IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

Kyowa Hakko Bio, Co., Ltd, et al Plaintiffs,	:	CIVIL ACTION
v.	:	NO. 17-cv-00313-MSG
Ajinomoto Co., Ltd. et al Defendants.	:	

CLAIM CONSTRUCTION OPINION

RICHARD A. LLORET
U.S. MAGISTRATE JUDGE

October 9, 2019

INTRODUCTION

Kyowa Hakko Bio, Co., Ltd. and related companies ("Plaintiffs," or "Kyowa") filed a complaint claiming that Ajinomoto Co. Ltd. and related companies ("Defendants," or "Ajinomoto") infringe their U.S. Patent No. 45,723 ("the '723 patent" or "'723") by making amino acids[1] by a method[2] claimed in the '723 patent. Docket Item ("D.I.") 1, ¶ 1-2. The case has been referred to me for claim construction under *Markman v. Westview Instruments, Inc.*, 517 U.S. 370 (1996). D.I. 76. The parties have briefed the issues thoroughly, and I held oral argument on July 29, 2019. This opinion construes the disputed claim language.

STANDARD OF REVIEW

"[T]he claims of a patent define the invention to which the patentee is entitled the right to exclude." *Eli Lilly and Company v. Eagle Pharmaceuticals, Inc.*, 2019 WL 1299212, at *1 (D.Del. 2019) (quoting *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1115 (Fed. Cir. 2004)). Claim construction is a

[1] Or by importing or selling them in the United States.
[2] Or an equivalent method.

question of law. *Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 135 S.Ct. 831, 837 (2015). Claim terms generally are given "the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005) (quoted in *Eli Lilly*, 2019 WL 1299212, at *1). This general rule gives way when the patentee sets out a defined term in the patent, or disavows the full scope of the term's ordinary meaning, either in the specification or during prosecution. *Unwired Planet, LLC v. Apple Inc.*, 829 F.3d 1353, 1358 (Fed. Cir. 2016).

Courts look for a term's ordinary meaning in the "intrinsic evidence," which is the claim language, the specification, and the prosecution history. *Leseman, LLC v. Stratasys, Inc.*, 730 F. App'x 912, 914 (Fed. Cir. 2018). If necessary, a court may also look to "extrinsic evidence," which includes "expert and inventor testimony, dictionaries, and learned treatises." *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 980 (Fed. Cir. 1995). Extrinsic evidence may not be used "for the purpose of varying or contradicting the terms of the claims." *Markman*, 52 F.3d at 981. "The construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction." *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998).

BACKGROUND

Amino acids are mass produced by fermentation. Declaration of Dr. Michael F. Doherty ("Doherty"), D.I. 84, at ¶¶16–18; Declaration of Dr. Allen S. Myerson ("Myerson"), D.I. 85, at ¶¶1-15. Fermentation is a process that uses microorganisms (often bacteria) to produce a chemical. *Id*. The bacteria are placed in a fermentation broth, also called a culture, in which the bacteria grow, releasing amino acids into the

broth as a by-product. *Id*. The amino acids eventually crystalize and can then be separated from the bacteria in the broth. '723 patent at 1:18–41.

The broth becomes more and more concentrated as the bacteria produces amino acids, until the broth reaches a point called saturation, which means that under the existing conditions the broth cannot hold any more dissolved amino acid. Doherty at ¶¶18 –19; Myerson at ¶15. If more amino acid is added to a saturated solution it becomes "supersaturated." *Id*. In a supersaturated solution, the amino acids precipitate ("nucleate out") and begin to form crystals. Doherty at ¶¶18 –19; Myerson at ¶¶15-16.

"Seeding" crystal particles into the broth can change the growth pattern of amino acid crystals. The amino acids latch onto the seed crystals and grow larger crystal particles than they would if nucleated out on their own. Myerson at ¶16. These larger crystals can then be more easily harvested from the broth. Doherty at ¶¶20–21. Seed crystals of the desired size can be introduced into the broth directly, or by different types of agitation, shock, friction, and pressure. Doherty at ¶23-25.

THE PATENT

Claim 1 of the '723 patent (referred to as "Claim 1") describes a process for efficiently growing amino acid crystals in an amino acid broth by adding ("seeding") amino acid crystals of a particular average size to the broth at a particular time in the brewing process. D.I. 1, ¶56. Claim 1 measures the results of the process by the concentration of the crystals produced. *Id*. Claim 2 of the '723 patent adopts the process in Claim 1, but measures the results differently. *Id*., ¶57. Claims 7 and 8 are dependent on Claims 1 and 2, respectively. *Id*., at ¶59. Both Claims 1 and 2 require that added crystals be within a specific size range, defined by their "average particle size," and be added at a particular time. Pl. Br. at 1.

