic beverages (hereinafter referred to as “deferred tax payments”). The primary modification is regarding the determination of the deferred tax payment due date, which is being harmonized with the entry summary date. In addition, CBP is consolidating all deferred tax entry bills from all ports of entry for one semi-monthly period into consolidated bill(s) viewable in ACE, with more detailed information available for viewing via an importer’s ACE Portal account. Other modifications that facilitate deferred tax payments include simplified requirements for importers to file entries with deferred taxes at all ports of entry; the elimination of the now unnecessary Semi-Monthly Excise Tax Form (Greater than 50) for importers who pay deferred taxes through Pay.gov; the addition of a new electronic payment method, using ACH debit and ACH credit via the Automated Broker Interface (ABI) in ACE; and, the elimination of a current, but lesser-used electronic payment method available through Fedwire.

CBP is making the modifications described above to streamline the collections system and facilitate the process for importers for making deferred tax payments. CBP has reviewed and assessed the collections requirements from fiscal year (FY) 2018, and after a thorough evaluation, identified the requirements and modernization opportunities to support users of CBP’s collections system. Throughout this evaluation, CBP has collaborated with stakeholders within CBP, as well as members of the trade community, and received valuable feed-

back, which was incorporated in the new ACE Collections requirements for deferred tax payments. The modifications announced in this notice will become operational on May 1, 2021, except for the elimination of Fedwire as a payment method. As of July 1, 2021, CBP will no longer accept payments of deferred taxes through Fedwire. A more detailed description of each of the modifications follows below.

*A. Harmonization of the Determination of the Due Date for Deferred Tax Payments*

An importer must pay internal revenue taxes on importations of alcoholic beverages pursuant to 26 U.S.C. 5061. *See generally*, 19 CFR 141.1 and 141.3, regarding the importer's obligations to pay these taxes upon entry of merchandise imported into the United States. According to the Internal Revenue Code, the last day for an importer to pay the tax levied on consumption entries of alcoholic beverages is the 14th day after the last day of the semi-monthly period during which the article is entered into the customs territory of the United States. 26 U.S.C. 5061(d)(2)(A). Under CBP regulations, an importer may choose to pay internal revenue taxes on imported alcoholic beverages at the time of entry or to apply for approval to defer the taxes and pay on a semi-monthly basis pursuant to 19 CFR 24.4(b). If an importer is approved by CBP for deferred tax payments, CBP's current practice is to use the date of entry (which is typically the time that merchandise is released from CBP custody) to set the semi-monthly period and thus determine the due date for an importer's payment of internal revenue taxes on consumption entries.

Currently, deferred tax payments are due on the 14th day after the last day of the semi-monthly period in which distilled spirits, wines, and beer are entered, or withdrawn from warehouse, for consumption. However, the entry summary date generally establishes the time of entry for goods in many instances, such as when goods are withdrawn for consumption from bonded warehouses, when goods are subject to quotas or immediate delivery procedures, and when the entry summary serves as the entry and entry summary, or when entries are certified from summary.

To streamline the collections process, this notice announces the harmonization of CBP's operations for determining the due date of deferred tax payments on consumption entries of imported alcoholic beverages. CBP will use the entry summary date when the entry summary is filed timely to fix the semi-monthly period under 26 U.S.C. 5061(d)(2)(A), and thus set the due date for the payment of deferred taxes. Where applicable, deferred tax payments will be due on the 14th day after the last day of the semi-monthly period in which



the entry summary date falls. Using the entry summary date to determine the date of payment when the entry summary date establishes the time of entry remains within the scope of the current CBP regulations.<sup>1</sup> Further, in some instances, the entry summary documentation may contain information that enhances CBP's ability to assess and collect internal revenue taxes, and thus, it is more operationally sound for CBP to rely upon timely submitted entry summary data to fix the semi-monthly period under 26 U.S.C. 5061(d)(2)(A). With this streamlined approach, CBP will be able to produce a more accurate bill for deferred taxes. It is important to note that the use of the entry summary date does not interfere with an importer's ability to pay the deferred taxes early. Early payment will still be allowed, but it will not change the semi-monthly period (which will be fixed based on the entry summary date when timely).

*B. Issuance of a Consolidated Bill (CBP Form 6084) and Availability of Detailed Billing Information in ACE Reports*

Currently, an importer who requests to receive a physical (hard copy) bill will receive a CBP Form 6084 by mail for each entry upon which the importer owes deferred taxes.<sup>2</sup> As a result, an importer who makes such a request may receive multiple, individual bills per payment period for each port where the importer filed entries with deferred taxes. Alternatively, an importer who does not wish to receive physical bills must identify and track its individual entries and the total amount of deferred taxes owed for one semi-monthly period in order to accurately pay the taxes owed. CBP notes that the majority of importers who pay deferred taxes elect not to receive physical bills and, instead, they track the amounts owed within their own internal systems.

To streamline the billing process and provide more transparency for importers, this notice announces that every importer who files entries with deferred taxes will receive one or more consolidated bills in ACE for each semi-monthly period. Consolidation into one bill is applicable to an importer who self-files (or employs a single licensed customs

---

<sup>1</sup> CBP notes that this change does not affect the applicability of the special rule set forth in 26 U.S.C. 5061(d)(6), which states that if the due date under 26 U.S.C. 5061(d) falls on a Saturday, Sunday, or a legal holiday, the due date for tax payment will be the immediately preceding day which is not a Saturday, Sunday, or holiday (or the immediately following day if the due date described in 26 U.S.C. 5061(d)(5) falls on a Sunday).

<sup>2</sup> An importer may request that CBP send a physical (hard copy) bill by mail by specifying a particular code when filing an entry with deferred taxes via ABI in ACE. For additional information, see the CBP and Trade Automated Interface Requirements (CATAIR), specifically the chapter entitled Entry Summary Create/Update, which is available online at: <https://www.cbp.gov/document/technical-documentation/entry-summary-createupdate-catair-draft>

broker) and uses the same bond to cover all entries filed with deferred taxes in a particular semi-monthly period. However, multiple consolidated bills will be issued when, in a particular semi-monthly period, an importer: self-files and employs a licensed customs broker(s) to file entries on the importer's behalf; employs multiple licensed customs brokers to file entries on the importer's behalf; and/or uses multiple bonds to cover the entries. In short, the consolidation is per importer of record number/per filer code/per bond number for a semi-monthly period.

The consolidated bills will be viewable only in ACE and will also include a consolidated bill number for reference. An importer may use the consolidated bill number to easily view all of the covered entries and the total amount of taxes owed in a semi-monthly period in ACE Reports, which is the data repository for ACE Collections. Only importers who have an ACE Portal account will be able to view the consolidated billing data in ACE Reports. CBP encourages importers who do not already have an ACE Portal account to apply for access to be able to view the necessary data to make accurate payments of deferred tax.<sup>3</sup> CBP will work with importers to provide any needed support when setting up ACE Portal accounts.

