May 7, 2025

Docket Number: BIS-2025-0022

Eric Longnecker
Deputy Assistant Secretary for Technology Security
Bureau of Industry and Security
U.S. Department of Commerce
14th Street and Constitution Avenue, NW
Washington, D.C. 20230

Re: Request for Public Comments on Section 232 Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients, XRIN 0694-XC120

Dear Deputy Assistant Secretary Longnecker:

American Regent appreciates the opportunity to respond to the recently published "BIS Section 232 Investigation of Pharmaceutical Imports" Notice Request for Comments (the "Notice"). We commend the Department for its focus on America's supply chain especially the domestic manufacture of products that prevent and treat chronic disease, as well as those that are important to health-related national security.

I. Company Background

Headquartered in New York State, American Regent owns and operates manufacturing sites to develop, formulate, fill and finish branded and generic prescription injectable medications in Ohio and New York. We employ approximately 1,400 people in various locations throughout the United States.

Our U.S. manufacturing facilities have undergone substantial expansion and modernization with over $250M invested since 2018, and over $370M for an additional project underway to enhance our capabilities and capacity. Capacity in New York and Ohio has doubled, increasing to over 100 million units annually.

High quality is paramount in American Regent's investments with our focus on systems that ensure sterility assurance and safety for our patients. American Regent's manufacturing

facilities are regularly inspected by the FDA; and ARI maintains an excellent cGMP status based upon those inspections.

American Regent has decades of U.S. research and development expertise (R&D) in injectable drug product development. Our state of the art laboratory facility of more than 14,000 square feet in New Albany, Ohio provides advanced end-to-end R&D capabilities to develop, characterize, test, scale-up and transfer technology for robust dosage forms to manufacturing finished goods.

Over 99% of American Regent's drugs are formulated, filled and finished in our U.S.-based manufacturing facilities. Further, the majority of ARI's product components are obtained from American sources. ARI evaluates and qualifies all of its suppliers of API and Key Starting Materials ("KSMs") through our Supplier Approval Program. The program ensures the building blocks of our products meet stringent standards for identity, strength, quality, purity, and potency. American Regent is also engaged in efforts to partner with additional domestic API manufacturers, with the goal of an end-to-end U.S.-based supply chain for our products. The Administration's efforts to bring manufacturing in all forms back to the U.S. will help us to eventually fully source within the U.S.

Injectable pharmaceuticals manufacturing is complex, at times requiring APIs, KSMs, and manufacturing equipment that can only be procured from suppliers outside of the U.S. While American Regent welcomes a future in which procurement by U.S. manufacturers could be done completely with U.S. suppliers, that will take at least a few more years even at the fastest timing possible. Therefore, our request is that the Administration take measures that will encourage U.S. manufacturing without harming U.S. manufacturers.

2. <u>Tariff Exemption or Tax Credit on Manufacturing Equipment</u>

Procuring equipment for sterile injectables manufacturing is challenging, especially for U.S. based companies attempting to source within the U.S. The equipment is not commoditized; and it is not a matter of price. There are only two aseptic filling equipment suppliers in the U.S. When their equipment does not meet our specifications ensuring product quality safety and efficacy, we

have no alternative but to procure from industry leading suppliers in Germany. Manufacturing equipment's quality must meet the requirements of Current Good Manufacturing Practices (cGMPs) to comply with expectations of rigorous U.S. FDA inspections. Equipment that does not meet these specifications can impact yields, and potential loss of entire batches due to equipment problems or outright failures, with the most serious potential impact being on patient safety due to pharmaceutical product quality itself. With complex manufacturing equipment costing tens of millions or even hundreds of millions for larger projects, a tariff that is not relieved by some other economic measure would have the unintended impact of costing the U.S. manufacturer substantially more money to invest in its U.S. manufacturing by substantially increasing the cost of equipment for U.S. manufacturing.

Therefore, for manufacturers procuring equipment that is specifically to be used for manufacturing within the U.S., we ask that the Administration consider either an exemption of tariffs on such equipment, or a tax credit for import and tariff expense.

3. Tariff Exemption or Tax Credit for API, KSM and Necessary Materials Finished in U.S.

For sterile injectable pharmaceutical manufacturing, there are a very limited number of API suppliers, as well as suppliers of KSM and other componentry. These materials must be of high quality since bottles, vials, stoppers, and related materials that touch the product can impact the quality of the product itself. Even outer packaging can increase the likelihood of breakage for glass vials.