Claim 1 of the patent reads as follows:[3]

1. A process for producing an amino acid, which comprises:

   [a] culturing a microorganism having an ability to produce the amino acid in a medium,

   [b] adding crystals of the amino acid having an average particle size of 7 to 50 μm to the medium at some time after the amino acid concentration in the medium reaches the saturation solubility and before crystals of the amino acid deposit in the medium so that the concentration of the crystals of the amino acid becomes 0.5 g/l or more,

   [c] culturing the microorganism having the ability to produce the amino acid in the medium,

   [d] allowing the crystals of the amino acid to grow to crystals of the amino acid having an average particle size of 30 μm or more and accumulate in the medium, and

   [e] recovering the crystals of the amino acid from the culture by separating the microorganism producing the amino acid and the accumulated crystals of the amino acid based on the difference in particle size or specific gravity between them.

D.I. 1, ¶56. Claim 2 tracks the language of Claim 1, but where Claim 1 requires the concentration of the crystals to reach a certain number of grams per liter (sub-paragraph (b)), Claim 2 requires the crystals in the medium to reach a certain total surface area. '723 patent at 11:8-10.

The '723 patent purported to solve some problems with then existing methods of collecting amino acids from a broth. One problem was that high concentration of amino acids in the broth tended to inhibit further production of crystals. '723 patent at 1:31-32.[4] Prior methods also yielded a lot of microcrystals that were difficult to separate from the broth because of their extremely small size. '723 patent at 1:42–51. Because the

[3] I have inserted subparagraph markings [a] – [e], for convenience, following the Complaint. D.I. 1, ¶ 56. The full text of the patent is reproduced as an Exhibit to the Complaint.
[4] Patent references are to the column numbers within the patent (listed before the colon) and lines (listed after the colon).

microcrystals were too small to be efficiently directly removed from the medium, the prior art required additional steps to harvest crystals, such as adding water and heat, or using a centrifugal or filtration separator. *Id.* at 1:46-51.

The '723 patent overcame the problems by its crystal seeding method. The inventors claimed that once the fermentation broth is saturated, adding seed crystals of a size range from 7–50 microns, at a great enough concentration (0.5 grams per liter or more), at a point in time after saturation but before crystals deposit, provided a dispersed crystal surface onto which amino acids will latch when forming crystals. *See id.* at 10:45–67. This method generates enough crystals of the correct size so that the suspended amino acid has somewhere to go once it nucleates, stimulating continued production. *See id.* at 10:12–24. It also generates crystals large enough to be easily separated from the microbes in the broth. *See id.* at 9:17-30.

THE DISPUTE

The parties dispute the construction of three phrases in Claims 1 and 2: "average particle size," in subparagraph [a], above, "adding crystals of the amino acid . . . to the medium" at the beginning of subparagraph [b], and "before crystals of the amino acid deposit in the medium," at the end of subparagraph [b]. D.I. 68-1 ("Joint Claim Construction Chart" or "JCCC").

A. Average particle size.

Kyowa contends that the phrase "average particle size" means "[t]he sum of particle sizes divided by the number of particles." *Id.* at 2. Ajinomoto argues that the phrase means "volume average diameter (or volume mean diameter)," or that alternatively, the term is indefinite. *Id.* at 2-3.

An ordinary use of the term "average" refers to a numeric average. If I mention that the average age of federal judges is 39 (a dubious assertion), it means to the ordinary user of English that I have added up the ages of all federal judges and divided that sum by the number of judges. "Average particle size" has an ordinary English meaning, in this sense: the size of each of the particles in a given set, added together, and divided by the number of particles. The question is whether this is the ordinary or customary meaning of the phrase to the person of ordinary skill in the art. *Phillips,* 415 F.3d at 1313. There are reasons to believe that "average particle size," as used in the patent, could have meant either what it would suggest to an ordinary speaker of English or a volume weighted average diameter. To understand these reasons, and to weigh them appropriately, it is necessary to explain some details about measuring particles and calculating average sizes. After doing so I will examine the parties' arguments.

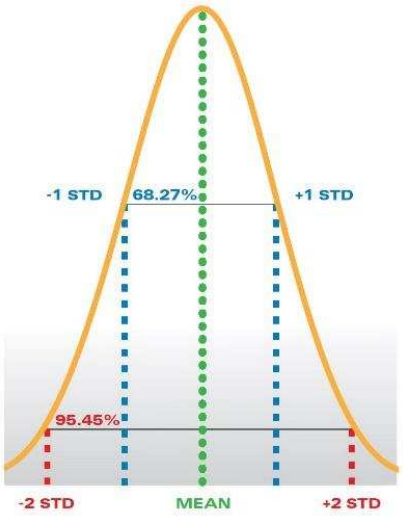
1. Measuring particles.

There are various ways to measure particles: sieving, in which particles are shaken over a sieve with specifically sized holes; image analysis, in which an image of the particle is measured against a reference scale; focused beam reflectance measurement ("FBRM"), which measures the light bouncing back from a laser directed into a group of particles; laser diffraction, which measures the amount of light scattered when a laser hits a particle; sedimentation, which equates how long a particle takes to fall through a known liquid to a sphere that would fall at the same rate through the same liquid; and electrozone sensing, which equates a particle's size to its electrical conductivity. Pl. Br. at 5-6; Doherty at ¶27; Myerson at ¶33.

