UNITED STATES COURT OF INTERNATIONAL TRADE

BEFORE:

RETRACTABLE TECHNOLOGIES, INC., Plaintiff, v. UNITED STATES OF AMERICA; OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE; KATHERINE TAI TRADE REPRESENTATIVE; UNITED STATES CUSTOMS & BORDER PROTECTION; TROY MILLER, in his capacity as Senior Official Performing the Duties of Commissioner, U.S. Customs & Border Protection, Defendants.	**Court No. 24-00185**

COMPLAINT

Plaintiff Retractable Technologies, Inc. ("Retractable"), by and through its undersigned attorneys, by way of this Complaint against Defendants the United States of America ("U.S."); the Office of the United States Trade Representative ("USTR"); Trade Representative Katherine Tai ("Ambassador Tai"); U.S. Customs & Border Protection ("CBT"); and U.S. Customs & Border Protection Acting Commissioner Troy Miller ("Commissioner Miller"), alleges as follows:

NATURE OF THE ACTION

1. This case concerns the fate of Plaintiff Retractable Technologies, a small Texas-based company that revolutionized syringe safety with patented technology.

2. Retractable has made significant positive contribution to public health, including the U.S. Government's pandemic response.

3. This action seeks a temporary restraining order and injunction against Defendants' imposition of a one hundred percent tariff increase on needles and syringes imported from The People's Republic of China pursuant to the Trade Act of 1974 ("Trade Act").

4. The resulting impact would not only force Retractable to shut down its operations, causing the loss of nearly two hundred high-paying American jobs, but also significantly impair both Retractable and the U.S. Government's ability to respond to a major public health emergency.

5. As more fully alleged herein, Retractable faces financial pressure due to its dominant competitor, Becton, Dickinson and Company ("BD"), who has openly supported the tariffs.

6. BD controls the majority of the U.S. syringe and needle market through its sheer size and its various efforts to keep Retractable from selling in major hospital systems.

7. These efforts have effectively forced Retractable to outsource its production to China.

8. Retractable's manufacturing in China sustains its current operations.

9. As more fully alleged herein, as part of a four-year statutory review of 2018 tariffs, USTR decided to impose new tariffs.

10. As to syringes and needles, these new tariffs were not considered or discussed in the four-year statutory review, but rather in an unrelated "supply chain resilience" inquiry.

11. Because of this, USTR did not provide notice of its intention to impose a syringe and needle tariff until it submitted a report to President Biden, urging him to impose a tariff, and before receiving any comments from Retractable.

12. Instead, as to syringes and needles, the one hundred and ninety three (193) page report (including annexes) contains a single sentence that addresses solely domestic source issues. This reflects the syringe and needle tariff's origin in an unrelated supply chain inquiry.

13. As to other categories of goods that the report recommends subjecting to tariffs, the report does consider trade practices and related reasons supporting a tariff.

14. The President then adopted USTR's recommendation to impose a tariff on syringes and needles in a Memorandum issued the same day as his receipt of the report.

15. After this Memorandum, USTR thereafter limited its inquiry to whether a syringe and needle tariff should exceed fifty percent, effectively cutting off Retractable and other interested parties (like the American Hospitals Association) from a meaningful opportunity to comment on these tariffs.

16. The USTR's final decision implementing a one hundred percent tariff on syringes and needles imported from China could drive Retractable out of business.

17. The two-week timeframe for tariff imposition makes it effectively impossible for Retractable to rebuild its supply chain in time to adapt to this tariff.

PARTIES

18. Plaintiff Retractable Technologies is a United States-owned business operating in Little Elm, Texas.

19. It has grown into a leading innovator and manufacturer of needles and syringes.

20. Defendant U.S. is the statutory defendant under 5 U.S.C. § 702 and 28 U.S.C. § 1581(i)(1)(B).

21. Defendant USTR is an executive agency of the U.S. charged with investigating a foreign country's trade practices under Section 301 of the Trade Act and implementing "appropriate" responses, subject to the direction of the President.

22. In matters of international trade, the USTR is the chief representative of U.S. responsible for negotiations and policy guidance.

23. Defendant Ambassador Katherine Tai serves as the director of USTR.

24. Defendant U.S. Customs and Border Protection ("CBP") is the agency that collects duties imposed under Section 301 on subject imports.

