**Slip Op. 20-14**

**UNITED STATES COURT OF INTERNATIONAL TRADE**

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| **JANSSEN ORTHO LLC,**<br><br>**Plaintiff,**<br><br>**v.**<br><br>**UNITED STATES,**<br><br>**Defendant.** | **Before: Jennifer Choe-Groves, Judge**<br><br>**Court No. 13-00296** |

## OPINION

[At the conclusion of a bench trial, holding that darunavir ethanolate is properly classified under HTSUS subheading 2935.00.60 and eligible for duty-free treatment under the Pharmaceutical Appendix.]

Dated: February 6, 2020

Gregory L. Diskant, Amy N. Vegari, Andrew D. Cohen, Daniel M. Eisenberg, Emma Ellman-Golan, and Joshua A. Kipnees, Patterson Belknap Webb & Tyler LLP, of New York, N.Y., argued for Plaintiff Janssen Ortho LLC. Of counsel was Kathryn A. Meisel, Johnson & Johnson of New Brunswick, N.J., and Richard M. Belanger, Sidley Austin, LLP, of Washington, D.C. Irina Royzman and Sean H. Murray, Patterson Belknap Webb & Tyler LLP, of New York, N.Y., also appeared.

Monica P. Triana and Guy R. Eddon, Trial Attorneys, U.S. Department of Justice, of New York, N.Y., argued for Defendant United States. With them on the briefs were Joseph H. Hunt, Assistant Attorney General, Patricia M. McCarthy, Assistant Director, and Jason M. Kenner, Trial Attorney, Commercial Litigation Branch, U.S. Department of Justice, Civil Division, New York, N.Y. Of counsel was Alexandra Khrebtukova, Office of Assistant Chief Counsel, International Trade Litigation, U.S. Customs and Border Protection of New York, N.Y.

Choe-Groves, Judge: The court conducted a bench trial to determine whether darunavir ethanolate, a medicine for the treatment of the human immunodeficiency virus (HIV), should be

classified as a pharmaceutical eligible for duty-free treatment when imported into the United States. Plaintiff Janssen Ortho LLC ("Plaintiff" or "Janssen") asserts that it has paid approximately $100 million in duties in this case for its Prezista medicine that should have been duty-free. The trial focused on the classification of darunavir ethanolate under the Harmonized Tariff Schedule of the United States ("HTSUS") and the treatment of the subject merchandise under the Pharmaceutical Appendix to the Tariff Schedule ("Pharmaceutical Appendix"). Based on the following findings of fact and conclusions of law, the court concludes that the subject merchandise is properly classified under HTSUS subheading 2935.00.60 and is eligible for duty-free treatment under the Pharmaceutical Appendix.

## PROCEDURAL HISTORY

Janssen filed this action to contest the denial by U.S. Customs and Border Protection ("CBP") of Janssen's protests as to the tariff classification of darunavir ethanolate. Compl. ¶¶ 1–4, Dec. 11, 2013, ECF No. 5; see also First Am. Compl. ¶¶ 1, 6–9, 75–76, Mar. 7, 2019, ECF No. 129 ("Am. Compl."). Plaintiff sought leave to amend its complaint to add a claim pursuant to the Due Process Clause of the Fifth Amendment of the United States Constitution on July 13, 2015. Pl. Janssen's Mot. Am. Compl. Opp. Def.'s Mot. Prot. Order, July 13, 2015, ECF No. 31; see U.S. Const. amend. V. The United States ("Government" or "Defendant") opposed. Def.'s Mem. Law Opp'n Pl.'s Mot. Leave to File Am. Compl., Aug. 24, 2015, ECF No. 37. Following oral argument, the court held Janssen's motion to amend in abeyance pending the resolution of the classification claim. Oral Argument, Nov. 18, 2015, ECF No. 56; Order, Nov. 19, 2015, ECF No. 59. Discovery concluded on November 1, 2016. See Scheduling Order, July 22, 2014, ECF No. 17; Scheduling Order, Aug. 3, 2016, ECF No. 100. The case remained pending without further action for several years.

The case was reassigned on January 18, 2019. Order of Reassignment, Jan. 18, 2019, ECF No. 123. Following a status conference, the court granted Plaintiff's motion to amend the complaint. Hr'g, Mar. 5, 2019, ECF No. 126; Order, Mar. 5, 2019, ECF No. 128. Janssen filed its First Amended Complaint on March 7, 2019. Am. Compl. ¶ 1. In addition to Plaintiff's claims contesting CBP's denial of Janssen's protests as to the tariff classification of darunavir ethanolate, Plaintiff alleged that the CBP officials involved in the protest denial "lacked the neutrality and detachment required by the Due Process Clause of the Fifth Amendment by virtue of their actual or institutional interest in the outcome of the proceeding." Id. ¶¶ 75–76, 79. Defendant filed a partial motion to dismiss. Def.'s Partial Mot. to Dismiss, Apr. 8, 2019, ECF No. 136 ("Def.'s Partial Mot. to Dismiss"). Plaintiff responded. Pl.'s Mem. Opp'n Def.'s Partial Mot. to Dismiss, Apr. 26, 2019, ECF No. 165; Pl.'s Mem. Opp'n Def.'s Partial Mot. to Dismiss, Apr. 29, 2019, ECF No. 167. Defendant replied. Def.'s Mem. Law Further Supp. Partial Mot. to Dismiss, May 6, 2019, ECF No. 168. The Parties submitted a list of stipulated facts. The Parties' List of Stipulated Facts for Trial ¶ 5, Apr. 26, 2019, ECF No. 164 ("Stipulated Facts").

