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Import Risks and Opportunities Life Sciences Industry

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James Sawyer
312-569-1156
james.sawyer@dbr.com

Importing Overview – Today's Roadmap

- Recent Administration Trade Actions
- Import Compliance Fundamental Concepts
- Reasonable Care Reminder
- Common Life Sciences Import Compliance Issues
  - Tariff Classification
  - Valuation
  - Country of Origin

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Update - Trump & Trade

- Initially targeting a total of $50 billion in Chinese imports pursuant to Section 301 determination of China's unfair trade practices (e.g., forced technology and IP transfers).
- First list (List 1) of retaliatory duties ($34 billion) against Chinese imports scheduled to be implemented July 6
  - Good news - finished drug products successfully removed from initial proposed 301 list
  - Bad news – many medical devices remain (*e.g.*, Headings 9018, 9022)
  - Opportunity to file exclusion requests for List 1 -- TBD
- Supplemental Section 301 (List 2) proposed ($16 billion)
  - Less direct impact, but potential raw materials or other inputs
  - Notice to appear due Friday, June 29
  - Comments due July 23
  - Public hearing July 24
- Potential for another $200 billion

Update - Trump & Trade (cont.)

- Section 232 duties in effect for steel and aluminum raw materials
  - Excluded countries S. Korea, Brazil, Australia, Argentina per voluntary restraint agreements
  - Overall increase in steel and aluminum costs
- Retaliatory duties implemented or soon to be implemented by Canada, EU, Mexico, China
  - Pharma and medical devices generally not directly targeted
- Administration initiatives to review GSP eligibility for certain countries, including Indonesia and Thailand
- Stalled (dead?) MTB process
- Proposal to reevaluate other FTAs
- Preliminary bilateral FTA discussions with Japan and the UK

Update - Trump & Trade (cont.)

- On-going NAFTA renegotiations
- If U.S. withdraws from NAFTA
  - Little duty impact on finished drug products (Heading 3004) and many medical devices (Heading 9018) that are otherwise unconditional duty free
  - Parts and components of medical devices may have increased duty liability
  - Potential significant impact on origin determination and country of origin marking if U.S. withdraws from NAFTA
    - NAFTA Marking Rules provide a unique benefit for some drug products manufactured in Canada/Mexico via NAFTA Preference Override
    - NAFTA Marking Rules on kits are more streamlined
  - No anticipated changes by Mexico to IMMEX/Maquiladora program

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Update - Trump & Trade (cont.)

- More aggressive and increased enforcement by CBP
- CEE increasing targeted enforcement
  - Pharmaceuticals, Health & Chemicals (JFK)
  - Broad ability to review import processes and patterns
- Recent turnover with CBP
  - loss of tribal knowledge and experience
- Increase in Requests for Information (CBP Form 28)
- Increase in Notices of Action (CBP Form 29)
- Increase challenges for duty preference eligibility
  - Pharmaceutical Appendix
  - Nairobi Protocol
  - GSP eligibility
  - Tariff classification
  - AD/CVD
  - Forced labor / responsible trade

With all the Changes – Some Things Remain the Same

- *Shared Responsibility*: Importers and Customs have a mutual responsibility to ensure compliance.
- *Informed Compliance*: Customs' responsibility is to clearly and completely inform importers of their legal obligations with regard to importing.
- *Reasonable Care*: *Requires importers to use reasonable care when they provide Customs with entry information, including the classification, value, and rate of duty applicable to their merchandise.*
- *Enforced Compliance*: Customs will transition from informed compliance to enforcement measures.

Fundamental Concepts

- *U.S. Importer* - A party or entity who causes an importation into the United States. Typically has ownership and/or risk of loss of the merchandise. *The Importer of Record is the primary responsible party for providing accurate information to Customs, and the party primarily liable for duties, fees, and assessed penalties for noncompliance.*
- *Customs Broker* - Licensed to "transact customs business" on behalf of the importer and hired to arrange for expeditious customs clearance as agent for importer. *Importer remains legally responsible for all entries*.
- *Scope of import activity* - Encompasses a broad range of physical merchandise crossing the U.S. border, including:
  - raw materials,
  - clinical trials,
  - finished goods,
  - samples, prototypes,
  - capital equipment and spare parts,
  - repairs and returns.
- Unlike exports, imports do not (yet) include electronic transmissions.

