WRITTEN SUBMISSION OF THE NATIONAL FOREIGN TRADE COUNCIL

Request for Comments on the Section 301 Investigation of China's Implementation of Commitments under the Phase One Agreement

Docket Numbers USTR–2025–0007, USTR– 2025–0020
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The National Foreign Trade Council (NFTC) appreciates the opportunity to provide input in response to the Office of the U.S. Trade Representative's (USTR) Federal Register notice, *Initiation of Section 301 Investigation: China's Implementation of Commitments under the Phase One Agreement* (the FR Notice) (90 FR 48733, October 28, 2025).

About NFTC

The NFTC, organized in 1914, is an association of U.S. business enterprises engaged in all aspects of international trade and investment. Our membership covers the full spectrum of industrial, commercial, financial, and service activities. Our members support establishing and maintaining international trade norms that reflect the critical role that an open, rules-based international economy plays in the success of American businesses, entrepreneurs, and workers, and shared global prosperity. The NFTC also supports the effective enforcement of those rules.

I. INTRODUCTION

NFTC is pleased to provide comments as part of USTR's Section 301 investigation into China's Implementation of Commitments under the Phase One Agreement.
In January of 2020, the National Foreign Trade Council (NFTC) welcomed the announcement of the Economic And Trade Agreement Between The United States Of America And The People's Republic Of China (Phase One Agreement) between the United States and China as a critical first step towards a more sustainable, predictable and mutually-beneficial trading relationship.[1] The inclusion of prohibitions on forced technology transfer, improved market access for financial services, disciplines on state-directed outbound investment, and enhanced protections of trade secrets and other intellectual property (IP) rights addressed areas critical to U.S. business, including many NFTC member companies.

[1] National Foreign Trade Council, Statement on the U.S.-China Phase One Agreement, January 15, 2020.

The Phase One Agreement was intended to eliminate the discriminatory and unduly burdensome technology transfer, intellectual property, and innovation measures identified in the Section 301 investigation and begin rebalancing the U.S.-China trade relationship.[2] We hoped it ultimately would enable the removal of U.S. tariffs imposed on $550 billion in U.S imports from China.

Unfortunately, the Phase One Agreement never achieved its potential. As with any trade agreement, the success of the Phase One Agreement depends on implementation and enforcement to ensure that commitments on paper translate into commercial opportunities for U.S. businesses. The non-implementation by China of several Phase One commitments, as further outlined in this submission, has denied important commercial benefits for U.S. companies operating in the affected industry sectors.

As USTR considers what action, if any, to take to address China's lack of full compliance with the Phase One Agreement, NFTC strongly urges USTR to look beyond tariffs for potential remedies. Section 301 tariffs – even when applied in addition to fentanyl and Section 232 tariffs – have not been effective in obtaining China's compliance with the Phase One Agreement. New or increased Section 301 duties are unlikely to have a different outcome and will only raise the cost of machinery, consumer goods, essential food ingredients, raw materials, and equipment that are not available from sources other than China.

It also is important to recognize that this investigation is not happening in isolation and should be approached as part of the Administration's overall bilateral trade policy towards China. With high tariffs already in place and more on the horizon, we urge the Administration to ensure that the focus of its policy remains on securing the full implementation of the commitments included in the Phase One Agreement to successfully remove barriers for US companies seeking to do business in China. However, it is critical to do so in a manner that avoids unintended harm to U.S. companies broadly or to U.S. supply chains. Any action taken pursuant to this Section 301 investigation should be part of a comprehensive strategy that seeks action by China to address measures covered by this investigation (and any other non-reciprocal trade barriers and national security concerns).

II. EXAMPLES OF CHINA'S NON-COMPLIANCE WITH SPECIFIC COMMITMENTS

NFTC is pleased to provide the comments below outlining specific Phase One Agreement commitments where China has failed to fully implement its obligations.

A. Chapter 1 - Intellectual Property Protection

The IP chapter addressed numerous longstanding concerns in China, including trade secrets, pharmaceutical-related intellectual property, geographical indications, trademarks, and

[2] https://ustr.gov/phase-one

enforcement against pirated and counterfeit goods. NFTC members are concerned that China has not fully implemented the obligations related to pharmaceutical IP protection and pirated and counterfeit goods.