The court bifurcated the action into two trials. Order, Jun. 28, 2019, ECF No. 187 ("Bifurcation Order"). The court ordered that the first trial would consider the merits of Janssen's First, Second, Third, and Fourth Claims for Relief pertaining to the classification of darunavir ethanolate. Id. at 1. The court ordered that the second trial would address Janssen's Fifth Claim for Relief as to whether Janssen's application for further review was "heard and decided by a neutral and detached CBP adjudicator." Id. at 2; see also Am. Compl. ¶¶ 53, 56, 117–21. The court scheduled the first trial to begin on July 29, 2019. Bifurcation Order at 2. The court stayed Defendant's Partial Motion to Dismiss and reserved scheduling of the second trial pending the outcome of the first trial. Id. at 1–2.

The Parties filed pretrial briefs and schedules. Pl. Janssen's Pretrial Mem., July 15, 2019, ECF No. 211 ("Pl.'s Pretrial Mem."); Def.'s Pretrial Brief, July 15, 2019, ECF No. 210; Pl. Janssen's Pretrial Schedules, July 9, 2019, ECF No. 192-1 ("Pl.'s Schedule"). Def.'s Pretrial Schedules, July 9, 2019, ECF Nos. 190–91 ("Def.'s Schedule"). The court conducted a bench trial in July 2019. Bench Trial, July 31, 2019, ECF No. 248. The court heard live testimony from: Ms. Sigrid Stokbroekx, M.S., Scientific Director, Global Head Scientific Integration Drug Product Development, Janssen Pharmaceutical Companies of Johnson & Johnson; Dr. Jeffrey Kinzer, Ph.D., Director, Regulatory Affairs, CMC, at Janssen Pharmaceutical Companies of Johnson & Johnson; Dr. Paul Reider, Ph.D., Professor, Princeton University Department of Chemistry; Dr. Bernhardt Trout, Ph.D., Massachusetts Institute of Technology Department of Chemical Engineering; Dr. Rao Kambhampati, Ph.D., U.S. Food and Drug Administration; Dr. Hugh Hemmings, M.D., Ph.D., Weill Cornell Medical College; and Dr. Matthew Toussant, Ph.D., CAS, a division of the American Chemical Society. Trial Transcript Vol. I, Sept. 3, 2019, ECF No. 253; Trial Transcript Vol. II, Sept. 18, 2019, ECF No. 261; Trial Transcript Vol. III, Sept. 18, 2019, ECF No. 262. The Parties filed post-trial briefs and responses. Pl. Janssen's Post-Trial Mem., Sept. 9, 2019, ECF No. 258; Post-Trial Br., Sept. 9, 2019, ECF No. 259; Pl. Janssen's Resp. to the Gov't's Post-Trial Mem., Oct. 4, 2019, ECF No. 265 ("Pl.'s Resp. to Gov't Post-Tr. Mem."); Def.'s Post-Trial Resp. Br., Oct. 4, 2019, ECF No. 266. Closing arguments were held in November 2019. Closing Arguments, Nov. 27, 2019, ECF No. 270.

## JURISDICTION AND STANDARD OF REVIEW

The court has jurisdiction pursuant to 28 U.S.C. § 1581(a) (2012). The court reviews classification cases based on the record made before the court. 28 U.S.C. § 2640(a).

## FINDINGS OF FACT

The court makes the following findings of fact:

1. The subject merchandise is darunavir ethanolate. Stipulated Facts ¶ 12.
2. The following chemical names describe darunavir ethanolate:

   Carbamic acid, N-[(1S,2R)-3-[[(4-aminophenyl)sulfonyl](2-methylpropyl)amino]-2hydroxy-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]-2hydroxy-1-(phenylmethyl)propyl]-, (3R, 3aS, 6aR)-hexahydrofuro[2,3-b]furan-3-yl ester, compd. with ethanol (1:1) (9CI).

   Stipulated Facts ¶ 33; Zregistry Entry for 635728-49-3, PTX-063.
3. Darunavir ethanolate is created by crystallizing darunavir and ethanol molecules into a crystal lattice structure. Ms. Sigrid Stokbroekx Test. 94:2–13; 107:10–12, Sept. 3, 2019, ECF No. 253 ("Stokbroekx Test.").
4. Darunavir ethanolate is a channel solvate. Stokbroekx Test. 94:17–19.
5. Ethanol molecules in the channels of darunavir ethanolate support the crystal lattice. Stokbroekx Test. 94:10–16.
6. Darunavir is crystalized in an ethanol bath to form darunavir ethanolate. Dr. Bernhardt Trout Test. 489:21–490:15, Sept. 18, 2019, ECF No. 261 ("Trout Test.").
7. Darunavir contains a sulfonamide moiety. Prezista Full Prescribing Information at 10, PTX-069.
8. Darunavir ethanolate is a sulfonamide. Dr. Hugh Hemmings Test., 653:5–11, 653:19–654:1–12, Sept. 18, 2019, ECF No. 262 ("Hemmings Test."); Elke Van Gyseghem,

Sigrid Stokbroekx, Hector Novoa de Armas, Jules Dickens, Marc Vanstockem, Lieven Baert, Jan Rosier, Laurent Schueller, Guy Van den Mooter, 38 EUR. J. OF PHARMACEUTICAL SCIENCES 489, 489–90, 494 (2009), PTX-020 ("VAN GYSEGHEM").

9. The International Non-proprietary Name ("INN") for Prezista is darunavir. Stipulated Facts ¶ 16; see also European Medicines Agency Assessment Report for Prezista at 1.1, PTX-102.

10. The INN for darunavir ethanolate is darunavir. Dr. Paul Reider Test. 338:13–341:14, 351:2–16, Sept. 18, 2019, ECF No. 261 ("Reider Test.").

