

**UNITED STATES COURT OF INTERNATIONAL TRADE**

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APPLIKON BIOTECHNOLOGY, INC.,	:	
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Plaintiff,	:	
	:	
v.	:	Before: R. Kenton Musgrave, Senior Judge
	:	Consol. Court No. 07-00364
UNITED STATES,	:	
	:	
	:	
Defendant.	:	

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**OPINION**

[On cross motions for summary judgment of classification of bioreactor systems, judgment for the plaintiff.]

Decided: December 12, 2011

*Law Offices of George R. Tuttle, A.P.C. (Carl D. Cammarata), for the plaintiff.*

*Tony West, Assistant Attorney General; Barbara S. Williams, Attorney-In-Charge, International Trade Field Office, Commercial Litigation Branch, Civil Division, U.S. Department of Justice (Beverly A. Farrell and Justin R. Miller), Office of the Assistant Chief Counsel, International Trade Litigation, U.S. Customs and Border Protection (Michael W. Heydrich), of counsel, for the defendant.*

Musgrave, Senior Judge: Plaintiff Applikon Biotechnology, Inc. (“Applikon”) challenges U.S. Customs and Border Protection’s (“Customs”) classification of “BioBundle Cell Culture Bioreactor Systems” and “ez-Control Cell Culture BioBundle Bioreactor Systems” imported from the Netherlands (both referred hereafter as the Bioreactor Systems). Proper administrative

protest procedure having been undertaken and all liquidated duties, taxes and fees having been paid,<sup>1</sup> *see* 19 U.S.C. §§ 1514, 1515, jurisdiction is proper pursuant to 28 U.S.C. § 1581(a).

### I. *Description of the Merchandise*

A “bioreactor” is “a device or apparatus in which living organisms and esp[ecially] bacteria synthesize useful substances (as interferon) or break down harmful ones (as in sewage).” *Merriam Webster Collegiate Dictionary* (10th ed. 1996). As their names imply, Applikon’s Bioreactor Systems maintain an aseptic and homogenous environment in which to culture cells. *See* Def. Ex. F (Autoclavable BioBundle 3L Manual) at 3-4. The homogeneous environment is accomplished by continuous mixing or stirring of the cell culture, and mixing is routinely utilized when operating the Bioreactor System.<sup>2</sup> The principal function of the Bioreactor is to grow cells in

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<sup>1</sup> The protests are numbered 2809-07-100575, dated August 31, 2007, denied September 21, 2007, and 2809-08-100604, dated November 5, 2008, denied March 30, 2009.

<sup>2</sup> Plaintiff’s Concise Statement of Facts (“Pl’s Stmt. of Facts”) ¶ 32. The facts cited in this opinion and averred in Pl’s Stmt. of Facts are either admitted by the government or deemed admitted because the government’s objections thereto were inapposite and unpersuasive. Mere “conclusory statements, conjecture, or speculation by the party resisting the motion will not defeat summary judgment.” *Kulak v. City of New York*, 88 F.3d 63, 71 (2d Cir. 1996) (citation omitted). As our appellate court stated recently:

The trial court found that Processed failed to allege facts sufficient to support a conclusion that the primary use of the backpacks and beach bag is as a toy (*i.e.*, for play). We discern no error in that finding. As noted by the trial court, “It is well settled that a conclusory statement on the ultimate issue does not create a genuine issue of fact.” *Applied Cos. v. United States*, 144 F.3d 1470, 1475 (Fed. Cir. 1998) (internal quotations and citation omitted). Also, as noted by the trial court, the nonmovant “must point to an evidentiary conflict created on the record at least by a counter statement of fact or facts set forth in detail.” *Barmag Barmer Maschinenfabrik AG v. Murata Machinery, Ltd.*, 731 F.2d 831, 836 (Fed. Cir. 1984).

*Processed Plastic Co. v. United States*, 473 F.3d 1164, 1170 (Fed. Cir. 2006).

an aseptic, homogeneous environment, and that homogeneous environment is maintained by the mixing function. Pl's Stmt. of Facts ¶¶ 16-17.

The cells are grown in the Bioreactor System for various applications in research or process development, such as for use in biopharmaceuticals, antibodies, enzymes, vaccines, antibiotics, vitamins, food additives, alcoholic beverages, biofuels, for commercial or organic waste treatment, or plant cell technology, all of which are referred to as the "cell culture process." A typical use is in the development of biopharmaceuticals where the bench-size Bioreactor Systems serve as smaller research and test environments before upscaling for production in larger bioreactors used in production. Pl's Stmt. of Facts ¶ 31.