1. Section C - Pharmaceutical -Related Intellectual Property

Robust protection of IP is critical to incentivizing the development of new and innovative treatments and cures. The IP chapter of the Phase One Agreement included important commitments intended to expand opportunities for the U.S. biopharmaceutical industry and strengthen U.S. and Chinese cooperation. Specifically, China agreed to:

- Consider supplemental data to meet relevant patentability criteria for pharmaceutical patent applications (Art. 1.10).
- Create an effective mechanism for the early resolution of pharmaceutical patent disputes, including enabling a patent holder to seek expeditious remedies before an infringing product is marketed in China (Art. 1.11) and
- Provide patent term extensions to compensate for unreasonable delays that cut into the effective patent term (Art. 1.12).

The successful implementation of these commitments would have helped to lay a solid foundation for investment and cooperation in the biopharmaceutical field between the two countries.

Unfortunately, China has completely failed to fulfill its obligations under Article 1.10 and Article 1.12, especially paragraph 2(b), and has only partially fulfilled its obligations under the remaining pharmaceutical-related IP provisions. China's failure to comply with these Phase One commitments has helped it to maintain an unlevel playing field to the detriment of American pharmaceutical companies and enable China to continue to unfairly exploit American innovation.

a) Article 1.10 (Consideration of Supplemental Data)

Article 1.10 requires China to permit pharmaceutical patent applicants to rely on supplemental data to support requirements for patentability, including sufficiency of disclosure and inventive step. The provision is intended to eliminate China's unique standard, which requires that the technical effect demonstrated by supplemental data must be "obtainable" from the original specification. The unique "obtainable" standard has no basis in China's patent statute, but both the Chinese patent office and Chinese courts have adopted and used the standard as an additional condition for the acceptance and consideration of supplemental data. Article 1.10 unambiguously requires China to eliminate the additional "obtainable" standard for supplemental data and treat supplemental data like any other evidence and subject supplemental data to the same evidentiary standard as any other evidence.

However, since the Phase One Agreement took effect, China has failed to comply with Art. 1.10 and continues to apply the "obtainable" standard and thereby deny protection to American innovation supported by supplemental data.

b) Article 1.11 (Effective Mechanism for Early Resolution of Patent Disputes)

China has partially failed to comply with Article 1.11, which requires China to establish an early patent dispute resolution mechanism (i.e., a patent linkage system) for "an applicable patent claiming the approved products or its approved method of use." Despite the mandate under Article 1.11, China has excluded from the patent linkage system certain type of patents, such as polymorph patents or biologic formulation patents covering the product at issue. To fully comply with Art. 1.11, China must include all type of qualified patents in the patent linkage system.

c) Article 1.12 (Effective Patent Term Extension)

China has completely failed to comply with Article 1.12, paragraph 2(b), which requires China to extend the patent term for a new pharmaceutical product if there is unreasonable curtailment of the effective patent term as a result of delays in the marketing approval process in China. China (1) fails to grant full patent term extensions to American products that are first approved in the U.S. before their China approvals and (2) also fails to provide the patent term extension to all authorized uses.

China contends that "new drug" for the purpose of patent term extension means a pharmaceutical product that has not previously been approved anywhere in the world. However, such distorted interpretation belies the original intent of the Phase One Agreement as well as the unambiguous text of Article 1.12. At the time USTR negotiated the Phase One agreement, no American company had ever approved its pharmaceutical product in China before all other countries. It is a blatant violation of Art. 1.12 for China to adopt an interpretation that would exclude all American products from coverage. Moreover, the language of Article 1.12 clearly requires the term of patent extension to apply to "a new pharmaceutical product that is approved for marketing in China" and "the first commercial use of that product in China" – not with approval or commercialization in other countries. Finally, all other major countries with patent term extension treat new drugs as the ones first approved in their respective jurisdictions, regardless of whether the same products have been approved in other countries.