Please note that while importers may continue to request to receive physical bills by mail for each entry upon which deferred taxes are owed at this time, CBP is advising that physical bills will likely be consolidated in a future deployment in ACE Collections. Like the consolidated bills in ACE, the consolidated physical bills are expected to include a reference number (without identifying all of the individual entries). To view all of the covered entries and the total amount of taxes owed in a semi-monthly period, importers who receive consolidated physical bills would need to have an ACE Portal account to access the data in ACE Reports.

The availability of consolidated bills in ACE will reduce the amount of time that importers have spent in the past on identifying and tracking individual entries, and determining the total amount owed for one semi-monthly period. Another anticipated benefit is the potential reduction of the number of items held temporarily on the budget clearing account (BCA)<sup>4</sup> until a payment has been matched to an entry bill. Because a consolidated bill must be paid in full to show each individual entry as paid, and before post-summary corrections may be filed, it is expected that this change will reduce the number of

---

<sup>3</sup> The step-by-step instructions to apply for an ACE Portal account are available online at: <https://www.cbp.gov/trade/automated/getting-started/portal-applying>.

<sup>4</sup> A budget clearing account (BCA) is an account that is used to deposit funds that are not immediately identifiable to be matched to an open receivable.

items on the BCA. This will, in turn, increase visibility of individual entries paid and provide a more timely and accurate billing and collection process. Lastly, CBP notes that this consolidation of bills is also consistent with 19 CFR 24.4(f), which does not limit deferred tax bills to one entry number per bill.

### *C. Expansion of Filing of Deferred Taxes to All Ports*

Currently, an importer may file for approval to make deferred tax payments with the Center of Excellence and Expertise (Center) director, either at a port of entry or electronically (19 CFR 24.4(a)).<sup>5</sup> However, the process for an importer to pay deferred taxes is not similarly centralized. In order to file entries with deferred tax, an importer must submit those entries at each port of entry where the merchandise is entered. As a result, an importer who wishes to import entries with deferred tax at multiple ports must file the deferred tax entries at each of those ports.

In order to facilitate the deferred tax payment process for importers, this notice announces that an importer is able to file entries with deferred taxes at any port nationwide. This change provides convenience to the importers when filing entries with deferred taxes as they are no longer limited to a particular port. CBP notes that the expansion of filing of deferred taxes to all ports is also consistent with 19 CFR 24.4, which does not require the use of a specific port for making deferred tax payments.

### *D. Elimination of Semi-Monthly Excise Tax Form (Greater Than 50) and Automatic Payment Processing*

Currently, an importer may use the Semi-Monthly Excise Tax Form (Greater than 50), which can be found on *Pay.gov*, when making deferred tax payments for more than 50 entries on *Pay.gov*.<sup>6</sup> To properly complete this form, an importer must manage its own tracking system to keep count of the amount of deferred taxes owed on the entries for a specific semi-monthly period. This is necessary because ACE lists only the individual entries with deferred taxes owed, but not the total amount owed. When making a payment for the total

---

<sup>5</sup> CBP recently made regulatory changes to 19 CFR 24.4, which transitioned the processing of tax deferral approval requests from the ports to the Centers. *See* 81 FR 92978 (December 20, 2016)

<sup>6</sup> As noted elsewhere in this notice, an importer currently has the option of paying deferred taxes using ACH debit on *Pay.gov* or Fedwire. When using Fedwire, the Semi-Monthly Excise Tax Forms for Greater than 50, and 50 and Under are not used. Instead, the importer transmits the relevant information in a separate email. Thus, the elimination of the Semi-Monthly Excise Tax Form (Greater than 50) announced in this notice is only relevant when payment is made on *Pay.gov*.

amount of deferred taxes for all the entries on *Pay.gov*, the importer must include an attachment that lists all the entries covered, along with the Semi-Monthly Excise Tax Form (Greater than 50). Not only is an importer burdened with the process of identifying and tracking entries, determining the total amount owed and submitting two types of documentation, but so is CBP. After payment, CBP manually processes each entry and associated payment by the importer by keying in the bill number for each unique entry in ACE.

This notice announces that CBP is eliminating the Semi-Monthly Excise Tax Form (Greater than 50) as it is no longer needed due to the change in the bill format to allow for consolidated billing, as described above. For a consolidated bill, an importer will make one lump sum payment of the consolidated amount on *Pay.gov*, referencing the consolidated bill number. Please note that an importer who continues to request to receive physical bills by mail will need to identify and track individual entries for each semi-monthly period to determine the taxes owed, and, in addition, contact CBP (at [ACECollections@cbp.dhs.gov](mailto:ACECollections@cbp.dhs.gov)) to obtain the consolidated bill number to provide when making tax payments on *Pay.gov*. CBP encourages importers to avoid this more cumbersome process by applying for access to an ACE Portal account for full viewing capacity for consolidated bills.

Despite the elimination of the now unnecessary Semi-Monthly Excise Tax Form (Greater than 50), CBP will continue to make available the Semi-Monthly Excise Tax Form (50 and Under) for importers making payments on *Pay.gov*. Importers will no longer need to list individual entries on this form, but only the consolidated bill number(s) and dollar amount(s). As soon as the payment is made on *Pay.gov*, the payment will be posted the same night in ACE, and the payment of all taxes within one consolidated bill will automatically be matched to each entry from the CIR file. This programming change to allow for automated processing will save CBP resources that were previously used for manual data entry, reconciliation, and other manual processes, and will also promote faster processing times of the taxes owed.

#### *E. Addition of a New Payment Method of ACH Debit and ACH Credit via ABI in ACE*

Currently, importers may use ACH debit on *Pay.gov* or Fedwire for the payment of deferred taxes. An importer who chooses to use *Pay.gov* will initiate the payment and select the next business day as the earliest payment date or a later date. An importer who chooses to use Fedwire will initiate a payment the same day up to the cutoff time

established by the bank used by the importer. Under both payment options, the settlement date is recorded as the collection date for the payment.

This notice announces that CBP is making available to importers an additional electronic payment method (for both ACH debit and ACH credit) via ABI in ACE for the payment of deferred taxes. In the case of payment by ACH debit, the importer may initiate a debit authorization through ACE, and the authorization date (which may be earlier than the settlement date) will be recorded as the collection date (to be consistent with the collection date for ACE payments for statements). See 84 FR 46678 (September 5, 2019). In the case of payment by ACH credit via an authorization in ACE, the importer may initiate the credit transaction through its financial institution, and the bank post date (which is the same as the settlement date) will be recorded as the collection date for the payment (to be consistent with the collection date for ACE payments for statements). See <https://www.cbp.gov/trade/basic-import-export/automated-clearinghouse-ach>.

