UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.

In the Matter of	)	
CERTAIN BOTULINUM TOXIN PRODUCTS, PROCESSES FOR MANUFACTURING OR RELATING TO SAME AND CERTAIN PRODUCTS CONTAINING SAME	)	**Investigation No. 337-TA-1145**

COMMENTS OF THE AMERICAN ANTITRUST INSTITUTE ON THE PUBLIC-INTEREST ISSUES

The American Antitrust Institute ("AAI") submits these public-interest comments pursuant to 19 CFR 210.50(a)(4) and the Commission's September 21 notice and schedule regarding its decision to review in part the Final Initial Determination ("FID"). AAI is an independent nonprofit organization devoted to promoting competition that protects consumers, businesses, and society. It serves the public through research, education, and advocacy on the benefits of competition and the use of antitrust enforcement as a vital component of national and international competition policy. *See* http://www.antitrustinstitute.org. AAI has a longstanding interest in ensuring a proper balance between intellectual property rights and competition to advance innovation and consumer welfare.

The FID is not in the public interest because it creates perverse incentives for dominant U.S. firms to purchase protection from competition. In this otherwise complex matter, three facts inform this problem. First, Complainant Medytox, a foreign firm that produces a foreign Botulinum Toxin product, allegedly owns a foreign trade secret that was allegedly misappropriated by another foreign firm (Respondent Daewoong) in a foreign country (Korea). Second, Medytox's foreign trade secret claim creates potential exclusionary rights against

Daewoong exclusively in Korea. Third, Co-Complainant Allergan, through its U.S. licensing arrangement with Medytox, now purports to assert Medytox's Korean exclusionary rights as the basis for an ITC exclusion order preventing Daewoong from entering the U.S. market through its U.S. counterpart Evolus, notwithstanding that Allergan maintains a monopoly in the U.S. Botulinum Toxin market through its well known Botox product.

Together, these facts raise fundamental questions as to whether allowing Allergan to seek an exclusion order on the basis of Medytox's Korean exclusionary rights would work for or against the basic goals of Section 337. The FID fails to consider or address these questions.

Under sound principles of competition policy, U.S. firms cannot be given an unfettered right to purchase a foreign firm's exclusionary rights. If a dominant U.S. firm can acquire a foreign firm's exclusionary rights when they become actionable and then use them to obtain an exclusion order to prevent competitive entry into the United States, the dominant U.S. firm will have a strong economic incentive to buy the rights, and the foreign firm often will have a strong economic incentive to sell them, without regard to the underlying innovation to which the rights attach. The result will be distorted markets for the affected products and significant anticompetitive harm to U.S. consumers, without any legitimate, corresponding protections for U.S. intellectual property.

Respondents correctly observe that it is contrary to the mission and policy of the ITC to "open the doors to U.S. courts or the ITC for foreign disputes over alleged foreign trade secrets that were allegedly misappropriated abroad." Pet'n for Rev. at 45–46. AAI emphasizes that this is independently problematic as a matter of U.S. competition policy. The FID leaves no room for the Commission to account for the serious risk that companies like Allergan will enter licensing arrangements with companies like Medytox as a pretext for transplanting exclusionary

rights from foreign markets to U.S. markets to shield monopolies. If a rational U.S. monopolist is able to purchase the right to exclude competition in the United States, it should be expected to pay any amount up to the difference between its monopoly profits and the normal profits it would earn in a competitive market to do so. The foreign firm, likewise, will sell its U.S. exclusionary rights whenever it can earn more from the sale than it can earn from competing. And where, as here, there is a monopoly profit available to be divided, a shared anticompetitive incentive can arise not only for the firms to make a pretextual, anticompetitive rights transfer, but also to conceal the nature and purpose of the transfer from regulators and antitrust authorities.

The U.S. experience with reverse-payment settlements of pharmaceutical patent infringement claims under the Hatch-Waxman Act illustrates the incentives that lead firms to engage in such pretextual transfers and disguise them. The Hatch-Waxman Act allows generic drug manufacturers to enter a U.S. pharmaceutical market prior to the expiration of a brand manufacturer's patent term if the generic can certify to the Food & Drug Administration that the brand's patent is invalid or will not be infringed. The Act gives generics an inducement to do so by awarding a 180-day period of marketing exclusivity to the first generic to file the certification. The exclusivity period can be worth several hundred million dollars to the generic firm.

