UNITED STATES OF AMERICA BEFORE THE FEDERAL TRADE COMMISSIO

COMMISSIONERS: Edith Ramirez, Chairwoman

Julie Brill

Maureen K. Ohlhausen Joshua D. Wright Terrell McSweeny

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In the Matter of)	
)	Docket No. 9358
ECM BioFilms, Inc.,)	
a corporation, also d/b/a)	
Enviroplastics International,)	PUBLIC DOCUMENT
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Respondent.)	
)	

RESPONDENT ECM BIOFILM'S BRIEF IN ANSWER TO COMPLAINT COUNSEL'S APPEAL

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TABLE OF CONTENTS

I.	SUMMARY1
II.	RESPONSE TO COMPLAINT COUNSEL'S SUMMARY OF FACTS 8
	A. ECM Plastics Are Biodegradable
	B. ECM's Testing Was Competent and Reliable
	C. Because the ECM Additive Is Efficacious, ECM Had no Duty to Warn Consumers that the Additive Did Not Work
III.	STANDARD OF REVIEW
IV.	ECM DID NOT MAKE THE ALLEGED IMPLIED CLAIMS
	A. "Biodegradable" Does Not Imply Decomposition Within One Year or Less
	B. Ad Interpretations
	C. The ALJ Correctly Credited Stewart's Testimony
	D. Dr. Stewart's Valid Survey Proves that ECM Made no Implied Rate Claims
	1. The Record Amply Supports the ALJ's Crediting of the Stewart Survey
	 No Significant Minority of American Consumers Define "Biodegradable" to Mean Complete Decomposition Within Any Specific Time Frame; Complaint Counsel's Manipulation of Stewart's Data Lacks an Expert Foundation and Is Improper 20
	E. The ALJ Correctly Rejected Complaint Counsel's Argument for Convergence Validity
	1. The Commission Must Hold Survey Evidence to Generally Accepted Standards 22
	2. The Synovate and APCO Surveys Were Invalid
	3. Frederick's Survey Did Not Satisfy the Standards for Reliable Surveys
	a. Overview of Frederick's Google Survey
	b. Frederick's Financial Incentive to Avoid Quality Research
	c. Frederick Failed to Define a Population; the Demographics of his Sample Are Unknowable
	d. Frederick Did Not Ask Appropriate Questions

	e. Frederick Did Not Properly Analyze Data
	f. Frederick's Survey Suffers from Disinterest Bias
	F. Convergence Validity Fails Because the Survey Results Are Dissimilar
V.	ECM PLASTIC EFFICACY IS SUPPORTED BY COMPETENT AND RELIABLE EVIDENCE
	A. The ALJ's Interpretation of "Biodegradable" As a Process, Not a Dated Endpoint, Is Supported by Record Science
	B. ECM Plastics Are Biodegradable
	The ALJ Properly Determined that ECM Possessed the Amount of Substantiation Necessary for Its Biodegradable Claims
	2. ECM's Biodegradable Claims Are Substantiated with Requisite Science
	a. The ALJ Identified the Mechanism by Which the ECM Additive Functions 40
	b. Minimum" 60% Conversion and Radiolabeled Testing Are Not Generally Accepted
	c. ECM's Scientific Proof Satisfies the Scientific Standard
	d. ECM's Test Data Was Competent and Reliable
VI.	A STRONGER REMEDY IS UNJUSTIFIED, ARBITRARY, AND CAPRICIOUS 49
VII.	CONCLUSION

TABLE OF AUTHORITIES

Cases

Cinderella Career & Finishing Schools, Inc. v. F.T.C., 425 F.2d 583 (D.C. Cir. 1970)	12, 13
F.T.C. v. US Sales Corp., 785 F. Supp. 737 (N.D. III. 1992)	16
Gibson v. Texas Dep't of Ins.—Div. of Worker's Compensation, 700 F.3d 227 (5th Cir. 2012)	51
Grant v. Astrue, 857 F. Supp. 2d 146 (D.D.C. 2012)	11
In re POM Wonderful, 155 F.T.C. 1 (2013)	3, 18, 24, 28
In re POM Wonderful, 2012 WL 2340406 (F.T.C. May 17, 2012)	18
In re Stouffer Foods Corp., 118 F.T.C. 746 (1994)	25, 26
In re Telebrands, 140 F.T.C. 278 (2005)	16, 26
In the Matter of Am. Home Prod. Corp., 98 F.T.C. 136 (1981)	23
In the Matter of Heinz W. Kirchner, 63 F.T.C. 1282 (1963)	18
Jones v. Astrue, 623 F.3d 1155 (7th Cir. 2010)	12
Letter Ruling Denying the Petition to Quash Four Civil Investigative Demands, 118 F.T.C. 1257 (1994)	14
Malletier v. Doone & Bourke, Inc., 525 F. Supp. 2d 558 (S.D.N.Y. 2007)	24
Morall v. Drug Enforcement Admin., 412 F.3d 165 (D.C. Cir. 2005)	12
Nat'l Football League Prop., Inc. v. N.J. Giants, Inc., 637 F. Supp. 507 (D.N.J. 1986)	24
New.Net, Inc. v. Lavasoft, 356 F. Supp. 2d 1071 (C.D. Cal. 2003)	51
Office of Consumers' Counsel, State of Ohio v. F.E.R.C., 783 F.2d 206 (D.C. Cir. 1986)	12
Ohralik v. Ohio State Bar Ass'n, 436 U.S. 447 (1978)	51
OKC Corp. v. F.T.C. 455 F.2d 1159 (D.C. Cir. 1972)	12

Pearson v. Shalala, 164 F.3d 650 (D.C. Cir. 1999)53
Schering-Plough Corp. v. F.T.C., 402 F.3d 1056 (11th Cir. 2005)
Standard Oil Co. v. F.T.C., 475 F. Supp. 1261 (N.D. Ind. 1979)
Thomas v. Astrue, 677 F. Supp. 2d 300 (D.D.C. 2010)
Thompson Medical, 104 F.T.C. 648 (1984)23, 25
U.S. v. Wilson, 605 F.3d 985 (D.C. Cir. 2010)
Utica Packing Co. v. Block, 781 F.2d 71 (6th Cir. 1986)
Withrow v. Larkin, 421 U.S. 35 (1975)
Other Authorities
FED. TRADE COMM'N, POLICY STATEMENT ON DECEPTION (1983)
Manual for Complex Litigation, Fourth § 11.493 (Federal Judicial Center 2004)
Regulations
16 CFR § 260 8

RECORD REFERENCES & ABBREVIATIONS

- ALJID or ID Initial Decision of the Administrative Law Judge
- ALJFF The Administrative Law Judge's Findings of Fact
- CCX Complaint Counsel's Exhibit
- RX Respondent's Exhibit
- JX Joint Exhibit
- Tr. Transcript of Testimony before the Administrative Law Judge
- Dep. Transcript of Deposition
- CCPB—Complaint Counsel's Pre-Trial Brief
- CCB Complaint Counsel's Post-Trial Brief
- CCRB Complaint Counsel's Post-Trial Reply Brief
- CCFF Complaint Counsel's Proposed Findings of Fact
- CCRRFF Complaint Counsel's Reply to Respondent's Proposed Findings of Fact
- CCOB Complaint Counsel's Opening Brief
- RPB Respondent's Pre-Trial Brief
- RB Respondent's Post-Trial Brief
- RRB Respondent's Reply to Complaint Counsel's Post-Trial Brief
- RFF Respondent's Proposed Findings of Fact
- RPCL Respondent's Proposed Conclusions of Law
- RRCCFF Respondent's Reply to Complaint Counsel's Proposed Findings of Fact
- ROB Respondent's Opening Brief
- "ECM Plastic" A plastic manufactured through heat molding to contain ECM's proprietary additive dispersed equally throughout, which additive causes plastics to biodegrade

 "Biodegradable Claim" - ECM's express claim that ECM Plastic is biodegradable and/or that tests prove that ECM Plastic is biodegradable

- "Implied One Year Claim" Complaint Counsel's charge that ECM's claim that ECM
 Plastics will biodegrade "in some time greater than a year" implies that ECM Plastics will
 completely biodegrade within one year after customary disposal.¹
- "Rate Claim" ECM's express claim that ECM Plastic is biodegradable in 9 months to 5 years and/or that tests prove that ECM Plastic is biodegradable in 9 months to 5 years
- "One Year Rule" Green Guide, 16 CFR § 260.8(c), statement that "[i]t is deceptive to make an unqualified degradable claim for items entering the solid waste stream if the items do not completely decompose within one year after customary disposal."
- "End-Use Consumer" A member of the general public exposed to ECM claims in the marketplace
- "Plastic Company Purchaser" Those companies to which ECM solicits business, sells its product, or sold its product

¹ As the ALJ explains, Complaint Counsel never clearly defined this implied claim, either as to the precise unit of time said to be implied or as to how the express language "some period greater than a year" reasonably connotes a period of less than a year. ALJFF ¶¶255, 257−58; ALJID at 167 at n. 18, 171, 178, 184, 220, 220 at n. 37 (explaining that "it is arguably absurd to suggest that reasonable consumers would infer that a claim that a product is 'biodegradable in some period greater than one year,' means that a product will completely biodegrade into elements found in nature, in a landfill, in less than one year"). As the ALJ found, Complaint Counsel never challenged the express claim as false or unsubstantiated. ALJID at 179.