25. Defendant Troy Miller is the Acting Commissioner of CBP. In this capacity, he oversees CBP's collection of duties.

JURISDICTION

26. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1581(i)(1)(B), which confers "exclusive jurisdiction" to the Court over "any civil action commenced against the United States, its agencies, or its officers, that arises out of any law of the United States providing for … tariffs, duties, fees, or other taxes on the importation of merchandise for reasons other than the raising of revenue." 28 U.S.C. § 1581(i)(1)(B).

STANDING

27. Retractable has standing to sue because it is "adversely affected or aggrieved by agency action within the meaning of" the APA. 5 U.S.C. § 702; see 28 U.S.C. § 2631(i) ("Any civil action of which the Court of International Trade has jurisdiction … may be commenced in the court by any person adversely affected or aggrieved by agency action within the meaning of Section 702 of title 5.").

28. If implemented with respect to syringes and needles, the new tariffs imposed by Defendants will severely disrupt Retractable's supply chain and operations, leading to irreparable loss to Retractable's business.

FACTUAL BACKGROUND

A. Retractable Technologies' Founding

29. Retractable Technologies is a small U.S. owned company based in Little Elm, Texas.

30. It embodies the spirit of American entrepreneurship and ingenuity through its development and manufacturing of innovative syringe and needle technology.

31. It was founded by Thomas Shaw, a mechanical and structural engineer, who felt compelled to invent new syringe technology that could all but eliminate accidental needlestick injuries.

32. Shaw was inspired to do so in the late-1980s, when a close friend was diagnosed with AIDS, and after seeing a news story about a doctor being infected with HIV due to a needlestick injury.

33. After four years and more than 150 design changes, Shaw developed a prototype for a new innovative syringe.

34. Shaw was awarded a $50,000 Small Business Innovation Research grant from the National Institute on Drug Abuse, a subsidiary of the National Institutes of Health ("NIH"), to further develop his design concepts.

35. This publicly funded research resulted in VanishPoint, a patented syringe with a needle that automatically retracts after use, preventing needlestick injuries and helping curb the spread of infectious diseases.

36. Shaw later received an additional $500,000 of NIH grant funding to commercialize VanishPoint and produce products for clinical trials.

37. This research led Shaw to form Retractable Technologies, Inc. in 1997 in his hometown of Little Elm, Texas, a Dallas-Fort Worth suburb on the shores of Lake Lewisville.

38. The then-mayor of Little Elm called it "the project of the century," with local officials pitching in hundreds of thousands of dollars for roads and other city improvements to prepare for the influx of jobs that would come with Retractable Technologies' new plant.

39. Today, Retractable is a public company that has created thousands of high-paying American jobs since its inception.

40. The company currently holds the only effective technology to prevent cross-contamination during ongoing immunizations.

41. Retractable's success has been championed by both the Trump and Biden administrations, contributing to a combined investment of more than $138 million of Retractable funds and American taxpayer dollars to expand its operations in Little Elm, Texas.

B. Becton Dickinson and Retractable's Struggles in the Syringe Market

42. Despite this success, unfortunately, Retractable has found its efforts to promote its lifesaving technology stymied by Becton, Dickinson and Company ("BD").

43. BD is the world's largest manufacturer of injection devices and dominates the U.S. market with 70-80% of the hospital syringe and needle industry.

44. Producing billions of syringes and needles annually through its global network, BD operates manufacturing facilities in both Mexico and Nebraska. Its operations are unaffected by tariffs on syringe and needle imports China.

45. Shortly after Retractable's founding, BD entered into exclusive contracts with nearly all the U.S. hospital Group Purchasing Organizations (GPOs), effectively barring Retractable's entry into most hospitals

46. In 2001, Retractable filed an antitrust suit against Becton Dickinson and two GPOs (Novation and Premier), which settled out of court in 2003.

47. Retractable filed another antitrust lawsuit against BD years later.

48. The trial court found BD had infringed Retractable's patents (a finding affirmed on appeal) and set the case for a September 2023 jury trial.

49. The trial resulted in a verdict that BD had included false claims about Retractable in its advertising and a $340 million dollar jury verdict against BD (including trebling) for attempting to monopolize the syringe market.