In their imported condition, both of the Bioreactor Systems consist of three major components. They are the Bioreactor, the Controller, and the Actuator. In the BioBundle System the Controller and Actuator are housed in separate cabinets, and in the ez-Control System they are both housed in one cabinet. In both Bioreactor Systems the principal component, in which the cell culture process occurs, is the bioreactor vessel. This consists of a dish-bottomed glass vessel configured with a stirring mechanism that is integral to sealing the vessel in set-up and the maintenance of the aseptic environment necessary for the cell culture process. The bioreactor stirrer motor and stirrer assembly rest on the bioreactor headplate so that the stirrer assembly shaft and impeller extend into the bioreactor vessel to continuously mix the liquid cell culture at a set rate of agitation to both prevent the cells from settling on the bottom of the bioreactor vessel and to uniformly expose them to the desired environment. Pl's Stmt. of Facts ¶ 18. "[O]nce the vessel is sterilized, the vessel is sealed to maintain the sterile environment, and the stirrer assembly is a

critical part of that sealing function.” Pl’s Reply to Def’s Resp. to Pl’s Statement of Material Facts Not in Genuine Dispute (“Pl’s Fact Reply”) at 46.

In addition to the bioreactor (consisting of the bioreactor vessel and the mechanical bioreactor mixing equipment), both Bioreactor Systems include equipment used to control mixing and optional functions, such as control of pH, dissolved oxygen, level/anti-foam and temperature. Pl’s Stmt. of Facts ¶ 15. These functions are configurable using a combination of eight digital and five analogue outputs, and twelve actuators incorporating various devices (pumps, valves, solenoid valves, motor speed controller, thermal mass flow controllers, rotameters, *et cetera*) which maintain the selected parameter set-points. The controller measures the process variables and calculates corresponding controller outputs in order to keep process conditions on set point. The controller’s functions are integrated into and complete the Bioreactor System. They are operated by adjusting the controller’s setpoints for the desired parameters, switching on the “thermocirculator,” stirrer motor, acid and/or base pumps and gas flow, and when the parameters reach their desired setpoints, the bioreactor is ready for inoculation. *See* Def. Ex. B (Autoclavable Bioreactor User Manual) at 3-2.

Utilization of the functions for control of pH, dissolved oxygen, or temperature, is optional and dependant on the type of cell culture being grown. However, when utilizing any of these optional functions, the mixing function must still be used in order to effectively control the optional functions. Pl’s Stmt. of Facts ¶ 33. Cells will die without mixing operations. Pl’s Stmt. of Facts ¶ 35. The continuous mixing or stirring of the liquid cell culture ensures that all cells will have equal access to the contents of the medium in which they are suspended. The mixing of the medium provides the cells with proper exposure to dissolved culture medium components, dilutes harmful

cell waste products, and is necessary to effectively control other parameters, such as the pH, dissolved oxygen, or temperature. PI's Stmt. of Facts ¶ 34.

Mammalian cell culture, for which the Bioreactor Systems are mainly sold, requires a temperature of approximately 37 degrees Celsius (*i.e.*, human body temperature), which is normally well above ambient room temperature. PI's Stmt. of Facts ¶ 37, and Def. Response thereto. The merchandise as imported includes temperature control features but does not include the electric heating blanket, which is procured separately in the U.S. by Applikon and packaged with the devices after importation. PI's Stmt. of Facts ¶ 26. The electric heating blanket is plugged into the actuator, and is not a permanent part of the Bioreactor System. Def's Resp. to PI's Stmt. of Facts ¶ 38. The heating blanket function is triggered when the medium's temperature drops by as little as 0.1 degree Celsius. Def. Ex. A at 4. The BioBundle literature describes the heating blanket "as an alternative for a thermocirculator" to maintain a desired temperature when wrapped around the bioreactor vessel containing the medium.

"For an optimum performance [*sic*] of any biological system, it is necessary to keep the environment of the micro-organisms at optimal conditions. Apart from temperature and medium composition, the two most important factors that effect [*sic*] this environment are the degree of mixing and aeration[.]" according to Applikon's literature. *See* Def. Ex. B at 2-1. Optimal temperature can be maintained by placement of the bioreactor vessel in a temperature-controlled room or an external temperature-controlled medium (such as hot water).

