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INSIGHTS FROM THE BDO LIFE SCIENCES PRACTICE

UNDERSTANDING CUSTOMS & TRADE FOR LIFE SCIENCES COMPANIES

Why it matters in the midst of the global supply chain crisis

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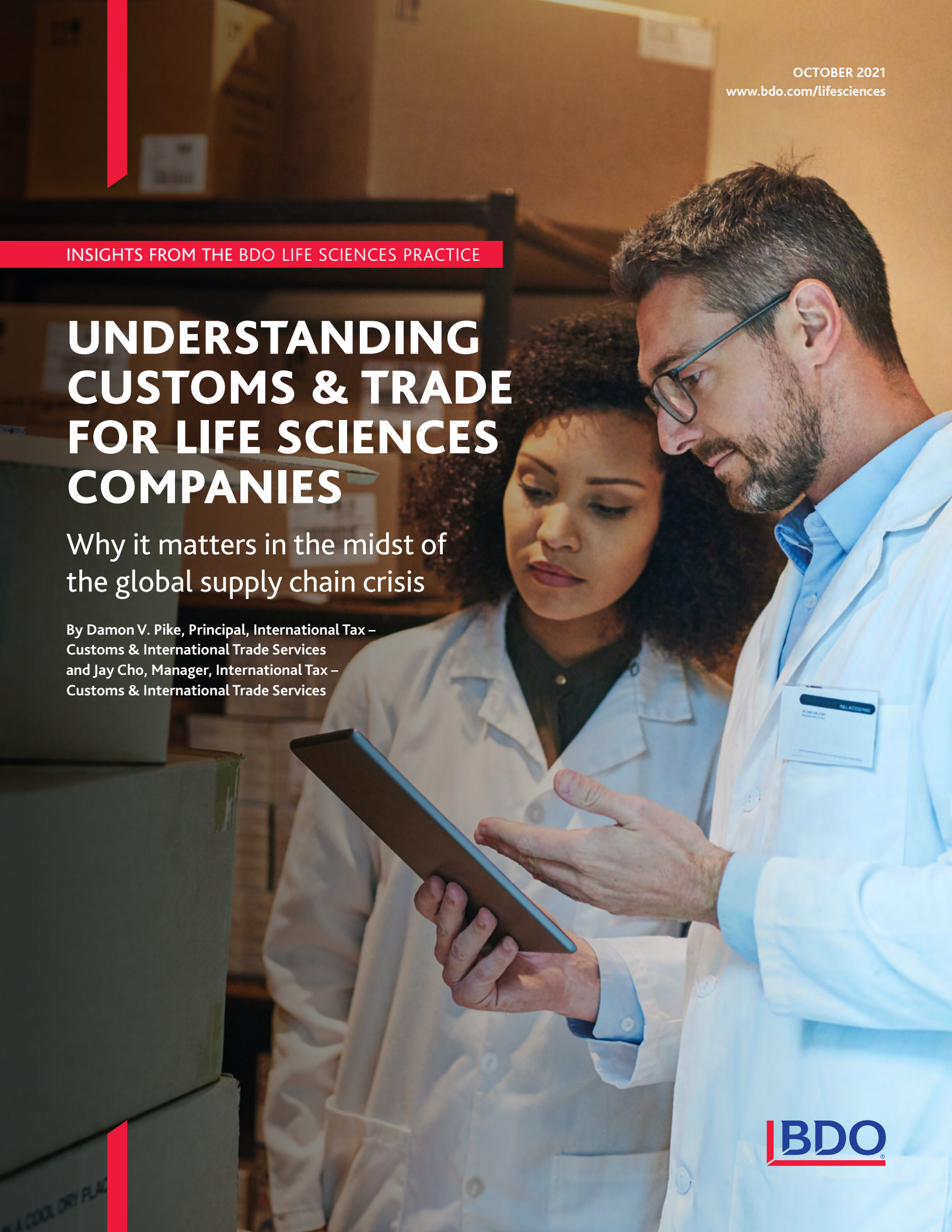

As life sciences organizations expand R&D investments and activities, global supply chain planning becomes more challenging and complex. The COVID-19 pandemic has severely disrupted the global supply chain crisis, resulting in shortages of key materials and inputs, freight interruptions and skyrocketing shipping costs, and new constraints have been placed on the import and export of certain products, etc. In addition to grappling with these externally driven pressures to keep businesses afloat and to meet intensifying demands for specific products, life sciences companies have had to ensure that they remain compliant with the myriad rules and regulations governing this sector. One such area is customs and international trade.