China also fails to comply with Article 1.12 by granting patent term extension only to the first authorized use, but not any subsequently authorized uses. However, Article 1.12 clearly states that any patent term "shall confer all of the exclusive rights, subject to the same

limitations and exceptions, of the patent claims" under the patent term extension. It is indisputable that (1) a compound patent covers all authorized uses and (2) all authorized uses rely on the same preclinical, pharmacological, and other information, and therefore suffer the same regulatory delay. Accordingly, under Article 1.12, all authorized uses should be covered by the patent term extension of the compound patent.

Although not strictly part of the U.S.-China Phase One Agreement, China also committed in its WTO Accession in 2001 to provide regulatory data protection in accordance with TRIPS Article 39.3 related to pharmaceutical products. However, China has never implemented this commitment, and pharmaceutical products approved first outside of China still do not receive regulatory data protection. In addition to full compliance with the Phase One obligations, China also should immediately implement regulatory data protection, consistent with best international practices, for all pharmaceutical products, including both small molecules and biologics, whether approved first in China or elsewhere in the world.

2. Section E: Piracy and Counterfeiting on E-Commerce Platforms and Section G: Manufacture and Export of Pirated and Counterfeit Goods

According to the Organization for Economic Cooperation and Development (OECD), China and Hong Kong continue to be the top source for pirated and counterfeit goods in international trade.[3] Chinese online marketplaces Temu, AliExpress, and SHEIN have become central actors in the global counterfeit economy. Pirated and counterfeit goods such as semiconductors, automobile parts, apparel, footwear, toys, cosmetics, and medicines endanger the public and pose significant health and safety risks.

The Phase One Agreement IP chapter included specific obligations to ensure China addressed these concerns. In particular, China committed to:

- Provide effective and expeditious action, including takedowns, against infringement in the online environment (Art. 1.13).
- Take effective action against e-commerce platforms that fail to take necessary measures against infringement (Art. 1.14).
- Take effective enforcement action against counterfeit pharmaceuticals and related products, including active pharmaceutical ingredients (Art. 1.18)
- Significantly increase actions to stop the manufacture and distribution of counterfeits with significant health or safety risks (Art. 1.19).

[3] OECD/EUIPO (2025), Mapping Global Trade in Fakes 2025: Global Trends and Enforcement Challenges, Illicit Trade, OECD Publishing, Paris, https://doi.org/10.1787/94d3b29f-en, p. 7.

As recently as this past September, submissions and testimony for USTR's 2025 Review of Notorious Markets for Counterfeiting and Piracy (Notorious Markets List, or NML) demonstrate that the outcomes sought through the above commitments still have not materialized due to China's failure to take effective action to address these issues as required. The 2024 NML reported on the growth of illicit online pharmacies and the risks of counterfeit medicines, including from sources in China.[4]

B. Chapter 4 – Financial Services

The Financial Services chapter addressed longstanding trade and investment barriers, including foreign equity limitations and discriminatory regulatory requirements affecting banking, insurance, securities, electronic payments, and credit rating services, among others. The Phase One Agreement sought removal of these barriers to allow U.S. financial service providers to compete on a more level playing field and expand their services export offerings in the Chinese market.

1. Article 4.4:1 (Electronic Payment Services)

China has a growing electronic payment services (EPS) market that has, for many years, been closed to foreign suppliers, including world-leading U.S. credit and debit card companies. In the Phase One Agreement, China committed to ensure that its regulatory authorities operate an improved and timely licensing process for U.S. EPS suppliers to facilitate their access to China's market.

China has not fully implemented this commitment. Article 4.4 of the Phase One Agreement, among other obligations, requires China to accept and act on any bank card clearing institution (BCCI) license application from a U.S. EPS supplier – including any license application of Mastercard, Visa, or American Express – within prescribed time limits and without regard to the applicant's ownership structure. Full implementation of these commitments would level the playing field for U.S. EPS suppliers so they can compete and do business in China's domestic market on equal terms with Chinese companies.