The updated ACE programming instructions and instructions regarding the format for making payments via ABI in ACE are available in a new CBP and Trade Automated Interface Requirements (CATAIR) document entitled “ACE Automated Broker Interface Automated Interface Requirements”. See <https://www.cbp.gov/document/guidance/draft-ace-catair-ach-debit-authorizationentry-summary-presentation> Also, the current payment method for ACH debit available through Pay.gov will not change and will continue to be available for the payment of deferred taxes.<sup>7</sup>

#### *F. Elimination of a Current Payment Method Using Fedwire*

This notice announces that CBP will eliminate the current payment method for Fedwire, which is a lesser-used method than another payment method available to importers through *Pay.gov*. Currently, CBP manually posts the deferred tax payments received through Fedwire, requiring additional CBP resources for data entry and processing. Even though the payment process is electronic for importers, the use of Fedwire places a significant burden on CBP. By eliminating the manual processing of Fedwire payments, CBP will conserve resources that can be used for other aspects of payment processing. Moreover, CBP is providing importers with a new payment method for ACH debit and ACH credit via ABI in ACE, in addition to the

---

<sup>7</sup> For guidance on using *Pay.gov*, go to <https://www.cbp.gov/trade/basic-import-export/acceptable-electronic-payment-methods>, click on the *Pay.gov* link and on the *Pay.gov* website, choose the applicable CBP form for making a payment.

already existing payment method for ACH debit in *Pay.gov*. Accordingly, importers will continue to have multiple convenient options to choose from when making deferred tax payments.

To enable those importers who currently use Fedwire to switch their payment method to *Pay.gov* or the new option available for ACH debit or ACH credit via ABI, CBP is announcing a transition period. Fedwire will continue to be available as a payment method through June 30, 2021. This transition period will allow for importers who have been using Fedwire as their preferred payment method to adjust their business processes for the use of another payment method. CBP will work with importers to provide any needed support during the transition period. As of July 1, 2021, CBP will no longer accept payments of deferred taxes through Fedwire.

Dated: April 23, 2021.

JEFFREY CAINE,  
*Chief Financial Officer,*  
*U.S. Customs and Border Protection.*

[Published in the Federal Register, April 29, 2021 (85 FR 22696)]

# U.S. Court of Appeals for the Federal Circuit

JANSSEN ORTHO, LLC, Plaintiff-Appellee v. UNITED STATES, Defendant-Appellant

Appeal No. 2020–1663

Appeal from the United States Court of International Trade in No. 1:13-cv-00296-JCG, Judge Jennifer Choe-Groves.

SEALED OPINION ISSUED: April 13, 2021

PUBLIC OPINION ISSUED: April 26, 2021\*

GREGORY DISKANT, Patterson Belknap Webb & Tyler LLP, New York, NY, argued for plaintiff-appellee. Also represented by ANDREW D. COHEN, DANIEL M. EISENBERG, EMMA ELLMAN-GOLAN, JOSHUA A. KIPNEES, AMY VEGARI; LARS-ERIK ARTHUR HJELM, Akin Gump Strauss Hauer & Feld LLP, Washington, DC.

GUY EDDON, International Trade Field Office, United States Department of Justice, New York, NY, argued for defendant-appellant. Also represented by JEFFREY B. CLARK, JEANNE DAVIDSON, JASON M. KENNER, PATRICIA M. MCCARTHY, MONICA PERRETTE TRIANA; ALEXANDRA KHREBTUKOVA, Office of Assistant Chief Counsel, United States Bureau of Customs and Border Protection, New York, NY.

Before PROST, *Chief Judge*, MAYER and WALLACH, *Circuit Judges*.

WALLACH, *Circuit Judge*.

Appellee, Janssen Ortho, LLC (“Janssen”), filed suit against Appellant, the United States (“the Government”), in the U.S. Court of International Trade (“CIT”), challenging U.S. Customs and Border Protection’s (“Customs” or “CBP”) classification of Janssen’s darunavir ethanolate, the active ingredient in Prezista®, a medication for the treatment of the human immunodeficiency virus (“HIV”), under the Harmonized Tariff Schedule of the United States (“HTSUS”) and the Pharmaceutical Appendix to the Tariff Schedule (“Pharmaceutical Appendix”).<sup>1</sup> Janssen alleges that it has paid approximately \$100 million in duties for entries of darunavir ethanolate that should have received duty-free treatment. Following a bench trial, the CIT concluded that the subject merchandise was properly classified under HTSUS subheading 2935.00.60 and subject to duty-free treatment under the Pharmaceutical Appendix. *Janssen Ortho LLC v. United States*, 425 F. Supp. 3d 1352, 1355 (Ct. Int’l Trade), *as amended* (Feb. 19, 2020), *judgment entered*, 429 F. Supp. 3d 1383 (Ct. Int’l Trade 2020); *see* J.A. 36 (Judgment).

\* This opinion was originally filed under seal and has been unsealed in full.

<sup>1</sup> All citations to the HTSUS are to the 2010 version, in keeping with Janssen’s initial entries at issue. *See LeMans Corp. v. United States*, 660 F.3d 1311, 1314 n.2 (Fed. Cir. 2011).

The Government appeals the CIT's decision as to darunavir ethanolate's duty-free treatment. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(5). We affirm.

## BACKGROUND

### I. Statutory Framework

The HTSUS governs the classification of merchandise imported into the United States. *See Wilton Indus., Inc. v. United States*, 741 F.3d 1263, 1266 (Fed. Cir. 2013). “The HTSUS scheme is organized by headings, each of which has one or more subheadings; the headings set forth general categories of merchandise, and the subheadings provide a more particularized segregation of the goods within each category.” *Id.* “The first four digits of an HTSUS provision constitute the heading, whereas the remaining digits reflect subheadings.” *Schlumberger Tech. Corp. v. United States*, 845 F.3d 1158, 1163 n.4 (Fed. Cir. 2017). “[T]he headings and subheadings . . . are enumerated in chapters 1 through 99 of the HTSUS (each of which has its own section and chapter notes)[.]” *R.T. Foods, Inc. v. United States*, 757 F.3d 1349, 1353 (Fed. Cir. 2014). There are two types of HTSUS headings, “eo nomine [and] use provisions.” *Schlumberger*, 845 F.3d at 1164. “[A]n eo nomine provision . . . describes an article by a specific name.” *CamelBak Prods., LLC v. United States*, 649 F.3d 1361, 1364 (Fed. Cir. 2011) (citation omitted). A use provision describes an article by its principal or actual use. *See Aromont USA, Inc. v. United States*, 671 F.3d 1310, 1313 (Fed. Cir. 2012).