Most companies in the life sciences sector operate globally and import a wide range of products, such as medical devices; chemical, pharmaceutical and biological materials; intermediate products; and finished drugs for various purposes such as testing, research, further processing, final domestic sales etc. However, many companies—including life sciences companies—may overlook the impact of the customs and trade regulatory environment on cross-border movements of their materials and products. In fact, many life sciences companies do not include customs or export controls as part of their regulatory compliance planning and/or tax optimization planning, which potentially could result in civil penalties and lead to overpaid duties in the long run.

Under **Section 484 of the Tariff Act,** the Importer of Record (i.e., the owner, purchaser or licensed customs broker) is responsible for using reasonable care to declare its imports to U.S. Customs and Border Protection (CBP), e.g., classifying and determining the value and country of origin of imported merchandise. If the U.S. Importer of Record fails to exercise "reasonable care," CBP may impose monetary penalties of up to four times the domestic value of the imported merchandise, depending on the level of culpability and whether any revenue loss is involved. Other countries have similar penalty regimes and also have strict rules regarding who can act as the importer of record (e.g., the EU does not allow non-resident importers of record).

Aside from the potential exposure for misreporting, compliance with customs rules may provide many opportunities for legitimate duty savings on imports. As such, life sciences companies should make customs an integral part of their business strategy, from supply chain and tax planning to compliance.

The following outlines some considerations to keep in mind as your company assesses how to best approach customs planning and compliance.

TARIFF CLASSIFICATION

Tariff classification is a critical component of customs compliance because it determines the applicable duty rate and special tariffs, as well as whether "partner government agencies" rules also apply to those of CBP for imported merchandise, e.g., both the Food and Drug Administration's regulations and CBP's regulations apply to imports of pharmaceuticals. Each time an item crosses a border from one country to another, a unique tariff code must be assigned to the product, which is reported to the local customs agency. All tariff codes are based on the global Harmonized Commodity Description & Coding System (HS) maintained by the World Customs Organization. An incorrect tariff code can lead to unnecessary inquiries/audits from CBP (or from the relevant local customs authority) and monetary penalties may result from such an inquiry. A completely revised and updated HS will go into effect globally as of Jan. 1, 2022, so the issue of tariff classification is especially ripe for review.

For imported merchandise, some companies use the tariff codes supplied by their vendors, manufacturers, middleman, customs brokers, etc., which may be incorrect. The detailed technical information about each item to be imported must be reviewed by BDO's customs team and the tariff classification reviewed must be based on the condition of the subject merchandise at the time of import. For instance, the classification of active pharmaceutical ingredients (API) under the Harmonized Tariff Schedule of the U.S. is extremely complex, and it can be challenging to ascertain the proper tariff code without assistance from an experienced professional who knows chemistry.

CUSTOMS VALUATION

Customs valuation is another critical area for the life sciences industry as many transactions do not involve sales of materials/drugs at the time of import but rather "works in progress" for further processing. Fortunately, all major trading nations use the same valuation rules (with minor exceptions) set forth in the 1979 GATT (now WTO) Valuation Agreement. The most predominant method of determining the value of imported goods is the "transaction value" method, which refers to "the price actually paid or payable for the merchandise when sold for export."

In some cases, the transaction value is the transfer price based on a transfer pricing study between related companies or the invoice price generated by the foreign vendor/manufacturer. However, relying on transfer prices to establish the transaction value may not always be allowed under the customs valuation rules. Standing alone, the intercompany price determined by a transfer pricing study is not acceptable for customs purposes because an inherent conflict exists between income tax and customs duty for purposes of the value of imports, i.e., lower customs values result in higher income tax and vice versa. Where transactions are concluded between unrelated parties, companies—as Importers of Record—must review how the invoice price was calculated and determine whether it meets CBP's valuation requirements.

Standing alone, the intercompany price determined by a transfer pricing study is not acceptable for customs purposes because an inherent conflict exists between income tax and customs duty for purposes of the value of imports, i.e., lower customs values result in higher income tax and vice versa.