50. BD managed to reverse this damages award on appeal.

51. Because of BD's near control of syringe production in the U.S., banks understandably are reluctant to provide loans or equity investments to support smaller medical device manufacturers such as Retractable. This has made it challenging for Retractable to invest in and grow its operations in Little Elm, Texas.

52. Moreover, GPO kickback schemes have made it ineffective for Retractable to interest hospitals systems based on price reduction and innovation.

53. Facing this hostile competitive environment and struggling to obtain bank loans or investment, Retractable was left with two options: either (1) declare bankruptcy (which would have terminated hundreds of employees and allowed government funded technology to be buried), or (2) approach Chinese suppliers to exchange Retractable's innovative syringe technology for Chinese tooling and assembly technology that Retractable desperately needs to survive.

54. Retractable chose to work with manufacturers in China, and it now relies on these key overseas partnerships to provide its innovative technology to the American public.

55. Moreover, its Chinese suppliers pay royalties to Retractable to license its patented innovative syringes, generating additional revenue for this American business to support its nearly two hundred employees.

56. With the help of these Chinese supply partners, Retractable managed to survive and eke out a tiny share of the syringe market with smaller contracts through government agencies, such as the Veteran's Administration, or other groups that negotiate directory with vendors (i.e., not through GPOs).

57. Retractable is also able to sell into systems that lack resources and are not large enough to interest GPOs, such as nursing homes and prisons.

58. Retractable's syringes sell at a price point of about one-third of BD's pricing before Retractable began bidding.

59. Thus, by simply existing in the marketplace, Retractable has caused BD to drop its prices almost two-thirds per syringe.

60. Upon information and belief, BD would realize an extra one-billion dollars or more in profits annually if it were able to eliminate Retractable as a competitor, notwithstanding Retractable miniscule market share.

C. USTR Declines to Impose a Syringe and Needle Tariff in 2018

61. On August 14, 2017, Former President Trump directed then-USTR Ambassador Lighthizer to consider initiating a targeted investigation pursuant to Section 301(b) of the Trade Act concerning China's laws, policies, practices, and actions related to intellectual property,

innovation, and technology. *Addressing China's Laws, Policies, Practices, and Actions Related to Intellectual Property, Innovation, and Technology*, 82 Fed. Reg. 39,007 (Aug. 17, 2017).

62. President Trump stated that certain Chinese "laws, policies, practices, and actions" on intellectual property, innovation, and technology "may inhibit United States exports, deprive United States citizens of fair remuneration for their innovations, divert American jobs to workers in China, contribute to our trade deficit with China, and otherwise undermine American manufacturing, services, and innovation." *Id*.

63. Section 301 of the Trade Act authorizes USTR to investigate a foreign country's trade practices. If the investigation reveals an "unreasonable or discriminatory" practice, USTR may take "appropriate" action, such as imposing tariffs on imports from the country that administered the unfair practice.

64. Four days later, on August 18, 2017, USTR formally initiated an investigation into "whether acts, policies, and practices of the Government of China related to technology transfer intellectual property, and innovation are actionable under [Section 301(b) of] the Trade Act." *Initiation of Section 301 Investigation; Hearing; and Request for Public Comments: China's Acts, Policies, and Practices Related to Technology Transfer, Intellectual Property, and Innovation*, 82 Fed. Reg. 40,213 (Aug. 24, 2017).

65. Seven months later, on March 22, 2018, USTR released a report announcing the results of its investigation. USTR found that certain "acts, policies, and practices of the Chinese government related to technology transfer, intellectual property, and innovation are unreasonable or discriminatory and burden or restrict U.S. commerce." OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, *Findings of the Investigation Into China's Acts, Policies, And Practices Related to Technology Transfer, Intellectual Property, and Innovation Under Section 301*

of The Trade Act of 1974 (Mar. 22, 2018), available at https://ustr.gov/sites/default/files/Section%20301%20FINAL.PDF.

66. On the same date, USTR published a "Fact Sheet" stating that "[a]n interagency team of subject matter experts and economists estimates that China's policies result in harm to the U.S. economy of at least $50 billion per year." OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, *Section 301 Fact Sheet* (Mar. 22, 2018), available at https://ustr.gov/aboutus/policy-offices/press-office/fact-sheets/2018/march/Section-301-fact-sheet.

