World Nutrition Incorporated v. Advanced Enzymes USA et al

2024 | Cited 0 times | D. Arizona | February 27, 2024

WO

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

World Nutrition Incorporated,

Plaintiff, v. Advanced Enzymes USA, et al.,

Defendants.

No. CV-19-00265-PHX-GMS ORDER

According to the stipulation of the parties, the Court held a bench trial from December 12 through December 15, 2023. The Court hereby makes its Findings of Fact and Conclusions of Law pursuant to Federal Rule of Civil Procedure 52.

FINDINGS OF FACT

Background 1. World) sells enzyme products to consumers. WNI is an Arizona corporation.

2. Mr. Ryuji Hirooka is the CEO, founder, and a shareholder of WNI. Mr. Hirooka is not involved in the day-to-day operations of WNI.

3. Advanced Supplementary Technology Corporation sells enzyme products to consumers. AST is a California Corporation.

4. WNI and AST are competitors, each selling enzyme products in the same markets directly to consumers, in health-food stores, and online.

5. Digestive enzyme products are designed to assist with digestion and are absorbed in the stomach and intestines.

6. Systemic enzyme products are designed to work throughout the entire body and should not be

absorbed until they have passed through the stomach to be effective.

7. Systemic enzymes will degrade in gastric acid in the stomach. 8. Enteric coating protects enzymes from degrading in the stomach allowing many, if not all, of the enzymes in a capsule to survive and be absorbed in the intestine.

9. AST sells four enzyme products relevant to this matter: Serracor NK, . These products are in a fine powder form, enclosed by a capsule. The capsule is not designed to survive stomach acid; rather, the enteric protection is supplied in the process that granulizes the powders before they are placed in the capsule.

10. The AST Products are systemic enzyme products. 11. WNI sells six enzyme products relevant to this matter: four Powder Products and two Liquid Products. These products are enclosed by a capsule made of Zein. The Zein capsule constitutes the enteric coating for the enzymes.

12. The Powder Products are Vitalzym Original Hybrid, Vitalzym Plus, Vitalzym Cardio, and Vitalzym X.

13. The WNI Powder Products labels indicate they contain both systemic and digestive enzymes.

14. The Liquid Products are Extra Strength and Vitalzym XE. 15. The WNI Liquid Products are systemic enzyme products. 16. The parties agree there is no liability for actions prior to 2016.

AST Products: Generally 17. AST uses enzyme blends in its AST Products. 18. . AST is member of SEB Group, a family of companies including Specialty.

19. The AST Products are manufactured by Advanced Enzymes Technologies .

20. Three of the AST Products were previously sold under different names.

a. Serrapeptase was formerly known as Peptizyme-SP. b. Excellacor was formerly known as Excelzyme. c. Ultimate Metabolic Formula was formerly known as Exclzyme-2AF. 21. The AST Products have been continuously advertised and sold in interstate commerce since January 1, 2016.

AST Products: Serrapeptase 22. Since January 2016, the labels for all four AST Products state the product contains enteric-coated serrapeptase.

23. AST advertisements repeatedly emphasized the efficacy of its enteric coating:

a. xperience and expertise, our entire line of enteric- coated enzymes are able to reach the small intestine with higher activity for full systemic enzyme therapy. (P. Tr. Ex. 46 at AST0005090.)

b. ve enzymes to survive the acidic conditions of the stomach, thus allowing them to pass into the circulatory system maintaining high activity levels. (P. Tr. Ex. 4 at AST0002558.)

c. SP allows the enzymes to survive the acidic conditions of the stomach, which increases absorption in the small intestine, systemic activity (P. Tr. Ex. 4 at AST0002567.) 24. As is stated above, AST does not use the same process as WNI to provide enteric protection to its enzymes. Rather than providing the enteric coating through the capsule in which they are sealed, AST mixes the polymer coating solution with the serratiopeptidase and other enzymes inside of a Rapid Mixer Granulator during the granulation process.

25. An RMG operates by moving a propellor in a large tub filled with the products to be placed inside the capsule. While the material is being moved, a blade chops at a very high rate of speed, mixing the ingredients.