The HTSUS is “considered . . . [a] statutory provision[] of law for all purposes.” 19 U.S.C. § 3004(c)(1). “The legal text of the HTS[US] includes all provisions enacted by Congress or proclaimed by the President,” HTSUS, *Preface* 1 (22d ed. 2010), including the headings, subheadings, “General Rules of Interpretation” (“GRI”), “Additional [U.S.] Rules of Interpretation” (“ARI”), “General Notes,” and “various appendices for particular categories of goods.” *R.T. Foods*, 757 F.3d at 1353 (footnote omitted); *see Chemtall, Inc. v. United States*, 878 F.3d 1012, 1026 (Fed. Cir. 2017) (explaining that “the tenth-digit statistical suffixes . . . are not statutory,” as those suffixes are not incorporated in the HTSUS’s legal text).<sup>2</sup>

“In 1995, the United States and [twenty-one] other countries” entered into the “Pharmaceutical Zero-for-Zero Initiative,” agreeing “to

---

<sup>2</sup> The GRI and ARI govern the classification of goods within the HTSUS. *See Otter Prods., LLC v. United States*, 834 F.3d 1369, 1375 (Fed. Cir. 2016). The GRI “govern the proper classification of all merchandise.” *Carl Zeiss, Inc. v. United States*, 195 F.3d 1375, 1379 (Fed. Cir. 1999). The ARI are specific to use provisions. *See Schlumberger*, 845 F.3d at 1163 n.5 (explaining that the ARI do not apply to eo nomine provisions).



[reciprocally] eliminate tariffs on pharmaceutical products, their derivatives, and certain chemical intermediates used to manufacture pharmaceuticals.” *Advice Concerning the Addition of Certain Pharm. Prod. & Chem. Intermediates to the Pharm. Appendix to the [HTSUS] (“USITC Pharma. Advice”)*, Inv. No. 332–476, USITC Pub. 3883, 2006 WL 2950495, at \*1 (2006). The United States codified this agreement through HTSUS General Note 13 and the Pharmaceutical Appendix. *Id.* at \*6. “General Note 13 permits duty free treatment of certain pharmaceutical products[.]” *Forest Labs., Inc. v. United States*, 476 F.3d 877, 882 (Fed. Cir. 2007). It provides that “[w]henever” an HTSUS heading or subheading has the “symbol ‘K’ in parentheses” in the “Special’ [duty rate] subcolumn,” “any product (by whatever name known) classifiable in such provision which is the product of a country eligible for tariff treatment . . . shall be entered free of duty, provided that such product is included in the [P]harmaceutical [A]ppendix.” HTSUS, General Note 13 (emphasis omitted); see *USITC Pharma. Advice*, 2006 WL 2950495, at \*6 (similar).

Table 1 of the Pharmaceutical Appendix “enumerates products described by International Non-proprietary Names [(‘INN’)],”<sup>3</sup> with “[t]he Chemical Abstracts Service [(‘CAS’)] registry numbers also set forth . . . to assist in the identification of the products concerned,”<sup>4</sup> to “be entered free of duty under [G]eneral [N]ote 13 to the [HTSUS].” Pharmaceutical Appendix at 2 (Table 1 Chapeau). The chapeau to Table 1 further provides that, “[f]or purposes of the [HTSUS], any references to a product enumerated in [Table 1] includes such product by whatever name known.” *Id.* Table 1 lists “darunavir,” along with the CAS registry number “206361–99–1.” Pharmaceutical Appendix at 15. Table 2 of the Pharmaceutical Appendix provides that the “[s]alts, esters[,] and hydrates of the products enumerated in [T]able 1 . . . that contain in their names any of the prefixes or suffixes listed [in Table 2] shall also be entered free of duty under [G]eneral [N]ote 13” so long as they are “classifiable in the same” HTSUS heading “enumerated in [T]able 1.” Pharmaceutical Appendix at 57 (Table 2 Chapeau); see *id.* (providing that Table 2 similarly covers “such product by whatever name known”).

<sup>3</sup> INNs are invented, non-proprietary names assigned to “[p]harmaceutical [s]ubstances” by the World Health Organization (“WHO”). J.A. 1348; see J.A. 369–70, 443–44.

<sup>4</sup> CAS is a division of the American Chemical Society that collects and indexes publications and research in chemistry and related sciences, including creating and maintaining a “registry of substances.” J.A. 1119–21, 1248. CAS assigns “[e]ach unique chemical substance” its own CAS registry number. J.A. 1153–54.

## II. The Subject Merchandise

This appeal involves multiple entries of darunavir ethanolate, made by Janssen at the port of San Juan, Puerto Rico, between September 2010 and March 2012. J.A. 1246, 4452–55; *see* J.A. 1246–50 (Stipulated Facts), 4452–55 (Summons); *see also* *Janssen*, 425 F. Supp. 3d at 1355, 1361.<sup>5</sup> Janssen is a subsidiary of Johnson & Johnson and the owner of U.S. Patent No. 7,700,645 (“the ’645 patent”), which discloses darunavir ethanolate. J.A. 1247; *see* ’645 patent, col. 29 l. 62–col. 30 l. 65 (claims 1–8) (expressly claiming darunavir ethanolate solvate).

“[D]arunavir in the form of darunavir ethanolate” is “[t]he active pharmaceutical ingredient in Prezista,” a medication for the treatment of HIV. *Janssen*, 425 F. Supp. 3d at 1357; *see id.* (“Prezista is a human [HIV-1] protease inhibitor indicated for the treatment of HIV-1 Infection.”); J.A. 1247 (“Darunavir is the non-proprietary or generic name for Prezista[.]”). “Darunavir” is the INN assigned to TMC-114, a compound developed by Janssen’s predecessor in interest to the ’645 patent, for the treatment of HIV. J.A. 1280–81 (INN Application), 1348–49 (INN Assignment). “Darunavir” is also the INN for Prezista and darunavir ethanolate. *Janssen*, 425 F. Supp. 3d at 1357.

Darunavir ethanolate has the chemical names “Carbamic acid, N-[(1S,2R)-3-[[4-aminophenyl)sulfonyl](2-methylpropyl)amino]-2-hydroxy-1-(phenylmethyl)propyl]-, (3R,3aS,6aR)-hexahydrofuro[2,3-b]furan-3-yl ester, compd. with ethanol (1:1)” and “Carbamic acid, [(1S,2R)-3-[[4-aminophenyl)sulfonyl](2-methylpropyl)amino]-2-hydroxy-1-(phenylmethyl)propyl]-, (3R,3aS,6aR)-hexahydrofuro[2,3-b]furan-3-yl ester, compd. with ethanol (1:1) (9CI).” *Janssen*, 425 F. Supp. 3d at 1356; *see* J.A. 1347; *see also* J.A. 1249 (stipulating to the same). It is a sulfonamide. *Janssen*, 425 F. Supp. 3d at 1356; *see id.* (“Darunavir contains a sulfonamide moiety.”). Further, as indicated by its chemical names, darunavir ethanolate is darunavir compounded with ethanol. *Id.* at 1356; *see* J.A. 1249. Darunavir ethanolate is produced “by crystallizing darunavir and ethanol molecules into a crystal lattice structure.” *Janssen*, 425 F. Supp. 3d at 1356; *see id.* (“Darunavir is crystallized in an ethanol bath to form darunavir ethanolate.”). “Darunavir ethanolate is a channel solvate,” *id.*, that presents as a “white powder,” J.A. 355; *see* J.A. 280–81 (explaining that, prior to crystallization, darunavir is a yellow liquid at normal temperature and pressure).