I. SUMMARY

Complaint Counsel have failed to prove by a preponderance of the evidence that ECM's Biodegradable Claim deceives.² The record overwhelmingly confirms that ECM's Biodegradable Claim is backed by competent and reliable scientific evidence, as the ALJ so found: (1) The accepted scientific standard for determining plastic biodegradability is a gas evolution test (e.g., ASTM 5511), not a radiolabeling test, ALJFF ¶¶704–860; ALJID at 234–45; (2) 20 positive gas evolution tests prove that ECM plastics biodegrade faster than conventional plastics, ALJFF ¶¶1043–1424, 1448–65; ALJID at 246–85; (3) those tests reveal statistically significant plastic losses ranging from 3.65% in 15 days to 71.8% in 197 days, ALJFF ¶¶1080– 1424, 1448–65; (4) one of the world's leading landfill biodegradation experts, Dr. Morton Barlaz, testified that the tests prove ECM's additive causes plastics to biodegrade in landfills, ALJFF ¶253; ALJID at 263–66, 284; (5) Barlaz, environmental scientist Dr. Ranajit Sahu, and microbiologist Dr. Ryan Burnette each testified, consistently, to the mechanisms of action present, explaining how biota are attracted to, colonize upon, and enzymatically break down plastics infused with the ECM additive and continue to do so for as long as the plastic is present in biologically active environments, ALJFF ¶¶122–43, 566–632, 870–1005; ALJID at 246–52, 276–85. In addition, (6) a well-designed, national telephone survey by Dr. David Stewart established that consumers do not associate the term "biodegradation" with a preconceived time by which a product will break down into elements in nature, ALJFF ¶¶144–51, 498–556; ALJID

² As found by the ALJ, the Complaint and Complaint Counsel's arguments below involve only the following claim challenges: (1) to Respondent's express "biodegradable" claim (alleged to be false or unsubstantiated); (2) to Respondent's express claim that ECM Plastics biodegrade "within 9 months to 5 years" (dealt with not here but in Respondent's separately filed brief on appeal); (3) to Respondent's alleged implied "biodegradable" claim (said to cause reasonable consumers to believe that ECM Plastics will completely biodegrade into elements in nature within one year after customary disposal); and (4) to Respondent's alleged Implied One Year Claim. ALJID at 173–223; ROB at 18–39 (explaining that ECM's Rate Claim was not material).

at 213–20. In this case, Complaint Counsel's case not only fails for want of evidence, it also fails because competent and reliable scientific evidence proves the opposite of Complaint Counsel's contentions, to wit: that the ECM additive causes biodegradation as claimed. ALJID at 284–85 ("Dr. Barlaz persuasively and credibly testified that competent and reliable scientific evidence shows that plastics manufactured with the ECM Additive are anaerobically biodegradable.").

Complaint Counsel depend on scant evidence, and long presentations based on conjecture. Their argument is contradicted by the record and defeated by their experts' bias and testimonial conflicts. (1) Complaint Counsel's lead expert McCarthy and rebuttal expert Michel have ties to ECM competitors and, for McCarthy, a direct financial interest in the outcome of the litigation³; (2) McCarthy testified that he did not run any statistics on the 20 gas evolution tests supporting ECM's Biodegradation Claim, did not test the ECM plastic, presumed without the benefit of testing or peer review that the additive itself degraded but did not degrade surrounding plastic, and deemed gas evolution tests insufficient to prove intrinsic biodegradability despite relying upon the very same kind of tests to adjudge biodegradability in his own patent and in his published articles, ALJFF ¶633–75, 716, 731, 745–46, 826–69, 900, 927–31, 1009–10; ALJID at 248–52, 270, 275–79. (3) Complaint Counsel depend heavily on one test, performed by Michel, as supposed proof that ECM plastics are ineffectual, despite the fact that the test was inconclusive, including no evaluation of why the inoculum and the plastic simultaneously

³ McCarthy owns intellectual property rights and receives royalties from bioplastic technologies that compete directly with ECM's, and his center at UMass-Lowell is heavily funded and operated by that same competitor, Metabolix. ALJFF ¶¶666–70. Michel has worked extensively for composting companies, and his testing on the ECM plastic was controlled by an ECM competitor, Myers Industries, that actually fabricated the plastic Dr. Michel tested and edited his analysis before it was published in violation of Elsevier's conflict of interest policy. ALJFF ¶¶1467, 1471–81, 85–92; ALJID at 254–55.

stopped biodegrading in the lab (failing to rule out the obvious confounders, including inoculum death, test plastic mis-manufacture, or negative ambient conditions), leading the ALJ to deem the test without "significant weight." ALJFF ¶¶1466–96; ALJID at 254–55. (4) McCarthy contradicted himself and Complaint Counsel's other expert witnesses: (a) admitting on cross that he did not author the definition of "biodegradation" in his expert report (Complaint Counsel did) and asking in open court if he could abandon the definition after admitting that his own published works and patent did not follow it, ALJFF ¶¶633–35, 638; ALJID at 226–29; (b) advocating radio label testing without the benefit of its general acceptance or feasibility, contradicting his fellow expert Tolaymat who testified that radio label testing was inappropriate and unproven⁴, ALJFF ¶¶827–47; and (c) arbitrarily deeming 60% degradation in a gas evolution test a minimum to prove biodegradation despite finding biodegradation present in his own patent and published works on as little as 14% biodegradation and in the presence of directly contradictory testimony from fellow expert Michel, ALJFF ¶716, 848–60; ALJID at 243–45. (5) Complaint Counsel expert Frederick dissembled under cross-examination, revealing that his single question Google consumer surveys failed to meet any of the generally accepted requirements for a competent survey, ALJFF ¶¶353–454; ALJID at 189–202.

Complaint Counsel failed to establish, as it must, *In re POM Wonderful*, 155 F.T.C. 1, 23 (2013), that the generally accepted scientific standard for biodegradation had not been met by ECM. Indeed, under the generally accepted gas evolution test standard ECM's Biodegradable Claim was proven true. The ALJ found Complaint Counsel's experts' theories unsupported and contradicted not only by the test data, the more credible opinions of Drs. Barlaz, Sahu, and Burnette, but also by Complaint Counsel's experts' own work outside of this litigation and by

⁴ Tolaymat explained that radiolabeled testing "could be as expensive ... as doing the study in a landfill environment" and "[i]ts not used frequently." ALJFF ¶¶839–40

their contradictory testimony at trial. ALJID at 226–30, 239, 242–45, 247–49, 251, 254–55, 269–84.⁵

McCarthy categorically rejected ASTM D5511 testing stating that the tests ran longer than the ASTM "validation" period, see CCX 891 at ¶89, but ASTM does not specify a cutoff time for D5511 tests. ALJID at 269. McCarthy demanded 60% biodegradation as a "minimum threshold" for gas evolution testing, but that 60% threshold is unknown in the peer reviewed science, is not followed in his own biodegradable polymer patent and articles (where as little as 14% sufficed), and is contradicted by his fellow expert Michel, ALJFF ¶848–60, ALJID at 245.6 McCarthy dismissed ECM testing without having run statistics and insisted on his priming effect theory without a single scientific article in support and direct test evidence to the contrary, including 20 positive gas evolution tests wherein the volume of measurable methane from plastic breakdown exceeded by as much as 44 times the quantity that could possibly be produced by the ECM additive alone. ALJFF ¶861–69, 1009, 1046–1424, 1448–65; ALJID at 281–84. On this record, if the Commission were to hold Complaint Counsel's burden met and reverse the ALJID, it would have to adopt as orthodox theories and standards nowhere endorsed in the scientific community (indeed, rejected by peers). That would give rise to Lysenkoism⁷. It would fail to guarantee that essential fairness, impartiality, and evidence based decision essential to Due

⁵ Complaint Counsel still cling to an illusory "priming effect" theory on appeal, despite the absence of a single proposed fact concerning the "priming effect" in the briefing before the ALJ.

⁶ Dr. McCarthy never held himself to that standard in his own work. ALJID at 243–45.

⁷ In the former Soviet Union, Trofim Lysenko's scientific theories became state sponsored orthodoxy despite lacking evidentiary support and contradicting generally accepted scientific principles. Lysenkoism thus refers to government adoption of "scientific" standards not generally accepted in the scientific community. *See Merriam-Webster Dictionary*, (Mar. 17, 2015), *available at* http://www.merriam-webster.com/dictionary/lysenkoism.

Process and compliance with the Administrative Procedure Act. *See Withrow v. Larkin*, 421 U.S. 35, 46 (1975); *Utica Packing Co. v. Block*, 781 F.2d 71, 76–78 (6th Cir. 1986).

By contrast, ECM's experts supported their consistent testimony with peer-reviewed literature, data from more than 30 gas evolution tests (the generally accepted standard, ALJID at 240–45), accepted principles of biochemistry and microbiology germane to plastics biodegradation, and detailed explanations of the mechanisms of action present. ALJID at 251 ("the opinions . . . were supported by peer-reviewed literature"), 270, 275, 279, 281, 283–85. ECM called three laboratory directors, the very ones who performed ECM Plastics testing, not for ECM but for ECM customers; Complaint Counsel called no fact witnesses. ALJFF ¶3, 90–100. The test data and expert testimony confirm that the ECM additive catalyzes biodegradation of plastics. ALJFF ¶1006–1042. Without contrary proof, the case against ECM has been a terrible waste of government and ECM resources. It has maligned the deserved good reputations of this small company's principals and of the product the company produces of critical import to the environment.⁸

Unable to prove an absence of competent and reliable scientific evidence, Complaint Counsel speculate that the word "biodegradable" implies that a product will completely biodegrade within one year after disposal. CCOB at 6–30. Indeed, Complaint Counsel drafted footnote 1 to Dr. McCarthy's expert report wherein they represented what McCarthy admitted upon cross to be false, that the arbitrary one year limit on biodegradation was "interchangeable" with the scientific definition of the term. ALJFF ¶633–35; ALJID at 227. Proven to be false (no published peer reviewed scientific article on biodegradation of plastics has ever defined

⁸ Dr. Barlaz testified that the ECM additive, unlike more rapidly degrading products, enables landfill collection of greenhouse gas emissions, thus serving that EPA goal. RPFF ¶¶1595, 1600, 1602–05.

biodegradation with a one year limit (not even McCarthy's own articles and patents (indeed, they contradict the premise))), McCarthy asked during cross that he be permitted to abandon the definition. ALJFF ¶¶633–75; ALJID at 226–29 ("McCarthy subsequently testified that he would like to change his testimony regarding the footnote one definition being 'interchangeable' with the scientific definition …").

The arbitrary one year limit is also not based on any valid consumer survey data. The limit is not only unscientific, having no scientific predicate, but is also contradicted by the competent and reliable consumer survey of Dr. David Stewart. ALJFF ¶¶498–556, 633–96; ALJID at 213–19, 224–34.

"Biodegradable" is defined as a process by which microorganisms decompose materials without regard to a set time for breakdown into elements in nature. ALJID at 230–34. Indeed, all experts who testified accepted the widely appreciated notion that a tree trunk, a banana peel, and an orange peel are biodegradable although they do not reliably break down into elements in nature within one year after customary disposal. ALJFF ¶673–74; ALJID at 229.