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Entry Summary - Declaration of Importer

EXP. 10-31-2017

DEPARTMENT OF HOMELAND SECURITY
U.S. Customs and Border Protection

ENTRY SUMMARY

1. Filer Code/Entry No.			2. Entry Type		3. Summary Date
4. Surety No.	5. Bond Type	6. Port Code			7. Entry Date
8. Importing Carrier		9. Mode of Transport	10. Country of Origin		11. Import Date
12. B/L or AWB No.		13. Manufacturer ID	14. Exporting Country		15. Export Date
16. I.T. No.	17. I.T. Date	18. Missing Docs	19. Foreign Port of Lading		20. U.S. Port of Unlading
21. Location of Goods/G.O. No.		22. Consignee No.	23. Importer No.		24. Reference No.
25. Ultimate Consignee Name and Address City State Zip			26. Importer of Record Name and Address City State Zip		

27. Line No.	28. Description of Merchandise 29. A. HTSUS No. B. ADA/CVD No.	30. A. Grossweight B. Manifest Qty.	31. Net Quantity in HTSUS Units	32. A. Entered Value B. CHGS C. Relationship	33. A. HTSUS Rate B. ADA/CVD Rate C. IRC Rate D. Visa No.	34. Duty and I.R. Tax Dollars Cents

	E. Ascertained Total	40. Total

I declare that I am the ☐ Importer of record and that the actual owner, purchaser, or consignee for CBP purposes is as shown above, **OR** ☐ owner or purchaser or agent thereof. I further declare that the merchandise ☐ was obtained pursuant to a purchase or agreement to purchase and that the prices set forth in the invoices are true, **OR** ☐ was not obtained pursuant to a purchase or agreement to purchase and the statements in the invoices as to value or price are true to the best of my knowledge and belief. I also declare that the statements in the documents herein filed fully disclose to the best of my knowledge and belief the true prices, values, quantities, rebates, drawbacks, fees, commissions, and royalties and are true and correct, and that all goods or services provided to the seller of the merchandise either free or at reduced cost are fully disclosed.
I will immediately furnish to the appropriate CBP officer any information showing a different statement of facts.

$	REASON CODE	C. Ascertained Tax	38. Tax
		D. Ascertained Other	39. Other
		E. Ascertained Total	40. Total

36. DECLARATION OF IMPORTER OF RECORD (OWNER OR PURCHASER) OR AUTHORIZED AGENT

I declare that I am the ☐ Importer of record and that the actual owner, purchaser, or consignee for CBP purposes is as shown above, OR ☐ owner or purchaser or agent thereof. I further declare that the merchandise ☐ was obtained pursuant to a purchase or agreement to purchase and that the prices set forth in the invoices are true, OR ☐ was not obtained pursuant to a purchase or agreement to purchase and the statements in the invoices as to value or price are true to the best of my knowledge and belief. I also declare that the statements in the documents herein filed fully disclose to the best of my knowledge and belief the true prices, values, quantities, rebates, drawbacks, fees, commissions, and royalties and are true and correct, and that all goods or services provided to the seller of the merchandise either free or at reduced cost are fully disclosed.
I will immediately furnish to the appropriate CBP officer any information showing a different statement of facts.

41. DECLARANT NAME	TITLE	SIGNATURE	DATE

42. Broker/Filer Information (Name, address, phone number)	43. Broker/Importer File No.

Paperwork Reduction Act Notice CBP Form 7501 (06/09)

Customs Primary Civil Penalty Statute – 19 U.S.C. § 1592

Requires material false statement, act, or omission made at entry.

- Materiality is not limited to revenue impact.

Requires a level of culpability.

- Negligence = failure to exercise reasonable care.
- Voluntary disclosure statue allows for reduced penalty exposure if filed prior to knowledge or the commencement of a formal investigation.