<sup>5</sup> Unless otherwise noted, we cite to the CIT’s undisputed recitation of the facts for ease of reference. *See Janssen*, 425 F. Supp. 3d at 1355–57.

In June 1998, CAS assigned darunavir CAS registry number 206361–99–1. J.A. 1248 (“CAS assigned the CAS registry no. 206361–99–1 to darunavir on June 4, 1998.”); *see* J.A. 1185. In January 2004, following publication of the application that led to the ’645 patent, CAS assigned darunavir ethanolate CAS registry number 635728–49–3. J.A. 1248 (“CAS assigned the CAS registry no. 635728–49–3 to darunavir ethanolate on January 9, 2004.”); *see* ’645 patent, Title Page; J.A. 1286 (parent PCT application); *see also* J.A. 1661 (CAS Registry). Generally, CAS does not separately index solvates, J.A. 1150, unless, for example the solvate is specifically patented, J.A. 1151–52, 1179–80.

In 2006, the U.S. Food and Drug Administration (“FDA”) approved Prezista. J.A. 1415–16, 1420. The FDA adopted Prezista’s existing INN, “darunavir,” as the generic name for darunavir ethanolate. J.A. 363, 457–58, 1005–06; *see Janssen*, 425 F. Supp. 3d at 1357 (“The prescribing information for Prezista describes the product as ‘PREZISTA (darunavir), in the form of darunavir ethanolate[.]’ (citation omitted)); *id.* (“The United States Adopted Name (‘USAN’) for Prezista is darunavir.”). Following importation, Janssen tablets darunavir ethanolate with various inactive ingredients to make Prezista. J.A. 354–56, 1418; *see Janssen*, 425 F. Supp. 3d at 1357 (“Darunavir ethanolate is the drug substance in Prezista.”). “Darunavir ethanolate is the only commercially available form of darunavir.” *Janssen*, 425 F. Supp. 3d at 1357; *see id.* (“Janssen has not developed darunavir in a form other than darunavir ethanolate for commercial use.”).

### III. Procedural History

Customs liquidated Janssen’s entries under HTSUS subheading 2935.00.95, at a duty rate of 6.5 percent *ad valorem*. J.A. 4453; *see* HTSUS subheading 2935.00.95 (covering “Sulfonamides: Other: Drugs: Other”). Janssen filed protests of these actions, asserting that its darunavir ethanolate should have been classified under HTSUS subheading 3003.90.00, duty free, or HTSUS subheading 2935.00.60, duty free. *Janssen*, 425 F. Supp. 3d at 1355; J.A. 4453; *see* 19 U.S.C. § 1514(a)(2) (providing that an importer may protest to Customs “the classification and rate and amount of duties chargeable” on an entry); HTSUS subheading 3003.90.00 (covering certain “[m]edicaments . . . consisting of two or more constituents which have been mixed together for therapeutic or prophylactic uses”); HTSUS, General Note 13 (providing for duty-free treatment for certain HTSUS headings or subheadings that have the “symbol ‘K’ in parentheses” in the “‘Special’ [duty rate] subcolumn” as “included in the [P]harmaceutical [A]ppendix”). Customs denied Janssen’s protests. *Janssen*, 425 F.

Supp. 3d at 1355; see 19 U.S.C. § 1515 (providing Customs with the authority to review protests made under 19 U.S.C. § 1514).

In December 2013, Janssen filed a summons and complaint before the CIT, contesting Customs' denial of its protests. *Janssen*, 425 F. Supp. 3d at 1355; see J.A. 76–97 (Complaint), 4452–55 (Summons); see also 28 U.S.C. § 1581(a) (giving the CIT “exclusive jurisdiction of any civil action commenced to contest the denial of a protest, in whole or in part, under [19 U.S.C. § 1515]”). Janssen subsequently amended its complaint to raise claims under the Due Process Clause of the Fifth Amendment. *Janssen*, 425 F. Supp. 3d at 1355; see J.A. 111–41 (First Amended Complaint).<sup>6</sup> The Government filed a partial motion to dismiss Janssen's Due Process claim. *Janssen*, 425 F. Supp. 3d at 1355. The CIT “bifurcated the action into two trials,” the first to address the merits of Janssen's tariff classification arguments, the second to address Janssen's Due Process claim. *Id.*; see *id.* (staying the Government's partial motion to dismiss and “reserv[ing] scheduling of the second trial pending the outcome of the first trial”). The parties filed pre-trial briefs, and in July 2019, the CIT conducted a three-day bench trial, hearing testimony from fact and expert witnesses. *Id.* Following post-trial briefs, in November 2019, the CIT heard closing arguments. *Id.*

The CIT held that darunavir ethanolate “is properly classified under HTSUS subheading 2935.00.60 and is eligible for duty-free treatment under the Pharmaceutical Appendix.” *Id.* The CIT explained that “[b]ecause darunavir ethanolate is a sulfonamide,” it “belongs to the ‘[s]ulfonamides’ class or kind of organic compounds that are classifiable under HTSUS subheading 2935.00.60.” *Id.* at 1363 (second alteration in original); see HTSUS subheading 2935.00.60 (covering “Sulfonamides: Other: Drugs: Other”).<sup>7</sup> The CIT then noted that HTSUS subheading 2935.00.60 lists the symbol “K” in the special

---

<sup>6</sup> Specifically, Janssen claimed that “the CBP officers who adjudicated Janssen's [claims] had institutional, structural, and financial interests in ruling against Janssen,” thereby “deny[ing] Janssen both the reality and the appearance of a neutral and unbiased decision” and violating the Due Process clause of the Fifth Amendment. J.A. 138. Janssen alleged that its tariff classification was the result of “the unique funding structure of CBP's Puerto Rico operations, the financial condition of those operations, and the huge sums potentially available to CBP as a result of the classification decision.” J.A. 124 (citing 48 U.S.C. § 740); see 48 U.S.C. § 740 (“The duties and taxes collected in Puerto Rico . . . shall be paid into the treasury of Puerto Rico to be expended as required by law for the government and benefit thereof[.]”); J.A. 124–25 (stating that “CBP's Puerto Rico operations . . . are financed” by duties and taxes collected), 125 (alleging that CBP began investigating the classification of Janssen's entries of darunavir ethanolate as a way of making up for “recurring budget shortfalls”).