In the five years since the Phase One Agreement entered into force, only two U.S. EPS suppliers have secured a BCCI license. The application of a third U.S. supplier has been pending since 2020. We encourage the Administration to prioritize the implementation of China's Article 4.4 commitments, which reflect nearly 25 years of effort to ensure American companies receive fair and reciprocal market access in China.

C. Chapter 6 – Expanding Trade

[4] United States Trade Representative, 2024 Review of Notorious Markets for Counterfeiting and Piracy, p. 3-10.

The Expanding Trade chapter included commitments from China to increase purchases of various U.S. goods and services by no less than $200 billion. China's commitments cover a variety of U.S. manufactured goods, food, agricultural and seafood products, energy products, and technology goods and services (including software). Not only did these purchases not materialize in the tech sector, China also has imposed restrictions on government and SOE procurement that create barriers for U.S. IT hardware, software, and services exports to China.

Specifically, China imposes both formal and informal restrictions that limit U.S. companies' ability to sell to government and state-owned enterprises (SOE). Most concerning is "Document 79" 2022 directing SOEs to reduce purchases of foreign hardware and software (particularly from U.S. companies) in favor of domestic suppliers. Consequently, procurement practices have become more aggressively anti-American leading to the broad decline of sales in China for major U.S. technology companies. USTR should press China to rescind Document 79 and other formal and informal guidance restricting U.S. technology to comply with both the letter and spirit o of the Phase One Agreement. Moreover, concrete commitments for SOEs to procure ICT hardware, software and services from U.S. companies should be part of any future U.S.-China agreement.

III. POTENTIAL ACTIONS TO ADDRESS NON-COMPLIANCE

NFTC supports U.S. efforts to ensure China fully implements its obligations under the Phase One Agreement but advises caution against raising tariffs further due to risks to supply chains and the economy. NFTC encourages this Section 301 investigation to focus on productive consultations for China's full compliance. In fact, under Article 7.4 of the Phase One Agreement, the United States and China agreed to a dispute resolution mechanism, where each side could raise concerns with implementation and one side could take proportionate action should a concern not be resolved.

While members want China to meet its commitments, the Administration should exercise caution before imposing additional tariffs since existing measures—including those from the Trump Administration and recent International Emergency Economic Powers Act (IEEPA) and Section 232 actions—have already raised the average U.S. tariff on Chinese imports to 47.5 percent according to the Petersen Institute for International Economics.[5]

The imposition of new Section 301 tariffs by the United States and potential Chinese retaliation against American commercial interests that is likely to follow, could adversely affect a broad swath of the U.S. economy. Some NFTC members believe new Section 301 tariffs would impose significant cost and supply chain disruptions on their supply chains and customers, and the U.S. economy more broadly. These unintended consequences could

[5] Bown, Chad, "US-China Trade War Tariffs: An Up-to-Date Chart," Petersen Institute of International Economics, November 10, 2025.

undermine the Administration's separate goals of reshoring more manufacturing production to the United States and lowering prices for consumers on products not available in the United States.

As the Administration seeks to resolve this issue, it should focus on pressing China to enact, modify, or withdraw policies necessary to fully comply with the Phase One Agreement. If China does not agree to address its non-compliance, NFTC urges the Administration to diversify its tools for enforcement, both within the authorities provided under Section 301 and beyond them, and to deploy them strategically in an effort to resolve the concerns raised in this comment.

After nearly seven years, Section 301 tariffs – even when applied in addition to fentanyl and Section 232 tariffs – have not been effective in obtaining China's compliance with the Phase One Agreement. New or increased Section 301 duties are unlikely to have a different outcome. It also is important to recognize that this investigation is not happening in isolation and should be approached as part of the Administration's overall bilateral trade policy towards China. Any action taken pursuant to this Section 301 investigation should be part of a comprehensive strategy that seeks action by China to address measures covered by this investigation (and any other non-reciprocal trade barriers and national security concerns).

IV. CONCLUSION

NFTC appreciates the opportunity to share our perspective on China's implementation of the Phase One Agreement. We look forward to working with you to make progress on these issues.

If you have questions, need additional information, or would like to discuss our input further, please reach out to Tiffany Smith at NFTC at tsmith@nftc.org.