26. The polymer coating solution is added to the dry materials inside the RMG and is thus granulized with the other powders. There is no other stage where enteric protection is provided.

27. After the solution is mixed in, the material is vacuum dried and sifted into a fine powder.

28. Scanning Electron Micrographs show that there is some enteric coverage of the resulting powder, but there are also large gaps or holes in all the enteric material that partially covers the granules. As a result, the enzymes in each of the granules is directly exposed to stomach acid through the gaps and holes. Although the granulized substance is then placed in capsules, those capsules do not provide any enteric protection for their contents.

29. AST does not assert that its process designed to provide enteric protection results in serrapeptase enzymes that are completely covered. It acknowledges that the AST products have gaps or holes in the polymer that surrounds the serrapeptase.

30. Drs. David Savello and Jason Clevenger, agree that the AST Products lost most of the serrapeptase they contained in the gastric acid designed to simulate the stomach. mated that 73% of enzyme activity would be lost through its exposure to stomach acid before it arrives at the intestines.

AST Products: Nattokinase 31. Serracor-NK contains an enzyme called nattokinase. 32. The nattokinase in Serracor-NK was not enteric coated from 2016 through the summer of 2021.

33. Prior to 2016, AST advertised Serracor-NK as containing enteric-coated serrapeptase and enteric-coated nattokinase.

34. Between 2016 and 2021, AST changed most of its advertisements for Serracor-NK to state -coated serrapeptase and nattokinase. (See, e.g., P. Tr. Ex 46 at AST0005067).

35. The Frequently Asked Question webpage (FAQ) of the Serracor-NK product represented that the nattokinase in Serracor-NK was enteric coated until June 2018.

36. The FAQ was the only instance showing AST claimed nattokinase was enteric coated from 2016 until 2021.

37. AST does not dispute that the enteric-coating claim made on the FAQ was false.

WNI Products: Generally 38. The WNI Products have been continuously advertised and sold since January 1, 2016, apart from Vitalzym Plus which was discontinued in or around 2019.

WNI Products: Buffer Enteric Coating 39. As stipulated to by the parties, from August 1, 2016, through May 18, 2021, WNI advertised on its website that the WNI Powder Products each contained buffer enteric-coated serrapeptase.

40. -coated serrapeptase as advertised.

41. Buffer enteric coating does not exist.

WNI Products: Labelling 42. WNI does not manufacture the enzyme products it sells. 43. WNI has never received GMP, GMP+, or NSF certification by any association or government entity.

44. While GMP has certification standards, it does not certify sellers as being compliant.

45. WNI purchases its Powder Products from Enzymology Research Center .

46. ERC has GMP and NSF certification from as early as February 14, 2012. 47. WNI purchases its Liquid Products from Suncho Pharmaceuticals Co., Ltd. .

48. Suncho was GMP certified under Japanese guidelines from August 10, 2018 to August 9, 2021.

49. Suncho was GMP and NSF certified on May 30, 2023. 50. Former product labels for Vitalzym Original Hybrid, Vitalzym X, Vitalzym Plus, and Vitalzym Extra Strength included the GMP+ symbol:

a. Vitalzym Original Hybrid was advertised as GMP+ Certified from January 2016 to May 2018. By June 2019, it was no longer advertised as GMP+ Certified.

b. Vitalzym X was advertised as GMP+ Certified from January 2016 to June 2019.

c. There is no evidence that Vitalzym Plus was advertised as GMP+ Certified after the liability period.

d. Vitalzym Extra Strength was advertised as GMP+ Certified for at least the 2020 and 2021 calendar years. 51. Former product labels for Vitalzym Cardio, Vitalzym Original Hybrid, and Vitalzym Extra Strength included a generic GMP symbol:

a. Vitalzym Cardio was advertised as GMP compliant from at least June 2019 through the 2020 calendar year.

b. Vitalzym Original Hybrid was advertised as GMP compliant from at least June 2019 through the 2020 calendar year.

c. Vitalzym Extra Strength was advertised as GMP compliant from 2014 through the 2019 calendar year. 52. Former product labels for Vitalzym Original Hybrid and Vitalzym Extra Strength included an NSF symbol:

a. Vitalzym Original Hybrid was advertised as NSF compliant from November 2015 to at least May 2018. By June 2019, it was no longer advertised as NSF certified.

b. Vitalzym Extra Strength was advertised as NSF compliant for at least the 2019 calendar year. 53. . Taryn Horr testified that WNI did not establish a GMP compliance program and that WNI only visited a single Suncho facility.