67. USTR also indicated that, consistent with a directive from President Trump, it would "propose additional tariffs" of 25% *ad valorem* "on certain products of China, with an annual trade value commensurate with the harm caused to the U.S. economy resulting from China's unfair policies." *Id.*; *see Actions by the United States Related to the Section 301 Investigation of China's Laws, Policies, Practices, or Actions Related to Technology Transfer, Intellectual Property, and Innovation*, 83 Fed. Reg. 13,099 (Mar. 27, 2018) (President Trump's directive).

68. The initial proposal included one thousand three-hundred and thirty-three Harmonized Tariff Schedule of the United States ("HTS") subheadings of products that could be subject to the tariff, including HTS subheading 9018.31.00 for needles and syringes.

69. After USTR sought comment on the tariffs, which included specific reference to tariffs on syringes and needles, Retractable's Chief Executive Officer, Thomas Shaw, submitted comments explaining why this tariff would harm the public and would not accomplish the goals of Section 301 of the Trade Act.

70. Shaw's comments explained the anti-competitive impact that such a tariff would have, and the harm that the American people would suffer should Retractable be forced to shut down its business, particularly given the risk of further global health crises.

71. Shaw's comments stated what officials from the United States Health and Human Services' ("HHS")'s Biomedical Advanced Research and Development Authority told Retractable: that a global flu pandemic was a question of "when, not if."

72. USTR ultimately imposed Section 301 tariffs pursuant to its July 6, 2018, and August 23, 2018, actions, as modified ("Two Actions"), but did *not* impose a tariff on needles and syringes.

73. USTR also did not impose tariffs on syringes and needles when modifying the Two Actions to impose additional duties on supplemental lists of products.

D. Retractable Technologies' Critical Role During the COVID-19 Pandemic

74. As Shaw and HHS had presciently predicted, the COVID-19 pandemic became a reality in 2020.

75. During this time, the U.S. Government primarily relied on Retractable's innovative syringes due to the company's innovative technology and dependability.

76. Retractable's patented technology allowed healthcare workers to withdraw additional doses from COVID-19 vaccine vials, accelerating the vaccination rollout by twenty percent.

77. From 2020 to the beginning of 2023, Retractable shipped over 700 million safety syringes.

78. During the period, Retractable received seven total reports of needlestick injuries, *i.e.* an injury rate of one out of a hundred million, compared to average reported rates of nearly one out of every *ten thousand*.

79. In March 2021, Dr. Ashish Jha (who later served as the White House COVID czar), confirmed that Retractable's low dead space syringes, increased the COVID vaccine supply by twenty to forty percent.

80. This significant contribution led to a joint decision by the government and Retractable to fund an expansion of Retractable's operations.

81. Together, Retractable and the U.S. government committed approximately $138 million to establish additional production lines in Little Elm, Texas, to one day enhance domestic manufacturing capacity.

82. Government-funded machines could allow Retractable the ability to domestically produce safety vaccination syringes and needles in the event of a public health emergency.

83. However, the COVID project production lines are exclusively designated for vaccination products and cannot make other syringes and needles (e.g. certain insulin syringes) that Retractable needs to sell to have a full product catalog for its customers.

84. The earliest Retractable can make those other syringes and needles (e.g. certain insulin syringes) in America is 2025.

E. USTR's Statutory Four-Year Tariff Review Did Not Include Needles and Syringes

85. On May 5, 2022, USTR initiated a four-year statutory review of the Two Actions pursuant to pursuant Section 307(c)(3) of the Trade Act (19 U.S.C. 2417(c)(3)).

86. Section 307(c) of the Trade Act of 1974 requires USTR to review the effectiveness and economic impact of Section 301 actions every four years to keep the tariffs in force.

87. This statute also mandates that tariffs will terminate unless a petitioner or domestic industry beneficiary asks USTR to continue the tariffs in the sixty days before the close of this four-year period.

88. Thus, per the USTR's announcement, the review concerned whether any of the tariffs imposed in the Two Actions *were subject to possible termination* on their respective four-year anniversary dates (i.e., July 6, 2022, and August 23, 2022, respectively).