Culpability	Violations Resulting in Revenue Loss	Non-Revenue Loss Violations
Fraud	up to the domestic value of the entry(ies)	up to the domestic value of the entry(ies)
Gross Negligence	Lesser of domestic value or 4 times the loss of revenue	40% of the dutiable value of the entry(ies)
Negligence	Lesser of domestic value or 2 times the loss of revenue	20% of the dutiable value of the entry(ies)

Reasonable Care

- ***All importers should work to***:
  - Document internal controls
  - Demonstrate management commitment to trade compliance
  - Identify trade compliance risk areas (and implement controls)
  - Identify duty savings opportunities (and implement controls)
  - Establish monitoring/audit activities for imports and customs brokers
  - Establish a comprehensive tariff classification database (including HTS details, FDA AoC, site registration, CAS, etc.)
  - Have access to ACE
  - Request ITRAC data annually (while available)
  - Participate in Customs' Reconciliation program for value
  - Request confidential treatment of ocean manifests
  - Record trademarks with Customs
  - Train supply chain (direct and indirect sourcing teams), finance, accounting, R&D, receiving, and legal departments
  - Access daily *Federal Register* and other publications
  - Have patience and don't let your guard down

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Common Life Sciences Importer Problem Areas

- **Tariff Classification**
  - Tariff classification controls
  - **Classification of parts and accessories**
  - **Classification of placebos**
  - Duty preferences – Pharma Appendix
  - **Application of Prototype Provision**
  - **Nairobi Protocol – chronic health issues**
  - Miscellaneous Trade Bill
  - NAFTA and other FTAs

- **Customs Valuation**
  - **Assists, foreign R&D and clinical trials**
  - **License fees, royalties, milestone payments**
  - **Tooling/mold charges, NRE, payments**
  - Toll manufacturing operations
  - **Transfer pricing and retroactive adjustments**
  - Terms and conditions of supply agreements and with CROs and CMOs
  - **Valuation of R&D imports**
  - "No charge" and nominal value shipments

- **Country of Origin**
  - Origin Determination (FDA vs. Customs)
  - **Origin Marking (FDA vs. Customs)**
  - **Repacking Certificates for bulk product**
  - Made in USA (FTC)
  - Trade Agreements Act compliance

- **Capital Equipment Purchases**
  - Allocation of contract expenses
  - Itemize non-dutiable costs
  - Progress payments
  - Split shipments
  - Inclusion of product samples for testing (FDA)

- **Third-Party Contracts**
  - Instructions/management of customs brokers
  - Invoice descriptions, required statements (USDA), coordination with foreign suppliers.
  - Incoterms®
  - OGA requirements, foreign site registration
  - NDA/IND approvals, 501(k) listings
  - ACE reporting

Why Is Tariff Classification Important?

- All imported merchandise must be assigned a tariff classification under the *Harmonized Tariff Schedule of the United States* (HTSUS).
- Internationally standardized at 6 digits, U.S. uses 10.
- HTSUS tariff classification will identify:
  - General duty rate
  - Identify duty preference opportunities (SPI)
  - FTA qualification
  - Application of FDA, USDA, and other PGA requirements
  - Application of antidumping/countervailing duties (CBP priority trade issue)
  - Application of retaliatory duties, *e.g.,* Sections 232 and 301
- Report relevant trade statistics - treaties, trade agreements
- Compliance measurement
- Quota and admissibility

Tariff Classification Examples

- Placebo
  - 9602.00.10 @ 3%, unfilled gelatin capsules
  - or 3824.90.9050 @ 5%, if placebo capsule is filled
  - or 2106.90.9998 @ 6.4%, if simply a starch or otherwise mimics a food preparation

- Dialysis drainage bags
  - What is it? How is used?
  - Part or accessory of medical device (heading 9018)?
  - Other articles of plastic (heading 3926)?
  - Harmonized tariff system