Particles come in all kinds of shapes. The parties agree that a standard convention used by persons of skill in the art is to assume that the measured particle is a

sphere. *See* '723 patent at 8:37-40; Doherty at ¶26; Myerson at ¶30, 32. This convention trades precision for the convenience of allowing practitioners to characterize particles by one number – a diameter. Doherty at ¶26; Myerson at ¶32-34.

2. Averaging the size of particles.



The various sizes of a group of particles may be reported as a curve, as in the image above. Pl. Br. at 7. Practitioners also have developed two categories of mathematical formulae for reporting on the size of a group of particles as a single number: "number average" and "weighted average." Doherty at ¶ 38; *see* Myerson at ¶35. These two categories of averaging methodology have different iterations and different statistical purposes. Doherty at ¶¶54-71; Myerson at ¶¶33-36. The number average category includes a "simple average" – also called an "arithmetic mean particle diameter" - equation: adding up the diameters of all particles in the set and dividing that sum by the number of particles. Doherty at ¶37-39. This formula is denoted mathematically as D[1,0]. Myerson at ¶35.

A "weighted" average works as the name suggests. The measurement of the particles is weighted against some other characteristic, such as surface area or volume. Doherty at ¶¶ 39, 64. The following chart illustrates the operation of two weighted average techniques, surface area weighted average, denoted D[3,2], and volume weighted average, denoted D[4,3]:

D [,] Expression	**Formula**	**Calculated Average** **(diameters of d1=1, d2=2, and d3=3)**
D[3,2]	$\frac{d_1^3 + d_2^3 + d_3^3}{d_1^2 + d_2^2 + d_3^2}$	$\frac{1 + 8 + 27}{1 + 4 + 9} = 2.57$
D[4,3]	$\frac{d_1^4 + d_2^4 + d_3^4}{d_1^3 + d_2^3 + d_3^3}$	$\frac{1 + 16 + 81}{1 + 8 + 27} = 2.72$

Pl. Br. at 8 (drawn from plaintiff's Ex. D).

A volume weighted average diameter will skew the average in favor of the diameter of higher volume particles. A surface area weighted average diameter will skew the average in favor of the diameter of particles with higher surface area.

The degree of skew is captured in the chart reproduced below:

D [ب] Expression	Formula	Calculated Average (µm)
Arithmetic Mean Particle Diameter	$\frac{x_1 + x_2 + \ldots + x_n}{n}$	5.14
Surface weighted Mean Particle Diameter	$\frac{d_1^3 + d_2^3 + d_3^3}{d_1^2 + d_2^2 + d_3^2}$	6.84
Volume Weighted Mean Particle Diameter	$\frac{d_1^4 + d_2^4 + d_3^4}{d_1^3 + d_2^3 + d_3^3}$	7.64

Pl. Br. at 8-9 (example drawn from plaintiff's Ex. E, ASTM, E2578-07).

Ajinomoto argues that a "volume weighted average" is the measurement that a person of ordinary skill in the art would understand the phrase "average particle size" referred to when used in the patent. Def. Br. at 7-12. Alternatively, Ajinomoto argues that the '723 patent is indefinite, because it does not specify which of the many different measures of "average particle size" was contemplated by the claim language. Def. Br. at 17-19.

3. "Average particle size" as a simple arithmetic mean.

The phrase "average particle size" is commonly used in the art to refer to a simple arithmetic mean. Doherty at ¶41; Pl. Answ. Br. at 11-13. Even Ajinomoto's expert, Dr. Myerson, has used the phrase this way on a number of occasions, as have other authorities, although Dr. Myerson has elsewhere used the phrase to refer to a weighted

average.[5] The phrase may be used to describe other measures of average particle size, but Kyowa's argument is fundamentally correct.

4. The patent does not mention "volume weighted average" or any other weighted or volume based averaging technique.

Ajinomoto asks me to interpret the phrase "average particle size" to mean "volume average (or volume mean)." JCCC at 2. Kyowa rightly asked for clarification of this proposal, because "volume average" or "volume mean" could mean a volume based number average or a volume weighted average. A volume based number average would add the particles' volumes and divide by the number of particles. Ajinomoto clarified that by the words "volume average (or volume mean)" Ajinomoto meant a volume weighted average. See Ex. G to Pl. Br.

The language of the claim reads "adding crystals of the amino acid having an average particle size of 7 to 50 μm to the medium[.]" '723 patent at 10:50-52. The patent does not use volume-centric vocabulary when describing "average particle size." The patent does not explicitly mention volume weighted averaging at all.

"Volume" is a species of the genus "size." Ajinomoto's proposed construction is restrictive, in the same way as insisting that the word "mammal" be read "human." When one word clearly describes a species within a genus described by another word, substituting the species-word for the genus-word markedly alters meaning. Unless the genus-word makes the phrase incoherent, the exercise should be avoided. Here, the genus-word "size," used in the patent, does not make the phrase incoherent.

[5] The articles are described at page 12 of Kyowa's answering brief ("Pl. Answ. Br."), D.I. 99. The articles are also attached as Exhibits to the answering brief.