No reasonable consumer thinks that a plastic product will biodegrade completely within one year. ALJFF ¶498–556 ("Not one respondent to Dr. Stewart's survey understood biodegradation to mean the complete breakdown of the substance . . . within one year after customary disposal."); ALJID at 213–17. Any presumption of an "implied claim" is rebutted by extrinsic evidence. ALJID at 431–34. Not upheld in the peer-reviewed science, Frederick's single question survey distributed through Google Consumer Surveys (which included no screening questions) failed to define any population, failed to survey any representative sample, excluded questions based on invalid criteria (excluding over 28% of responses), was not blinded, and failed to ask questions in a way that minimizes bias. ALJFF ¶353–454; ALJID at 189–202.

The survey experts and the ALJ agreed that the APCO and Synovate surveys were fatally flawed. ALJID at 202–08. As the ALJ explained, "there is no legal precedent for permitting the results of seriously flawed surveys to validate one another for purposes of evidentiary proof in adjudication." ALJID at 208–13. As explained below, that unprecedented "convergent validity" theory fails. ALJID at 211.

The ALJ correctly found that ECM's Biodegradable claim was not deceptive but was supported by competent and reliable scientific evidence; and that none of the two allegedly implied claims was reasonably implied, a conclusion supported by the overwhelming weight of extrinsic evidence. Complaint Counsel have ignored that record here, as they did below: reciting the phrase *Complaint Counsel has no specific response* for 2,776 (or 92.41%) of ECM's 3,004 proposed findings of fact. On the record, it would disserve the public interest and justice to destroy ECM and the environmental benefits stemming from its only product on the false basis that the additive does not work or that consumers were deceived. The record science proves the product works; the competent survey evidence proves that no one was deceived.

⁹ Complaint Counsel did not argue below, and, so, cannot argue on appeal, that Respondent's claim that ECM Plastics biodegrade "in some period greater than a year" is a false or unsubstantiated express claim. ALJID at 167at nn. 17–18. Below, Complaint Counsel argued only that the claim falsely implied "complete biodegradation within one year" (the "Implied One Year Claim" in AJID at 174). Based on the whole record, the ALJ specifically held that ECM made none of the implied claims charged by Complaint Counsel, including the Implied One Year Claim. ALJID at 220–22. Because the Implied One Year Claim and the Biodegradable Claim were said below to imply complete biodegradation within one year of customary disposal, the ALJ assessed whether on their face and against extrinsic evidence of record those alleged claims were reasonably implied. *See, e.g.*, ALJID at 223, 275, 284. As the ALJ found, the overwhelming weight of extrinsic evidence supports the conclusion that they were not. ALJID at 246–85; *infra* at Part IV.

¹⁰ See CCRRFF.

II. RESPONSE TO COMPLAINT COUNSEL'S SUMMARY OF FACTS

On appeal, Complaint Counsel have not cited to the ALJ's findings, violating Rule 3.52(c). 16 CFR § 3.52(c). Rather than do so, Complaint Counsel improperly regurgitate the very proposed findings the ALJ rejected below without regard to the ALJID. Without waiving the objection that the rule violation should result in summary denial of the appeal, ECM substantively answers in detail below.

A. ECM Plastics Are Biodegradable

Complaint Counsel mistakenly assert that the Biodegradable Claim is false because "physically blending the Additive with plastic does nothing to change a molecular structure that extant microorganisms cannot break down." *See* CCOB at 3. To the contrary, the ECM additive is heat melded into every part of the plastic (in the same manner as a colorant), altering the plastic's chemical composition. ALJFF ¶¶183–95, 870–94; ALJID at 249–50. Its efficacy is substantiated, *proven* to work, based on over 20 competent and reliable gas evolution biodegradation tests, the industry "gold standard." ALJID at 240–45, 262–85.

B. ECM's Testing Was Competent and Reliable

The ALJ correctly found that over 20 competent and reliable gas evolution tests substantiate ECM's Biodegradable Claim. ALJID at 284–85. Ignoring that finding, Complaint Counsel cite a few inconclusive gas evolution tests, most of which were notably flawed, as proof to the contrary. CCOB at 35, 43, 46 at n. 36; ALJID at 252–62. The problem with those tests is that not a single one involves an evaluation to determine the cause of test failure and, so, they are not "negative" but only "inconclusive." "[M]any variables could influence the outcome of a gas evolution test, and [] an inconclusive test is expected in light of those variables and must be examined and assessed to determine what, if anything, those tests reveal." ALJID at 261. Not

even in the Michel test, heavily relied on by Complaint Counsel, did scientists proceed beyond inconclusive results to determine the precise cause of test failure. Without an identified cause, the tests are not "negative" and are insufficient to disprove the 20+ positive tests, which, as Dr. Barlaz well explained, ALJID at 284–85, demonstrably prove that the ECM additive causes the plastics to biodegrade. A gas evolution test is a closed-system, and biodegradation can continue only to the extent that biota in test vessels survive; keeping the biota alive is somewhat difficult, with inconclusive tests expected due to premature biota death. ALJFF ¶¶722, 791–807. In this case, the 20+ supportive ECM tests (containing positive evidence of substantial plastic loss) overwhelm the few inconclusive tests cited by Complaint Counsel. ALJFF ¶¶1043–1424, 1448–96.

The inconclusive Michel test, ALJID at 254-55, is tainted and unreliable. Michel never submitted his data to the peer-reviewers, who only reviewed the facial article supplied to them. ALJFF ¶1483-84. Michel failed to disclose conflicts of interest, in direct violation of the rules of the journal that published his article. ALJFF ¶1485-96. Michel did not know how the test plastic was made, whether in fact it contained the additive, or whether the additive had been properly manufactured into the plastic or had been scorched and rendered ineffective. ALJFF ¶1471-75. He obtained the plastic not from ECM but from a direct ECM competitor, Myers Industries, with economic interests adverse to ECM. ALJFF ¶1472. Most tellingly, he never performed any analysis to determine the actual cause of test failure. ALJFF ¶1474-78. Because Michel used the very same ASTM D5511 test model in his study that Complaint Counsel argue is improper for ECM, Michel undermines Complaint Counsel's argument against

the standard test. Indeed, Michel testified that the ASTM D5511 test is the scientific standard and is predictive of biodegradation in landfills. ALJFF ¶1469; RPFF ¶¶2917–20.¹¹

C. Because the ECM Additive Is Efficacious, ECM Had no Duty to Warn Consumers that the Additive Did Not Work

Complaint Counsel argue that ECM knew that NAD and two foreign courts found that two ECM customers made false and unsubstantiated biodegradation claims. CCOB at 5. The ALJ efficiently dispatched this specious argument:

The findings in these cases, in which ECM was not a party or represented, were not offered, or accepted, for the truth of the matters asserted therein []. Thus, as a matter of fairness, these cases do not constitute prior "violations" by ECM, or notice that the ECM Additive "did not work."

ALJID at 307 at n. 62. The NAD and foreign proceedings did not involve expert testimony or a documentary record sufficient to vet the issues presented in this case and were, of course, under legal standards different from those here. ECM was not a party. The evidence presented to the ALJ was not available in those cases. Despite a far less exhaustive record than that present here, the NAD found that ECM's biodegradable claims were supported: "[T]the advertiser provided support that its own plastic product, because of its additive, will degrade at a faster rate than conventional petroleum-based plastics" and that "the advertiser provided scientific bases for the theory that its product will degrade more rapidly than conventional ... plastics in specified anaerobic conditions." *See* CCX 28 at 15. In light of the testing proof of ECM product efficacy, Complaint Counsel's hyperbole, the "product was a hoax," is chimerical. *Compare* CCOB at 5–6 with ALJID at 246–85.

¹¹ ECM provides a "Certificate of Biodegradability" to customers, certifying that plastics properly manufactured with the ECM additive are biodegradable as defined by the ASTM. ALJID at 174–75; ALJFF ¶¶266–76. That certificate uses the ASTM definition of "biodegradable" which does not include a rate or time element.

III. STANDARD OF REVIEW

"[A]n ALJ's assessment of credibility is 'entitled to great weight and deference, since he had the opportunity to observe the witness's demeanor." *Grant v. Astrue*, 857 F. Supp. 2d 146, 157 (D.D.C. 2012) (quoting *Thomas v. Astrue*, 677 F. Supp. 2d 300, 307 (D.D.C. 2010)); *see also Jones v. Astrue*, 623 F.3d 1155, 1160 (7th Cir. 2010) ("The ALJ's credibility determinations are entitled to special deference because the ALJ has the opportunity to observe the claimant testifying."). Appellate bodies "reverse credibility determinations only if they are patently wrong." *Id.* Here the ALJ determined that ECM witnesses were credible and reliable, based on the consistency of their testimony and the scientific proof, and he determined that Complaint Counsel's witnesses were unreliable, biased, or incredible, based on the inconsistency of their testimony and the want of supportive science. ALJFF ¶324; ALJID at 188, 196–97, 208, 242–43, 245, 270, 275, 278, 281, 283–85.

The Commission may not "ignor[e] the testimony of many witnesses and the findings of the [ALJ]." *Cinderella Career & Finishing Schools, Inc. v. F.T.C.*, 425 F.2d 583, 589 (D.C. Cir. 1970); *Morall v. Drug Enforcement Admin.*, 412 F.3d 165, 177 (D.C. Cir. 2005) ("The agency's departures from the ALJ's findings are vulnerable if they fail to reflect attentive consideration to the ALJ's decision") (citations omitted); 16 CFR § 3.54(b). The Commission must "review the entire record" when "reviewing the findings of its trial examiner." *Cinderella*, 425 F.2d at 585 at n. 3; *see also Office of Consumers' Counsel, State of Ohio v. F.E.R.C.*, 783 F.2d 206, 238 (D.C. Cir. 1986) ("[i]n developing remedies, the Commission must consider the . . . record as a whole"); *Schering-Plough Corp. v. F.T.C.*, 402 F.3d 1056, 1070 (11th Cir. 2005) ("Substantial evidence requires a review of the *entire* record . . ., and that most certainly includes the ALJ's credibility determinations and the overwhelming evidence that contradicts

the Commission's conclusion.") (emphasis in original, citations omitted); *OKC Corp. v. F.T.C.*, 455 F.2d 1159, 1162 (D.C. Cir. 1972).