It is not the customary practice (although it can be done) for the user to add cold medium to the bioreactor vessel and then use the heating blanket and temperature control to raise the temperature of the medium to the desired set point; the medium is almost always pre-warmed

in a water bath or warm room overnight before starting the experiment in the bioreactor and the combination of pre-warmed medium and cells are then added to the bioreactor. Pl.'s Fact Reply ¶ 39. The Bioreactor Systems are not apparatus that only or principally function to control temperature automatically. Def's Resp. To Pl's Stmt. of Facts ¶ 41. A Bioreactor System is normally only used when the mixing function is required and utilized. Pl's Stmt. of Facts ¶ 46.

## II. *Applicable Legal Standards*

Proper tariff classification is determined by the General Rules of Interpretation ("GRIs") of the Harmonized Tariff System of the U.S. ("HTSUS") and the Additional U.S. Rules of Interpretation. *Orlando Food Corp. v. United States*, 140 F.3d 1437, 1439 (Fed. Cir. 1998). The GRIs are applied in numerical order. *BASF Corp. v. United States*, 482 F.3d 1324, 1326 (Fed. Cir. 2007). It is a question of law requiring ascertainment of proper meaning in relevant tariff provisions and determining whether the merchandise comes within the description of such terms. *Pillowtex Corp. v. United States*, 171 F.3d 1370, 1373 (Fed. Cir. 1999).

Interpretation of the HTSUS begins with the language of the tariff headings and subheadings of the HTSUS and their section and chapter notes, and may also be aided by the Explanatory Notes published by the World Customs Organization. *Trumpf, supra*, 34 CIT at \_\_\_, 753 F. Supp. 2d at 1305 & 1306 n.20. The chapter and section notes are not optional interpretive rules but statutory law. *Libas, Ltd. v. United States*, 193 F.3d 1361, 1364 (Fed. Cir. 1999).

Both parties move for judgment pursuant to USCIT Rule 56, which is appropriate "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." USCIT R. 56(c); *see also Celotex Corp. v. Catrett*,

477 U.S. 317, 322 (1986). The movant bears that burden, *see, e.g., Adickes v. S.H. Kress & Co.*, 398 U.S. 144, 157 (1970), and a fact is “material” only if it would affect the outcome of the action. *See Trumpf Med. Sys., Inc. v. United States*, 34 CIT \_\_\_, \_\_\_, 753 F. Supp. 2d 1297, 1305 (2010) (“*Trumpf*”).

The court will grant a motion for summary judgment “if the pleadings, discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law.” USCIT R. 56(c); *see Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247-48 (1986). Accordingly, summary judgment in a classification case is appropriate only if the material facts of what the merchandise is and what it does are not at issue. *Diachem Indus. Ltd. v. United States*, 22 CIT 889, 893 (1998) (citation omitted). The court may not resolve or try factual issues on a motion for summary judgment. *Phone-Mate, Inc. v. United States*, 12 CIT 575, 577, 690 F. Supp. 1048 (1988) (citation omitted).

At the summary judgment stage, facts must be viewed in the light most favorable to the nonmoving party only if there is a “genuine” dispute as to those facts. Fed. Rule Civ. Proc. 56(c). As we have emphasized, “[w]hen the moving party has carried its burden under Rule 56(c), its opponent must do more than simply show that there is some metaphysical doubt as to the material facts . . . . Where the record taken as a whole could not lead a rational trier of fact to find for the nonmoving party, there is no ‘genuine issue for trial.’ ”

*Scott v. Harris*, 550 U.S. 372, 380 (2007), quoting *Matsushita Elec. Industrial Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586-587 (1986).