<sup>7</sup> Neither the Government nor Janssen challenge this classification on appeal. See generally Appellant's Br.; Appellee's Br.

duty rate subcolumn and, therefore, “cross-references the Pharmaceutical Appendix.” *Janssen*, 425 F. Supp. 3d at 1364; see HTSUS, General Note 13. The CIT concluded that “‘darunavir’ is a product listed on the Pharmaceutical Appendix” for duty-free treatment. *Janssen*, 425 F. Supp. 3d at 1364; see Pharmaceutical Appendix at 2, 15. The CIT further found that, because the “evidence at trial” established “that darunavir ethanolate is a name by which the INN darunavir is known,” darunavir ethanolate falls “within the terms of Table 1 of the Pharmaceutical Appendix” and should receive duty-free treatment. *Janssen*, 425 F. Supp. 3d at 1365; see *id.* (discussing exemplary evidence in support, including expert testimony); see also *id.* at 1357 (finding, inter alia, that “[t]he INN for darunavir ethanolate is darunavir,” “[d]arunavir ethanolate is also known as darunavir,” and “[d]arunavir ethanolate is the only commercially available form of darunavir”). The CIT reasoned that, while “darunavir ethanolate [has been] assigned a separate CAS registry number” from “darunavir,” this did not alter its conclusion, because “[b]y the terms of the chapeau, CAS registry numbers are not exclusive or exhaustive identifiers as to whether a named product is within the scope of the Pharmaceutical Appendix.” *Id.* at 1364–65.<sup>8</sup>

## DISCUSSION

### I. Standard of Review and Legal Standard

In reviewing a decision of the CIT, “we give great weight” to its “informed opinion”; “it is nearly always the starting point of our analysis.” *Schlumberger*, 845 F.3d at 1162 (internal quotation marks, alterations, and citation omitted); see *Chemtall*, 878 F.3d at 1018 (noting the CIT’s “expertise in international trade matters, including classification rulings”). “The classification of merchandise involves a two-step inquiry.” *ADC Telecomms., Inc. v. United States*, 916 F.3d 1013, 1017 (Fed. Cir. 2019). First, we “determin[e] the proper meaning” of the terms within the relevant tariff provision and, second, we determine whether the subject merchandise “falls within” those terms. *Sigma-Tau HealthSci., Inc. v. United States*, 838 F.3d 1272, 1276 (Fed. Cir. 2016). “The first step presents a question of law that we review de novo, whereas the second involves an issue of fact that we review for clear error.” *Schlumberger*, 845 F.3d at 1162. “Where . . . no genuine dispute exists as to the nature of the subject merchandise, the two-step inquiry collapses into a question of law we review

<sup>8</sup> The CIT subsequently dismissed Janssen’s Due Process claim as moot. J.A. 39.

de novo.” *ADC*, 916 F.3d at 1017 (internal quotation marks and citation omitted).<sup>9</sup>

## II. The CIT Properly Classified Janssen’s Darunavir Ethanolate as INN “Darunavir”

The CIT concluded that darunavir ethanolate “is properly classified under HTSUS subheading 2935.00.60 and is eligible for duty-free treatment under the Pharmaceutical Appendix.” *Janssen*, 425 F. Supp. 3d at 1355. The CIT explained that because “‘darunavir’ is a product listed on the Pharmaceutical Appendix,” and “‘darunavir ethanolate’ is a name by which darunavir is known,” it “is within the terms of Table 1 of the Pharmaceutical Appendix.” *Id.* at 1364–65. The Government argues that the CIT erred “in its interpretation of General Note 13 and the Pharmaceutical Appendix,” Appellant’s Br. 9 (capitalization normalized), because neither the “INN ‘darunavir’” nor “CAS Registry No. 206361–99–1 . . . identif[ies] darunavir ethanolate,” *id.* at 10, 12 (capitalization normalized).<sup>10</sup> We disagree with the Government.

First, the Pharmaceutical Appendix expressly includes products described by the INN “darunavir.” Table 1 of the Pharmaceutical Appendix “enumerates products described by [their] International Non-proprietary Names” or “INN” for duty-free treatment, with “any references to a product enumerated” encompassing “such product by whatever name known.” Pharmaceutical Appendix at 2. It further provides associated “[CAS] registry numbers . . . to assist in the identification of the products concerned[.]” *Id.* That is, by its plain language, the Pharmaceutical Appendix covers “such products,” by “whatever name known,” that are “described by” an INN listed in Table 1. *Id.*; see *United States v. Clarke*, 445 U.S. 253, 254 (1980) (“[T]his is a case in which the meaning of a statute may be determined by the admittedly old-fashioned but nonetheless still entirely appropriate ‘plain meaning’ canon[.]”). CAS registry numbers are

<sup>9</sup> “[A] tariff classification has no claim to judicial deference under *Chevron*, there being no indication that Congress intended such a ruling to carry the force of law”; rather, generally, Customs’ “ruling is eligible to claim respect according to its persuasiveness” under *Skidmore*. *United States v. Mead Corp.*, 533 U.S. 218, 221 (2001) (citing *Chevron U.S.A., Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837 (1984); *Skidmore v. Swift & Co.*, 323 U.S. 134 (1944)). Here, however, the Government “has represented that it will not seek deference in accordance with *Skidmore* . . . with respect to [Customs] ruling HQ H231485[.]” J.A. 4457; see J.A. 4456–57 (Order Regarding [Government’s] Motion for a Protective Order). The Government states that Customs’ classification ruling is “presumed to be correct.” Appellant’s Br. 8 (quoting 28 U.S.C. § 2639(a)(1)). However, § 2639(a)(1) does not impact or “change the rules of construction of the HTSUS”; rather, it means that the “burden of proof [is] on the importer[.]” *Anhydrides & Chems., Inc. v. United States*, 130 F.3d 1481, 1486 (Fed. Cir. 1997).

<sup>10</sup> “There is no dispute that the products [at issue] were imported from eligible countries.” *Janssen*, 425 F. Supp. 3d at 1364 n.6; see generally Appellant’s Br.; Appellee’s Br.

provided to “assist in the identification of the products,” and, therefore, while helpful, are not dispositive. Pharmaceutical Appendix at 2; see *Barnhart v. Peabody Coal Co.*, 537 U.S. 149, 168 (2003) (“We do not read the enumeration of one case to exclude another unless it is fair to suppose that Congress considered the unnamed possibility and meant to say no to it.”). Table 1 lists the INN “darunavir,” along with the CAS registry number “206361–99–1.” Pharmaceutical Appendix at 15. Therefore, the Pharmaceutical Appendix covers “such products,” by “whatever name [otherwise] known,” that are “described by” the INN “darunavir,” with the CAS registry number 206361–99–1 provided to “assist in [its] identification[.]” *Id.* at 2, 15; see *Carl Zeiss*, 195 F.3d at 1379 (“Absent contrary legislative intent, HTSUS terms are to be construed according to their common and commercial meanings, which are presumed to be the same.”).