Ajinomoto's construction restricts the meaning of the phrase "average particle size" to a measure that is not mentioned in the patent, while excluding a measure for which the phrase is commonly used, even by Ajinomoto's expert. Both technical and non-technical dictionaries define "average" as an arithmetic average.[6] While these sources are extrinsic to the patent, they are helpful.[7]

Claim limitations should not be read into a patent, unless there has been a clear disavowal. *Cont'l Circuits LLC v. Intel Corp.,* 915 F.3d 788, 797 (Fed. Cir. 2019). There has been no disavowal here. Nothing in the specification contains the clear expression of "exclusion or restriction" necessary to constitute a disavowal of the scope of the claim language. *Id.* (quoting *Retractable Techs., Inc. v. Becton, Dickinson & Co.*, 653 F.3d 1296, 1306 (Fed. Cir. 2011) (quoting *Epistar Corp. v. Int'l Trade Comm'n*, 566 F.3d 1321, 1335 (Fed. Cir. 2009))).

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[6] *See* Pl. Br. at 14-15, citing McGraw-Hill Dictionary of Scientific and Technical Terms, 6th ed., 2003, definition of Arithmetic Mean. ("The average of a collection of numbers obtained by dividing the sum of the numbers by the quantity of numbers. Also known as arithmetic average; average"); Chambers Dictionary of Science and Technology, 1999, definition of Average ("Loose term usually for mean; less commonly used to mean median or mode."); Merriam-Webster's Collegiate Dictionary, 11th ed., definition of Average ("1a : a single value (as a mean, mode, or median) that summarizes or represents the general significance of a set of unequal values b: MEAN 1b 2 a : an estimation of or approximation to an arithmetic mean. Average adj "equaling an arithmetic mean"); The New Oxford American Dictionary, 2001, definition of Average ("the result obtained by adding several amounts together and then dividing this total by the number of amounts; the mean"); The American Heritage Dictionary, 4th ed., 2000, definition of Average ("A number that typifies a set of numbers of which it is a function. b. see arithmetic mean").

[7] Ajinomoto argues the phrase should be considered as a whole, "average particle size," rather than by considering the definition of each word, *e.g.* "average," "particle," and "size." Def. Br. at 6. It is true enough that the phrase should be considered as a whole. But definition necessarily involves an understanding of each component of the phrase, as well. If the phrase "big red truck" has some specialized meaning in a particular art, that is no reason to ignore the ordinary meaning of "big," or "red," or "truck." Evidence of meaning should not be ignored or dismissed, but considered and weighed against other available evidence, in accordance with the interpretive guides supplied by the Federal Circuit and Supreme Court. Interestingly, instances of the phrase "average particle size" being used to signify a volume weighted mean, without explicitly saying so, are not mentioned by Ajinomoto's expert. *See Myerson* at ¶¶35-37. At most, the authorities cited explain that the type of average used should be specified, and that the industry prefers reports couched in volume weighted averaging. Myerson at ¶35.

5. Using an arithmetic mean as an averaging technique makes sense in the context of the process claimed by the patent.

If using an arithmetic mean to calculate the average particle size made the patent unworkable or incoherent, the argument in favor of a volume weighted average would gain force. But calculating average particle size by using an arithmetic mean does not make the patent incoherent or unworkable. The point of the invention is to maximize the number of crystals within a relatively narrow size range, not fix the total volume of crystals in a solution without regard to how evenly the crystal volume is distributed. Total crystal volume is not the only preoccupation of the patent, when it comes to the seed crystals. If it were, one colossal crystal would do the trick, to exaggerate for the sake of making a point. Calculation of an arithmetic mean based on the sum of the diameters of the seed crystals matches the patent's concern with maximizing the number of crystals within a narrow size range. At the very least, a volume weighted average is not a more compelling or elegant fit, on this score.

Ajinomoto points out that a numerical average has the disadvantage of requiring that the number of particles be counted, which makes it impractical for large volume industrial uses. Myerson, at ¶36. Given the patent's emphasis on a process that will lead to greater production efficiency (*see* '723 patent 10:33-38), the argument makes sense. The danger is that reading a "better" or "more efficient" measuring process into the language used by a patent may give the patentee a windfall – intellectual property he did not actually claim. Alternatively, retrospectively reading a process into a claim may deprive the patentee of what he actually claimed, however less "efficient" or "useful" the actual claim may be than the alternative process. The ultimate question is always what the patentee meant to convey by the words of the patent, not whether the patent will

work more or less efficiently, given a particular construction. The utility of a patent under one construction or another is an aid to its interpretation, but it is only that. Ajinomoto's argument has some force, but I do not find it overly convincing.

6. The patent does not limit measuring techniques to laser diffraction.

Ajinomoto contends that laser diffraction is the measuring technique contemplated in the patent. Def. Br. at 8 (citing '723 patent at 8:33-37; 10:1-4). The significance is that laser diffraction is particularly well suited to volume weighted particle size averaging. *Id*. at 8-10 The argument is that if the patent's inventors were using laser diffraction to measure average particle size, it is likely they would be referring in the patent to volume weighted average particle size when they used the phrase "average particle size." *Id*.