54. Ms. Horr further testified that WNI and ERC did not have a co-manufacturing agreement or quality agreement until 2019.

55. An FDA inspection in 2018 found that WNI did not maintain product records or establish written procedures for holding and distributing operations, review and investigation of product complaints, or handling of returned supplements.

WNI Products: 100% Efficacy 56. WNI advertised the Liquid Products as having an enteric coating that 100 percent of the enzymes survive the harsh acidic environment of the stomach (D. Tr. Ex. 548 at 3).

57. WNI also advertised the Liquid Products as having enteric coating that makes nearly 100% of the enzyme contents available for absorption into the bloodstream. (Id. at 5).

58. WNI Liquid Products use a polymer called Zein to enterically coat the WNI Liquid Products. The Serrapeptase is placed in a capsule made of Zein to provide the coating.

59. In May 2021, Dr. Savello evaluated the enteric coating of the AST products, as well as Vitalzym Extra Strength and Vitalzym Original Hybrid.

a. Dr. Savello testified that disintegration data indicates the Zein capsule can survive to protect its contents for at least three hours in either an acidic or basic solution.

b. Dr. Savello did not measure to total activity of the serrapeptase in the WNI Products because the capsules remained intact after two hours. 60. Dr. Clevenger evaluated the efficacy of certain AST products as well as the efficacy of Vitalzym XE.

a. Dr. Clevenger used a variant of Model. Even the unaltered Infogest Model has not been adopted by an American authority.

b. Dr. Clevenger modified the Infogest Model by reducing the total time the Vitalzym XE was exposed to intestinal fluid by 90 minutes. The Infogest Model calls for 30 minutes of exposure in stomach acid followed by 120 minutes in intestinal fluid. Dr. Clevenger only exposed the capsules in intestinal fluid for 30 minutes in each before measuring for enzyme activity.

c. Dr. Clevenger testified that, when measuring for a baseline of enzyme activity before conducting the testing he never scraped the material contained in the Vitalzym XE capsule.

d. When he was measuring enzyme activity, Dr. Clevenger did not distinguish serrapeptase activity from other potential enzymic activity. Furthermore, Dr. Clevenger did not offer measurement of other enzymes included in the Vitalzym XE capsules.

e. Dr. Savello testified the variability inherent in the Infogest Model is high.

Profits: Generally 61. Plaintiff hired Mr. Michael Fahlman to analyze financial data of the WNI and AST products for the liability period, starting in 2016.

62. Defendant hired Ms. Jacqueline Smart to analyze financial data of the WNI and AST products for the liability period, starting in 2016.

Profits: AST 63. Mr. Fahlman determined that from 2016 through March 2021, the relevant AST products generated $5,234,801.00 in revenue.

a. Mr. Fahlman made an initial calculation of revenue based on gross receipts.

b. Next, Mr. Fahlman made two adjustments. He first added estimated Serracor-NK revenue.

c. He next made an adjustment for Amazon sales revenue. AST began netting its Amazon fees in its 2021 accounting. Mr. normalization undid that netting to determine the actual revenue and made the 2021 accounting data comparable to previous years. 64. Mr. Fahlman estimated that AST received approximately $72,000.00 in revenue per month starting in April 2021 from the relevant products.

a. trial testimony indicated that sales serrapeptase products since 2021 have not experienced large declines and likely

remain steady.

b. Based on Mr. $2,340,000.00 in additional revenue from April 2021 through the start of trial for its four serrapeptase products. 65. Ms. revenue by using Mr. revenue number and adjusting it.

a. Ms. was for $5,111,848.00 in revenue. b. Her calculation did not initially a fees in its 2021 accounting.

c. After Ms. n updated calculation of generated by at issue products, which was $5,225,298.00.

d. Ms. 016 through 2021 was $16,660,587.00. According to Ms. Products account for 31. revenue in the period at issue.