Complaint Counsel improperly rely on their own proposed (and rejected) findings of fact to the exclusion of the ALJID findings. Their opening brief cited the ID six times to findings of fact apparently disputed; nine to undisputed facts concerning expert credentials; and four to undisputed facts concerning ECM. *See generally* CCOB. By failing to cite the ALJ's substantive findings, Complaint Counsel have violated Rule 3.52(c).

Complaint Counsel misrepresent the evidence of record. They charge that ECM was "well aware" of Michel's study "but hid [it] from prospective customers." CCOB at 4. To the contrary, the ALJ sanctioned Complaint Counsel for improperly withholding that study from Respondent. Complaint Counsel also claim that "Frederick ... explained that it is highly significant that *four* studies, conducted with *four* distinct methodologies, at different times, by *four* sets of researches reached similar results." CCOB at 7–8 (emphasis added). That misrepresents Frederick's testimony. As the ALJ explained: "Frederick's convergent validity theory was expressly based on the purported 'convergence' of results of *three* surveys, the APCO, Synovate, and Google Surveys, and *does not refer to the results of Dr. Stewart's theory*." ALJID at 208 at n. 34 (emphasis added).

Deference is due the ALJ's well-reasoned decision, for "it is as preposterous for the Commission to ... decide a case de novo as it would be for [the D.C. Circuit Court] to claim a right to ignore the findings of fact and conclusions of law of a district court in a proceeding [before the D.C. Circuit Court], substituting the judgment of [the D.C. Circuit] on a cold record for that of the finder of the fact below." *Cinderella*, 425 F.2d at 588.

¹² See Order Granting in Part and Denying in Part Respondent's Motion for Sanctions (Mar. 21, 2014).

IV. ECM DID NOT MAKE THE ALLEGED IMPLIED CLAIMS

Complaint Counsel bear the burden of proving by a preponderance of the evidence that ECM made the implied claims alleged. ALJID at 181 (citation omitted). As the ALJ found, Complaint Counsel failed to prove the claims reasonably implied. ALJID at 180–223.

A. "Biodegradable" Does Not Imply Decomposition Within One Year or Less

Complaint Counsel improperly raise new argument on appeal. For the first time they define their implied "reasonably short time" claim not as at trial (wherein they mimicked the Green Guides' one year after customary disposal) but as "five years or less." CCOB at 1–2, 6, 8, 11, 12, 27. That tactic redounds to their detriment because it confirms that no precise implied claim ever existed and supports the ALJ's conclusion that there are no reasonably implied claims at issue in this case. ALJID at 220–23. Beginning with the Initial Prehearing Conference ("IPC") and continuing through closing argument, Complaint Counsel argued that the unqualified biodegradable claim implied decomposition within *one year* after customary disposal, never contending an implication of "five years or less." *See* 16 CFR § 260.8. *See* IPC at 8:5–22; *see also* CCX 890 (Frederick, Rep. at 13–14); CCX 891 (McCarthy, Rep. at 5 at note 1, 36); CCX 893 (Tolaymat, Rep. at 5); CCPB at 22; CCB at 20; Closing Arguments at 19:8–13; 25:13–19; 36:13–19; 36:22–24.

Having not presented the alleged "five years or less" implied claim in its Complaint or at trial, Complaint Counsel are foreclosed from doing so on appeal. *Letter Ruling Denying the Petition to Quash Four Civil Investigative Demands*, 118 F.T.C. 1257 (1994) ("The Commision is not required to, and normally would not, consider new arguments raised on appeal."). Indeed, doing so violates ECM's Due Process rights. *See Standard Oil Co. v. F.T.C.*, 475 F. Supp. 1261,

1275 (N.D. Ind. 1979) (citations omitted) ("The essence of due process ... is the requirement of prior notice of the charges against a person and a fair opportunity to be heard ...").

Assuming *arguendo* that the governing law is not followed, Complaint Counsel's attempt to change "reasonably short period of time" from one year to five is still unavailing. As explained below, *see infra* Part IV.D, extrinsic survey evidence confirms that consumers do not interpret "biodegradable" to mean decompose into elements found in nature within any specific time frame; rather, they interpret "biodegradable" "to mean a process by which a product breaks down or decays; and consumers understand that the time for this . . . varies depending on the materials involved and that the process of biodegradability is not always, or even often, a rapid process." ALJFF ¶554.

The implied "five year" claim presented on appeal is thus as unsupported as the implied "one year" claim presented at trial. CCOB at 29–30. There is no record evidence that the "9 Months to 5 Years" claim *expressly* made by ECM to certain of its plastic manufacturer customers ever appeared on a plastic purchased by consumers. ALJID at 300–01 at nn. 58–59 (explaining that "the products in the record displaying the ECM logo do not set forth the claims that ECM Plastics will fully biodegrade in a landfill within 9 months to 5 years"). An implied "5 year" claim would have required end-consumers who purchased plastics to have actually seen the "5 year" claim. No evidence proves (or even suggests) that occurred. ALJID at 175–77. ALJFF ¶269; *see also* Sinclair, Tr. 768–69. ¹³ In *Telebrands*, the Commission explained that "a

¹³ ECM discontinued its "9 months to 5 years" claim after the FTC revised the Green Guides in 2012, permanently removing the claim in 2013, and testified unequivocally that it would not make the claim in the future. ALJFF ¶¶256, 258–62. On the testimonial record, the ALJ found that to the extent a rate claim was made after October 2012, it was inadvertent, the result of mistake by ECM's Sales Manager. ALJFF ¶¶212, 259.

showing of intent" is relevant only to the extent that consumer purchasers did see it. 140 F.T.C. 278, 304 (2005).

B. Ad Interpretations

Advertisements are only misleading if they would mislead consumers acting reasonably. *F.T.C. v. US Sales Corp.*, 785 F. Supp. 737, 745 (N.D. Ill. 1992) (citations omitted; emphasis added). As the ALJ found, the "plain meaning of the word 'biodegradable' ... does not include any . . . time frame for complete decomposition, much less complete decomposition, into elements found in nature, in a landfill, within one year." ALJID at 183–84 (citing *Merriam-Webster* and *Collins English* (10th ed.) dictionaries); *see also* ALJID at 221 ("Nothing in the foregoing [dictionary] definitions supports a conclusion that a significant minority of reasonable consumers would interpret 'biodegradable,' to mean completely breakdown into elements found in nature, in a landfill, within one year."); ALJ Conclusions of Law ¶18 (same).

The scientific definition of biodegradable likewise does not include a time constraint.

ALJFF ¶633–96. Complaint Counsel's own experts testified that the definition does not include a time constraint. ALJFF ¶693 (citing Tolaymat's testimony); ALJFF ¶694 (citing Michel's testimony). McCarthy defined biodegradation "as a chemical process by which microorganisms such as bacteria and fungi use the carbon found in organic materials as an energy source."

ALJFF ¶636; CCX 891 (McCarthy, Rep. at 8). Outside of this litigation, McCarthy never defined biodegradation to include a time constraint, and it was Complaint Counsel, not he, who drafted footnote 1 to his expert report wherein a one year limit was specified, a definition he abandoned during cross examination at trial. ALJFF ¶633–35, 638.

¹⁴ See also Fed. Trade Comm'n, Policy Statement on Deception, available at http://www.ftc.gov/public-statements/1983/10/ftc-policy-statement-deception (last visited March 3, 2015).

ECM experts Sahu, Burnette, and Barlaz all testified that the scientific definition of biodegradable contains no time constraint and viewed such a limit as arbitrary and unscientific. ALJFF ¶680–84, 686–92. Fact witness Dr. Timothy Barber testified that "[b]iodegradation is a process by which microbial organisms sustain their life by eating and metabolizing a material" and that "[b]iodegradation is not subject to a time span limitation because it is an ongoing process." ALJFF ¶695–96. The scientific definition of biodegradable is memorialized in ASTM D883-12, which is repeated on ECM's Certificate of Biodegradability, and contains no time limit. ALJFF ¶679.

Consumer perception evidence proves that consumers' definition of "biodegradable" is similar to the dictionary and scientific definitions: no set time limit. ALJID at 222. Moreover, experts agreed that even rapidly biodegrading substances will not biodegrade within ten years in a landfill, making a "one year" interpretation an effective absolute prior restraint on use of the term biodegradation on anything from saleable paper, wood, oranges, and bananas to the ECM additive. ALJFF ¶673–74; ALJID at 229.

As the Commission explained:

An advertiser cannot be charged with liability [for] every conceivable misconception, however outlandish, to which his representations might be subject among the foolish or feeble-minded. Some people, because of ignorance or incomprehension, may be misled by even a scrupulously honest claim. Perhaps a few misguided souls believe, for example, that all "Danish pastry" is made in Denmark. Is it, therefore, an actionable deception to advertise 'Danish pastry' when it is made in this country? Of course not. A representation does not become 'false and deceptive' merely because it will be unreasonably misunderstood by an insignificant and unrepresentative segment of the class of persons to whom the representation is addressed.

In the Matter of Heinz W. Kirchner, 63 F.T.C. 1282, *6 (1963). ECM should not be held liable for unscientific, illogical, and unreasonable interpretations, even if it could be shown that such interpretations were held by some minority of consumers (proof not in the record below). To the contrary, Stewart's survey evidence and testimony support the conclusion that no identifiable subgroup of the population actually understands the term biodegradable to imply a time limit. ALJID at 219–20.

C. The ALJ Correctly Credited Stewart's Testimony

The ALJ gave "Dr. Stewart's opinions ... greater weight" than Dr. Frederick's because "Stewart's opinions [were] well supported and . . . more well-reasoned, credible, and persuasive . .." ALJFF ¶¶ 323–24; *see also* ALJID at 187–91. Complaint Counsel protest citing *POM Wonderful*, 155 F.T.C. at 35 at n. 23. In *POM*, the Commission held that the ALJ erred when he discounted an expert's testimony "that [the] Global Assessment Questionnaire ('GAQ') is not a validated measure for assessing erectile function," because the expert had "not heard of the term 'GAQ' prior to forming his opinions in [that] case." *POM Wonderful*, 2012 WL 2340406, at *230 (F.T.C. May 17, 2012); *see also POM Wonderful*, 155 F.T.C. at 35 at n. 23. Because the witness's testimony was separately validated by other testifying experts, the Commission held the discounting unwarranted. *POM Wonderful*, 155 F.T.C. at 35 at n. 23.