For example, items may be imported for further processing or testing/trials without a sale for exportation. All of the other valuation methods after the transaction value method must be examined in sequential order.

In addition, various R&D payments and other types of payments for services or intangibles made to foreign parties outside of the import transaction must be examined for potential dutiability. For example, CBP generally draws a line between non-dutiable conceptual research and dutiable research based on the connection between the end product and the research activities. CBP generally applies a "totality of the circumstances" standard to determine the dutiability of any payment made by the importer to a foreign company. If CBP determines that a sufficient link between the payment and the imported products appears, the payment would likely be dutiable.

BIDEN ADMINISTRATION'S BUY AMERICAN POLICIES – COUNTRY OF ORIGIN

Country of origin is always an issue for imported products and must be properly declared to CBP or other local customs authority in the country of import. However, even domestically-manufactured goods can be impacted by CBP's country of origin rules. For instance, many life sciences companies manufacture final products in the U.S. using imported raw materials, ingredients or intermediate products. If those companies wish to sell products to federal agencies, they must be familiar with the Buy American Act (BAA).[1] The BAA establishes a preference for goods and services produced in the U.S. and promotes federal procurement of "domestic end products" that help U.S. businesses compete in strategic industries. The BAA generally uses the following two-part test to determine whether a finished product qualifies as domestic:

- The items must be manufactured in the U.S.; and
- The cost of the domestic components must exceed 55% of the cost of the end product (and it may increase to 75% by 2029 if the Biden Administration's proposal is enacted).

The first requirement is perhaps the most difficult to meet. Although the term "manufactured" is not defined in the regulations, government agencies use CBP's "substantial transformation" standard which ordinarily determines the country of origin of imported goods—but is used in this context to determine whether the U.S. is the country of origin for the finished goods manufactured in the U.S. for which BAA status is sought.

Businesses that wish to review the eligibility of their products should confer with BDO's customs team, who are well-versed in both the BAA requirements and relevant CBP rules to confirm that they qualify as U.S. domestic end products. Of special importance is the determination of the country of origin of the finished goods made in the U.S. with imported components. CBP is the agency charged with making this determination and whether waivers from BAA are available.

1 President Biden signed an **Executive Order** on January 25, 2021 outlining his vision for a new "Made in America" policy that would strengthen the terms and conditions of financial assistance awards and procurement agreements with the federal government under the BAA. In addition to promoting the use of American-made supplies, the Executive Order also appears to promote accountability in government procurement procedures by vesting waiver authority (to grant exceptions from Made in America laws or procedures) in senior agency leadership and implement additional transparency requirements. You can find more information on the Executive Order **here**.

WHERE DO YOU GO FROM HERE?

Many life sciences companies place too much reliance on external customs brokers and/or freight forwarders or lack adequate internal resources. Global duty spend should be part of any multinational's tax planning agenda; tariffs (customs duties) are an indirect tax and are squarely part of understanding total tax liability on a worldwide basis. Given the complex tariff classification and customs valuation issues often encountered in the life sciences industry, expert advice should be sought and budgeted for. We suggest the following preliminary steps to stay current with customs compliance and make the most of opportunities to save on import duties:

- Review and update the company's import/export compliance policies and procedures and documentation, including the internal tariff code database;
- Assess the company's transfer pricing policy covering import transactions with related parties to evaluate the intercompany price under the customs valuation rules;
- Examine whether any payments related to imported or exported items are dutiable;
- Undertake a comprehensive review of the company's supply chain to identify vulnerabilities, how materials and active ingredients, etc. are sourced to develop a flexible and resilient model that can adapt to a quickly-changing world; and
- Evaluate supply chain models to gauge whether the products effectively meet the requirements of the BAA (including CBP's substantial transformation rules) to confirm the U.S. origin and thus eligibility of the subject merchandise for BAA contracting.

Dive into our full list of recommendations to optimize your trade compliance program here.

BDO is experienced in working with life sciences organizations to facilitate global duty spend optimization and minimize risk and exposure. Understanding your global customs obligations is important to avoiding costly fees and regulatory challenges while maximizing the potential cost savings wherever you do business.

People who know Life Sciences, know BDO.

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