11. Darunavir ethanolate is also known as darunavir. Reider Test. 416:8–11; AIDS*info* Drug Database, PTX-104.

12. Other names for darunavir include: darunavir ethanolate, Prezista, TMC-114, and TMC114.ethanolate. Stokbroekx Test. 93:9–22; Hemmings Test. 687:8–688:1; Chemical Abstracts Service ("CAS") Entry Registry Number 206361-99-1, PTX-062; Johnson & Johnson Pharmaceutical Research & Development Mem., Subj: TMC114.ethanolate: Evaluation of TMC114.ethanolate. (Aug. 1, 2002), PTX-317.

13. The prescribing information for Prezista describes the product as "PREZISTA (darunavir), in the form of darunavir ethanolate[.]" Full Prescribing Information at 29, PTX-069.

14. The United States Adopted Name ("USAN") for Prezista is darunavir. Dr. Jeffrey Kinzer Test. 151:11–20, Sept. 3, 2019, ECF No. 253 ("Kinzer Test."); Hemmings Test. 687:16–688:1; Reider Test. 356:2–11.

15. Prezista is a human immunodeficiency virus (HIV-1) protease inhibitor indicated for the treatment of HIV-1 Infection. Full Prescribing Information at 1, PTX-069.

16. Darunavir ethanolate is the drug substance in Prezista. Full Prescribing Information at 1, PTX-069; Label for Prezista (Darunavir) 800 mg Tablets, PTX-615.

17. The active pharmaceutical ingredient in Prezista is darunavir in the form of darunavir ethanolate. Stipulated Facts ¶ 5.

18. Janssen has not developed darunavir in a form other than darunavir ethanolate for commercial use. Stokbroekx Test. 93:6–8.

19. Darunavir ethanolate is the only commercially available form of darunavir. Reider Test. 416:8–17.

## CONCLUSIONS OF LAW

### I. Legal Framework

Classification of goods under the HTSUS is a two-step process that involves: (1) determining the proper meaning of terms in the tariff provisions, and (2) determining whether the goods fall within those terms. Kalle USA, Inc. v. United States, 923 F.3d 991, 995 (Fed. Cir. 2019). The proper meaning of a tariff provision's terms is a question of law. Rubies Costume Co. v. United States, 922 F.3d 1337, 1342 (Fed. Cir. 2019). Whether the subject merchandise falls within the description of a tariff provision is a question of fact. Id. When there is no dispute as to the nature of the merchandise, the two-step classification analysis collapses entirely into a question of law. Gerson Co. v. United States, 898 F.3d 1232, 1235 (Fed. Cir. 2018).

Customs is afforded a statutory presumption of correctness in classifying merchandise under the HTSUS, but this presumption does not apply to pure questions of law. 28 U.S.C. § 2639(a)(1); see Universal Elecs. Inc. v. United States, 112 F.3d 488, 492 (Fed. Cir. 1997). The court has an independent responsibility to decide the legal issue of the proper meaning and scope of HTSUS terms. Warner-Lambert Co. v. United States, 407 F.3d 1207, 1209 (Fed. Cir. 2005).

It is the court's duty "to find the *correct* result, by whatever procedure is best suited to the case at hand." Jarvis Clark Co. v. United States, 733 F.2d 873, 878 (Fed. Cir. 1984) (emphasis in original).

The classification of merchandise under the HTSUS is governed by the General Rules of Interpretation ("GRI") and, if applicable, the Additional U.S. Rules of Interpretation ("ARI"), which are applied in numerical order. Rubies Costume Co., 922 F.3d at 1342. Under GRI 1, "classification shall be determined according to the terms of the headings and any relative section or chapter notes." GRI 1. Absent contrary legislative intent, HTSUS terms are to be construed according to their common and popular meaning. Baxter Healthcare Corp. v. United States, 182 F.3d 1333, 1337 (Fed. Cir. 1999).

In construing the terms of the headings, the court may rely upon its own understanding of the terms used and may consult lexicographic and scientific authorities, dictionaries, and other reliable information sources. Carl Zeiss, Inc. v. United States, 195 F.3d 1375, 1379 (Fed. Cir. 1999). The court may also consult the World Customs Organization's Harmonized Commodity Description and Coding System Explanatory Notes ("Explanatory Notes"), which are not legally binding or dispositive, but provide a commentary on the scope of each heading of the Harmonized System and are generally indicative of proper interpretation of the various provisions. Kahrs Int'l, Inc. v. United States, 713 F.3d 640, 645 (Fed. Cir. 2013); H.R. Rep. No. 100–576, 549 (1988), reprinted in 1988 U.S.C.C.A.N. 1547, 1582; see also E.T. Horn Co. v. United States, 367 F.3d 1326, 1329 (Fed. Cir. 2004). Tariff terms are defined according to the language of the headings, the relevant section and chapter notes, the Explanatory Notes, available lexicographic sources, and other reliable sources of information. See Kahrs Int'l, Inc., 713 F.3d at 644–45.

## II. Competing Tariff Provisions

The Government maintains that the subject merchandise should be classified under HTSUS subheading 2935.00.60. Def.'s Schedule D-2. The tariff provision reads:

2935.00 Sulfonamides.

Other:

Drugs:

2935.00.60 Other.

HTSUS subheading 2935.00.60.[1] Janssen argues that if the subject merchandise is classified under 2935.00.60, then the subject merchandise is entitled to duty-free treatment under either Table 1 of the Pharmaceutical Appendix or a combination of terms in Tables 1 and 2 of the Pharmaceutical Appendix. Pl.'s Schedule D-1; Pl.'s Resp. to Gov't Post-Tr. Mem. at 11. The Government contends that the subject merchandise is not entitled to duty-free treatment. Def.'s Post-Tr. Br. at 12.