66. Ms. in producing the relevant products as $3,900,261.00.

a. Ms. Smart based her calculation of costs attributable to the relevant products on account descriptions and conversations with AST employees.

b. Ms. Smart did not match claimed costs to any invoices, accounting data, receipts, or third-party documentation.

c. Ms. Smart did not factor in the change in cost of sales between private label and consumer sales when calculating costs.

d. Ms. . She did so by estimating the pe matter. She then applied that percentage to the payroll costs.

e. When applying this payroll percentage to costs, Ms. Smart did not completed in furtherance of the AST products relevant to this case.

f. Ms. Smart found that AST spent $254,219.00 on advertising from 2016 through 2020. She further found 2021 advertising spending to be $45,522.00. Ms. ng costs for the relevant products alone. including those not at issue here. In total, Ms. Smart deducted $299,741.00 in

advertising expenses.

g. Ms. Smart found that AST spent $768,499.00 on employee wages, commissions, and payroll taxes from 2016 through 2021. Like the advertising costs, these costs represent wages, commissions, and payroll taxes expended on both the relevant products and products not at issue here. 67. Mr. Fahlman

did not calculate an affirmative number for

a. Mr. Fahlman testified that he requested and never received documents from AST that detailed product-by-product costs and spending.

Profits: WNI 68. Mr. $2,438,571.00.

a. Mr. $14,286,748.00. b. Mr. Fahlman found that WNI Liquid Products and WNI Powder .

c. Mr. d. Mr. Fahlman tied 83% of reported costs to underlying invoices, payroll provider reports, and third-party documentation.

e. Mr. Fahlman classified Category 1 and 2 costs as those with a showable nexus to the at issue products. The Category 1 and 2 costs from 2016 through 2021 is $11,694,377.00: $8,636,319.00 for the Liquid Products and $3,058,058.00 for the Powder Products.

f. Mr. Fahlman classified expenses that did not have a confirmed nexus with the products . This included advertising costs. The total Category 3 costs for both sets of products from 2016 through 2021 is $101,500.00: $76,982.00 for the Liquid Products and $24,518.00 for the Powder Products.

g. Mr. Fahlman classified expenses without a nexus to the products as products is $49,817.00: $37,240.00 for the Liquid Products and $12,577.00 for the Powder Products. 69. Ms.

a. Ms. costs.

b. Ms. Smart agreed with Mr. $14,286,748.00.

c. Ms. Smart provided a revenue by product analysis that Mr. Fahlman does not dispute.

d. Ms. Smart found that from 2016 through March 2021, the Powder Product revenues totaled $2,790,364.00.

e. Ms. Smart approximated the final three quarters of 2021 to reach an approximate revenue of $3,388,768.00 from 2016 through all of 2021.

CONCLUSIONS OF LAW

Lanham Act 1. Claimants have a burden of proving five elements of a false advertising claim under the Lanham Act:

(1) a false statement of fact by the defendant in a commercial advertisement about its own or another

s product; (2) the statement actually deceived or has the tendency to deceive a substantial segment of its audience; (3) the deception is material, in that it is likely to influence the purchasing decision; (4) the defendant caused its false statement to enter interstate commerce; and (5) the plaintiff has been or is likely to be injured as a result of the false statement, either by direct diversion of sales from itself to defendant or by a lessening of the goodwill associated with its products. Southland Sod Farms v. Stover Seed Co., 108 F.3d 1134, 1139 (9th Cir. 1997); 15 U.S.C. § 1125(a).

2. The parties stipulate that under Ninth Circuit law, representations that are literally false are rebuttably presumed to be misleading and material. Avid Info. Sys., Inc. v. Schering-Plough Corp., 33 Fed. Appx. 854, 856 (9th Cir. 2002); U-Haul International Inc. v. Jartran, Inc., 793 F.2d 1034, 1040, 41 (9th Cir. 1986).

3. The U-Haul Court notes, however, that the presumption is justified because expenditure by a competitor of substantial funds in an effort to deceive consumers and

influence their purchasing decisions justifies the existence of a presumption that consumers are, in fact, being deceived. He who has attempted to deceive should not complain when required to bear the burden of rebutting a presumption that he succeeded Id. at 1041.