89. Essentially, this review concerned terminating or continuing *existing tariffs*, not adding new tariffs.

90. Accordingly, USTR sought comment from "representatives of domestic industries that benefit from the trade actions" who could ask that tariffs be continued, and not terminated. *See Initiation of Four-Year Review Process: China's Acts, Policies, and Practices Related to Technology Transfer, Intellectual Property, and Innovation*, 87 Fed. Reg. 26,797 (May 5, 2022).

91. Retractable did not submit comments concerning this notice because syringes and needles were not on the list of products under review.

92. On September 8, 2022, USTR announced that it would not terminate prior tariff actions based on the comments.

93. Pursuant to Section 307 of the Trade Act, USTR was then to required to "conduct a review" of such actions' "effectiveness in achieving the objectives of section 301 [of the Trade Act]."

94. This review was to also include a consideration of "other actions that could be taken (including actions against other products or services), and the effects of such actions on the United States economy, including consumers."

95. On October 17, 2022, USTR announced that it would conduct a review of the tariff actions pursuant to this requirement.

96. The October 17, 2022 announcement did not mention syringes or needles or indicate any intention to impose a tariff on HTS subheadings 9018.31.00 or 9018.32.00.

97. Retractable did not submit comments to this October 17, 2022 notice.

98. USTR received nearly 1,500 comments in response to this notice.

99. None of the comments referenced syringes or needles, or sought a tariff on syringes or needles.

F. USTR's Backdoor Introduction of a Syringe and Needle Tariff Proposal

100. USTR then formed a Section 301 Committee, a staff-level body of the USTR-led, interagency Trade Policy Staff Committee (TPSC).

101. Through 2023 and early 2024, this Section 301 Committee held numerous meetings with other agency experts, ostensibly regarding the review and the comments received.

102. During this time, upon information and belief, BD's Chief Executive Officer ("CEO") spoke with the Secretary of Commerce at the Department of Commerce and the White House National Economic Council to drum up support for a syringe and needle tariff.

103. BD's CEO has close ties to the Secretary of Commerce and worked with the Secretary during the COVID-19 pandemic to procure microchips for machines and tools for BD production lines for various medical devices.

104. He serves on the Secretary's Advisory Committee on Supply Chain Competitiveness, where he spoke about the need for government action for syringes and needles at an August 2023 meeting.

105. The August 2023 meeting also revealed that BD's CEO had conversations with National Economic Council Special Assistant to the President for Manufacturing & Industrial Policy in the White House about actions the federal government could take to support the domestic supply chain for drug delivery devices.

106. BD's CEO all but confirmed these discussions with the Secretary of Commerce in a 2024 interview with Jim Cramer while discussing the effect of higher prices for domestically manufactured medical devices.

107. On March 7, 2024, USTR published a notice to interested persons titled "Promoting Supply Chain Resilience," requesting comments on general considerations concerning domestic supply chains.

108. The Promoting Supply Chain Resilience notice was unrelated to the Section 301 inquiry.

109. This notice did not mention syringes or needles once, nor did it indicate any intention to impose a tariff on HTS subheadings 9018.31.00 (for syringes) or 9018.32.00 (for needles).

110. BD provided comments urging "USTR to leverage section 301 and other trade measures to protect our national security and public health in areas." Comment Letter from Elizabeth Woody, Senior Vice President, Public Affairs, BD, to Juan Millán, Acting Gen. Counsel, and Victor Ban, Assistant Gen. Counsel, Off. of the U.S. Trade Representative, Re: Comments on Promoting Supply Chain Resilience [Docket Number USTR-2024-0002] (Apr. 22, 2024).

111. Later, at a May 2, 2024 USDT hearing on supply chain resilience, a representative from the Coalition for a Prosperous America criticized U.S. reliance on Chinese syringe manufacturers, making inaccurate comments that the syringes are "substandard."

112. Upon information and belief, Coalition for a Prosperous America was at the time providing consulting services to BD.

113. Notably, The Antitrust Division of the United States Department of Justice ("DOJ") commented on this docket stating, "Any proposal to increase supply chain resilience that would result in increased consolidation in an industry that already is highly concentrated therefore should be with skepticism." Comment of the Antitrust Div., U.S. Dep't of Just. on Promoting Supply Chain Resilience [Comment ID USTR-2024-0002-0152] (Apr. 22, 2024).