The patent explicitly refers to laser diffraction measurement in the specification, and only as an example of how to measure the specific surface area of crystals. It is not a claim limitation. '723 patent at 8:33-37. Nor is there perfect correspondence between laser diffraction and volume weighted average particle size. As Ajinomoto acknowledges, laser diffraction is used to take measurements other than volume weighted average particle size. *See* Def. Br. at 8-9.

The fact that laser diffraction is mentioned as a measuring device in the specification does not justify the conclusion that the patentee intended to include laser diffraction in the claim language as the exclusive means for measuring particle size. As Kyowa points out, a common industrial technique is to use an "in-line" measurement technique, such as FBRM, to measure crystal seeds directly in a vessel, rather than pulling out a sample to measure on a laser diffraction machine. Pl. Answ. Br. at 18

(citing Dr. Myerson's deposition testimony). The fact that laser diffraction is acknowledged and mentioned in the specification, but not in the claim itself, supports the view that the patentee *did not* intend to limit the claim by requiring laser diffraction as the exclusive measuring technique. The absence of laser diffraction measurement in the claim language was not an oversight, but a deliberate choice by a patentee who well knew of the technology.

7. Extrinsic evidence that another Kyowa patent by the same inventor defines "average particle diameter" as a volume weighted average does not weigh in Ajinomoto's favor.

Ajinomoto argues that another Kyowa patent (the '308 patent)[8] by the same inventor defines "average particle diameter" as a volume weighted average. Def. Br. at 16-17. The fact that the same inventor saw it necessary to explain that average particle diameter meant a volume weighted average in one patent, yet did not do so in the '723 patent, suggests instead that the inventor was aware that if he wanted to associate the phrase "average particle size" with weighted averaging he needed to make that association explicit. This evidence does not weigh in Ajinomoto's favor.

8. Measurements derived from Figure 1 of the '723 patent indicate the inventors did not use an arithmetic mean to calculate "average particle size" in Figure 1.

Ajinomoto argues that measurements derived from Figure 1 of the '723 patent indicate that average particle sizes stated in the illustration were not derived through application of an arithmetic mean, but of some type of volume weighted average. Def. Br. at 12-14. Kyowa does not directly contradict Ajinomoto's math, but responds that

[8] U.S. Patent No. 8,188,308 (Ajinomoto Ex. 17) issued to the same lead inventor listed in the '723 patent: Tsuyoshi Shimose. The '308 patent is based on a Japanese application filed about 18 months after the application that resulted in the '723 patent. It is therefore a useful, although not conclusive, indication of the technology and specialized jargon in use at the time.

Figure 1 was not designed to be a limitation on the scope of the phrase "average particle size," but a demonstration of the relationship between seeded various crystal sizes and the crystals ultimately produced by the process contemplated in the patent claim. Pl. Answ. Br. at 9-10.

For the reasons explained in Ajinomoto's brief and at oral argument (Tr. 7/29/2019 at 43-45), I am convinced that the average particle sizes referred to in the top row of Figure 1[9] were not calculated using an arithmetic mean.[10] Kyowa's rejoinder is true, so far as it goes: Figure 1 was not designed to define or limit the phrase "average particle size," but to illustrate the significant effect on recovery rates of crystals by using various sizes of added crystals, dependent upon the average particle size of the crystals.

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[9] I have reproduced a copy of the first two rows of Figure 1 here:

	①	②	③	④	Control
Particle size of crystals added (μm)	30	45	70	110	—
Addition amount (g/l)	5.5	5.5	5.5	5.5	—

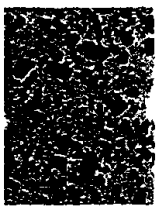
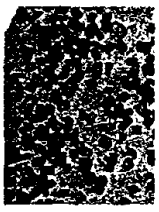
[10] I have reproduced Ajinomoto's graphic representation of its proof, which relies on the acknowledged fact that an arithmetic mean must be less than a surface-area mean, which in turn must be less than a volume weighted mean.

Experiment number from the patent	SSA (m^2/cm^3) in the patent	calculated surface-area mean MA = 6/SSA	Average particle size in the patent	MN < MA < MV shows that the average particle size is too large to be MN
①	0.24	25 μm	30 μm	MN < 25 < MV ∴ 30 μm ≠ MN
②	0.16	38 μm	45 μm	MN < 38 < MV ∴ 45 μm ≠ MN
③	0.10	60 μm	70 μm	MN < 60 < MV ∴ 70 μm ≠ MN
④	0.07	86 μm	110 μm	MN < 86 < MV ∴ 110 μm ≠ MN

Kyowa also argues that the numbers in the first row of Figure 1 (labelled "Particle size of crystals added") are not referred to as averages. This is incorrect. The numbers are not labelled as "averages" on Figure 1 itself, but the patent's description of Figure 1 explains that it "shows the relationship between the *average particle size,* specific surface area and total surface area of the crystals of the amino acid added…" '723 patent, 2:62-64 (emphasis added).[11]

Ajinomoto's argument makes sense. The inventors were not using an arithmetic mean when they measured and disclosed average particle size in the top row of Figure 1. Thus, when the phrase "average particle size" is used in the description of Figure 1 ('723 patent, 2:62-64), it is not referring to an arithmetic mean. Ajinomoto cannot prove that average particle size in Figure 1 refers to volume weighted average (D[4,3]) but neither does the math rule that possibility out. Tr. 7/29/2019 at 46.