Harper House, Inc. v. Thomas Nelson, Inc., 889 F.2d 197, 209 (9th Cir. 1989). Therefore, while the presumption has sometimes been described as being generally applicable without preconditions, other courts have declined to apply the presumption absent a showing it was made alongside an expenditure of substantial funds to promote its falsity or within a comparative statement with a specific competing product. See Soilworks, LLC v. Midwest Indus. Supply, Inc., 575 F. Supp. 1118, 1135 (D. Ariz. 2008).

4. Here, the parties have stipulated that, should the court find actual falsity, the presumption is applicable. The Court will therefore find that there is no question about sufficient justification to apply the presumption.

5. Damages for proven violations of false advertising include disgorging profits. 15 U.S.C. § 1117(a). Profits are revenue minus costs. The claimant has the burden of proving revenue while the defendant has the burden of proving costs. 15 U.S.C. § 1117(a). Where a defendant does not carry its burden to show costs, the plaintiff is entitled to all revenue generated by the offending product. Nintendo of Am., Inc. v. Dragon Pac. Intern., 40 F.3d 1007, 1012 (9th Cir. 1994).

6. Recovery for false advertising is subject to principles of equity. Id. 7. Under the Lanham Act, courts may impose injunctions violation of 15 U.S.C. § 1125(a). 15 U.S.C. § 1116.

8. Injunctions are appropriate where a plaintiff can show the following elements:

(1) that it has suffered an irreparable injury; (2) that remedies available at law, such as monetary damages, are inadequate to compensate for that injury; (3) that, considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction. eBay Inc. v. MercExchange, L.L.C., 547 U.S. 388, 391 (2006).

AST Falsely Advertised 9. Defendant AST falsely advertised the AST products by continuously claiming they were enterically coated.

10. Drs. Savello and Clevenger agreed that the AST Products degraded substantially in stomach acid. AST did not dispute these findings.

11. The AST process of mixing its enteric polymer does not result in an enteric coat. The process may provide some protection from the enteric process but it neither coats the enzyme granules nor protects the majority of the enzymes as they pass through the stomach. . Coating, https://www.merriam-webster.com/dictionary/coating (last visited Dec. 27, 2023). . . . . Cover, https://www.merriam-webster.com/dictionary/covers (last visited Dec. 27, 2023). The Products. A coating process does not, as a matter of course, result in holes or gaps in the substance to be covered. . As Dr. Clevenger, 73% of the serrapeptase will be degraded by the time it reaches the intestines.

. Moreover, because the purpose of advertising that the serrapeptase is generically coated is to represent to the market that it will survive the gastric acid that the serrapeptase encounters in the stomach, when, as here, the granulation process does not result in a covering of the serrapeptase, the statement has the tendency to deceive a substantial segment of its audience, and the deception is material.

12. Further, b there is a rebuttable presumption its claims were misleading and material. The presumption is appropriate here because evidence indicates AST centered its advertising and spent substantial funds on the claim that its products were more effective because of the enteric coating. AST did not present evidence to rebut those presumptions.

13. 14.

15. Mr. . revenue differs by $9,503.00. The Court finds Mr. based on his methods and the errors made by Ms. Smart initially.

revenue from 2016 through 2021 is $5,234,801.00.

16. The Court further accepts Mr. .00 of revenue per month generated by the AST Products. This number is the middle point between average monthly revenue from the entire liability period and the average monthly revenue from 2021. Since AST continued to market the AST products as enteric

coated during the pendency of this matter, $72,000.00 month not already accounted for by Mr. Fahlman. Those months are January 2022 through December 2023. This adds an additional 24 months of revenue for a total of $1,728,000.00.