Tariff Classification — Reasonable Care

- Defined rules and steps (GRIs)
- HTSUS is a statute and rules of statutory construction apply
- Careful review of relevant Chapter and Section Notes apply
- Administrative and judicial precedent available to support an importer's reasonable care obligations
- Case law, administrative precedent, Explanatory Notes
- Tariff classification can be very specific and not always easy
  - principle and actual use of the product
  - materials - *e.g.,* steel, aluminum, plastic, titanium
  - chemical structure, CAS No.
  - Part/accessory
- Rulings from Customs are possible, but not always advisable
- Legal obligation is to exercise reasonable care
  - Coordination and training with in-house experts
  - Coordination from outside experts
  - Document process and determination

Invoice Description Essential

- Proper and clear invoice descriptions allow for:
  - accurate tariff classification by importer and customs broker
  - easy confirmation by Customs and FDA and reduction of inquiries
  - fewer shipment inspections and delays
- Problem with poor invoice descriptions
  - Haystack machine: Harvesting, threshing or haymaking machinery? Sophisticated compound management analysis and library system?
  - Chemical Catalyst
  - Internal Research Designations “ABC-52”
- Clear communication and instructions to customs broker
- Inclusion of required FDA/USDA statements on commercial invoice or supporting documentation
- Remember enforcement is on the upswing.

Duty Preference Programs

- In the U.S., many HTS headings are unconditionally duty free
  - 3002 (antisera, blood fractions, and modified immunological products), 3003 (mixed bulk drugs), 3004 (dosage form), 9018 (medical, surgical, dental instruments and appliances), 9021 (orthopedic appliances).
- If not duty free, there are duty preference programs available:
  - Free Trade Agreements (e.g., NAFTA)
  - Free Trade Programs (e.g., Generalized System of Preferences)
- Common Life Sciences Duty Preference Programs include:
  - Pharmaceutical Appendix
  - Prototype Provision
  - Nairobi Protocol
  - Chapter 98 programs
- All duty preference claims are OPTIONAL.
- Preference programs will not avoid Section 301, AD/CVD
- Always apply easiest duty preference program first
- If a duty preference claim is made, ensure support is available.
- Detailed instructions should be provided to customs broker for which products qualify and when claim may be made.

Pharmaceutical Appendix - “Special K”

- HTSUS General Note 13
  - Any product (by whatever name known) classifiable in a “Special K” provision shall be entered free of duty, provided the product is included in the Pharmaceutical Appendix.
  - May contain in their names any of the prefixes or suffixes listed in table 2 of the appendix, 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.
- Recent CEE inquiries –
  - Requests for Information (CBP Form 28)
  - Notices of Action (CBP Form 29)
  - Ensure proper mail room routing or ACE access

PHARMACEUTICAL APPENDIX TO THE TARIFF SCHEDULE

Table 1.
This table enumerates products described by International Non-proprietary Names INN which shall be entered free of duty under general note 13 to the tariff schedule. The 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.

ABACAVIR	136470-78-5	ACETORPHINE	25333-77-1
ABAFUNGIN	129639-79-8	ACETRYPTINE	3551-18-6
ABAGOVOMAB	792921-10-9	ACETYLCHOLINE CHLORIDE	60-31-1
ABAMECTIN	65195-55-3	ACETYLCYSTEINE	616-91-1
ABANOQUIL	90402-40-7	ACETYLDIGITOXIN	1111-39-3

Table 2.
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 a product covered by this table includes such product by whatever name known.

(PIVALOYLOXY)METHYL HYDROCHLORIDE	AXETIL
(PIVALOYLOXY)METHYL	BARBITURATE
1-PYRROLIDINEETHANOL	BENETONIDE
1-ACETOXYETHYL	BENZATHINE
1,2-ETHANEDISULFONATE	BENZENESULFONATE
1,2-ETHANEDISULPHONATE	BENZENESULPHONATE
1,5-NAPHTHALENEDISULPHONATE	BENZOACETATE
1,5-NAPHTHALENEDISULFONATE	BENZOATE
2-NAPHTHALENESULPHONATE	BENZYL

Table 3.
This table enumerates further products which shall be entered free of duty under general note 13 to the tariff schedule. The 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.