There is no parallel here. Frederick admitted that he neither designed his survey to follow, nor followed, generally accepted survey standards. ALJFF ¶¶314–15, 353–454; ALJID at 200–02. The ALJID here is far more robust. The ALJ found that Frederick's approach, testimony, and survey data lacked basic indicia of reliability and conflicted with generally accepted survey standards. "Frederick [was] not familiar with standards applying to the

¹⁵ That exact passage is quoted verbatim in FTC's Policy Statement on Deception. *See* FED. TRADE COMM'N, *supra* note 14.

evaluation of survey evidence" and did "not believe there are any specific criteria that a survey must meet in order to be valid." ¹⁶ ALJFF ¶314–15. Without knowing the standards to apply, Frederick created his own invalid survey model. ALJFF ¶353–453; ALJID at 189–202. He asked only one question per respondent, relied on no screening questions, failed to define a population, failed to collect any demographic information on his respondents, ignored disinterest bias, ignored nearly one third of code-able responses, failed to analyze data under accepted statistical principles, and failed to ensure blinding. ALJFF ¶371, 395, 404, 425–26.

D. Dr. Stewart's Valid Survey Proves that ECM Made no Implied Rate Claims

1. The Record Amply Supports the ALJ's Crediting of the Stewart Survey

"Dr. Stewart's survey was . . . very consistent with accepted standards and best practices in the design of survey research," an ALJ determination that Complaint Counsel do not challenge. ALJFF ¶ 552; see CCOB at 6–30. Complaint Counsel fault Stewart for not asking "how much time it would take plastic products labeled biodegradable to biodegrade." CCOB at 26–27 (emphasis in original). Complaint Counsel speculate that if that question were asked, respondents would have answered with more rapid biodegradation times. On speculation alone, Complaint Counsel leap to the conclusion that consumers interpret "biodegradable" to mean decomposition within a year or, now on appeal, within five years.

Complaint Counsel further assert the unsupported charge that Dr. Stewart's study "was designed to maximize respondents' uncertainty about time for biodegradation . . ." CCOB at 28.

To the contrary, Stewart's survey questions and the blinded manner in which his survey was

¹⁶ Complaint Counsel mislead by stating that the ALJ's credibility findings were based solely on the fact that Frederick "could not recite legal standards." CCOB at 9 at n. 8. The ALJ's credibility findings were based primarily on Frederick's ignorance of, and failure to abide by, generally accepted survey standards. ALJFF ¶¶314–15. He also found Frederick's survey biased and unreliable. ALJID at 190–202.

administered were specifically designed to avoid bias. Stewart, Tr. 2989–90. The ALJ found no evidence of bias or any other reason to call into question the validity of Stewart's survey. ALJID at 213–20.

Complaint Counsel misrepresent Stewart's testimony concerning the order of questioning. CCOB at 28–29. Stewart designed his questions to avoid suggestive answers while inviting full responses from those with some knowledge of the term "biodegradation." Stewart, Tr. 2812–13. His was a live interview format, recording the precise answers given by each respondent. ALJFF ¶¶511–14. His main questionnaire employed a generally accepted "funnel approach" which "starts with open-ended questions and progresses to more specific open-ended questions, and finally to some closed-ended questions." ALJFF ¶538.

Complaint Counsel argue that "58% of Dr. Stewart's respondents were age 50 and older," even though in the general population only 40% of persons age 15 and above are 50 and older." CCOB at 17 (emphasis added). They ignore the fact that the survey was appropriately age adjusted, ALJFF ¶517, and that the relevant population consisted of adults 18 years and older (not 15 and older). ALJFF ¶518. Complaint Counsel's argument, void of expert testimonial support, is based on a misrepresentation, and misuse, of population data. CCOB at 17; RRB at 55–57. It is improper, indeed invalid, for Complaint Counsel to presume the role of an expert and opine as to an expert interpretation of test data without relying on a qualified witness. Complaint Counsel of course are not survey experts and were not available as such for cross examination at hearing. They may not therefore opine as if experts. *See U.S. v. Wilson*, 605 F.3d 985, 1026 (D.C. Cir. 2010) (citations omitted).

2. No Significant Minority of American Consumers Define "Biodegradable" to Mean Complete Decomposition Within Any Specific Time Frame; Complaint Counsel's Manipulation of Stewart's Data Lacks an Expert Foundation and Is Improper

The ALJ determined that "no significant minority of Americans define 'biodegradation' to mean that a product will completely biodegrade into elements in nature within one year after customary disposal," ALJFF ¶555. Rather, the competent survey evidence confirms that "consumers interpret the term, 'biodegradable,' to mean the process by which a product breaks down or decays; and consumers understand that the time for this process varies depending on the materials involved and that the process of biodegradability is not always, or even often, a rapid process." ALJFF ¶554;Stewart, Tr. 2586. Complaint Counsel endeavor to challenge Stewart's opinion based on a selective reading of data in his survey, conveniently excluding answers and results not to their liking in an effort to force fit Stewart's data into their own preconceived notion of consumer perception (i.e., that consumers understand "biodegradable" to mean, now on appeal, five years or less). CCOB at 26–29. At trial, Complaint Counsel confronted Stewart with their selective adduction approach. Stewart explained in detail that Complaint Counsel's data manipulation was improper and the selective culling of data excluded information which, when properly included, established no basis to conclude the existence of any set time limit within which biodegradation takes place. See Stewart, Tr. 2782–84.

For example, Complaint Counsel argue that nearly half (194) of the responses to Question 4 of Stewart's survey ("[i]f something is biodegradable, how long do you think it would take for it to decompose or decay?") "are irrelevant" because they do not contain "units of time." CCOB at 27. Inexpert, Complaint Counsel reach their desired conclusion only by disregarding answers to open-ended questions and do so to force fit selective Stewart data into Complaint Counsel's narrative. ALJID at 195, 215; ALJFF ¶396–97, 403; RX 856 (Stewart,

Rep. at 12–13); Stewart, Tr. 2601–02. That process is improper. Complaint Counsel may not substitute themselves for a competent survey expert and lack persuasive power when they endeavor to interpret data selectively in ways contradicted by expert opinion.

E. The ALJ Correctly Rejected Complaint Counsel's Argument for Convergence Validity

Below Complaint Counsel rely on three flawed studies—the Frederick, Synovate, and APCO surveys—to argue that all three validate the conclusion that a certain group of consumers had similar beliefs. Each of those studies is independently unreliable and the results of each not credible. Superficially noting serendipitous similarity of results from three flawed studies does not validate those results. No Commission or judicial precedent supports the practice. It is unscientific on the order of wishful thinking. It is also a form of circular reasoning, erecting a false tautology, in which Complaint Counsel begin with the conclusion they wish to reach and then deem each separate survey response that can, with stretching, be interpreted to support that conclusion to be validation of a single, presumed rate. The illogic is profound because the surveys are of different design, involve different groups of people, and in fact ask different questions.

As the ALJ concluded, "there is no legal precedent for permitting the results of seriously flawed surveys to validate one another for purposes of evidentiary proof in adjudication." ALJID at 211. Complaint Counsel rely on inapposite precedent. "[I]n contrast to *Bristol-Myers*, the evidence fails to show that the APCO, Synovate, and Google surveys are valid for the evidentiary purposes urged by Complaint Counsel." ALJID at 212. "[T]he characteristics of [the APCO, Synovate, and Google] surveys have little in common with the characteristics cited by the Commission as supporting the reliability and validity of the test reports in *Bristol-Myers*." ALJID at 212; see ALJFF ¶327–35, 363, 368, 372, 396–99, 403–04, 409–30. Unlike in

Thompson Medical, here Complaint Counsel would impose liability and establish a definition of "reasonably short period" solely on coincidental groupings of data from three demonstrably flawed surveys. The ALJ in American Home never held that convergence of flawed survey results can correct for deficiencies and make flawed surveys "reasonably reliable and valid." Only after the ALJ first determined that the surveys were "of the kind and quality normally used by business firms" did he then proceed to an assessment of their results, thereupon finding that the "studies generated consistent results" because that factor "enhanced" already established reliability. In the Matter of Am. Home Prod. Corp., 98 F.T.C. 136, at *90 (1981).

Dr. Frederick's survey is so flawed that no reliable conclusions can be drawn from it. Moreover, Frederick, Stewart, and the ALJ are in agreement that the APCO and Synovate surveys were seriously flawed. ALJFF ¶455–97; ALJID at 202–08. The ALJ was correct that "it defies logic to contend that three flawed surveys can somehow rehabilitate one another and create probative weight that otherwise does not exist, on the ground that the results are 'fairly similar.'" ALJID at 211.¹⁷

1. The Commission Must Hold Survey Evidence to Generally Accepted Standards

Frederick's survey work was unreliable, flawed, and abided by none of the generally accepted standards for survey research. ALJFF ¶¶325–479; ALJID at 189–202. Courts depend on evaluative criteria to assess the admissibility and weight of survey evidence. *See, e.g.*, *Malletier v. Doone & Bourke, Inc.*, 525 F. Supp. 2d 558 (S.D.N.Y. 2007). Some of those

¹⁷ Complaint Counsel misleadingly argue that "Frederick ... explained that it is highly significant that four studies, conducted with four distinct methodologies, at different times, by four sets of researches reached similar results," CCOB at 7–8, citing CCPFF ¶208. Neither anything argued below nor the Frederick testimony cited included Stewart's survey in "convergence validity." The statement made to the Commission is therefore false and misleading.

criteria, adopted from the Manual for Complex Litigation and the Reference Manual on Scientific Evidence, include:

(1) the proper universe was examined and the representative sample was drawn from that universe; (2) the survey's methodology and execution were in accordance with generally accepted standards of objective procedure and statistics in the field of such surveys; (3) the questions were leading or suggestive; (4) the data gathered were accurately reported; and (5) persons conducting the survey were recognized experts.

Id. (citing Manual for Complex Litigation, Fourth § 11.493 (Federal Judicial Center 2004) (setting out seven criteria); Reference Manual on Scientific Evidence at 236–72 (Federal Judicial Center, 2d ed. 2000)); see also Nat'l Football League Prop., Inc. v. N.J. Giants, Inc., 637 F. Supp. 507, 513–14 (D.N.J. 1986).