In the alternative, Janssen contends that the subject merchandise is classifiable under HTSUS subheading 3003.90.00. Pl.'s Pretrial Br. at 25. The tariff provision provides:

3003 Medicaments . . . consisting of two or more constituents which have been mixed together for therapeutic or prophylactic uses, not put up in measured doses or in forms of packing for retail sale:

3003.90.00 Other.

HTSUS subheading 3003.90.00.

[1] The subject merchandise was entered between September 2010 and April 2012. Summons, Aug. 21, 2013, ECF No. 1; Case File. The effective editions of the HTSUS include the: 2010 Revision 2 Edition, 2011 Basic Edition, 2011 Revision 1 Edition, 2012 Preliminary Edition, 2012 Basic Edition, and 2012 Revision 1 Edition. See 19 C.F.R. § 141.69. There are no material differences between the terms of the relevant tariff provisions in the effective editions of the HTSUS. See also Pl.'s Pretrial Mem. vi, n.1, 5; Def.'s Pretrial Br. at 1 & n.2, July 15, 2019, ECF No. 209.

## III. Analysis of the Tariff Terms

Before addressing the classification of the subject merchandise, the court first assesses whether the tariff terms are *eo nomine* or use provisions. An *eo nomine* provision "describes an article by a specific name," whereas a use provision describes an article according to its principal or actual use. Schlumberger Tech. Corp. v. United States, 845 F.3d 1158, 1164 (Fed. Cir. 2017).

HTSUS subheading 2935.00 provides for "Sulfonamides." HTSUS subheading 2935.00. Both Parties agree that HTSUS subheading 2935.00.06 is an *eo nomine* provision. Def.'s Schedule D-2; Pl.'s Pretrial Mem. at 4. Sulfonamides are a class of chemicals containing the general formula ($R^1SO_2NR^2R^3$). Explanatory Note 29.35. Because the tariff term identifies subject merchandise by name, the court concludes that HTSUS subheading 2935.00.06 is an *eo nomine* provision.

HTSUS Heading 3003 provides for "Medicaments . . . consisting of two or more constituents which have been mixed together for therapeutic or prophylactic *uses*, not put up in measured doses or in forms of packing for retail sale[.]" HTSUS Heading 3003 (emphasis added). The Parties agree that HTSUS Heading 3003 is a use provision. Pl.'s Pretrial Br. at 4; Def.'s Pretrial Br. at 31; Def.'s Post-Tr. Br. at 19. Because HTSUS Heading 3003 describes articles by use, the court concludes that HTSUS Heading 3003 is a use provision. See also Warner-Lambert Co. v. United States, 28 CIT 939 (2004), aff'd, 425 F.3d 1381 (Fed. Cir. 2005) (noting that the court previously found that HTSUS subheading 3003.90.00 is a principal use provision).

## IV. Classification

### A. Classification Under HTSUS Subheading 2935.00

Because HTSUS Heading 3003 pertains to a "mixed" product, and all goods classified under HTSUS Chapter 29 are to be treated as unmixed products, the court begins its analysis as

to whether the subject merchandise is classified under HTSUS subheading 2935.00.[2] HTSUS subheading 2935.00 provides for "Sulfonamides." The HTSUS Chapter 29 Notes state that:

> 1. Except where the context otherwise requires, the headings of this chapter apply only to:
>
> (a) Separate chemically defined organic compounds, whether or not containing impurities;
>
> . . .
>
> (e) Products mentioned in (a) . . . above dissolved in other solvents provided that the solution constitutes a normal and necessary method of putting up these products adopted solely for reasons of safety or for transport and that the solvent does not render the product particularly suitable for specific use rather than general use;
>
> (f) The products mentioned in (a) . . . or (e) above with an added stabilizer . . . necessary for their preservation or transport[.]

See also Explanatory Note 1 to Chapter 29. The Chapter 29 Subheading Note adds that:

> 1. Within any one heading of this chapter, derivatives of a chemical compound (or group of chemical compounds) are to be classified in the same subheading as that compound (or group of compounds) provided that they are not more specifically covered by any other subheading and that there is no residual subheading named "Other" in the series of subheadings concerned.

The Explanatory Notes state that: "[a] separate chemically defined compound is a substance which consists of one molecular species (e.g., covalent or ionic) whose composition is defined by a constant ratio of elements and can be represented by a definitive structural diagram. In a crystal lattice, the molecular species corresponds to the repeating unit cell." Explanatory Notes,

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[2] The HTSUS Chapter 30 Notes state, in relevant part, that:

> 3. For the purposes of headings 3003 . . . the following are to be treated--
>
> (a) As unmixed products:
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> . . .
>
> (2) All goods of chapter 28 or 29[.]

Chapter 29, Chapter Note 1, VI-29-3 (2007); Explanatory Notes, Chapter 29, Chapter Note 1, VI-29-3 (2012).

To be classified in HTSUS Chapter 29, darunavir ethanolate must be a "[s]eparate chemically defined organic compound[]" whether or not it contains impurities. HTSUS Chapter 29 Note 1(a). Janssen argues that the subject merchandise should not be classified under HTSUS subheading 2935.00 because darunavir ethanolate is not a separate chemically defined compound. Pl.'s Post-Trial Mem. at 3. Janssen contends that darunavir ethanolate is a channel solvate and that because ethanol and water molecules can exchange position in the channels, darunavir ethanolate does not exhibit a constant ratio of elements such that darunavir ethanolate can be classified under Chapter 29. Id. at 3–8. Defendant counters that darunavir ethanolate is classified under HTSUS subheading 2935.00 because the subject merchandise consists of a separate chemically-defined organic compound containing impurities. Def.'s Post-Tr. Br. at 7.