Prototype Legislation – HTSUS Subheading 9817.85.01

- Prototypes defined as
  - originals or models in the pre-production, production or post-production stage
  - used exclusively for development, testing, evaluation or quality control.
  - imported in limited, noncommercial quantities
  - may not be sold after importation.
- Must report underlying tariff classification and accurate value.
- Port director may request proof of actual use.
- Available for
  - importation of library compounds
  - clinical trial imports
  - bulk API or chemical compounds in non-commercial quantities to be further processed and subject to testing for pharmacological properties or use in clinical trials

Nairobi Protocol – HTSUS Subheading 9817.00.96

- Implements policy determination to enable products for the use or benefit of the blind or other physically or mentally handicapped persons to enter free of duty.
- Customs has held that the provision applies to persons suffering from a *permanent* or *chronic* physical or mental impairment which substantially limits one or more major life activities, such as caring for one's self, performing manual tasks, walking, seeing, hearing, speaking, breathing, learning, or working.
- Acute or transient illnesses would not be covered.
- Examples of covered illnesses: diabetes, incontinence, asthma, prosthetics.
- Articles must be specifically designed almost exclusively for the benefit of the permanent or chronic impairment
- Customs looks to disqualify based on general public use
- Can extend to parts and components of qualified items

Nairobi Protocol – HTSUS Subheading 9817.00.96 (cont.)

- "Specially designed or adapted" has been decided on a case-by-case basis.
- Customs will consider
  - the physical properties of the article itself, i.e., whether the article is easily distinguishable, by properties of the design, from articles useful to non-handicapped persons;
  - whether any characteristics are present that create a substantial probability of use by the chronically handicapped so that the article is easily distinguishable from articles useful to the general public;
  - whether articles are imported by manufacturers or distributors recognized or proven to be involved in this class or kind of articles for the handicapped;
  - whether the articles are sold in specialty stores which serve handicapped individuals; and
  - whether the condition of the articles at the time of importation indicate that these articles are for the handicapped.

Customs Valuation – 5 Hierarchical Valuation Methods

- Like tariff classification rules, there are defined rules of the game which are internationally harmonized.
  - Transaction Value
  - Transaction Value of Identical or Similar Merchandise
    - Based on the transaction value of previously imported merchandise
    - Applicable for physician samples
  - Deductive Value
    - Selling price in the US less certain post-importation costs
  - Computed Value
    - Foreign supplier cost information for materials, processing, profit, general expenses, etc.
    - Applicable for certain R&D materials and prototype samples
  - Fallback Method
    - Methodology based on a modified version of one of the first four methods
    - Must first review and disqualify above appraisement methods
    - Applicable for imports of used equipment, samples, R&D materials

Transaction Value Defined

- Price actually paid or payable for the merchandise when sold for exportation to the United States, *plus certain statutory additions* to the price.
- "Price actually paid or payable"
  - the total payment (whether direct or indirect) for the imported merchandise from the buyer to the seller.
  - often the invoice price, but certain upward and downward adjustments may be made.
- Must have sale (no consignment shipments, no sample shipments).
  - If no sale, alternative method of appraisement apply
  - Potential exemptions for vendor-owned inventory models
- Related party sales must be at arm's length,
  - all costs plus a reasonable profit, or
  - comparable to sales to unrelated parties in the U.S.
  - Careful coordination with transfer pricing team is advised

Import Valuation Primer

- Transaction Value – the price paid or payable, plus certain statutory additions . . .
- Are any of the following related to the imported product, but their cost excluded from the invoice price of the imported goods?
  - **C**ommissions – selling commissions paid by the buyer
  - **R**oyalties
  - **A**ssists
  - **P**acking costs paid by buyer
  - **P**roceeds of any subsequent resale paid directly/indirectly to the seller
- If not included within the invoice value, the total value should likely be declared to Customs.
- There are certain exclusions also allowed if verified and included in invoice price.
- *Generally, payments made to the foreign supplier are "dutiable" unless established that they are unrelated to the production and sale of the imported merchandise.*
  - For example, separate payment for foreign research or clinical trials
  - Payments for NRE or tooling charges

