United States Court of Appeals for the Federal Circuit

JANSSEN ORTHO, LLC,
Plaintiff-Appellee

v.

UNITED STATES,
Defendant-Appellant

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.

---

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

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").[1] 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,

---

[1] 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).

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).

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).[2]

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

---

[2] 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).

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')]," [3] with "[t]he Chemical Abstracts Service [('CAS')] registry numbers also set forth . . . to assist in the identification of the products concerned," [4] 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

---

[3] 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.

[4] 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.

Chapeau); *see id.* (providing that Table 2 similarly covers "such product by whatever name known").

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.[5] 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-

---

[5] 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.

(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 crystalized 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).

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).[6] 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

---

[6] 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").

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").[7] The CIT then noted that HTSUS subheading 2935.00.60 lists the symbol "K" in the special 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

---

[7] Neither the Government nor Janssen challenge this classification on appeal. *See generally* Appellant's Br.; Appellee's Br.

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.[8]

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 de novo." *ADC*, 916 F.3d at 1017 (internal quotation marks and citation omitted).[9]

---

[8] The CIT subsequently dismissed Janssen's Due Process claim as moot. J.A. 39.

[9] "[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

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

---

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).

ethanolate," *id.* at 10, 12 (capitalization normalized).[10] 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 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*

---

[10] "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.

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 ethanolate 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 of 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.[11] Accordingly, the

---

[11] 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

Judgment of the U.S. Court of International Trade is

AFFIRMED

---

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)).