

# Court of International Trade Ruling Provides Tariff Relief for Cell Culture Bioreactors

*January 18, 2012 by Curt Dombek and Mark Jensen*

A recent ruling from the U.S. Court of International Trade has the potential to reduce customs duties significantly for some biotechnology companies. In *Applikon Biotechnology Inc. v. United States*, 07-364 (Ct. Int'l Trade Dec. 12, 2011), the court changed the tariff classification of Cell Culture Bioreactors from heading 8419, "machinery...for the treatment of materials by a process involving a change of temperature", to heading 8479, "machines...having individual functions, not specified or included elsewhere in this chapter; parts thereof." The change resulted in a zero rate of duty instead of the 4.2% rate that had previously been imposed under the classification given by U.S. Customs and Border Protection ("CBP").

The court described Cell Culture Bioreactors as machines that act to maintain an aseptic and homogeneous environment in which to culture cells, especially bacteria, that are used to break down harmful substances. The cells are grown for use in various applications in research or process development, including the development of biopharmaceuticals.

In its ruling, the court found a stirring component that allows continuous mixing of cell culture to be a key mechanism of bioreactor systems in their primary function of maintaining an aseptic and homogeneous environment for the growth of cells. Although the equipment also included a temperature control function that was used and necessary for some applications, the court concluded that temperature control was "subsidiary to the primary function of the device." In making the distinction, the court noted that the mixing function was always used when the Bioreactor System is in operation, and that the electric blanket used for heating was not imported with the system and not always used. The court thus distinguished the Cell Culture Bioreactors from machines that involved heating or cooling of DNA strands, *Applied Biosystems*, 715 F. Supp. 2d 1327 (2010), and the CPU of mainframe computer systems, *Fujitsu America*, 342 F. Supp. 2d 1326 (2004).

The court's ruling, and the accompanying savings that will accrue to biotechnology companies under the ruling, underscore the importance of proper tariff classification according to the primary function of complex or novel items. In part because biotechnology equipment does not have its own tariff classification provision, classification of biotechnology items can be more difficult than other equipment. In this case, for example, the plaintiff initially proposed three separate alternative tariff classifications, two of which fell under entirely different tariff headings. The *Applikon* case demonstrates the potential benefit of close company attention to tariff classifications affecting biotech products and the willingness to use new classifications where warranted by the facts and applicable law.