Plaintiff's argument against classification of the subject merchandise under HTSUS Chapter 29 is unavailing. Janssen agrees that darunavir ethanolate is a crystal lattice made of darunavir and ethanol molecules. Pl.'s Post-Trial Mem. at 3–4; Stokbroekx Test. 94:2–13; 107:10–12. The Explanatory Notes clarify that "[i]n a crystal lattice, the molecular species corresponds to the repeating unit cell." Explanatory Notes, Chapter 29, Chapter Note 1, VI-29-3 (2007); Explanatory Notes, Chapter 29, Chapter Note 1, VI-29-3 (2012). In this case, the repeating unit cell is comprised of four darunavir molecules linked to four ethanol molecules by hydrogen bonds. VAN GYSEGHEM at 494; Hemmings Test. 662:8–20.[3]

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[3] Q: Does the fact that darunavir – that in darunavir ethanolate, the darunavir and ethanol molecules are linked by hydrogen bonds rather than covalent, ionic, and . . . metallic bonds . . . does that change your opinion that darunavir ethanolate consists of one molecular species?

Dr. Hemmings: No. I think having the crystal structure showing the precise arrangement of the ethanol and the darunavir is really the definition of molecular species. It shows the stable

The evidence in this case shows that the composition of the repeating unit cell is defined by a constant ratio of elements, consisting of four darunavir molecules and four ethanol molecules. Hemmings Test. 661:16–665:12; VAN GYSEGHEM at 494. Plaintiff argues that there is not a constant ratio of ethanol to darunavir in darunavir ethanolate. Pl.'s Post-Trial Br. at 1, 5, 7. Plaintiff's argument overlooks the word "defined" in the Explanatory Notes. The Explanatory Notes define the question of determining whether a substance consists of a molecular species as whether the "composition is defined by a constant ratio of elements[.]" Explanatory Notes, Chapter 29, Chapter Note 1, VI-29-3 (2007); Explanatory Notes, Chapter 29, Chapter Note 1, VI-29-3 (2012). Whether the purity of darunavir ethanolate decreases over time and the rate at which it does so does not bear on the controlling question of whether the composition of darunavir ethanolate is defined by a constant ratio of elements. Hemmings Test. 664:22–665:7.[4]

In this case, the tariff schedule accounts for the conversion of darunavir ethanolate to darunavir hydrate as an impurity. Note 1(a) to HTSUS Chapter 29 identifies that the tariff provisions apply to separate chemically defined organic compounds, whether or not those compounds contain impurities. HTSUS Chapter 29 Note 1(a). "The term 'impurities' applies

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interaction between the ethanol and darunavir through a chemical bond to form the molecular species in a precise ratio.

Hemmings Test. 662:8–20.

[4] Q: In your opinion, does the fact that the darunavir ethanolate product can degrade over time, does that change your opinion that there is a constant ratio of darunavir to ethanol in this product?

Dr. Hemmings: No. I think there's an ideal ratio in the preparation, but like all drugs, the stability is an issue, and over time they degrade.

Hemmings Test. 664:22–665:7.

exclusively to substances whose presence in the single chemical compound results solely and directly from the manufacturing process (including purification). These substances may result from any of the factors involved in the process[.]" Explanatory Notes, Chapter 29, Chapter Note 1.

The evidence and testimony at trial shows that the presence of darunavir hydrate in the subject merchandise is an impurity resulting from the manufacturing process. Janssen manufactures darunavir ethanolate by crystalizing darunavir in an ethanol bath. Trout Test. 493:15–495:5. Darunavir ethanolate converts to darunavir hydrate when exposed to ambient atmosphere over time. Reider Test. 314:15–315:6; Stokbroekx Test. 84:17–86:15; Trout Test. 496:11–497:7, 501:2–505:19; VAN GYSEGHEM at 494. To preserve the ethanol in the subject merchandise, darunavir ethanolate is removed from the ethanol bath and packed in two low density polyethylene bags or liners that are closed with plastic seals. Container Closure System, PTX-422. The two polyethylene bags are placed in an aluminum-polyethylene laminated bag, which is hot-sealed, and a high-density polyethylene open top drum with a high-density polyethylene lid and steel clamping ring. Id. The subject merchandise is then shipped to Puerto Rico for further manufacturing. Reider Test. 333:8–13. This process is described as "continuous manufacturing." Stokbroekx Test. 135:18–136:5. Janssen's manufacturing, storing, and packing procedures for the subject merchandise are designed to maximize the ethanol in channels of darunavir ethanolate and minimize ethanol loss. Kinzer Test. 202:19–203:3 (testifying that "we know that the ethanol is lost during routine handling, exposure to environmental conditions, shipment [and] manufacturing[.]").

The evidence also shows that the molecular species, i.e., the repeating unit cell, can be represented by a definitive structural diagram, as structural diagrams have been published in the scientific literature. VAN GYSEGHEM at 496 (representing the repeating unit of the darunavir ethanolate molecule as depicted below).