17. The AST Products Revenue from 2016 through today is $6,962,801.00. 18. AST did not carry its burden to deduct Ms. entire $3,900,261.00 estimate of costs from the AST Products Revenue.

a. First, Ms. Smart included advertising costs in her estimated expenses. The Court agrees with Mr. Fahlman that advertising costs are attenuated enough from the products sold to not count them as deductible expenses; especially because the advertising costs included by Ms. Smart presumably include costs for products not at issue in this case. Accordingly, advertising costs will not be deducted from . As such, Ms. .00 in costs.

b. Second, Ms. Smart included wages, commissions, and payroll taxes as expenses. While overhead costs can be deducted from revenue when disgorging profits, those costs need to have a proven and clear nexus with the product sold. It . Testimony at trial indicated that Ms. Smart did not inquire into such, Ms. Smart does not know whether there is a nexus between the wages she

deducted and the relevant products sold. Since the AST Products account for only 31.36% of its revenue, AST cannot claim employee wages are inherently related to the AST Products. In other words, it is highly likely that much of the employee wages were spent working on products not at issue here. AST thus fell short of its burden to show employee wages, commissions, and payroll taxes should be deducted from its revenue. Ms. .00 in employee

c. Finally, AST did not provide evidence of costs beyond 2021. In equity, the Court will credit AST costs for these months using the same method as Mr. Fahlman used: the middle point between the average costs over the entire liability period and the average costs from 2021. Using this method, AST is entitled to average monthly costs of $37,587.81. For the entire 24 month period after 2021, AST is entitled to $902,107.44 in deductions. 19. AST is thus entitled to $3,734,128.44 in deductions. 20. present is $3,228,672.56.

WNI Labelling Was Misleading 21. Three labels are at issue in this case: GMP, GMP+, and NSF. The labels differ in visual design, wording, ownership, and qualifications.

a. The GMP label Manufacturing Process. Unlike the other two labels, use of the GMP label is not certified by a centralized regulator. Instead, GMP refers to a set of standards issued by the FDA. The FDA issues different GMPs for individual product types. While the FDA sets forth GMP standards, it does not certify that a particular manufacturer . Other private organizations, e.g., NSF, may offer certification for GMP compliance. There is no organization that regulates use, or the right to use,

b. The GMP+ label used by WNI states Assurance. The GMP+ label is owned by GMP+ International.

GMP+

International certifies companies that prove compliance with schema set by GMP+ International itself. Once certified, GMP+ International allows companies to use its GMP+ label. Use of the GMP+ label thus indicates compliance with GMP+ Accordingly, only companies certified by GMP+ International may properly use the GMP+ label.

c. The NSF label . Like GMP+ International, NSF itself sets out certain requirements by which companies can be certified. The label itself is owned by NSF and may only be properly used by companies that are NSF certified. As an institution, NSF also certifies companies as being GMP compliant. 22. AST met constituted false advertising.

a. : WNI used a label Evidence at trial revealed that WNI itself never had GMP certification or GMP compliant programs in place. Accordingly, AST is and material.

b. WNI did not offer sufficient evidence to rebut this presumption. ply not sufficient. GMP standards set by the FDA apply not only to manufacturers, but to packagers, labelers, or holders of the dietary supplement. 21 C.F.R § 111.1(a). Not only does the record fail to rebut the presumption, but it also affirmatively establishes that WNI was subject to GMP regulations and never received certification.

c. GMP Certified symbol. Accordingly, AST succeeds on its claim as to the GMP

Certified symbol. 23. AST met its burden to show use of the GMP+ symbol constituted false advertising.

a. improper and literally false: WNI used a label that stated, ance Evidence at trial revealed that GMP+ is a certification for animal feed rather than human foods. It is not an accepted certification for dietary supplements. Furthermore, neither WNI nor its manufacturers have ever been GMP+ certified or have had Assurance. label was material and misleading.

b. Like the GMP Certified label, the record is insufficient to rebut the presumption as to the GMP+ label. in error does not hold water while facing a rebuttable presumption, especially

because that argument amounts to an admission that WNI intended to mislead but accidently did so using the wrong label.

c. GMP+ symbol. Accordingly, AST succeeds on its claim as to the GMP+ symbol.

24. symbol on Vitalzym Extra Strength in the 2019 calendar year was false advertising. AST failed to meet its burden for the other products.

a. revealed that WNI itself never had NSF certification. Accordingly, AST is entitled

b. Like the GMP Certified and GMP+ labels, the record is insufficient to rebut the presumption as to the NSF label. were compliant is simply not sufficient because WNI implied that it had NSF

certification. Additionally, Suncho, the manufacturer of the Liquid Products, was not even NSF certified until 2023.

c. NSF symbol on its labels. Accordingly, AST succeeds on its claim as to the NSF

symbol.

