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The Buy American Act and Trade Agreements Act: Implications for Pharmaceutical Companies Manufacturing in India

The US government procures goods and services subject to a complex web of laws and regulations. These requirements are also a key part of President Donald J. Trump's "America First" platform. Non-US companies seeking to bid on US government contracts – including pharmaceutical companies manufacturing their products abroad for importation into the US – must understand how these laws may affect their efforts to enter this lucrative market, while at the same time monitoring political developments in Washington DC.

US Government Procurement Law

US government procurements are subject to a variety of "domestic preference" and "country of origin" requirements. Of the US laws regulating government procurement, the most frequently encountered are the Buy American Act (BAA) (41 U.S.C. § 10) and the Trade Agreements Act (TAA) (19 U.S.C § 2511).

The Buy American Act. The BAA generally requires federal agencies to purchase "domestic end products" and use "domestic construction materials" on contracts performed in the US that exceed a certain micro-purchase threshold. Unmanufactured products qualify as "domestic" if they are mined or produced in the US, while manufactured products are considered "domestic" if they are manufactured in the US, and either (1) the cost of components mined, produced or manufactured in the US exceeds 50% of the cost of all components; or (2) the items are commercially available "off-the-shelf."

The BAA generally establishes a price preference for domestic products. The Federal Acquisition Regulation (FAR) requires that if a domestic offer is not the lowest offer, the government agency must increase the lowest offer's price (including any duty) by a certain percentage before comparing it to other bids and determining which offer is the "best value" for the US government. However, if the foreign offer is still the lowest price, the agency may usually award the contract to the foreign offerer, as the BAA permits the purchase of foreign products when the costs of domestic ones are "unreasonable."

In addition to this "unreasonable" cost exception, the BAA also permits US government agencies to purchase foreign supplies in other exceptional circumstances, including when:

- The procurement of domestic goods would be "impracticable" or "inconsistent with the public interest"
- Domestic products are unavailable "in sufficient and reasonably available commercial quantities and of a satisfactory quality"
- The goods are acquired specifically for commissary resale
- The agency procures commercial information technology

Notably, procurements with a value below the micro-purchase threshold and procurements for use outside the US are often considered additional exceptions to the BAA.

In most cases, including for pharmaceutical contracts, the procuring agency has the discretion to determine whether to apply a BAA exception.

The Trade Agreements Act. The TAA permits the waiver of the BAA, allowing eligible products from "designated countries" to be equally considered alongside domestic offers when certain federal agencies procure such goods whose value exceeds certain monetary thresholds. In practice, this waiver limits the applicability of the BAA, as its requirements only apply when (1) the anticipated value of the procurement is below the relevant monetary thresholds prescribed by trade agreements; (2) the acquisition involves agencies or supplies explicitly excluded from the coverage of particular trade agreements; or (3) the acquisition is exempted from the TAA's waiver of the BAA.

A product is TAA-compliant if it "substantially transformed" into a "new and different article of commerce" in the US or a "designated country." The TAA prohibits procurement of products from non-designated countries, such as India, subject to exceptions and waivers, including a determination of non-availability. However, it does not apply to certain US government acquisitions, including acquisitions set aside for small businesses and of products for resale, amongst others. In these cases, the BAA or another US law may apply.

What Does This Mean for Non-US Companies?

Direct sales to non-US government consumers. The BAA and TAA are laws that regulate government procurement, not the direct sale of products to other US consumers. However, many non-government US consumers may still conduct business with the US government and accordingly, would need to be careful in ensuring compliance with the BAA and the TAA. Notably, contractors could be liable for misrepresentation concerning country of origin. As a result, these US laws could negatively affect the overall level of direct sales to US consumers. However, contracting agencies, such as the Department of Veterans Affairs (VA) and the Department of Defense (DOD), can make non-availability determinations for their own contracts, thus mitigating the impact on companies in non-designated countries.