### III. *Competing Tariff Provisions*

The parties agree the merchandise is properly classifiable in Chapter 84, HTSUS and the court’s review has not uncovered a more apt classification elsewhere in the tariff. *See Jarvis Clark v. United States*, 733 F.2d 873, 878 (Fed. Cir. 1984) (“the court’s duty is to find the *correct*

result, by whatever procedure is best suited to the case at hand”) (emphasis in original); *see, e.g.*, Pl’s Br. at VI-3. The government classified the Bioreactor Systems under heading 8419, HTSUS, as follows (italics added):

- 8419: Machinery, plant or laboratory equipment, whether or not electrically heated . . . , *for the treatment of materials by a process involving a change of temperature* such as heating, cooking, roasting, distilling, rectifying, sterilizing, pasteurizing, steaming, drying, evaporating, vaporizing, condensing or cooling, other than machinery or plant of a kind used for domestic purposes; instantaneous or storage water heaters, nonelectric; parts thereof:  
  - \* \* \*
  - Other machinery, plant or equipment:  
    - \* \* \*
- 8419.89: Other:  
  - \* \* \*
- 8419.89.95: Other . . . . . 4.2% *ad valorem*

Applikon contends the merchandise is classifiable under subheading 8479.82.00, HTSUS (italics added):

- 8479: Machines and mechanical appliances having individual functions, not specified or included elsewhere in this chapter; parts thereof:  
  - \* \* \*
  - Other machines and mechanical appliances:  
    - \* \* \*
- 8479.82.00: *Mixing*, kneading, crushing, grinding, screening, sifting, homogenizing, emulsifying or *stirring* machines . . . . . Free

IV. Analysis

Applikon’s motion for summary judgment is solely directed to its first cause of action, although its complaint claims alternative classification under HTSUS subheadings 9032.89.60, 8479.89.98, or 8543.89.97. Defendant cross-moves for summary judgment in favor of



the classification as entered, under subheading 8419.89.95. Considering the parties' motions, the court is of the opinion that no material facts remain in dispute, that a hearing on the motions is unnecessary, and that the matter may be resolved summarily. The court finds that the imported merchandise is properly classified in heading 8479, for the reasons set forth below.

A

Under GRI 1, classification is determined according to “the terms of the headings and any relative section or chapter notes[.]” In this case, the terms of the headings and the applicable notes are dispositive. The government contends the Bioreactor Systems are classifiable in heading 8419, which provides in pertinent part:

Machinery, plant or laboratory equipment, whether or not electrically heated . . . , for the treatment of materials by a process involving a change of temperature such as heating, cooking, roasting, distilling, rectifying, sterilizing, pasteurizing, steaming, drying, evaporating, vaporizing, condensing or cooling, other than machinery or plant of a kind used for domestic purposes . . . .

Application of this heading to the merchandise at issue requires resolution of a series of questions. As will be explained *infra*, the imported merchandise constitutes a type of machine, and is also laboratory equipment. However, the distinction between the two for purposes of the initial analysis is immaterial. Likewise, the parties do not dispute that the machine's function includes a “treatment of materials” as that phrase is used in heading 8419. See *Fujitsu America, Inc. v. United States*, 28 CIT 1261, 1272-74, 342 F. Supp. 2d 1326, 1336-37 (2004), *aff'd*, 422 F.3d 1364 (Fed. Cir. 2005). Again, however, that is not dispositive.

The parties disagree as to whether the imported merchandise is “for the treatment of materials by a process involving a change of temperature.” Plaintiff contends that the machines are

not intended to “change the cells by a change in temperature” such as through the cooking or roasting examples from heading 8419. Pl’s Fact Reply at 55. Defendant argues that the “[t]he bioreactor systems treat a medium containing cells by a process that involves a change of temperature.” Def’s Reply Memorandum at 4.

The facts before the court demonstrate that while the Bioreactor Systems can control the temperature of the cell medium, that function is subsidiary to the overall function of the device. The Bioreactor Systems can operate without the heating blanket, and do not include the electric heating blanket upon importation. The heating blanket is not permanently attached to the Bioreactor System, it is plugged in when necessary. The merchandise’s temperature control capability is not used by every process to which the machine is suitable. The Bioreactor System can grow cells without the blanket, using a heated chamber or vessel in which the bioreactor is placed. Finally, the Bioreactor System, even when equipped with the blanket, is not designed to change the temperature at which the cell culturing is performed (*e.g.*, by cooking or roasting), rather it is designed to keep the temperature constant. Any temperature change is therefore minor, on the order of 0.1 degrees Celsius. The automatic maintenance of temperature at a set point by the heating blanket, although used in some applications and necessary for those applications, is subsidiary to the primary function of the Bioreactor Systems, which is to maintain an aseptic and homogeneous environment for the growth of cells. The court finds that after reviewing the applicable law and the material facts not in dispute, the Bioreactor Systems are not for the “treatment of materials by a process involving a change of temperature[.]” Plaintiff prevails on this key point.