WNI 100% Efficacy Claim Was Not Misleading 25. 100% or nearly 100% effective enteric coating was false.

26. To support its claim, AST relied on testimony from Dr. Clevenger. Dr. does not sufficiently carry for the following reasons.

a. First, testimony revealed that Dr. Clevenger modified the Infogest Model when conducting his tests. The Infogest Model requires two hours of exposure in intestinal fluid prior to testing; Dr. Clevenger only exposed samples to intestinal fluid for 30 minutes. Dr. Clevenger never provided a compelling justification for this modification. WNI claimed that its enteric coating could last inside the small intestine for at least two hours. Because the Infogest Model measured the active presence of enzymes released after the capsule was exposed for 30 minutes in intestinal fluid, the results claims regarding its enteric coating. After 30 minutes in intestinal fluid the capsule

might be entirely intact and thus, as opposed to enzymes being destroyed by exposure to gastric acid, no or few enzymes would have been released to measure enzyme activity.

b. Second, Dr. out its contents also undermines the reliability of his methods. Testimony at trial

established that the contents of the WNI Liquid Products was a thick paste and did not immediately fall out when cut in half. Accordingly, Dr. results are unreliable because the capsules might have retained the vast majority of

the enzymes, which thus would have remained unmeasured.

c. Third, Dr. Clevenger testified that certain capsules visibly ruptured, evidenced by the release of a yellow substance into the simulated gastric acid. WNI established, however, that riboflavin . . As such, it was also likely the released yellow color was attributable to released riboflavin as the capsule eroded as opposed to released enzyme. To further bolster the possibility, the non- riboflavin capsules

did not release a yellow color under the same conditions. At base, the yellow color observed by Dr. 27. Dr. Savello because the capsules in his tests remained intact after two hours.

28. 100% efficacy was false. this ground.

WNI Buffer Enteric Coating Claim Was Misleading 29. These representations have been stipulated to have occurred from August

1, 2016, through May 18, 2021. Evidence of WNI making claims beyond this time period was not presented.

30. to a presumption the claim was material and misleading. WNI did not rebut this

presumption with its argument.

31. WNI argues the claim was immaterial because the enzyme was digestive (i.e., it was designed to be absorbed in the stomach and, thus, enteric coating was not material). Evidence at trial established that WNI consistently designed labels calling the WNI Powder Products as containing both digestive and systemic enzymes. As such,

32. te commerce. 33.

Mr. Hirooka Is Not Jointly Liable 34. AST did not carry its burden to prove Mr. Hirooka was jointly liable for AST did not present sufficient evidence to show Mr. Hirooka was involved in daily operations of WNI.

35. AST is entitled to disgorged profits from the Powder Products from August 2016 through May 2021, the time period when WNI claimed it used buffer enteric coating. This time period is also co-false labelling on the Powder Products.

36. Mr. Fahlman and Ms. Smart generally agree on revenue numbers for the Powder Products. Accordingly, Ms.

a. Ms. Fahlman found the Powder Product revenue from 2016 through March 2021 to be $2,790,364.00. This number is not fully accurate because it over includes seven months in 2016 (the liability period for this claim begins in August of 2016) and under includes five months in 2021 (the liability period ends in May 2021). To adjust for these discrepancies, a monthly rate for 2016 and 2021 can be reached by dividing the reported revenue from those years and dividing them by the months they include (12 for 2016 and three for 2021). Under this rate, the Powder Product revenue is $294,966.58 for 2016 and $322,446.67 for 2021. Adding these sums to the revenue from the remaining middle years adds to a total Powder Product revenue of $2,712,652.25. 37. Because Mr. -party

documentation, the Court finds his testimony to sufficient .

38. Like AST above, WNI is only credited with expenses with a proven nexus. Expenses like advertising are not credited to WNI.