Applying FTC precedent, the ALJ explained that "[t]o demonstrate that the survey possesses any probative value, and is therefore admissible, the proponent of the survey must prove the survey is 'methodologically sound,' which requires proving that the survey draws valid samples from the appropriate population, asks appropriate questions in ways that minimize bias, and analyses results correctly." ALJID at 189 (citing *POM Wonderful*, 155 F.T.C. 1 at *17; *Thompson Medical*, 104 F.T.C. 648, 790 (1984)). "[I]f the methodology of a consumer survey is fundamentally unsound, then that survey cannot assist the Commission in deciding whether an advertisement communicates a particular claim to consumers... The Commission's practice is, in this regard, consistent with that of most federal courts when evaluating surveys purporting to assess the meaning that consumers take from ads." *In re Stouffer Foods Corp.*, 118 F.T.C. 746, 807 (1994).

Repeatedly an FTC expert whose surveys the Commission has relied upon, Stewart explained that the FTC accepts and applies the standards that are articulated by professional survey organizations, as well as in the Manual for Complex Litigation. ALJFF ¶ 325, 326; *see*

also ALJID at 190 at note 27 (explaining that "the Commission's standards are substantially the same as those that Dr. Stewart identified as broadly accepted standards, derived from the Manual for Complex Litigation"). Frederick admits that his survey was not designed to satisfy any of those standards. ALJFF ¶¶314–15. Stewart explained that, indeed, Frederick's survey failed to satisfy any of those standards. Stewart, Tr. 2598–2604 (explaining how Dr. Frederick's survey failed each of those standards and concluding that Dr. Frederick's survey "is clearly not a reliable or valid survey").

2. The Synovate and APCO Surveys Were Invalid

Complaint Counsel argue that the ALJ erred by finding that the APCO and Synovate studies have little probative value. CCOB at 10–12. In addition to the surveys' flaws, the ALJ appropriately found that the APCO and Synovate questions "shed[] little, if any, light" on the material issue in this case of "whether the term biodegradable communicates to the consumer any messages to a rate for complete biodegradation in the first instance, and then, if so, what that rate message is." ALJFF at 204.

Stewart and Frederick agreed that the APCO and Synovate surveys were flawed because they were entirely dependent on closed-ended questions. *Id.* "[O]pen-ended questions allow survey participants themselves to articulate the central claim or claims in the ad" and "marketing experts have found that credible evidence comes in response to open-ended questions..." *Telebrands*, 140 F.T.C. at 318; *Stouffer*, 118 F.T.C. 746 at 781. The closed-ended nature of the relevant APCO and Synovate questions adversely affected the validity of the answers to those questions by resulting in a misleading homogeneity of responses. ALJID at 205 (explaining that, in the APCO survey, where 4 of the 6 possible responses stated a year or less, "the fact that 60% of respondents selected one of those options is not entitled to significant weight"). In addition to

Stewart and Frederick, the Commission also faulted the APCO and Synovate surveys "for lacking control groups and presenting the timeframe questions with close-ended, rather than open-ended, answers..." ALJFF ¶496. Because the APCO and Synovate surveys are flawed, they cannot be relied upon to support Complaint Counsel's convergence validity theory.

3. Frederick's Survey Did Not Satisfy the Standards for Reliable Surveys

Against the weight of the record, Complaint Counsel assert in a conclusory fashion that Frederick's survey "more than meets the legal standard," failing to define how it is met. CCOB at 12. It would be a logical impossibility, except by serendipity, for an expert who is admittedly unfamiliar with generally accepted standards for survey research to produce a survey that meets those legal standards. ALJFF ¶313–15. Therefore, it is not surprising that Frederick's survey "is not reliable," "is not valid," "cannot be relied upon to draw any conclusions" or to validate any other surveys, "cannot be characterized as a valid survey," and "does not meet generally accepted standards for survey research." ALJFF ¶ 431–34. Indeed, the only survey expert familiar with the survey research standard, Stewart, confirmed at length that Frederick's survey satisfied none of the criterion required for a competent survey. ALJFF ¶372–75, 382–84, 386, 388, 396–400, 403–04, 407–08, 420, 425–27, 431–34.

a. Overview of Frederick's Google Survey

Frederick created a single question per respondent survey through Google Consumer Surveys ("GCS") to test "the APCO and Synovate results." ALJFF ¶353. GCS works by allowing internet users to answer a pop-up question when attempting to access "premium content." If the user chooses to answer the question, the user will be permitted to view the premium content regardless of the answer; if the user does not want to answer the question, he or she must either pay to view the content, or leave the website. ALJFF ¶357. No GSC survey has

ever been admitted into evidence in any legal proceeding (FTC or otherwise). ALJID at 200–01. Frederick and Stewart were not aware of any peer-reviewed study that relied upon results from a GCS study. ALJFF ¶361–62.

b. Frederick's Financial Incentive to Avoid Quality Research

Complaint Counsel argued that the ALJ erred in finding that Frederick "was motivated to use a Google survey ... because he was paid a flat fee and the less he had to pay for a survey the more money he would net as compensation in this case." CCOB at 15 at note 13. Frederick admitted that cost was an important factor in choosing his single question Google Consumer Surveys. ALJFF ¶365. Complaint Counsel paid Frederick a flat \$40,000.00 fee for all of his work, including the costs of any surveys he conducted. ALJFF ¶364. Consequently, the less Frederick spent on the survey, the more he pocketed. *Id.* Frederick's Google survey ultimately cost very little indeed, an estimated \$2,000.00 (by contrast, Stewart's survey cost approximately \$37,500.00). ALJFF ¶366. Frederick testified that he could have asked more than one question, he could have asked screening questions, he could have obtained direct demographic information from respondents, and he could have performed an internet panel survey, but he did not do so for cost reasons. ALJFF ¶¶366–67, 414–15. In short, the record confirms that he was motivated to design a cheap and simple survey because he was paid a flat fee. ALJFF ¶364–70. It is a fact that he pocketed almost all of the \$40,000 paid him by choosing not to undertake a more robust and costly survey. ALJFF ¶¶364–66.

¹⁸ Complaint Counsel contend that Frederick used GCS in a recently publish peer-reviewed article. CCOB at nn. 11, 13. Stewart clarified that the article Complaint Counsel refer to, CCX 977, merely cited a GCS study in a footnote and that the reference to GCS was not supportive of what was actually contained in the article text. ALJFF ¶362.

c. Frederick Failed to Define a Population; the Demographics of his Sample Are Unknowable

A valid survey must have a defined population and the sample surveyed must be representative of that population. ALJFF ¶326; *see also NFL*, 637 F. Supp. at 513–14. Frederick failed to define a relevant population. ALJFF ¶420, 425–27; ALJID at 197–200. His respondents' demographics are unknown. ALJFF ¶409–11, 416–19ALJID at 197–200. Little weight is accorded surveys that lack that essential definition. *See POM Wonderful*, 155 F.T.C. 1 at *17.

Unsupported assertions to the contrary notwithstanding, the population Frederick surveyed was anyone who encountered his online pop-up question. ALJID at 190–91; ALJFF ¶432. That population necessarily includes children, people who refuse to purchase plastics, and even those who might not read English. The Google survey population is not defined by age and there is no lower bound. ALJFF ¶420. The ALJ appropriately concluded that:

Frederick's Google survey failed to properly choose and define a population, because it is not clear what the population was that he was analyzing. Rather, the population is defined in terms of who participated in the survey, which is not an appropriate way to define a population.

ALJFF ¶425.

Similarly, his demographics are unknown. Frederick testified that Google provided respondents that "are demographically representative of U.S. adults, and tend to yield similar results to other internet panels." ALJID at 197. As Stewart testified, however, "there is no way to know whether . . . Frederick's Google survey population was representative of any identifiable populations." ALJID at 197; ALJFF ¶¶426–27.

Google provided only indirect information by drawing inferences about demographics, such as age and gender, based on the respondent's Internet Protocol ("IP") address and

"cookies." ALJID at 198; ALJFF ¶411. Google inferred the respondent's location, income, and urban density based on IP address alone. *Id.*; ALJFF ¶410. Frederick admitted that Google's inferred demographics can be wrong. ALJFF ¶416; Frederick, Tr. 1229–30. For example, when multiple members of a household use a single computer, each visiting different websites, GCS makes an inference as to which specific household member answered the survey question based on the computer's usage history. ALJFF ¶416, 418. In addition, cookies can be deleted and website history may be insufficient to make demographic inferences. *Id.* Frederick admitted that a valid IP address can only tell Google the location, but not the age, nationality, or gender of the person answering. ALJFF ¶319.

"Screening questions" are essential to ensure that a survey sample is representative.

ALJFF ¶¶338, 344 ("A survey without screening questions is not capable of being analyzed for the general representativeness of the sample."). Frederick refused to pay the additional fee to include two-part questions that would have provided direct information about his sample.

ALJFF ¶414–15; Frederick, Tr. 1226–27 (explaining that asking screening questions is "one of the options" but was declined because it is "dramatically more expensive to do that"). Therefore, "[t]here is no way to ascertain the degree to which the sample of respondents surveyed in the Google survey is representative of any identifiable population; the sample itself is unknown and unknowable, because there is no verification of respondents with the Google survey; rather information on respondents is merely inferred by Google from information associated with or that resides on a computer." ALJFF ¶427.

Extrinsic evidence does not cure Frederick's survey flaws. Complaint Counsel falsely represent that the ALJ disregarded three pieces of evidence supportive of GCS sample validity,

CCOB at 17: (1) a comparison by Google to other internet panel results;¹⁹ (2) a report by the Pew Research center (CCX 874); and (3) a New York Times blog post authored by Nate Silver (CCX 872). CCOB at 17–19.