Second, darunavir ethanolate is a product described by the INN “darunavir.” The CIT found that “[t]he INN for darunavir ethanolate is darunavir,” “[d]arunavir ethanolate is also known as darunavir,” and the INN for Prezista, of which “[t]he active pharmaceutical ingredient” is “darunavir in the form of darunavir ethanolate,” is also “darunavir[.]” *Janssen*, 425 F. Supp. 3d at 1364; see J.A. 1246–50 (Stipulated Facts). The CIT further found, based on “evidence at trial,” that the “INN darunavir” is commonly and commercially used to refer to “darunavir ethanolate.” *Janssen*, 425 F. Supp. 3d at 1364; see *id.* at 1357 (finding that “[t]he prescribing information for Prezista describes the product as ‘PREZISTA (darunavir), in the form of darunavir ethanolate,’” and “[d]arunavir ethanolate is the only commercially available form of darunavir”); *id.* at 1364 (finding that the WHO “identifies that the INN ‘[d]arunavir’ is manufactured as ‘[d]arunavir (ethanolate),” as well as the National Institute of Health, National Center for Biotechnology Information PubChem Compound database, and the FDA (citing, *inter alia*, J.A. 1778–83, 1784–91, 1860–62)). The CIT acknowledged the Government’s evidence that “darunavir ethanolate is assigned a separate CAS registry number” from darunavir, *Janssen*, 425 F. Supp. 3d at 1364–65; see J.A. 1248, but found this difference “unavailing” because, by Table 1’s plain language, “CAS registry numbers are not exclusive or exhaustive identifiers as to whether a named product is within the scope of the Pharmaceutical Appendix,” *Janssen*, 425 F. Supp. 3d at 1365. Based on the evidence presented, the CIT concluded that darunavir ethanolate falls within the products described by the INN “darunavir.” *Id.* We perceive no clear error in this finding. See *Renda Marine, Inc. v. United States*, 509 F.3d 1372, 1378 (Fed. Cir. 2007) (“A finding is ‘clearly erroneous’

when although there is evidence to support it, the reviewing court on the entire evidence is left with the definite and firm conviction that a mistake has been committed.” (quoting *United States v. U.S. Gypsum Co.*, 333 U.S. 364, 395 (1948)).

The Government’s counterarguments are unpersuasive. First, the Government argues that the CIT “erroneously construed” Table 1 to the Pharmaceutical Appendix because both “the INN ‘darunavir’ and the CAS registry number ‘206361–99–1[]’ uniquely identify the darunavir molecule, not darunavir ethanolate.” Appellant’s Br. 10 (capitalization normalized). Framing an issue of fact as a legal challenge, the Government asserts that “[b]ecause the INN ‘darunavir’ does not describe darunavir ethanolate, and because the unique CAS registry number assigned to darunavir ethanolate, number 635728–49–3, is not included in [T]able 1, darunavir ethanolate is not a ‘product enumerated in [Table 1].” *Id.* (capitalization normalized). The Government is incorrect.

Table 1’s listing of INN “darunavir” does not uniquely identify the darunavir molecule. Table 1 expressly “enumerates products,” not molecules, “described by” their INN. Pharmaceutical Appendix at 2; see *Forest Labs.*, 476 F.3d at 882 (“General Note 13 permits duty free treatment of certain pharmaceutical *products* [.]” (emphasis added)); cf. J.A. 1348 (WHO, noting that INNs are assigned broadly to “[p]harmaceutical [s]ubstances”). It is well-established that “HTSUS terms are to be construed according to their common and commercial meanings” and that “eo nomine designation[s] . . . will ordinarily include all forms of the named article.” *Carl Zeiss*, 195 F.3d at 1379 (internal quotation marks and citations omitted). Further, contrary to the Government’s understanding, darunavir ethanolate is the darunavir molecule. Specifically, darunavir ethanolate is the darunavir molecule compounded with ethanol to form a solvate. *Janssen*, 425 F. Supp. 3d at 1356 (finding that “[d]arunavir ethanolate is created by crystallizing darunavir and ethanol molecules into a crystal lattice structure,” “[d]arunavir ethanolate is a channel solvate,” and “[e]thanol molecules in the channels of darunavir ethanolate support the crystal lattice”); see *id.* (finding that the chemical names for darunavir ethanolate are darunavir “comp[oun]d[ed] with ethanol” in equal parts); see J.A. 1249 (same).

Nor does Table 1’s listing of the CAS registry number “206361–99–1” exclude all but the darunavir molecule. As explained above, Table 1 provides that CAS numbers are included “to assist in the identification of the products” listed by INN. Pharmaceutical Appendix at 2. That is, as the Government acknowledges, CAS numbers are not dispositive and cannot be read to exclude other CAS



numbers. See Appellant's Br. 14 ("The Government [has] never contended that CAS registry numbers are 'dispositive[.]'"). It is unclear, then, what result the Government expects from its assertion that the CIT should have, nonetheless, more closely "evaluated" "the listed CAS registry numbers." *Id.*; see 28 U.S.C. § 2111 (explaining that, under the "[h]armless error" rule, we "give judgment after an examination of the record without regard to errors or defects which do not affect the substantial rights of the parties"). Further, the Government's own expert witness testified that CAS numbers default to including both the indexed compound and their solvate forms, J.A. 1150 (Government's expert, testifying that "solvates are not indexed in the system generally"), 1179 (Government's expert, agreeing that "CAS[,] as a baseline rule, won't separately index solvates" but rather indexes them "under the unsolvated form"); see *Janssen*, 425 F. Supp. 3d at 1356 (finding that "darunavir ethanolate is a channel solvate" formed by "crystallizing darunavir and ethanol"), such that, while darunavir ethanolate, having been patented, has its own CAS registry number, J.A. 1661 (CAS registry entry for darunavir ethanolate); see J.A. 1151–52 (Government's expert, explaining that "in the case of solvates, those would be separately registered when they're in a patent example or claim" because "it's a disclosure"), 1179–80 (similar), the CAS number for darunavir may nonetheless "assist in the identification" of darunavir ethanolate as the product INN "darunavir," Pharmaceutical Appendix at 2, 15; see J.A. 1178–79 (Government's expert, agreeing that "if you search [the CAS registry] for [darunavir's CAS registry number]" or the name "darunavir," "it will return the entry for darunavir ethanolate"); see also J.A. 1012–13 (the Government's second expert, testifying that "[o]bviously" "if you use the structure of the darunavir molecule to search in the CAS system, among the associated index entries is the entry for darunavir ethanolate"); J.A. 633 (Janssen's expert, explaining that the CAS registry number for darunavir "assists in identifying darunavir ethanolate" because their CAS registry numbers "are linked numbers").