Defendant’s citations to *Applied Biosystems v. United States*, 34 CIT \_\_\_, 715 F. Supp. 2d 1327 (2010) and *Fujitsu America, supra*, 28 CIT 1261, 342 F. Supp. 2d 1326, *aff’d*, 422

F.3d 1364, are inapposite due to the methods by which the machines involved therein used temperature to achieve their functions, and especially to the centrality of temperature control to their function. In *Applied Biosystems*, the machine at issue heated and cooled DNA strands to perform its function. Clearly, the process involved treatment of materials by a change in temperature, akin to heading 8419's examples of "cooking, roasting, distilling, rectifying, [etc.]."

The task, operation, or activity performed by a thermal cycler is "the treatment of materials by a process involving a change of temperature," HTSUS Heading 8419 (2000-2002). The PCR method of amplification described by Plaintiff necessarily involves temperature change. More specifically, denaturation of the DNA involves heating, annealing of the primers to their complementary DNA segments involves cooling, and synthesis of the new strands may involve reheating. . . . A thermal cycler effects these precise temperature changes. It does nothing more.

*Applied Biosystems*, 34 CIT at \_\_\_, 715 F. Supp. 2d at 1333 (citations omitted).

In this case, the merchandise can regulate the temperature of the material placed in it, but that is not its primary function. Its primary function, undisputedly, is to grow cells. The heat control function (putting aside the fact that the merchandise is not imported with the heat blankets) is not essential to achievement of this purpose in the same manner that the mixing function is always used when the Bioreactor System is in operation.

The same analysis applies to the holding in *Fujitsu America*. In that case, the merchandise involved was a coolant distribution unit, or CDU. Its function was to circulate water through plates attached to the CPU of a mainframe computer system. The water absorbed heat from the CPU and cooled it by running it through a radiator. See *Fujitsu America*, 422 F.3d at 1365. Though plaintiff argued that the CDU operated to keep the CPU's temperature constant, the court found that the operation of the CDU was to warm and then cool water. See *id.* at 1367. It is clear that the function of the *Fujitsu* CDU was primarily to "effect a change in temperature," whereas the

function of the Bioreactor System herein is to grow cells, a process that may be aided by using a heat blanket. If in this case the court were classifying the heating blanket, the question might be answered differently, but that is not the issue before the court.

## B

The conclusion that the heating function of the Bioreactor System is subsidiary to its primary function of promoting cell growth means that Note 2(e) to Chapter 84 excludes the Bioreactors from classification in heading 8419. That Note provides:

Subject to the operation of Note 3 to Section XVI . . . , a machine or appliance which answers to a description in one or more of the headings 8401 to 8424, or heading 8486 and at the same time to a description in one or more of the headings 8425 to 8480 is to be classified under the appropriate heading of the former group or under heading 8486, as the case may be, and not the latter group.

Heading 8419 does not, however, cover:

\* \* \*

(e) Machinery or plant, designed for mechanical operation, in which a change of temperature, even if necessary, is subsidiary.

HTSUS Chapter 84, Note 2(e) (2007).

The parties disagree on the proper construction and operation of Chapter 84 Note 2(e). Plaintiff asserts, at p. VI-16 of its Memorandum in Support of its Motion for Summary Judgment on the First Cause of Action (“Pl’s Memo in Support”), that “[t]he subject Bioreactor Systems are machines designed for the mechanical operation of mixing the cell culture in the vessel to provide a homogenous environment [for cell growth] and are not designed to change temperature.” The government contends that the exclusion from heading 8419 is limited to machinery or plant, not laboratory equipment. Def’s Cross-Motion for Summary Judgment at 18-19.

It is clear, however, from the agreed facts that the Bioreactor Systems constitute “machines” as that term is understood in common meaning. “A ‘machine’ is, *inter alia*, ‘an assemblage of parts that are usu[ally] solid bodies but include in some cases fluid bodies or electricity in conductors and that transmit forces, motion and energy to one another in some predetermined manner and to some desired end.’” *Applied Biosystems*, 34 CIT at \_\_\_, 715 F. Supp. 2d at 1333, quoting *Webster’s Third International Dictionary* (2002) (and holding that the thermal cyclers at issue therein qualified as both machinery and laboratory equipment). Because it cannot be disputed that the Bioreactor Systems constitute “machines,” the government’s argument that they are exempt from Note 2(e)’s exclusion, because they are also laboratory equipment, is to no avail. The temperature control function is subsidiary to the overall operation of the Bioreactor System. Chapter 84 Note 2(e) excludes the Bioreactor System from classification in heading 8419.