Brand firms quickly realized they could game the Hatch-Waxman system because, faced with the threat of competitive entry, both the brand firm and the generic firm stand to earn more money by splitting the monopoly profit than by competing with each other. *See* Aaron Edlin, Scott Hemphill, Herbert Hovenkamp & Carl Shapiro, *Activating Actavis*, 28 Antitrust 16, App'x (2013) (specifying the economic model under which brand and generic firms mutually profit when they divide the monopoly profit and delay competitive entry). Only consumers, whose drug prices would remain high, and who would be denied the benefits of a competitive process,

stand to lose. For years, the federal courts, to the detriment of consumers, adopted a permissive standard that allowed branded and generic drug manufacturers to enter such "pay-for-delay" agreements provided that generic entry was not delayed beyond the length of the patent term. *See* Michael Kades, *Underestimating the Cost of Underenforcing U.S. Antitrust Laws*, Wash. Center for Equitable Growth (Dec. 13, 2019) (describing "scope of the patent" test that cost consumers over $63 billion).

In 2013, however, the Supreme Court recognized that "it would be incongruous to determine antitrust legality by measuring the settlement's anticompetitive effects solely against patent law policy, rather than by measuring them against procompetitive antitrust policies as well." *FTC v. Actavis, Inc*., 570 U.S. 136, 148 (2013). The Court held that large "settlement" payments from brands to generics that are unjustified by reasonable litigation costs are illegal under antitrust law where "[t]he payment in effect amounts to a purchase by the patentee of the exclusive right to sell its product." *Id*. at 153.

Brand and generic firms responded to the *Actavis* ruling by attempting to disguise their exclusion payments using in-kind rather than cash transfers, including, as relevant here, by entering into pretextual licensing arrangements. *See, e.g., FTC v. AbbVie Inc.*, No. 18-2621, 2020 WL 5807873, at *17–18 (3d Cir. Sept. 30, 2020) (brand settled infringement litigation by licensing generic on terms that netted a $100 million loss to brand and $100 million gain to generic). But under U.S. antitrust law, paying another firm for the right to exclude competition and maintain a monopoly is equally problematic—and illegal—regardless of whether the payment is in cash or in kind. *Id*. at *17.

By evaluating Complainants' expansive subject matter jurisdiction, standing, and domestic industry claims in strictly formalistic terms, the FID adopts the incongruous approach

that the Supreme Court rejected in *Actavis*. It also turns a blind eye to the risks and costs of encouraging pretextual cash or in-kind foreign rights transfers, effectively creating a market for such transfers dedicated to nothing more than gaming and abusing Section 337 to anticompetitive ends. The lengths to which pharmaceutical IP owners have already gone toward such ends, including Allergan in particular, belie any wisdom in such a credulous approach. *See, e.g., Tawfilis v. Allergan, Inc.*, No. 8:15-cv-00307 (filed Feb. 24, 2015) (denying motion to dismiss claims that Allergan's licensing arrangement with Medytox is a pretextual market allocation scheme that violates Sherman and Cartwright Acts); Complaint, *In the Matter of Allergan, Inc. and Inamed Corp.*, Docket No. C-4157 (F.T.C. filed Mar. 7, 2006) (describing government challenge to anticompetitive merger in which Allergan sought to purchase "the expected first serious competitor to Botox"); *see also Allergan, Inc. v. Teva Pharm. USA, Inc.*, No. 2:15-CV-1455-WCB, 2017 WL 4619790, at *2 (E.D. Tex. Oct. 16, 2017) (describing Allergan payments to a Native American Tribe "to purchase—or perhaps more precisely, to rent—the Tribe's sovereign immunity" from patent challenge); Complaint, *FTC v. Allergan*, No. 3:17-CV-00312 (N.D. Cal. filed Jan. 23, 2017) (describing novel Allergan pay-for-delay agreement involving hidden, in-kind payment).

III. Conclusion

If the FID is not overturned, the ITC risks becoming a "market maker" for the sale of foreign exclusionary rights to U.S. firms and facilitating monopolists' efforts to appropriate U.S. consumer surplus without any corresponding benefits to the legitimate protection of U.S. intellectual property rights. Because it creates perverse incentives without serving the underlying goals of U.S. competition or intellectual property policy, the Commission should not allow the FID's formalistic approach to stand.