G. USTR's Ultra Vires Proposal to Impose a Tariff

114. On May 14, 2024, USTR sent a report to President Biden entitled "Four-Year Review of Actions Taken in The Section 301 Investigation: China's Acts, Policies, And Practices Related to Technology Transfer, Intellectual Property, And Innovation" (the "Report").

115. The Report urged President Biden to consider new tariffs, including on syringes and needles.

116. The one hundred and ninety-three (193) page Report (including annexes) devotes only one sentence to syringes and needles.

117. In a wholly conclusory fashion, the Report asserts that "increasing section 301 duties on syringes and needles, which are critical to U.S. preparedness and response to public health emergencies, will help maintain alternative sources."

118. The same day, President Biden issued a "Memorandum on Actions by the United States Related to the Statutory 4-Year Review of the Section 301 Investigation" (the "Memorandum").

119. This Memorandum directs USTR to impose tariffs "no less than" those described in the Memorandum.

120. The Memorandum directed USTR to impose a tariff "For personal protective equipment (facemasks, medical gloves, and syringes and needles)."

121. Notably, syringes and needles are not personal protective equipment ("PPE").

122. Also notably, President Biden's Memorandum directed the highest increase of PPE tariffs for syringes and needles, directing USTR to "[i]ncrease rate to 50 percent in 2024."

123. Section 307 of the Trade Act (in pertinent part) also allows USTR to "modify or terminate" an action taken pursuant to Section 301 of the Trade Act either when the "burden or restriction on United States commerce" imposed by the investigated foreign country's practice has "increased or decreased" or when the action "is no longer appropriate."

124. Moreover, Section 307 of the Trade Act's modification is limited to actions "being taken under Section 301."

125. Notably, USTR did not undertake an analysis of any Section 301 factors in connection with the proposed syringe and needle tariff.

126. Its Report to the President discusses Chinese trade policies and other Section 301 factors as to all other categories of new tariffs, *except syringes and needles*.

127. In addition, USTR did not consult with Retractable before proposing this tariff.

128. Section 307 of the Trade Act requires that the Trade Representative "shall consult with the petitioner, if any and with representatives of the domestic industry concerned, and shall provide opportunity for the presentation of views by other interested persons affected by the proposed modification or termination concerning the effects of the modification or termination and whether any modification or termination of the action is appropriate" before taking any action.

129. Here, USTR did not consult with Retractable or even provide it with adequate notice prior to advising the President to impose a needle and syringe tariff.

130. By the time Retractable had notice and could submit comments, USTR had already limited its inquiry to whether a tariff should exceed fifty percent.

131. Indeed, USTR's May 28, 2024, request for comments on the tariff explicitly limits its inquiry on syringe and needle tariffs to whether tariffs should be greater than fifty percent.

H. Retractable's Attempts to Consult with Government Officials

132. Retractable's Project Manager and internal public affairs consultant, Woot Lervisit, submitted comments to USTR on June 4, 2024 about supply chain resiliency with information specifically regarding syringes and needles.

133. His comments echoed the DOJ's concerns to ensure that tariffs were not used for anticompetitive purposes. Comment from Woot Lervisit, Project Manager, Retractable Techs., Inc., to Juan Millan, Acting Gen. Counsel, & Victor Ban, Special Counsel, Off. of the U.S. Trade Representative, on Promoting Supply Chain Resilience [Comment ID USTR-2024-0002-0293] (June 4, 2024).

134. Lervisit also submitted comments for Retractable concerning the tariff on June 28, 2024.

135. These comments explained that the fifty percent tariff would devastate Retractable. The comments also explain how the tariff will favor big businesses.

136. Meanwhile, BD submitted comments requesting "maximum tariff level available."

137. During this time, Lervisit spoke with the Section 301 Committee Co-Chair and other federal officials, but he was repeatedly told it was too late to challenge the tariff or the failure of USTR to consult with Retractable.

I. USTR Imposes One Hundred Percent Tariffs in Two Weeks

138. On September 13, 2024, USTR issued a press release announcing a one hundred percent tariff on syringes and needles, effective September 27, 2024.