39. For Powder Products costs from 2016 through 2021, Mr. Fahlman calculated costs with a direct nexus to the product, to be $3,058,058.00. This number, however, reflects the entire 2016 and 2021 years. To reach a more accurate number, a per month rate is calculated by taking the annual Category 1 and 2 costs ($445,362.00 for 2016 and $724,853.00 for 2021) and developing a monthly rate. Next, that monthly rate should be multiplied by the number of months in the stipulated time period (seven months for 2016 and five months for 2021). The adjusted cost for the WNI Powder Products is $2,449,659.58.

40. AST is August of 2016 through May of 2021. ($2,712,652. .58). In total, AST is entitled to

$262,992.67 in disgorged profits from WNI for the buffer enteric coating claim.

41. and NSF labels on Vitalzym Extra Strength. The record indicates WNI used at least one of these three labels continuously from the onset of the liability period on January 1, 2016, through the 2021 calendar year. AST is entitled to disgorged profits from Vitalzym Extra Strength for these years, totaling $1,138,028.21.

a. its Extra Strength line for the above time period: 2016 through 2021. The total revenue for the Extra Strength line from 2016 through 2021 was $5,416,306.

b. Next, the Court calculated the reduceable costs for the Extra Strength line from the above time period. To do this, the Court added the Category 1 and 2 Costs for each relevant year. This resulted in a total cost of $8,255,506.00 for the Liquid Products from 2016 through 2021.

c. Next, the Court reduced the Liquid Products costs, year-by-year, to reflect only Vitalzym Extra Strength. To do this, the total cost for the Liquid Products in each year was multiplied by the percentage of revenue the Extra Strength line represented within the Liquid Products for each year. This resulted in a total cost of $4,278,277.79 for the Extra Strength Line from 2016 through 2021.

d. Finally, the Court calculated the total profit of the Extra Strength from 2016 through 2021 by subtracting the above calculated costs from revenue. In total, AST is entitled to $1,138,028.21 in d labels on Vitalzym Extra Strength.

42. $1,401,020.88.

43. ($1,401,020.88 ($3,228,672.56). Accordingly, WNI is

awarded a total of $1,827,651.68 from AST.

WNI is Entitled to an Injunction 44. AST continues to advertise and market Excellacor, Serracor-NK, Serrapeptase, or Ultimate Metabolic Formula as being enterically coated. As explained above, this claim is literally false and a violation of 15 U.S.C. § 1125(a).

45. Plaintiffs seeking injunctions under § presumption of irreparable harm upon a finding of a violation . . . 15 U.S.C. § 1116. 46. Monetary damages are not adequate for continuing violations by AST. 47. There are no substantial hardships faced by AST. It is not a sufficient hardship for AST to change its marketing to comply with the Lanham Act. Not providing an injunction, however, would present hardships to WNI including the responsibility to consistently monitor the advertising materials of its competitor.

48. Finally, there is no public interest in denying an injunction. In fact, the opposite is true. By granting a permanent injunction, AST will be prohibited from continuing to publish literally false advertising in interstate commerce. As such, the public, too, is served by a permanent injunction.

49. Finding that WNI has carried its burden proving the four elements for a permanent injunction under the Lanham Act, AST is permanently enjoined from making claims that its current versions of Excellacor, Serracor-NK, Serrapeptase, or Ultimate Metabolic Formula or any powder-based product containing serrapeptase where the polymer is applied through the granulation process are enterically coated.

CONCLUSION For the reasons stated above, the Court finds in favor of WNI and AST respectively. Because WNI award is greater than

IT IS THEREFORE ORDERED finding in favor of WNI and directing the Clerk of Court to enter judgment accordingly and terminate this case. IT IS FURTHER ORDEDED AST shall pay WNI $1,827,651.68 in disgorged profits. IT IS FURTHER ORDERED AST, or any of its officers, agents, servants, employees, attorneys, or others in active concert with AST, is enjoined from advertising any of its powder-based products containing serrapeptase as being enterically coated when the polymer is applied to the powder or powders in such a way that it does not provide a complete covering to the powder or powders. This permanent injunction thus applies -NK, Serrapeptase, and Ultimate Metabolic Formula products, including under any new name for these products. AST is further enjoined from making such claims regarding any powder-based product containing serrapeptase where the polymer is applied through its current, or similar, a granulation process. Dated this 27th day of February, 2024.