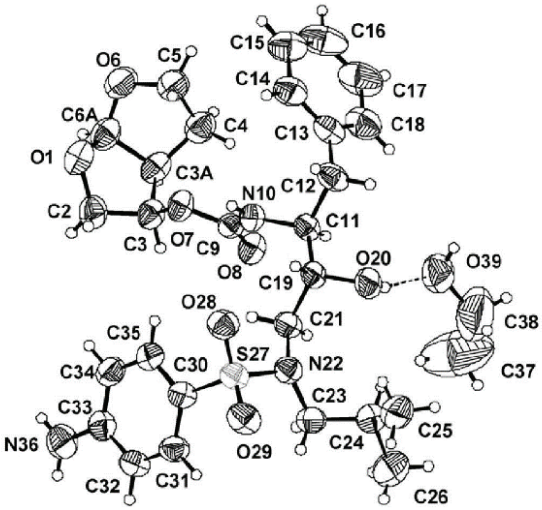


**Fig. 8.** Oak ridge thermal ellipsoid plot (ORTEP) showing the conformation of the TMC114 ethanolate molecule in the crystalline state and its atomic numbering scheme. Displacement ellipsoids are drawn at 50% probability level for non-H atoms. The hydrogen bond linking the ethanol molecule to the host TMC114 molecule is denoted by dashed lines.

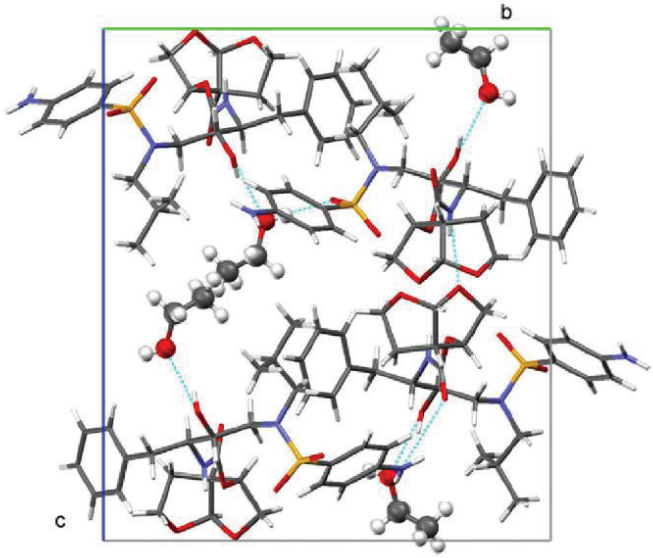


**Fig. 9.** Unit cell view showing the packing of the TMC114 ethanolate molecules down crystallographic axis *a*. The hydrogen bonds are denoted by dashed lines and the ethanol molecules are depicted as ball and stick models.

Because the repeating unit cell is defined by a constant ratio of elements and can be represented by a definitive structural diagram, the subject merchandise meets the criteria of a separately chemically defined organic compound subject to HTSUS Chapter 29. HTSUS Chapter 29 Note 1(a).

Having concluded that darunavir ethanolate is a separate chemically defined compound, the court addresses whether the subject merchandise is classifiable under HTSUS subheading 2935.00, "Sulfonamides," an *eo nomine* provision. HTSUS subheading 2935.00.

An *eo nomine* provision includes all forms of the named article. Kahrs Int'l., Inc., 713 F.3d at 646 (citation omitted). "Sulphonamides have the general formula ($R^1SO_2NR^2R^3$) where $R^1$ is an organic radical of varying complexity having a carbon atom directly attached to the $SO_2$ group and $R^2$ and $R^3$ are either : [*sic*] hydrogen, another atom or an inorganic or organic radical

of varying complexity (including double bonds or rings)." Explanatory Note 29.35. A separate chemically defined compound including this formula are forms of sulfonamides. Id.

The evidence at trial shows that darunavir ethanolate is a sulfonamide. Dr. Kinzer testified that darunavir ethanolate contains a sulfonamide moiety. Kinzer Test. 245:7–16. The prescribing information for Prezista establishes that darunavir, as darunavir ethanolate, contains a sulfonamide moiety. Prezista Full Prescribing Information at 7, 10, PTX-069. Dr. Hemmings testified that darunavir ethanolate is a sulfonamide. Hemmings Test. 653:5–11, 653:22–654:1.[5] The scientific literature published about darunavir ethanolate also shows that darunavir ethanolate has the form $R^1SO_2NR^2R^3$. See VAN GYSEGHEM at 496, Figure 8, PTX-020. Based on the evidence and testimony at trial, the court concludes that darunavir ethanolate is a sulfonamide. Because darunavir ethanolate is a sulfonamide, the court concludes that the subject merchandise belongs to the "[s]ulfonamides" class or kind of organic compounds that are classifiable under HTSUS subheading 2935.00.60.

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[5] Dr. Hemmings: [T]his shows the molecular structure of darunavir, which is an organic molecule formed by chemical bonds between carbons, nitrogens, hydrogens, and sulfur. The sulfur is part of the sulfonamide moiety of darunavir, and the sulfonamide consists of the sulfonyl group with an amide. So it's the sulfur with the two double bonded oxygens, and the amide is the sulfur nitrogen bond.

So with the phenol amine, that makes the sulfonamide moiety, and the rest of the molecule consists of Bis, tetrahydrofuran . . . . And then there's also another amide ester . . . .

Q: So if I understand correctly, you're testifying that this is the sulfonamide here, the sulfur with the two oxygens; is that right (indicating)?

Dr. Hemmings: Correct.

Hemmings Test. 653:22–654:21.

**B. Classification Under HTSUS Heading 3003**

Alternatively, Plaintiff argues that darunavir ethanolate is a mixture classifiable under HTSUS Heading 3003. Pl.'s Pretrial Mem. at 34; Pl.'s Schedule D-1. The Government argues that the subject merchandise is excluded from classification under HTSUS Heading 3003 by operation of HTSUS Chapter 30 Note 3. Def.'s Pretrial Br. at 31. HTSUS Heading 3003 covers "[m]edicaments . . . consisting of two or more constituents which have been mixed together for therapeutic or prophylactic uses, not put up in measured doses or in forms or packings for retail sale[.]" HTSUS Heading 3003. The HTSUS Chapter 30 Notes state, in relevant part, that:

> 3. For the purposes of headings 3003 . . . the following are to be treated--
>
> (a) As unmixed products:
>
> . . .
>
> (2) All goods of chapter 28 or 29[.]