[11] Rows 4 and 5 on Figure 1 supply surface area measurements:

	①	②	③	④	Control
Particle size of crystals added (μm)	30	45	70	110	—
Addition amount (g/l)	5.5	5.5	5.5	5.5	—
Photograph of crystals added					—
Specific surface area of crystals added (m^2/cm^3)	0.24	0.16	0.10	0.07	—
Total surface area of crystals added (m^2/L)	0.86	0.57	0.36	0.25	—

Kyowa argues that the first row of figures was unlikely to have been generated by laser diffraction, because of the imprecision of the figures used. Pl. Answ. Br. at 10. That may be, but the rejoinder does not address the deeper argument, which is that however the figures in the first row were derived, the figures are 1) labelled "average particle size" by the patent, and 2) cannot represent an arithmetic mean if the other figures on the page (specific surface area and total surface area) are correct. D.I. 1-1, at 4 (Fig. 1). There has been no evidence indicating that the specific surface area and total surface area reported in Figure 1 are inaccurate.

I find that the figures in the first row of Figure 1 were labelled "average particle size," but were not derived by using an arithmetic mean.

9. Statements made by Kyowa in European patent proceedings cast doubt on Kyowa's construction of the phrase "average particle size" in this case.

Kyowa's expert, Dr. Richard Rosseau, in European patent proceedings concerning a closely related patent, opined that "average particle size" means "volume weighted average particle size." Def. Br. at 14-16. Kyowa argues that the statements were not directed toward the specific language at issue in this case but were comments on specification paragraphs describing the use of laser diffraction to measure particle size. Pl. Answ. Br. at 20-22.

Statements made in European patent proceedings should be used cautiously, because the patent standards are different than in a U.S. proceeding. *See AIA Engineering Ltd. v. Magotteaux Intern. S/A*, 657 F.3d 1264, 1279 (Fed. Cir. 2011). The statement does not qualify as a disclaimer, nor does Ajinomoto argue a disclaimer. Nevertheless, the statements were made in pre-litigation submissions to the European Patent Office (EPO), for the European counterpart patent to the '723 patent. The two

patents share the same specification and the same claim term, "average particle size." Def. Br. at 14. Kyowa does not dispute these realities.

Dr. Rousseau's declaration was submitted to bolster Kyowa's position that the phrase "average particle size" was not indefinite because it referred to volume weighted average particle size. *See* D.I. 80-11, at 217-19, ¶¶ 4.1 to 4.1.4 (September 16, 2016 reply to opposition). Kyowa's position in the European patent proceeding does not preclude, as a matter of law, its contrary position in this case. After all, its position might have been wrong in the EPO proceeding, just like Ajinomoto's construction might be wrong here. But this "blatant admission" by Kyowa in the European proceeding puts Kyowa's construction in this case in doubt. *Gillette Co. v. Energizer Holdings, Inc.*, 405 F.3d 1367, 1374 (Fed. Cir. 2005). I take Kyowa's statement "with the requisite caution" due statements in foreign proceedings, *Starhome GmbH v. AT & T Mobility LLC*, 743 F.3d 849, 858 (Fed. Cir. 2014)), but one thing I take as plain and certain: Kyowa construed the same phrase, "average particle size," to mean two different things for two virtually identical patents.

I grant that there are contextual variations between the European proceeding and this litigation, as described by Kyowa in its answering brief (at page 20-22). Kyowa is entitled to pursue its interest as it sees fit, both here and abroad, within the limits of the law. That does not mean I must ignore the probative value of its having taken two diametrically opposed positions about the meaning of the same phrase. A patentee's two different definitions of the same measurement phrase in two related patent proceedings strongly suggests that the claim is indefinite. *See Teva Pharmaceuticals USA, Inc. v. Sandoz, Inc.*, 789 F.3d 1335, 1345 (Fed. Cir. 2015) (the patentee in one instance stated the term "molecular weight" meant one thing and in another instance something else,

leaving the phrase indefinite). If even Kyowa is uncertain what the phrase means, this lends force to the argument that the phrase is irresolvably ambiguous and indefinite.

10. Extrinsic evidence that Kyowa did not use an arithmetic mean to calculate average particle size when measuring its seed crystals in 2012 is of limited probative value.

I permitted limited discovery into Kyowa's commercial practices in 2012 to determine whether Kyowa used laser diffraction and volume weighted averaging when specifying crystal seed size in its own fermentation process in 2012.[12] The discovery resulted in a Joint Stipulation (D.I. 78); *see* Def. Br. at 17. Ajinomoto argues that the information discovered suggests that the inventors meant volume weighted averaging when they used the phrase "average particle size." But the commercial documents that form the basis of the Joint Stipulation themselves leave no doubt about the type of averaging being used: the labeling of non-arithmetic averages is clear. This suggests that non-arithmetic mean averaging is typically labelled explicitly as such.