A review of the Explanatory Notes is helpful in this instance. The Explanatory Note to heading 8419 provides in part:

[T]he heading covers machinery and plant designed to submit materials (solid, liquid, or gaseous) to a heating or cooling process in order to cause a simple change of temperature or to cause a transformation of the materials resulting principally from the temperature change (*e.g.*, heating, cooking, roasting, distilling, rectifying, sterilising, pasteurising, steaming, drying, evaporating, vaporising, condensing or cooling processes). But the heading **excludes** machinery and plant in which the heating or cooling, even if essential, is merely a secondary function designed to facilitate the main mechanical function of the machine or plant, *e.g.*, machines for coating biscuits, *etc.*, with chocolate, and conches (**heading 84.38**), washing machines (**heading 84.50** or **84.51**), machines for spreading and tamping bituminous road-surfacing materials (**heading 84.79**).

Explanatory Note to Heading 84.19, World Customs Organization (2010) (emphasis in original).

The heating blanket is subsidiary to the cell growth function of the Bioreactor in the same manner

that the water heating circuit in a washing machine is subsidiary to its function of cleaning clothes. Therefore, Note 2(e) to Chapter 84 excludes the Bioreactor Systems from classification in heading 8419.

### C

The parties also disagreed over the correct application of Notes 3 and 4 to Section XVI, HTSUS to the classification issues at hand. Because the Bioreactor System is excluded from heading 8419 by Chapter 84 Note 2(e), the court need not reach the issue of whether mixing or temperature control constitute the “principal function” of the Bioreactor System or rest its decision on a torturous interpretation of whether mixing or heating more clearly “define” the function of the Bioreactor System. *Cf., e.g., Fuji America Corp. v. United States*, 30 CIT 1058 (2006), *aff’d*, 519 F.3d 1355 (Fed. Cir. 2008) (argument that chip placer’s principal function is “lifting and storing” does not take into account its “entire function” of the process to which it is actually purposed). The facts clearly show that cell growth is the primary, clearly defined function of these machines, but that function is not described in any heading of the HTSUS, and therefore fitting the Bioreactor Systems within the ambit of Notes 3 or 4 is inordinate.<sup>3</sup>

### D

Applikon argues that the Bioreactor Systems are “not specified elsewhere” in Chapter 84 and are properly classified in heading 8479 because even if the parties agree that the “principal function” or “principal purpose” of the bioreactor systems is “to provide an aseptic homogenous

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<sup>3</sup> As noted in note 4, *infra*, the Bioreactor System does not qualify as a composite machine for purposes of Note 3 to Section XVI in any event.

environment to facilitate the growth of cells suspended in a liquid culture or medium,” the mixing function is essential to the operation of the Bioreactor System.

Plaintiff’s argument is buttressed by Note 7 to Chapter 84. That note provides in pertinent part:

A machine which is used for more than one purpose is, for the purposes of classification, to be treated as if its principal purpose were its sole purpose. \* \* \* Subject to note 2 to this chapter and note 3 to section XVI,<sup>[4]</sup> a machine the principal purpose of which is not described in any heading or for which no one purpose is the principal purpose is, unless the context otherwise requires, to be classified in heading 8479.

Chapter 84, Note 7, HTSUS (2007) (footnote added). Because it is undisputed that the principal purpose of the Bioreactor System is to grow cells, a purpose which is not described in any heading in Chapter 84, the Bioreactor System falls to be classified in Heading 8479 by operation of Note 7 to Chapter 84.

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<sup>4</sup> Note 3 to Section XVI is inapplicable because the Bioreactor Systems are not composite machines. The Explanatory Notes to Note 3 to Section XVI explain that composite machines are:

taken to be fitted together to form a whole when incorporated one in the other or mounted one on the other, or mounted on a common base or frame or in a common housing. \* \* \* Assemblies of machines should not be taken to be fitted together to form a whole unless the machines are designed to be permanently attached either to each other or to a common base, frame, housing, *etc.*

The Bioreactor Systems are made up of separate machines connected by cables, *etc.*, and are not designed to be permanently mounted to each other, and thus do not fall within the term “composite machine” as it is used in Note 3 to Section XVI.