Assists — Defined

- Assists include
  - materials, components, parts and other items used in production
  - tools, dies, molds, etc. used to produce product
  - merchandise consumed in production
  - engineering, development, artwork, design work, plans and sketched produced other than in U.S.
- Provided free of charge or at a reduced cost
- Not included in invoice price
- Watch out for payments for “assists”

Assists / Additions to Value

- Importer supplies its related French supplier, free of charge, with plastic resin used to mold a component in a medical device imported into the U.S.
- U.S. importer supplies, free of charge, to its Canadian toll manufacturer API used to make dosage pharmaceutical products imported into the U.S.
- U.S. importer pays a tooling charge and a NRE fee separate from unit cost of imported medical device housing product.
- Bottles, inserts, and syringes are provided free of charge to Mexican assembler to be used in the production of kits imported into the U.S.
- Chinese R&D Center provides research used for development of new drug compound to be produced in India and imported into the U.S.
- Payment to Irish CRO to conduct clinical trials for product ultimately produced in India and imported into the U.S.
- Was payment necessary for production? Related to the imported item?

Other Import Valuation Concerns

- Royalties or license fees related to patent, technology, know-how.
- Careful review of license agreements is warranted to determine other payments related to product production and import valuation.
  - *E.g.*, $5,000,000 milestone payment triggered upon successful completion of FDA Phase II clinical trials.
- Proceeds of a subsequent resale with foreign seller (profit sharing)
- Foreign R&D expenses or foreign clinical trials
- Importation of capital equipment or other indirect materials often provides new challenges for life science importers (*e.g.*, progress payments, split shipments).
- Post-importation debit and credit notes can cause reporting obligations.
- Careful drafting can help avoid liability or reduce compliance risks.
- If possible, establish written agreements that negotiate the value of R&D materials, product samples or demonstration models.

- ***All required value adjustments can be made via the Company's participation in Reconciliation.***
- ***ACE reconciliation process resulting in numerous speed bumps.***

Rules of Origin

- Not necessarily a simple matter to determine the “country of origin” of a finished product or good.
- DO NOT presume that country of origin equals:
  - Country of exportation
  - Country of final manufacturing
  - Country of final packaging
  - Country of A/P payment address
  - Country of seller
- Raw materials, parts, and inputs that are used in production of the final product may come from different countries.
- Raw materials may be sourced from multiple countries.
- Manufacturing, processing and assembly operations may occur in different countries.
- System and ERP restrictions may add impediment to trade compliance.
- Watch out for sourcing changes – communication is key to compliance.
- Different rules of origin may apply (depends why you’re asking).

Depends on Why You're Asking

What	Rule	Why
General Imports into U.S.	Substantial Transformation	Declaration, Admissibility and Marking
Textile Imports into U.S.	19 CFR § 102.21	Declaration, Admissibility and Marking
NAFTA, New FTAs, DR-CAFTA	Rules of Origin, Tariff Shift and/or RVC	Originating Good? Marking Req't (NAFTA only)
GSP, Israel-U.S. FTA, etc.	Local Content Req'ts and Double Substantial Transformation	Duty Preference Qualification
9801/9802	Substantial Transformation	Duty Preference Qualification
FTC and State unqualified "Made in USA" claims	All or Virtually All Standard California Thresholds	Protection Against Deceptive Trade Practices
Department of Commerce	Substantial Transformation	Subject to AD/CVD Orders
Trade Agreements Act	Substantial Transformation	Eligibility for Federal Supply Schedule (FSS) listing
Foreign Export Jurisdictions	Various	Admissibility and Marking

Origin of Medical Devices

- Substantial transformation test will generally apply for products imported into the U.S. (non-NAFTA).
- Rules of origin are not harmonized internationally.
- For U.S. imports, required to determine the last production step that creates a product with a new name, character, or use.
- Nature of process used to make finished article.
  - Processing operations which are *minimal or simple* will generally not result in a substantial transformation.
  - Processing or manufacturing operations that are *complex or meaningful* will generally result in a substantial transformation.
  - Packaging or kitting is almost never a substantial transformation!
- Each case is fact specific
- Generally no bright line tests or dollar/value thresholds
- Some opportunity for advocacy and product expertise
- Essential character of inputs vs. finished product.
- Other countries generally apply a substantial transformation standard akin to NAFTA, with tariff shift and/or regional value content standards.