Ajinomoto's argument assumes that the patentee, when conducting experiments that led to the patent, measured seed crystals the same way Kyowa did in its commercial practice in 2012. The assumption is not irrational, but neither is it clear and convincing. Kyowa's commercial practice gives me brief pause, but the patent used the generic phrase "average particle size," while the commercial documents discovered by Ajinomoto clearly identify the non-arithmetic averaging method used to measure seed crystal size. The Japanese patent application upon which priority is claimed dates from April 2005, seven years before the 2012 commercial documents that form the basis of the Joint Stipulation. '723 patent, at 1 (Ex. 1 to Complaint; D.I. 1-1 at 2). There is no

[12] Because the details of Kyowa's commercial process are legitimately guarded as trade secrets, I will not disclose the details in this opinion. The details are adverted to in the Joint Stipulation and the record of oral argument.

conclusive link between the measurement practices used by the patentee and those used by Kyowa in full-fledged production in 2012.

Kyowa asks me to ignore this evidence as extrinsic. I am not bound to ignore extrinsic evidence, but I am bound not to overvalue it. The ultimate question remains how a person of ordinary skill in the art would have read the patent. That person would have no knowledge of the details of Kyowa's closely guarded commercial practice in 2012. In the end this evidence does not convince me that the patent meant volume weighted average particle size when it used the phrase "average particle size."

11. The phrase "average particle size" is indefinite.

Ajinomoto argues that if the phrase "average particle size" does not mean "volume weighted average" it is, in the alternative, indefinite. Def. Br. at 17-18. I agree. I find that persons of ordinary skill in the art would have significant doubt about whether to interpret the phrase "average particle size" to call for application of an arithmetic mean (D[1,0]), volume weighted averaging (D[4,3]), or some other measure.

The heart of the invention focuses on adding a specific size and quantity of crystals at a specific time in the fermentation process to produce the desired effect. Measurement of the average size of seed crystals is not a peripheral issue. A patent must specify the claim with reasonable certainty. *See Dow Chemical Co. v. Nova Chemicals Corp. (Canada)*, 803 F.3d 620, 634 (Fed. Cir. 2015). Where the type of measurement chosen makes the difference between practices that infringe or do not infringe the patent, ambiguity in the patent about exactly which measurement to employ creates indefiniteness. *Id; see Teva,* 789 F.3d at 1341 (three different possible measures of "molecular weight" made for three different results and an indefinite claim).

In its answering brief Kyowa argues that Ajinomoto has not proven that differences between the measuring techniques are significant. Pl. Answ. Br. at 23 (citing *Takeda Pharm. Co. v. Zydus Pharm. USA, Inc.*, 743 F.3d 1359, 1367 (Fed. Cir. 2014). This is wrong. When measured by volume weighted mean diameter, Kyowa's own added crystals came within the patent's size restriction; when measured by a simple arithmetic mean, the crystals were outside the patent's size restriction. Def. Br. at 18 (citing Exhibits 19 and 12). Similarly, the "sole documented instance where the D[1,0] value of Ajinomoto's seed crystals fell within the claimed range of 7–50 μm the D[1,0] value was 49.993 μm—only 7 *nanometers* from the edge of the range." Def. Answ. Br. at 16 (citing Exhibit 33, p. 25, 37). The "larger D[4,3] values are well outside of the claimed range." *Id.* Kyowa does not dispute these facts.

It is understandable that the measurement technique used to practice the patent may often be the difference between whether a given practice infringes or not, because of the narrow crystal size range claimed in the patent. Tellingly, the notion that the measurement technique is insignificant is contradicted by Kyowa's vigorous argument in favor of an arithmetic mean, and against a volume weighted averaging technique. If the measuring technique was insignificant, Kyowa could have stipulated to that fact and saved the parties and the court a great deal of time and energy. Instead, as Kyowa argued in its opening brief, "[t]he difference between the two constructions can be quite dramatic." Pl. Br. at 1. Kyowa devoted the first two pages of its opening brief to explaining just how dramatic those differences were. Good advocates use the first pages of an opening brief to make important points. Kyowa's advocates are excellent. I am convinced that measuring technique is important in this case, not insignificant.

Here, both intrinsic and extrinsic evidence demonstrate that there is ambiguity about whether the phrase "average particle size" refers to an arithmetic mean or something else. The phrase is used by those practiced in the art, including Ajinomoto's expert witness, to refer to an arithmetic mean. Definitions drawn from dictionaries favor an arithmetic mean, though the particulars of the patent should weigh more heavily than general definitions drawn from outside sources. *Phillips* 415 F.3d at 1321. The description of Figure 1, intrinsic to the patent, refers to "average particle size" listed in Figure 1, but the reference is not to a simple arithmetic mean. Tr. 7/29/19 at 45; Myerson at ¶53.[13] Kyowa's position in the European proceedings, though extrinsic to the '723 patent, concerned its European cognate. Kyowa argued in the European proceeding that the phrase "average particle size" referred to volume weighted mean diameter.