HTSUS Chapter 30 Note 3(a)(2).

Plaintiff's arguments in favor of classification under HTSUS Heading 3003 are unpersuasive. Because the court has determined that the subject merchandise is classifiable under Chapter 29, the notes to Chapter 30 require that the subject merchandise be treated as an unmixed product for the purposes of HTSUS Heading 3003. HTSUS Chapter 30 Note 3(a)(2). Because HTSUS Heading 3003 pertains only to mixed products, the subject merchandise does not meet the terms of the heading and is not classifiable under HTSUS Heading 3003. This analysis is consistent with the Explanatory Notes, which state, in relevant part, that:

> This heading covers medicinal preparations for use in the internal or external treatment or prevention of human . . . ailments. These preparations are obtained by mixing together two or more substances. . . . The heading includes:
>
> (1) Mixed medicinal preparations such as those listed in an official pharmacopoeia, proprietary medicines, etc., including those in the form of . . . other preparations **not falling** in **heading 30.02, 30.05** or **30.06**.

> However, this should not be taken to mean that preparations listed in an official pharmacopeia, proprietary medicines, etc. are always classified in **heading 30.03**. . . .

Explanatory Note 30.03, VI-3003-1 (2012) (emphasis in original). The court concludes that the subject merchandise is not classifiable under HTSUS Heading 3003.

## V. Pharmaceutical Appendix

Plaintiff contends that if darunavir ethanolate is classifiable under HTSUS subheading 2935.00.60, then the subject merchandise is eligible for duty-free treatment under the Pharmaceutical Appendix. Janssen argues that: (1) darunavir ethanolate is also known as darunavir, and that "darunavir" is listed on Table 1 of the Pharmaceutical Appendix, or in the alternative, that (2) darunavir ethanolate is identifiable based on a combination of terms in Tables 1 and 2 of the Pharmaceutical Appendix. Pl.'s Schedule D-1. The Government counters that darunavir ethanolate is not eligible for duty-free treatment because (1) darunavir ethanolate is not identified by the CAS registry number adjoining darunavir in the Pharmaceutical Appendix, and (2) "ethanolate" is not a permissible suffix under Table 2 of the Pharmaceutical Appendix. Def.'s Pretrial Br. at 22, 26–29.

HTSUS subheading 2935.00.60 lists "K" in the special duty rate column, which cross-references the Pharmaceutical Appendix. As part of the Uruguay Round Agreements, the United States agreed to the reciprocal elimination of duties on approximately 7,000 pharmaceutical products, chemical intermediates to be used for the production of pharmaceuticals, and certain derivatives of pharmaceutical products. Advice Concerning the Addition of Certain Pharmaceutical Products and Chemical Intermediates to the Pharmaceutical Appendix to the Harmonized Tariff Schedule of the United States, Inv. No. 332-476, USITC Pub. 3883 (Sept. 2006), available at 2006 ITC LEXIS 978 ("Addition of Certain Pharmaceutical Products and

Chemical Intermediates to the Pharmaceutical Appendix"). The elimination of duties on certain pharmaceutical products, their derivatives, and chemical intermediates was reflected in the tariff schedule by changes to HTSUS Chapters 29 and 30 as well as by the addition of the Pharmaceutical Appendix. Id. The Pharmaceutical Appendix is applied through HTSUS General Note 13, which states, in relevant part:

> [w]henever a rate of duty of "Free" followed by the special symbol "K" in parentheses appears in the "Special" subcolumn for a heading or subheading, any product (by whatever name known) classifiable in such provision which is the product of a country eligible for tariff treatment under column 1 shall be entered free of duty, provided that such product is included in the pharmaceutical appendix to the tariff schedule.

General Note 13.[6] Table 1 of the Pharmaceutical Appendix "enumerates products described by International Non-proprietary Names (INN) which shall be entered free of duty under general note 13 to the tariff schedule." Pharmaceutical Appendix, Table 1, Chapeau. The chapeau to Table 1 adds that "[t]he Chemical Abstracts Service (CAS) registry numbers also set forth in this table are included to assist in the identification of the products concerned. For purposes of the tariff schedule, any references to a product enumerated in this table includes such product by whatever name known." Id. Table 1 lists "darunavir[,]" along with the CAS registry number "206361-99-1[.]" Pharmaceutical App'x Table 1 at 16.[7]

**A. Identification of Darunavir by Other Known Names**

There is no dispute that "darunavir" is a product listed on the Pharmaceutical Appendix. Rather, the Parties dispute whether "darunavir ethanolate" is a name by which darunavir is

[6] There is no dispute that the products were imported from eligible countries. See Case File (identifying the subject merchandise country of origin as either Ireland or Switzerland); Am. Compl. ¶ 48; Label for Prezista (Darunavir) 800 mg Capsules, PTX-615; see also Compl. ¶ 48.
[7] The INN darunavir was included in the proposed additions to the Pharmaceutical Appendix in 2006. Addition of Certain Pharmaceutical Products and Chemical Intermediates to the Pharmaceutical Appendix, 2006 ITC LEXIS 978, at *30.

known, and therefore is within the term "darunavir" as listed in Table 1 of the Pharmaceutical Appendix. Janssen argues, *inter alia*, that (1) the INN "darunavir" describes darunavir ethanolate, a name by which darunavir is known, and (2) CAS number 206361-99-1 assists in the identification of darunavir ethanolate. Pl.'s Post-Tr. Mem. at 11. The Government contends that darunavir ethanolate is not within the scope of Table 1 of the Pharmaceutical Appendix because darunavir ethanolate is assigned a separate CAS registry number. Def.'s Post-Tr. Br. at 14–16.