To the contrary, the ALJ evaluated each, finding none relevant. ALJID at 198–200. He reasoned that the Silver blog concerning the 2012 presidential race was inapplicable to "the type of open-ended questions that are appropriate to determine consumers' interpretation of the term 'biodegradable.'" ALJID at 199. He also reasoned that, because it did not analyze Frederick's survey, the PEW study "carries little, if any, weight on the question of whether the Google survey . . . drew valid samples from a representative population." *Id.* He explained that the PEW study actually reached conclusions contrary to the validity of Frederick's survey. *Id.* at 199–200. For example, the PEW study concluded that the GCS sample is not "the general public" and that demographic information is wholly unavailable (that is, GCS cannot even make inferences) for 30–40% of GCS respondents. *Id.* at 200. The ALJ properly discounted Google's own study because of Google's obvious economic interest in justifying results. *Id.*

d. Frederick Did Not Ask Appropriate Questions

Complaint Counsel contend that Frederick "asked the relevant question—how much time does it take a plastic product labeled biodegradable to biodegrade—dozens of different ways." CCOB at 20. However, "none of the Google survey questions actually asked the survey respondent how the respondent interpreted the word 'biodegradable,' which is the material issue for purposes of the Implied One Year Claim." ALJID at 193. Instead, the "questions assumed

¹⁹ In support of this argument, CCOB at 17–18, Complaint Counsel cited their proposed findings of fact 248–250. Those findings go to one exhibit, CCX 872. CCX 872, however, is not a comparison of GCS to internet panel survey results; it is the blog post written by Silver. *See* CCX 872. ECM revealed the error below, but Complaint Counsel chose to make the error again on appeal. *See* RRCCFF ¶¶248–50.

that the representation of 'biodegradable' communicates a biodegradation rate, and asked only for the respondents' 'best estimate of the amount of time,' or for the respondents to report 'how long,' or 'how much time,' they think that a plastic product that is labeled 'biodegradable' 'would' or 'will take' to decompose or biodegrade." ALJID at 194. In this way, the questions injected a bias, that a response of a specific number for rate was expected. The ALJ thus concluded that Frederick's questions "were not asked in a way to minimize bias." *Id*.

Further, even if Complaint Counsel could prove that a set rate of biodegradation is somehow implicit in the term "biodegradable," that rate is "slowly," the opposite of what they contend; it is not "reasonably short" or "within one year after customary disposal." CCOB at 20 (citing Merriam-Webster definition of "biodegradable").

Complaint Counsel's "aspirin" analogy is unhelpful. *See* CCOB at 20–21. Headaches are a personal malady that generally last for a matter of hours. Headaches are in vivo, acute and personal; consumers have a direct interest in wanting aspirin to work right away. The fate of disposed plastics is ex vivo, chronic and impersonal; it is a general societal interest. Because discarded items, trash, do not directly affect consumers like aspirin, the analogy in entirely inapt. ALJFF ¶898; ALJID at 266, 283–84.

Complaint Counsel argue that asking only one question per respondent enabled "Frederick to avoid influencing respondents' answers . . ." CCOB at 21. To the contrary, the absence of screening and the demand for a numerical unit response biased answers. All reliable studies credited by the Commission have involved multiple questions, particularly so for terms like "biodegradable" that are not commonly surveyed. As the ALJ found, "[h]ow consumers interpret the term 'biodegradable' . . . cannot be addressed and determined with a single question." ALJID at 193. As Dr. Stewart testified and the ALJ found:

A good open-ended question might provide some dimension of consumer perception of the term 'biodegradable,' but it will not provide other dimensions, such as nuances, dependencies, or context effects. Moreover, when there is only one question asked of a survey respondent, a researcher cannot know whether it is a sincere response, and/or whether it is a response that would be subject to qualification if there had been a follow-up question.

Id.

Complaint Counsel's contention that Frederick's questions "mimicked the varying ways ECM's 'biodegradable' claims reach consumers" is false. CCOB at 21–22. Frederick's assistants (who were not blinded) digitally altered ("photoshopped") images of plastic products, superimposing exaggerated ECM logo and biodegradable claims upon them. ALJID at 195; ALJFF ¶ 443–44, 446–47; Frederick, Tr. 1316–18. The images of "ECM" plastics were thus fictitious, as Frederick admits. Frederick, Tr. 1317. Frederick and his assistants, aware of the survey goals, altered the images to their liking. *See, e.g.*, ALJFF ¶ 447 (survey question showing an image of a bag completely covered with the ECM logo; no such bag existed).

Finally, Complaint Counsel argue Frederick's questions were appropriate because they allowed him to "arrive[] at the same results despite asking questions in different ways." CCOB at 22. He did not, however, "arrive at the same results," rather, he concluded based on flawed data analysis, *see infra* Part IV.E.3.e., that the percentage of respondents giving one year or less was imprecise in the extreme "ranging from 20 percent to 52 percent." ALJID at 209–10.

e. Frederick Did Not Properly Analyze Data

Frederick obtained approximately 29,000 responses, and should have coded them all, ALJFF ¶395, but adopted instead a "bright-line" rule excluding every response not containing a numeric specification and an accompanying temporal unit (*i.e.* "one year"). ALJFF ¶392. Frederick excluded approximately 28% of the responses to his survey, thereby biasing the results by excluding truthful answers such as "it depends" and "I don't know." ALJFF ¶¶393, 395.

Meanwhile, using that same "bright-line" rule Frederick added more bias by coding nonsensical responses (such as "one nanosecond" and "immediately") as "less than one year." ALJFF ¶401; ALJFF ¶402 (inexplicably coding "never").

Complaint Counsel argue Frederick's coding rules minimize bias. CCOB at 24. To the contrary, as the ALJ explained by coding only those responses containing a numeric specification and an accompanying temporal unit, "Frederick effectively turned open-ended questions into closed-ended questions, by limiting the range of acceptable responses to those that fit Dr. Frederick's pre-determined format, or 'bright-line' rule.'" ALJID at 194. It was inappropriate for him to "force-fit' responses into a pre-existing structure of biodegradation time categories...such methodology is also improper because it limits the range of responses considered, and by definition creates greater homogeneity of responses than would be the case if the respondents were allowed more latitude in responding." *Id.* at 195. Moreover, "Frederick's coding methodology is particularly egregious because it reduces the denominator of the percentage results reported by Frederick which has the effect of inflating the reported percentages." Id. at 195–96. Finally, the coding was invalid because it was performed by individuals who were not blinded. ALJFF ¶¶407–08; ALJID at 196 at n. 30. The responses Frederick failed to code are necessarily different from those he did; otherwise he would have coded all responses. ALJID at 196.

f. Frederick's Survey Suffers from Disinterest Bias

"Disinterest bias refers to the fact that if people are uninterested in a survey, if they are disengaged, or even worse, if the survey serves as an interruption for an activity in which they are more interested, those people will be likely to give insincere, random and often nonsensical responses to simply get past what is essentially an interruption in what they were doing before

confronted by the survey."²⁰ ALJFF ¶383. Frederick's single question survey suffers from disinterest bias. "Because questions in the Google survey are answered by respondents in exchange for access to internet-based content in which they may be interested, the questions are a distraction, at best, and a barrier to respondents whose objective is to access information, not to complete a survey." ALJID at 192.

Certain responses which Frederick coded, such as "1 nanosecond," were likely protest responses because no reasonable person would believe that a plastic biodegrades within one nanosecond. ²¹ ALJFF ¶401. Because all questions required a response before accessing desired internet content, and because no follow-up questions or screening questions were asked, there is no way to discern whether any response was legitimate or was given in a flip manner just to gain access to desired content. ALJID at 192–93; Frederick, Tr. 1305–06. Frederick admitted under cross examination that he had no way of reasonably assaying the sincerity of any response. ALJFF ¶375; ALJID at 193; Frederick, Tr. 1248–54.

Complaint Counsel also argue that average response times to Frederick's survey were 20 seconds which it concludes show that responses were intended and meaningful. CCOB at 23. That conclusion is a non-sequitur; requisite proof is lacking. ALJID at 192–93.

ALJFF ¶359. It is entirely conceivable that a respondent would spend a half minute (1) trying to read the beginning of the partially masked article before deciding to answer the question; (2) experiencing distraction from, e.g., computer work in another window, a phone call, or a person entering the room; or (3) being wary of clicking within an unconventional (and surprise) pop-up

²⁰ Stewart testified, without contradiction, that the Greenbook Blog, which Stewart cited as a reference for disinterest bias, "is a publication that is well known in the practicing market research community and among well-read researchers." ALJID at 192.

²¹ Either that, or they properly accepted that "biodegradation" is the start of a process and not a defined endpoint, which conclusion would have been misinterpreted in Frederick's analysis.

screen and looking for a way to close-out the pop-up. ALJFF ¶¶ 359, 389. Suggesting that the average 20-second answering time indicates a "meaningful response" is conjecture.

F. Convergence Validity Fails Because the Survey Results Are Dissimilar

Complaint Counsel's convergence validity theory is based on the premise that all three studies "reached a strikingly similar conclusion." CCOB at 7. That is not so. "[T]he evidence does not show that results of the three surveys are similar with respect to whether consumers believe biodegradable items will biodegrade in less than one year, such that convergent validity theory would even be applicable." ALJID at 211. The APCO survey concluded that 60% of respondents "believed" that less than one year "is a reasonable amount of time for a plastic product to biodegrade in a landfill;" the Synovate survey concluded that only 25% of respondents indicated less than one year; Dr. Frederick's Google survey allegedly revealed a remarkably imprecise range of 20 to 52 percent of consumers interpret biodegradable claims to mean biodegrade within one year. *Id.* "Accordingly, the results are not similar for purposes of the convergent validity theory." *Id.*

V. ECM PLASTIC EFFICACY IS SUPPORTED BY COMPETENT AND RELIABLE EVIDENCE

The reliable test data of record proves that ECM plastics—and not just the ECM additive within those plastics—biodegrade. ALJID at 246-84 ("Dr. Barlaz credibly and persuasively testified that Respondent's testing constitutes competent and reliable scientific evidence demonstrating that plastics manufactured with the ECM additive are anaerobically biodegradable"); ALJFF ¶¶870–1447. Complaint Counsel ignore the scientific record, including the ALJ's applicable Findings. Complaint Counsel did not address Barlaz's statistical analysis of test data or even *mention* Barlaz's analysis at any point in their brief. *See* CCOB; ALJFF

¶¶1006-1447. Citing none of the ALJ's substantive factual findings, Complaint Counsel utterly fail to justify under the standard of review overturning the ALJ's reasoned decision.