139. USTR published a notice to this effect on September 18, 2024.

140. USTR never explained how Retractable's comments factored into its decision.

141. Notably, this decision exceeds the President's directive which sought tariff no less than fifty percent tariff in 2024.

142. Instead, USTR seeks to impose a one hundred percent tariff, essentially immediately.

143. USTR's decision does not appear to be based on its inquiry into Chinese practices related to intellectual property transfer.

144. As stated in the Report, the decision purely arises out of domestic supply concerns for "alternative sources."

145. The reason for this is that USTR received no comments concerning syringes and needles in its section 301 inquiry prior to drafting the Report. Rather, these comments came from a wholly unrelated inquiry on domestic supply chain resiliency.

146. After receiving a request from both Georgia Senators, USTR also issued a tariff exclusion for enteral (feeding) syringes, effective until January 1, 2026.

147. One of the largest enteral syringe manufacturers is in Georgia, a key state in the upcoming election.

J. Retractable Will Suffer Irreparable Harm

148. Retractable cannot comply with the imposed *ad valorem* tariff of one hundred percent on the two-week timeline provided by USTR.

149. Retractable has long standing relationships with manufacturers in the People's Republic of CHina that would need to be renegotiated, and this will take time.

150. It will also take time to establish new contracts and supply chains.

151. In addition, Retractable's domestic supply capabilities will not be validated and cleared until 2025.

152. Given the price point of its syringes, Retractable will be forced to sell tariffed syringes and needles at a loss if it were to place any further orders with its Chinese suppliers under the proposed tariff regime.

153. At present it is expecting shipments of syringes and needles to arrive from China in October, all of which will be subject to a one hundred percent *ad valorem* tariff.

154. Retractable simply cannot afford to place orders and sell these syringes at a loss.

155. At the same time, Retractable's customers will need syringes, and if Retractable is unable to supply them it is likely to lose those customers and significant business goodwill.

156. Were Retractable to attempt to cut overhead by reducing employee payroll, this could send the company into a death spiral.

157. Ultimately, were Retractable to shutter as a business, this would mean that government backed and funded life-saving technology would be buried, harming the U.S. healthcare system and the American people.

FIRST COUNT

(Preliminary Injunction)

158. Plaintiff repeats and realleges the preceding paragraphs of the Complaint as if more fully stated here.

159. Retractable is likely to suffer irreparable harm absent an injunction.

160. The severity of the tariff forces Retractable into an impossible choice between stopping all orders of syringes from its suppliers, or ordering and selling syringes at a loss.

161. Retractable will need time to renegotiate supply contracts or increase domestic capacity, which it cannot do on the two week timeline imposed by USTR.

162. Moreover, Retractable is likely to succeed in its claim that the tariff was wrongly imposed.

163. USTR did not impose this tariff as the result of a Section 301 inquiry, but rather an unrelated "supply chain resilience" inquiry.

164. Thus, the imposition of the tariff is not a valid exercise of USTR's review or modification powers under Section 307 of the Trade Act.

165. Moreover, USTR never consulted Retractable as required under Section 307 of the Trade Act.

166. In addition, USTR failed to give Retractable fair notice or an opportunity to be heard before deciding to impose this tariff.

167. Finally, USTR's decision was arbitrary and capricious as it does not reflect a rational analysis of any trade factors, inconsistently excludes enteral syringes from the tariff, and imposes a tariff that will actual harm domestic supply chain resiliency.

168. Further, the equities favor Retractable, who will suffer irreparable harm absent an injunction, over USTR and the U.S., who will merely suffer a delay in collecting tariffs should the injunction wrongly issue.

169. Finally, the public interest supports granting an injunction due to the need to preserve Retractable as a business and its provide access to its government funded, patented technology.

170. Plaintiff is therefore entitled to a preliminary injunction.

SECOND COUNT

(Declaratory Judgment – Violation of Trade Act of 1974 19 U.S.C. § 2411 et seq.)

171. Plaintiff repeats and realleges the preceding paragraphs of the Complaint as if more fully stated here.

172. The Declaratory Judgment Act authorizes any court of the United States to "declare the rights and other legal relations of any interest party seeking such declaration, whether or not further relief is or could be sought." 28 U.S.C. § 2201(a).