The Government's arguments are unavailing. First, the chapeau to Table 1 of the Pharmaceutical Appendix states that "any references to a product enumerated in this table include such product by whatever name known." Pharmaceutical App'x, Table 1, Chapeau. The evidence at trial shows that darunavir ethanolate is a name by which the INN darunavir is known. For example, the World Health Organization ("WHO") identifies that the INN "[d]arunavir" is manufactured as "[d]arunavir (ethanolate)[.]" Medicines/finished pharmaceutical products, Reference Number HA529 (a) at 1–2, PTX-108; see also World Health Organization Application to Add "Darunavir" to the Essential List of Medicines at 1, 3, PTX-106 (identifying the International Non-proprietary Name as "[d]arunavir" and reporting that approved formulations included "[d]arunavir (as ethanolate)[.]"). AIDS*info*, which is a database maintained by the National Institutes of Health, states that another name for "[d]arunavir" is "darunavir ethanolate[.]" AIDS*info* Drug Database at 1, PTX 104. The National Center for Biotechnology Information PubChem Compound database identifies "darunavir" as also known as "[d]arunavir ethanolate[.]" PubChem Compound Summary for: CID23725083, PTX-613. The prescribing information for Prezista describes the product as "PREZISTA (darunavir), in the form of darunavir ethanolate[.]" Full Prescribing Information at 29, PTX-069; see also Dr. Rao Kambhampati Test. 564:5–565:2, Sept. 18, 2019, ECF No. 261 ("Kambhampati Test.") (Dr. Kambhampati, a chemist with the U.S. Food and Drug Administration, who was called as a

witness by the Government at trial, testified that the USAN for the drug substance in Prezista is darunavir, and that the USAN does not include the name of the solvent in the name). Based on these facts established at trial, the court finds that darunavir ethanolate is a name by which darunavir is known.

Second, a CAS number listed on the Pharmaceutical Appendix is not dispositive as to whether a particular product is covered by the Pharmaceutical Appendix. The chapeau to Table 1 of the Pharmaceutical Appendix directly addresses this issue. Pharmaceutical App'x, Table 1, Chapeau ("The Chemical Abstracts Service (CAS) registry numbers also set forth in this table are included *to assist* in the identification of the products concerned." (emphasis added)). By 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.

The court concludes that darunavir ethanolate is a name by which darunavir is known, and is within the terms of Table 1 of the Pharmaceutical Appendix.

### B. Whether Darunavir Ethanolate Receives Duty-Free Treatment Based on a Combination of Terms in Tables 1 and 2 of the Pharmaceutical Appendix

Plaintiff argues that the subject merchandise should receive duty-free treatment because darunavir ethanolate is included in the Pharmaceutical Appendix through a combination of terms on Tables 1 and 2, i.e., "darunavir" on Table 1, and either "ethyl hydroxide" or "ethyl hydrate," which are combinations of terms on Table 2. Plaintiff avers that "ethyl hydroxide" or "ethyl hydrate" are synonymous for ethanol. Pl.'s Post-Trial Mem. at 1–2. The Government counters that the subject merchandise should not receive duty-free treatment because "ethanolate" is not a term listed on Table 2 and that the terms ethyl, hydrate, or hydroxide cannot be combined to

create a new prefix or suffix that may be appended to a product of Table 1. Def.'s Post-Tr. Br. at 17–19.

The chapeau to Table 2 of the Pharmaceutical Appendix states that:

> Salts, esters and hydrates of the products enumerated in table 1 above that contain in their names any of the prefixes or suffixes listed below shall also be entered free of duty under general note 13 to the tariff schedule, provided that any such salt, ester or hydrate is classifiable in the same 6-digit tariff provision as the relevant product enumerated in table 1. For purposes of the tariff schedule, any reference to the product covered by this table includes such product by whatever name known.

Pharmaceutical App'x, Table 2 at 61. "Ethyl[,]" "Hydrate[,]" and "Hydroxide" are prefixes or suffixes listed on Table 2 of the Pharmaceutical Appendix.

Because the court concludes that the subject merchandise is entitled to duty-free treatment per Table 1 of the Pharmaceutical Appendix, the court does not reach the issue of whether the subject merchandise qualifies for duty-free treatment under a combination of terms in Tables 1 and 2.

## CONCLUSION

For the foregoing reasons, the court concludes that Plaintiff's subject merchandise is classified properly under HTSUS subheading 2935.00.60 and is eligible for duty-free treatment under the Pharmaceutical Appendix. Judgment will be entered accordingly.

/s/ Jennifer Choe-Groves
Jennifer Choe-Groves, Judge

Dated: February 6, 2020
New York, New York

ERRATA

Janssen Ortho LLC v. United States, Court No. 13-00296, Slip Op. 20-14, dated February 6, 2020.

Page 10: On lines 7–8, replace <Both Parties agree that HTSUS subheading 2935.00.06 is an *eo nomine* provision. Def.'s Schedule D-2; Pl.'s Pretrial Mem. at 4.> with <Both Parties agree that HTSUS subheading 2935.00.60 is an *eo nomine* provision. Def.'s Schedule D-2; Pl.'s Pretrial Mem. at 4.>

Page 10: On lines 9–11, replace <Because the tariff term identifies subject merchandise by name, the court concludes that HTSUS subheading 2935.00.06 is an *eo nomine* provision.> with <Because the tariff term identifies subject merchandise by name, the court concludes that HTSUS subheading 2935.00.60 is an *eo nomine* provision.>

February 19, 2020