I find that, given the conflicting evidence in this case, the phrase "average particle size" is ambiguous and indefinite.[14] Claims 1 and 2 are therefore invalid, because indefinite.

B. "[A]dding crystals of the amino acid . . . to the medium."

Kyowa asks me to construe this phrase as "[i]ntroducing crystals to the medium that were not there before, which are the same crystals that the claim later requires "grow . . . and accumulate in the medium." JCCC at 3. Ajinomoto asks me to construe

[13] "[W]e know from this mathematical undisputed relationship that the average particle size for experiment one reported in the top row [of Figure 1] cannot be either D[1,0] [arithmetic mean] or D[3,2] [surface weighted mean diameter]."

[14] Two highly qualified and credible experts, Dr. Doherty and Dr. Myerson, are at odds about what the phrase means. Their disagreement does not create a factual dispute that stymies claim construction, because interpretation of the patent's language is a legal issue, not a fact issue. *Teva,* 789 F.3d at 1344. Nevertheless, that two highly qualified experts in good faith have come to different conclusions about what the phrase "average particle size" means, based on the evidence in this case, reinforces my conclusion that the phrase is indefinite.

the phrase to mean "putting crystals of the amino acid . . . into the medium. This term does not encompass crystals that form in the medium." *Id.*

The effect of Ajinomoto's proposed construction is to limit the addition of crystals to pouring or dumping pre-sized crystals into the broth. Ajinomoto argues that the patent specification contemplates adding crystals by pouring or dumping, not by shocking the broth. But pouring or dumping pre-sized seed crystals into the broth is not the only way known to the art to introduce crystals into a broth. One can pour oversized crystals in the broth and then break them up with agitator blades. *See* Doherty at ¶¶23-24. One can also shock the amino acids in solution to form seed crystals. *Id.* at 25. "Adding" can reasonably mean all three.

There is nothing in the patent that disavows using any of these three methods to "add" crystals to the broth. Limiting claims only to those embodiments contained in the specification is usually the wrong way to construe claims. *Phillips* 415 F.3d at 1323 ("although the specification often describes very specific embodiments of the invention, we have repeatedly warned against confining the claims to those embodiments") (citations omitted).

I conclude that Kyowa's construction is the more reasonable. I therefore adopt it.

C. "[B]efore crystals of the amino acid deposit in the medium."

Kyowa asks me to construe this phrase to mean "[p]rior to the deposit of more than a slight amount of crystals of amino acid produced by the microorganism." Pl. Br. at 26; JCCC at 4. Ajinomoto asks me to define the phrase to mean "[p]rior to the presence of more than a slight amount of amino acid crystals in the medium. This term is a temporal limitation on the "adding" step." *Id.*

The patent claim requires that seed crystals must be added at a specific time in the fermentation process: after the inflection point at which the broth becomes saturated with amino acids, and before microcrystals begin to deposit. '723 patent at 6:35-45. This deposit process happens without the addition of seed crystals. As used in the patent, the words "deposit" and "adding" refer to two different processes. The deposit of microcrystals is a chemical reaction that occurs when the broth has become super-saturated with amino acids. Myerson, at ¶¶15-16. The adding of seed crystals is a consequence of human and mechanical activity, whether through pouring, agitating, or shocking the broth. Doherty, at ¶¶23-25.

Ajinomoto's substitution of the word "presence" for "deposit" shifts the focus from the deposit process to a more general question whether there are any crystals present in the broth, however introduced. That is not true to the patent. Kyowa's proposal adds language that is confusing, by focusing on crystals produced by the microorganism, as if there is some means of distinguishing "added" crystals and "native" crystals once the two are mixed together. The patent, and the record in this case, discloses none. Besides, as Kyowa argues in connection with the "adding" phrase, above, the patent covers crystals that are "added" by shocking the broth. These crystals clearly are produced by the microorganism in the broth, rather than imported from elsewhere. Thus, using the phrase "produced by the microorganism" does not clearly distinguish between "added" and unadded crystals, at least in the case of crystals added through shock.

I construe the phrase to mean that seed crystals must be added to the medium before the point in time when microcrystals would begin depositing in the medium, unaided by the addition of seed crystals. Both parties agree that a slight amount of

deposited crystals in the medium does not violate the "before" phrase in the patent. I adopt this qualification, because it is intrinsic to the patent ('723 patent at 6:34-49) and because some estimation is necessarily involved, by the claims' terms, in the matter of when to add crystals.

CONCLUSION

For the reasons explained, I find that Claims 1 and 2 of the '723 patent are invalid because the phrase "average particle size" is indefinite. I construe the phrase "adding crystals of the amino acid . . . to the medium" to mean "[i]ntroducing crystals to the medium that were not there before, which are the same crystals that the claim later requires 'grow . . . and accumulate in the medium.'" Finally, I construe the phrase "before crystals of the amino acid deposit in the medium," to mean "before the point in time when more than a slight amount of microcrystals would begin depositing in the medium, unaided by the addition of seed crystals."

BY THE COURT:

s/Richard A. Lloret
RICHARD A. LLORET
U.S. MAGISTRATE JUDGE