Sale of finished pharmaceutical products to the US government. While the BAA does not prohibit the purchase of foreign-made products, it does provide a price preference for US-finished products by requiring the procuring agency to add a certain percentage of the foreign low offer's price (inclusive of duty) to that offer before determining which offer is the lowest. This percentage typically ranges from 6%, in cases where the lowest domestic offer is from a large business, to 12%, when the lowest domestic offer is from a small business. For DOD procurements, the percentage can increase to 50%. US agencies may also adopt higher percentages by regulation. However, if the foreign offer remains the lowest, the purchase is permitted under the BAA under the "unreasonable" cost exception. The BAA also permits the purchase of foreign-made goods in other exceptional circumstances, outlined above, as well as when the purchase is below the micro-purchase threshold amount.

The TAA generally prohibits the purchase of products and services that are not "substantially transformed" in the US or a "designated country," with certain exceptions. However, a non-availability determination by the procuring agency may allow companies in non-designated countries, such as India, to sell their products to the US government. Last year, the VA published a significant change to its Federal Supply Schedule (FSS) contracts, permitting contracting officers to make individual non-availability determinations for any covered drug that does not originate in a TAA-designated country. This policy change provides pharmaceutical manufacturers in non-designated countries access to the US government market through the FSS program. DOD can similarly waive TAA requirements under certain circumstances.

Notably, the BAA and TAA do not directly affect the sale of foreign pharmaceutical products under Medicare and Medicaid, two US government-administered health programs. Medicare is a health insurance program for individuals over the age of 65 and/or with certain conditions. Individuals eligible for Medicare generally pay a monthly premium for prescription drug coverage, provided through private companies, not the US government. Medicaid is a joint federal-state program that provides health coverage to eligible low-income adults, children, pregnant women, elderly adults and people with disabilities. While some states may exclude certain drug coverage under Medicaid, such action is unrelated to the BAA or TAA. Whether a particular pharmaceutical product is available under these programs generally depends on approval from the US Food and Drug Administration (FDA). While an Indian-origin pharmaceutical product may not be FDA-approved, such lack of approval would not impact the Indian pharmaceutical industry as a whole when it comes to Medicare and Medicaid.

Sale of unfinished pharmaceutical products to the US government. A "substantial transformation" test is used to determine the country of origin under the TAA. Under this test, a product of a country is determined to originate in a designated country if (1) it is wholly the growth, product or manufacture of that country; or (2) in the case of an article that consists in whole or in part of materials from another country, it has been substantially transformed into a new and different product with a name, character or use distinct from the original article.

For pharmaceutical manufacturers, the unfinished products, such as the active pharmaceutical ingredient (API) and the excipients, are not fit for use as medication until processed in accordance with the approved New Drug Application, taking into account US Food and Drug Administration requirements. However, US Customs and Border Protection has consistently ruled that an API remains substantially unchanged, regardless of processing. Therefore, the API's country of origin is generally also considered the finished product's country of origin.

Indian pharmaceutical industry's competitive edge. While both the BAA and TAA curb Indian pharmaceutical companies' competitive edge vis-a-vis US-made and "designated country"-made products, the exceptions under both laws still provide the industry with an opportunity to provide finished and unfinished products through various exceptions and waivers. Indian pharmaceutical companies' advantage as low-cost manufacturers is preserved because of the BAA's "unreasonable cost" exception.

New Developments

On April 18, 2017, President Trump signed an Executive Order (EO) titled "Buy American and Hire American" to maximize the federal government's use of goods, products and materials produced in the US. While the EO does not change existing US law or preference standards, it does require US government agencies to increase monitoring, enforcement and compliance with US procurement laws, while minimizing the use of waivers. Notably, the EO provides an additional basis for agencies to continue their already heightened scrutiny of compliance with BAA and TAA requirements. Current government contracts involving waivers may be reevaluated given the Trump Administration's increased scrutiny of these waivers, so companies involved in such contracts should take care to ensure compliance with US law. Recently, members of the World Trade Organization, including Israel, Japan, Canada and the European Union, have expressed concern that the EO might harm international supply chains, but it remains to be seen how stricter implementation and compliance by US agencies will impact foreign manufacturers.

Indian pharmaceutical companies doing business in the US should pay close attention as the Trump Administration promotes new policies for federal procurements and their impact on foreign bids. While this uncertain political landscape may continue to present new challenges for foreign manufacturers, Squire Patton Boggs and SKP are well positioned to provide interested parties with rapid, professional and tailored advice and compliance tools.

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