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Origin of Pharmaceutical Products

- General (non-NAFTA) rule, origin determinations for pharmaceutical products follow a “substantial transformation” test.
- U.S. Customs administrative precedent has consistently held that the processing of a single API product into tablet or dosage form is insufficient to effect a substantial transformation.
- In other words, the country of origin of single API finished dosage product will track to the origin of the API (essential character).
  - Unless production results in a chemical reaction to the API or other substantial change in the essential character of the API.
  - Presentation of API on a transdermal patch, inhaler, or sublingual sheet has been considered a substantial transformation
- Dual or multi-API products are generally considered to have been substantially transformed when combined.
- However, U.S. Customs HQ has indicated that they are reviewing dual API origin determinations.

Origin of Pharmaceutical Products (cont.)

- CIT case *Acetris Health LLC v. United States* filed in March 2018
- Complaint challenge CBP's TAA origin determination for a single API finished dose product, arguing that:
  1. Indian origin API is substantially transformed in the U.S.
  2. CBP misapplied the Federal Acquisition Regulations (FAR) concerning when a product is a "U.S.-made end product," without regard to the country of origin of the components or whether the product is substantially transformed in the United States.
  3. CBP had no authority to issue a binding decision regarding the products' eligibility under the FAR when the product is produced in the U.S. (instead of outside the U.S.).
- Litigation creeping forward.

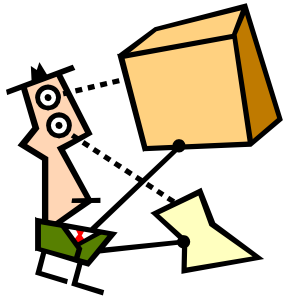
NAFTA Origin

- Under the NAFTA, the NAFTA Marking Rules determine the county of origin of goods imported from Canada or Mexico. 19 CFR Part 102.
- Substantial transformation rule is not directly applicable.
- Origin determinations are based on a hierarchy of rules similar to NAFTA Rules of Origin, where origin often relies on a tariff shift rule (19 CFR 102.20)
- It is possible that the origin determination for country of origin marking for a supply chain that runs through a NAFTA country is different than the identical supply chain through a non-NAFTA country.
- Application of the NAFTA preference override (19 CFR 102.19) may create a favorable origin result.
- It is likely that a single API finished drug product from Canada will be county of origin Canada, rather than the country of origin of the API.
- Caution that TAA rules are not directly impacted by NAFTA and substantial transformation analysis would continue to apply.

Customs Marking Rules

- Every foreign article or its container must be marked with its country of origin. That mark must be:
  - Legible (*i.e.,* not hard to read),
  - Indelible (*i.e.,* must not fade or smear),
  - Permanent *(i.e*., will not fall off unless deliberately removed),
  - Conspicuous (*i.e.,* easy to find), and
  - In English.
- The purpose of these requirements is to let the "ultimate purchaser" in the United States know the foreign origin of the goods.
- Ultimate purchaser may be a hospital, healthcare facility, or pharmacy

Special Marking Rules - 19 C.F.R. § 134.46



- If U.S. address is listed, such as required by FDA (e.g., 21 CFR § 201.1) additional requirements.
  - Country of origin must appear
    - in close proximity to
    - same size letters as
    - same type letters as
  - Must include “Made in” or “Product of” or words of similar meaning.
- Repacking Imported Products:
  - Imported in Bulk
  - Repackaged in United States
  - Must Mark New Containers and provide
    - Certification to Customs at the time of entry
    - Notification to subsequent repacker

Origin Marking Violations - Customs

- Denial of entry.
- Seizure of goods.
- Demand for redelivery.
- Liquidated damages.
- Marking duties – 10% ad valorem.
- Criminal penalties.
- Not exclusive remedy
  - 19 USC § 1592 for origin declaration errors
  - FCA and potential private right of action

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Thank You!

James Sawyer
312-569-1156
james.sawyer@dbr.com