The Government further asserts that "[w]ithout explanation," the CIT erroneously "disregarded the CAS registry number identified in [T]able 1." Appellant's Br. 14. However, as noted above, the CIT did address darunavir's CAS registry number. See *Janssen*, 425 F. Supp. 3d at 1365 (explaining that, while darunavir has a different CAS registry number than darunavir ethanolate, that difference was not "dispositive"). In effect, the Government argues that the CIT failed to give sufficient weight to the fact that darunavir and darunavir etha-

nolate have different CAS registry numbers. See Appellant's Br. 14. This argument is misplaced. "The weighing of conflicting evidence is a task within the special province of the trial judge who, having heard the evidence, is in a better position than we to evaluate it." *Pac. Gas & Elec. Co. v. United States*, 668 F.3d 1346, 1353 (Fed. Cir. 2012) (citation omitted).

Second, the Government asserts that the CIT's "expansive reading of" the Table 1 chapeau "renders [T]able 2 [of the Pharmaceutical Appendix] inoperative." Appellant's Br. 18. The Government argues that the "purpose of [T]able 2" is to "identif[y] . . . the specific derivative forms of the products listed [i]n [T]able 1 that are afforded duty-free treatment," such that, in order for Janssen's product to receive duty-free treatment, it must be listed in both Table 1 and Table 2. *Id.* at 18–19 (citing *Sigma-Tau HealthSci., Inc. v. United States*, 98 F. Supp. 3d 1365, 1377 (Ct. Int'l Trade 2015), *rev'd and remanded on other grounds*, 838 F.3d 1272 (Fed. Cir. 2016)); see *Sigma-Tau*, 98 F. Supp. 3d at 1377 (quoting General Note 13 and concluding that "[t]hus to qualify for K designation, the [derivative] products at issue must be listed in both Table 1 and Table 2"); see also *Sigma-Tau*, 838 F.3d at 1277 n.2 (noting that the CIT's conclusions as to General Note 13 were not at issue on appeal). This argument is without merit.

General Note 13 provides that "product[s] in the [P]harmaceutical [A]ppendix" may be entered "free of duty," and, further, that "[p]roducts in the pharmaceutical appendix include the salts, esters and hydrates [of INN] products enumerated in [T]able 1 . . . that contain in their names any of the prefixes or suffixes listed in [T]able 2[.]" HTSUS, General Note 13 (emphasis added). "[T]he term 'include' . . . signifies a non-exhaustive list." *Apple Inc. v. Voip-Pal.com, Inc.*, 976 F.3d 1316, 1323 (Fed. Cir. 2020). Table 1 "enumerates products" to "be entered free of duty under [G]eneral [N]ote 13," Pharmaceutical Appendix at 2, and Table 2 further provides that the "[s]alts, esters[,] and hydrates of the products enumerated in [T]able 1 . . . that contain in their names any of the prefixes or suffixes listed" in Table 2, may "also be entered free of duty under [G]eneral [N]ote 13 . . . provided that [each] is classifiable in the same 6-digit tariff provision as the relevant product enumerated in [T]able 1," *id.* at 57 (emphasis added). That is, by its plain language, Table 2 provides an additional list of products that may "also be entered duty free." *Id.* ; see *King v. St. Vincent's Hosp.*, 502 U.S. 215, 221 (1991) ("Words are not pebbles in alien juxtaposition; they have only a communal existence[.]" (quoting *NLRB v. Federbush Co.*, 121 F.2d 954, 957 (2d Cir. 1941) (L. Hand,

J.)); *cf. USITC Pharma. Advice*, 2006 WL 2950495, at \*1 (explaining that the “Pharmaceutical Zero-for-Zero Initiative,” as codified at General Note 13, “eliminate[s] tariffs on pharmaceutical products, their derivatives, and certain chemical intermediates”).

Here, because Table 1 covers “such products,” by “whatever name [otherwise] known,” that are “described by” the INN “darunavir,” Pharmaceutical Appendix at 2, 15, and darunavir ethanolate is a product described by the INN “darunavir,” *Janssen*, 425 F. Supp. 3d at 1357 (“The INN for darunavir ethanolate is darunavir.”), it is unnecessary to reach Table 2. *Janssen*’s entries of darunavir ethanolate are subject to duty-free treatment under Table 1. *See* HTSUS, General Note 13. The CIT did not erroneously “render” Table 2 inoperative, Appellant’s Br. 2; Table 2 is simply irrelevant to the classification of darunavir ethanolate, *see* Pharmaceutical Appendix at 2, 57. Accordingly, the CIT did not err in concluding that *Janssen*’s entries of subject merchandise, “properly classified under HTSUS subheading 2935.00.60,” are “eligible for duty-free treatment under the Pharmaceutical Appendix.” *Janssen*, 425 F. Supp. 3d at 1366.

#### CONCLUSION

We have considered the Government’s remaining arguments and find them unpersuasive.<sup>11</sup> Accordingly, the Judgment of the U.S. Court of International Trade is

#### AFFIRMED

---

<sup>11</sup> Because we resolve darunavir ethanolate’s classification as INN “darunavir,” duty free, at Table 1 of the Pharmaceutical Appendix, we do not reach the parties’ arguments as to how darunavir ethanolate may or may not be classified under Table 2, or *Janssen*’s Due Process claim, as they are moot. *See E.T. Horn Co. v. United States*, 367 F.3d 1326, 1336 (Fed. Cir. 2004); *NEC Corp. v. United States*, 151 F.3d 1361, 1369 (Fed. Cir. 1998); *see also* Appellee’s Br. 20 (noting that *Janssen*’s Due Process claim has been mooted by the duty-free classification), 57 (arguing that “[i]n the event of reversal, *Janssen*’s Due Process claim remains to be tried” (capitalization normalized)).



# Index

*Customs Bulletin and Decisions*  
*Vol. 55, No. 18, May 12, 2021*

## *U.S. Customs and Border Protection*

### *General Notices*

	<i>Page</i>
Quarterly IRS Interest Rates Used in Calculating Interest on Overdue Accounts and Refunds on Customs Duties . . . . .	1
Modifications to the Collections Process for Deferred Tax Payments on Consumption Entries of Distilled Spirits, Wines, and Beer Imported Into the United States . . . . .	5

### *U.S. Court of Appeals for the Federal Circuit*

	<i>Appeal No.</i>	<i>Page</i>
Janssen Ortho, LLC, Plaintiff-Appellee v. United States, Defendant-Appellant . . . . .	2020-1663	15