If the price of API and/or KSMs increase on a product due to tariffs, American Regent's ability to increase the price of the final finished product to account for its increased costs is limited by contracts that limit price increases, as well as by the complex pricing, reimbursement, and Medicare price penalty rules in the U.S.

Therefore, American Regent requests that the Administration not impose, or delay, any tariffs on API, KSM, and necessary materials (excipients, packaging) needed for domestic fill-finish operations to ensure that existing domestic capacity is not harmed by a requisite increase in prices. Tariffs imposed on imported production inputs would negatively impact our U.S.-based

manufacturing operations by impacting prices; and thereby reducing our ability to offer more affordable generic medicines to patients.

Alternatively, we ask that U.S. manufacturers be able to take a tax exemption for import or tariff expense.

I. Answers to BIS's Specific Questions

(i) the current and projected demand for pharmaceuticals and pharmaceutical ingredients in the United States;

The demand for certain pharmaceutical ingredients cannot be met domestically. For certain sterile injectable pharmaceutical products, there are a very limited number of API suppliers. This is also true for suppliers of certain KSM and other componentry. Certain products cannot be made in the U.S. without procurement of components from outside the U.S.

(ii) the extent to which domestic production of pharmaceuticals and pharmaceutical ingredients can meet domestic demand;

As seen from the chronic public health problem of drug shortages in the U.S., domestic demand is not being met for many products. Most products on shortage are genericized injectable pharmaceuticals, with margins so low or negative that no one wants to get into the business of selling them.

For U.S. manufacturers, competing against companies that can drive down prices because they manufacture in countries with low wages and cost of goods has been a problem. We can invest in producing more capacity, but it does not make sense to do so if there is literally no profit margin on certain products.

U.S. manufacturers could be incentivized to fulfill domestic production requirements of pharmaceuticals with: (1) long-term guaranteed federal supply contracts; and/or (2) grants to invest in new product manufacturing lines such as those needed to increase the domestic production of antibiotics.

(iii) the role of foreign supply chains, particularly of major exporters, in meeting United States demand for pharmaceuticals and pharmaceutical ingredients;

For sterile injectable pharmaceutical manufacturing, there are a very limited number of API suppliers, as well as suppliers of KSM and other componentry. Certain products cannot be made in the U.S. without procurement of components from outside of the U.S.

(iv) the concentration of United States imports of pharmaceuticals and pharmaceutical ingredients from a small number of suppliers and the associated risks;

American Regent has no comment.

(v) the impact of foreign government subsidies and predatory trade practices on United States pharmaceuticals industry competitiveness;

American Regent has no comment.

(vi) the economic impact of artificially suppressed prices of pharmaceuticals and pharmaceutical ingredients due to foreign unfair trade practices and state-sponsored overproduction;

For U.S. manufacturers, competing against companies that can drive down prices because they manufacture in countries with low wages and cost of goods has been a problem. In some cases, product produced in foreign countries is sold for a lower price than we can even purchase the components for, before adding the labor of formulation, filling and testing. We can invest in producing more capacity, but it does not make sense to do so if there is literally no profit margin on certain products. American Regent is not commenting on whether or when this may be impacted by foreign unfair trade practices or state sponsored overproduction.

(vii) the potential for export restrictions by foreign nations, including the ability of foreign nations to weaponize their control over pharmaceuticals supplies;

American Regent has no comment.

(viii) the feasibility of increasing domestic capacity for pharmaceuticals and pharmaceutical ingredients to reduce import reliance;

Companies who already have U.S. manufacturing are best placed to provide the quickest increases in domestic capacity for pharmaceuticals. Guaranteed long-term federal contracts and/or grants with U.S. based manufacturers could be a relatively quick means to substantially increase domestic capacity especially of products on drug shortage or other essential medicines.

(ix) the impact of current trade policies on domestic production of pharmaceuticals and pharmaceutical ingredients, and whether additional measures, including tariffs or quotas, are necessary to protect national security

Please see Company Background section, above, and comments throughout this document.

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We appreciate the Administration's support of U.S. manufacturers, and its work to ensure a diverse and resilient pharmaceutical supply chain based in the U.S. We look forward to continuing to provide our input and are ready and willing to provide any supplemental information that may be needed. Please contact me at pdiolosa@americanregent.com if we can provide anything further.

Sincerely,

DocuSigned by:
Paul Diolosa
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Paul Diolosa, President & CEO