173. Section 307 of the Trade Act provides that already imposed Section 301 tariffs will expire in four years absent a petition or request from a domestic industry that benefits to continue the tariffs.

174. This four-year review does not authorize USTR to enact new tariffs except pursuant to its modification authority under Section 307.

175. But this modification authority concerns tariffs imposed under Section 301 of the Trade Act.

176. Thus, any modification must be based on some section 301 inquiry.

177. The tariffs at issue here were not based on any section 301 inquiry.

178. Moreover, Section 307(a)(2) of the Trade Act expressly requires the USTR to "consult with ... representatives of the domestic industry concerned" before modifying or terminating any action under Section 301 (emphasis supplied). 19 U.S.C. § 2417(a)(2).

179. Here, USTR failed to consult with any representative of Retractable, a member of the domestic industry concerned with the needle and syringe tariff.

180. Plaintiff is therefore entitled to a declaratory judgment that Defendants' actions were unauthorized by the Trade Act and are an ultra vires and invalid tariff imposition.

THIRD COUNT

(Violation of Administrative Procedure Act 5 U.S.C. § 551 et seq.)

181. Plaintiff repeats and realleges the preceding paragraphs of the Complaint as if more fully stated here.

182. USTR urged President Biden to impose a syringe and needle tariff without engaging in any Section 301 Trade Act inquiry or notifying concerned industry representatives such as Retractable.

183. After the President issued his Memorandum, USTR issued a request for comments regarding new tariffs.

184. Ultimately, it decided to impose tariffs in excess of the minimum tariff directed by the President and on a faster time frame than directed by the President

185. For these and other reasons, the USTR's action is an agency action subject to Administrative Procedure Act ("APA") review.

186. The APA requires reasoned decision-making and consideration of relevant factors to support agency action.

187. The APA further requires a Court to hold unlawful and set aside agency action that is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.

188. It also requires setting aside agency action that is in excess of statutory jurisdiction, authority, or limitations, or short of statutory right

189. It further requires setting aside agency action that is without observance of procedure required by law, or unsupported by substantial evidence.

190. USTR's actions in imposing a one hundred percent *ad valorem* tariff on syringes and needles were arbitrary and capricious, in excess of USTR's statutory authority, done without observance of procedure required by law, and unsupported by substantial evidence.

191. Indeed, it does not appear that USTR considered Retractable's comments whatsoever, given the artificially limited scope of its inquiry.

192. Moreover, the USTR's action was not based on a rationale consistent with Section 301 of the Trade Act.

193. The USTR's action will also promote a needle and syringe monopoly, harming the U.S. healthcare system and the American people.

194. Therefore, this court should hold unlawful and set aside USTR's imposition of a one hundred percent *ad valorem* tariff on HTS subheadings 9018.31.00 (for syringes) and 9018.32.00 (for needles) imported from the People's Republic of China.

PRAYER FOR RELIEF

Wherefore, Plaintiff respectfully requests that this Court issue an order:

(1) preliminarily enjoining Defendants from imposing tariffs on HTS subheadings 9018.31.00 (syringes) and 9018.32.00 (needles) imported from the People's Republic of China until resolution of Retractable's claims in this proceeding;

(2) enjoining CBP from assessing any tariffs on HTS subheadings 9018.31.00 (syringes) and 9018.32.00 (needles) imported from the People's Republic of China until resolution of Retractable's claims in this proceeding;

(3) enjoining liquidation of any assessed items of HTS subheadings 9018.31.00 (syringes) and 9018.32.00 (needles) imported from the People's Republic of China until resolution of Retractable's claims in this proceeding

(4) declaring that the one hundred percent *ad valorem* tariffs on HTS subheadings 9018.31.00 (syringes) and 9018.32.00 (needles) imported from the People's Republic of China are invalid as an ultra vires exercise of USTR authority under the Trade Act

(5) setting aside as unlawful and invalidating tariffs of HTS subheadings 9018.31.00 (syringes) and 9018.32.00 (needles) imported from the People's Republic of China under the APA;

(6) awarding Plaintiff its costs and reasonable attorney fees; and

(7) granting such other and further relief as may be just and proper.

Dated: September 26, 2024
New York, New York

Respectfully submitted,

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