

Evolus, Inc.
International Trade Commission (“ITC”) FAQ

What is the nature of the ITC action between Allergan and Medytox on the one hand, and Daewoong and Evolus on the other hand?

On January 30, 2019, Allergan and Medytox filed a complaint against Evolus and Daewoong in the U.S. International Trade Commission (ITC) alleging a violation of Section 337 of the Tariff Act of 1930. The complaint alleges that Daewoong, a Korean pharmaceutical company, misappropriated certain Korean trade secrets of Medytox, another Korean pharmaceutical company. Specifically, it was alleged that Daewoong misappropriated (i) Medytox’s *clostridium botulinum* strain and (ii) Medytox’s manufacturing process for producing a product known as “Meditoxin.” It is further alleged that those misappropriated trade secrets are used by Daewoong to manufacture botulinum toxin products, specifically Jeuveau®, which is imported into the United States.

Separately, there is a case pending in South Korea directly between Medytox and Daewoong related to this same dispute, which has been ongoing since 2017.

Why is Evolus named in the case?

Evolus owns a license to distribute Jeuveau® in the United States, in addition to other regions around the world. As the importer of Jeuveau® into the United States, Evolus is subject to the ITC’s jurisdiction and decision-making.

Does this case pertain to BOTOX® trade secrets?

No. The allegedly misappropriated trade secrets relate to a developmental liquid botulinum toxin product created by Medytox, known as MT10109L. Those trade secrets are not used to manufacture BOTOX®, BOTOX® Cosmetic, or any other commercially available botulinum toxin product sold by Allergan. For background, Medytox licensed MT10109L to Allergan in 2013. At this time, MT10109L remains a development stage product and is not approved by the U.S. FDA or available for sale in the United States.

What is the procedural history of the ITC case?

- **January 30, 2019:** Allergan and Medytox filed a complaint with the ITC.
- **July 7, 2020:** The Administrative Law Judge (ALJ) assigned to the ITC action to which we are a party issued an initial determination in which the judge found a violation of Section 337 of the Tariff Act of 1930 had occurred by reason of a misappropriation of trade secrets and recommended the entry of a limited exclusion order that would prevent us from importing Jeuveau® into the United States for a period of ten years and a cease and desist order that would prevent us from selling Jeuveau® in the United States for the same period of time.

- **July 20, 2020:** Daewoong and Evolus filed a petition for review of the ALJ's initial determination with the ITC. Specifically, the petition for review raised important legal, jurisdictional, and factual errors with the initial decision.
- **September 25, 2020:** The ITC provided notice of its intention to review the ALJ's initial determination. Specifically, it undertook to review the initial determinations findings with respect to subject matter jurisdiction, standing, trade secret existence and misappropriation, and domestic industry, including the existence of such domestic industry as well as any actual or threatened injury thereto.
- **October 22, 2020:** The ITC announced its decision to extend the target date for its final determination from November 6, 2020 to November 19, 2020.
- **November 19, 2020:** The ITC announced its decision to extend the target date for its final determination from November 19, 2020 to December 16, 2020.
- **December 16, 2020:** Target date for the ITC's final determination.

When will this case conclude?

A final determination by the ITC is currently expected to be issued on December 16, 2020. In the event that the ITC issues an exclusion order or cease and desist order as part of such final determination, the final determination is then subject to a 60-day presidential review period before becoming final.

Is an appeal possible?

Any person adversely affected by an ITC decision under Section 337 may appeal the decision to the U.S. Court of Appeals for the Federal Circuit.

Is a settlement possible?

Yes. Settlement is often how legal cases are resolved in order to reduce risk and solve legal issues. Settlements may allow for a more constructive use of resources, which is especially important when one company has significantly greater financial resources than the other.

Evolus maintains that it desires a fair solution to this expensive and distracting case. Evolus will consider reasonable settlement terms that allow the company to continue operating its start-up enterprise and investing in marketing programs to support its customers and their patients. Evolus believes that any settlement arrangement should be designed to enhance competition and not unfairly disadvantage small companies or seek to put them out of business.

Evolus does not comment on whether settlement discussions are in progress or on the status of any potential settlement discussions.