A. The ALJ's Interpretation of "Biodegradable" As a Process, Not a Dated Endpoint, Is Supported by Record Science

Complaint Counsel argue that the ALJ "never makes a specific finding that ECM Plastic is less resistant to biodegradation than conventional, untreated plastic, including in a landfill." *See* CCOB at 31. To the contrary, the ALJ found that competent and reliable evidence proves that ECM's additive actually causes plastics to biodegrade in landfills. *See* ALJID at 240 (holding that the lab experiments prove "biodegradability for multiple materials"). Indeed, the point of these tests by prospective ECM customers critical of the additive was to determine whether in fact ECM plastics biodegrade in landfills. ALJFF ¶1530–32, 1535–36, 1539. When the ALJ held that ECM's biodegradability claim was supported by competent and reliable evidence, he found that ECM plastics fundamentally change the biodegradable properties of the plastic, enabling them to biodegrade in landfills. ALJID at 224–33, 238–84.

B. ECM Plastics Are Biodegradable

The ALJ relied on at least twenty (20) competent and reliable tests that prove the ECM additive causes plastics to biodegrade to a significant extent where untreated plastics do not. *See* ALJFF ¶1006–1465. ECM had submitted more than thirty (30) tests showing that ECM plastics are biodegradable. *See* RPFF ¶2129–2706.²² Anaerobic testing showed that ECM plastics biodegraded more than 50% in laboratory environments within just several years. *See* ALJFF ¶1267–85 (citing RX 836). In those ECM anaerobic studies, the negative control (i.e., the untreated "conventional" plastic) did not biodegrade at all. *See*, *e.g.*, ALJID at 241, 266; ALJFF

²² Although the ALJ disregarded "aerobic" tests because landfills are anaerobic environments (mostly but not exclusively), ECM submitted aerobic tests that confirmed the biodegradable properties of ECM plastics in aerobic environments. *See* RPFF ¶2130–79.

¶¶1046–1447. Expert analysis proved that ECM plastics would continue to biodegrade if ambient environmental conditions favored biodegradation. *See* ALJID at 231, 238–40, 263–67, 276–83. Based on that competent and reliable evidence, the ALJ held that the ECM additive facilitates plastic biodegrade in landfills and environments conducive to biodegradation. ALJID at 284. To the extent environmental conditions favor biodegradation—requisite for biodegradation of any material—ECM plastics were proven to biodegrade in a fraction of the time it would take conventional plastics to biodegrade. ALJFF ¶¶1046–1465; ALJID at 284.²³

1. The ALJ Properly Determined that ECM Possessed the Amount of Substantiation Necessary for Its Biodegradable Claims

Complaint Counsel argue that the ALJ should have credited its experts over Respondents because the backgrounds of their experts are impressive. *See* CCOB at 32–36. Possessed of impressive backgrounds or not, Complaint Counsel's experts were not reliable based on their lack of peer-reviewed support, their failure to supply any valid testing evidence, their conflicts in testimony, and their bias. *See* ALJID at 227–28; RPFF ¶1353–80 (discussing McCarthy bias and unreliability); RPFF ¶2707–2885 (discussing Tolaymat inconsistencies and unreliability); ALJID at 254–55; ALJFF ¶1466–96 (discussing Michel's inconclusive test, purposeful non-disclosure of test data and financial support to peer reviewers and journal, and Michel's submission of his article for editing by ECM competitor Myers Industries before submitting it for publication). In addition, the immediate backgrounds of two of Complaint Counsel's experts

²³ Complaint Counsel mislead by arguing that "because all things biodegrade eventually (given hundreds of millions of years)," a definition of "biodegradable" that focuses on process deceives. *See* CCOB at 31. Experts testified that plastics will eventually "biodegrade," but conventional plastic biodegradation is barely perceptible, and, so, is deemed non-biodegradable by scientists. ALJFF ¶898–901. ECM's experts cited evidence of plastics biodegrading to disprove an unscientific dogma of Complaint Counsel that conventional plastics were not biodegradable in the least. ALJFF ¶870–955. The gas evolution testing of the ECM plastic proves that while conventional plastics do not biodegrade within the short interval of that closed system test, ECM plastics do. ALJFF ¶1006–1465.

reveal ties to ECM competitors and, in the case of McCarthy, a direct economic interest in the outcome of the litigation. ALJFF ¶¶666–70, 1467, 1471–72, 1479–81. By contrast, as the ALJ found, ALJID at 242, 270, 275, 279, 281, 283, there is no record basis to challenge the reliability and credibility of ECM's experts.

Hereinabove at pages 5–6, McCarthy's dissembling on the penultimate definition of "biodegradable" and his interests in the outcome of the litigation are explained with record citations. ALJFF ¶633–38, 666–70. Tolaymat, Complaint Counsel's expert on biodegradation and waste management, contradicted McCarthy's testimony. Tolaymat rejected McCarthy's recommended standard of radiolabeling. ALJFF ¶839-40. He admitted to having used gas evolution tests himself (like the BMP testing) to measure plastics biodegradability. Tolaymat, Tr. 239; ALJID at 269. He conceded that Barlaz—ECM's expert—was the authority in the field of biodegradation research. Tolaymat, Tr. 233–34; ALJFF ¶139.

Complaint Counsel rebuttal witness Michel based his opinion on very limited evidence—two inconclusive tests in lieu of the dozens of positive tests of record. Michel, Tr. 2965–66; CCX 895 (Michel, Rebuttal Rep.). Michel had performed a biodegradation test said to involve ECM plastic obtained not from ECM but from an ECM competitor, Myers Industries. No chain of custody evidence exists that the test plastic was properly infused with the ECM additive. ALJFF ¶1466–69, 1471–75, 1479–82. Complaint Counsel held out Michel's test as the gold-standard. CCOB at 35. Michel used the very same test method used in dozens of supportive ECM tests (e.g., the ASTM D5511 test), which McCarthy deemed insufficient, albeit he too used the same kind of gas evolution tests in his biodegradable patent and published works. ALJFF ¶716, 731, 769,780, 843–45, 850, 852, 1469. Michel misrepresented critical information to the peer-reviewed journal that published his article and never disclosed that the source of his funding

and the ECM test sample came from an ECM competitor. ALJFF ¶1485–96.²⁴ The data strongly suggested that the failed test was a result of laboratory conditions (premature death of the inoculum, mis-manufacture of the test plastic, or other ambient conditions not conducive to survival of the biota). ALJID at 255; CCX 164 at 8 (showing system-wide plateau).²⁵ Michel could not answer critical questions concerning how the ECM additive was incorporated into the test plastic. ALJFF ¶1472–74; Michel, Tr. 2926–28. That information was critical because failure to adhere to ECM manufacturing specifications renders the ECM additive ineffectual.²⁶ Significantly, Complaint Counsel called <u>no fact witnesses</u> in support of Michel's test, or any other test.²⁷

ECM's experts testified consistently and credibly based on the complete record. One of the foremost authorities in biodegradation research, Dr. Barlaz, ALJFF ¶¶131–39, published more than 115 peer-reviewed publications, at least a half of which concern biodegradation of materials. ALJFF ¶132. He authored test standards in the field of biodegradable research. ALJFF ¶137. The EPA hired him as an expert in waste management and biodegradation.

 $^{^{24}}$ The peer reviewers never examined Michel's raw data or considered manufacturing issues because Michel's conflict of interest was never disclosed to the peer reviewers. ALJFF ¶¶1483–95. Michel also testified evasively and misleadingly concerning Myers' involvement in his work. *Id*.

²⁵ In Michel's study, even cellulose (the positive control) plateaued after a short period of biodegradation, rendering the entire test a failure. ALJID at 255.

²⁶ Indeed, ECM principal Robert Sinclair has to work with manufacturers to avoid problems like additive scorching during heat melding, which renders the additive inefficacious. ALJFF ¶194, 875.

²⁷ By contrast, ECM produced three laboratory directors each of whom testified before the ALJ concerning the test methodologies employed to critically assess ECM plastic biodegradability for parties other than ECM. *See* ALJFF ¶¶90–94 (Dr. Timothy Barber), 95–97 (Thomas Poth), 98–100 (Alan Johnson).

ALJFF ¶136. ²⁸ He demonstrated through relevant testing data that ECM's technology was efficacious. Although a critical part of the record, Dr. Barlaz's credentials and opinion are omitted from Complaint Counsel's appeal. CCOB at 32–36. ²⁹

Dr. Ranajit Sahu explained the peer-reviewed science concerning plastics biodegradation and how ECM's additive hastens biodegradation. Sahu, Tr. 1848, 1858–59. Sahu has an extensive background in polymer science, organic chemistry, chemical engineering, and polymer manufacturing. ALJFF ¶¶122–30. His experience includes work with polymer biodegradation and landfill remediation sites. *Id.* He qualified as an expert on environmental matters in federal court, and has been retained by government agencies. ALJFF ¶128. Unlike Complaint Counsel's experts, Sahu backed his opinions with peer-reviewed literature. ALJID at 230–31.

Dr. Ryan Burnette testified concerning the microbiological processes of biodegradation.

ALJID at 232. Burnette explained the types of microbes that function in anaerobic and aerobic environments. *Id.* He has a Ph.D. in biochemistry and molecular biology, having trained under pre-eminent microbiologists in the field of anaerobic microbiology. ALJFF ¶140–43.

Burnette's original research involves anaerobic microorganisms and microbiology. ALJFF ¶140. He worked for multinational environmental consulting firms as an environmental scientist.

ALJFF ¶141–43. Burnette has experience with landfill sites, groundwater, and soil testing. *Id.* He was well-qualified to opine on the specific bacterial species that cause biodegradation of plastic materials. Complaint Counsel's experts professed ignorance as to which bacterial species

²⁸ Complaint Counsel's own expert, Tolaymat, acknowledged Barlaz's expertise, and testified that he and the EPA have sought Barlaz's guidance on issues of biodegradation. ALJFF ¶139.

²⁹ Complaint Counsel had no rebuttal to Barlaz's dispositive testimony confirming ECM additive efficacy. Their witnesses did not testify in rebuttal to Barlaz's calculations and testimony. Their witnesses did not perform a review of the testing data. Michel, Tr. 2966; McCarthy, Tr. 359–480; Tolaymat, Tr. 314–15. Tolaymat conceded that Dr. Barlaz's analysis was appropriate. Tolaymat, Tr. 303–06, 316–22.

were responsible for biodegradation in landfills, and had no knowledge beyond the superficial, of the mechanisms of action present. RPFF ¶¶1524–26, 2796–98.

The ALJ correctly weighed the substantive opinions and credibility of each expert, and placed "substantial weight on the better supported and more credible testimony of Respondent's experts." ALJ ID at 284. The ALJID contains 1,539 findings of fact, which included at least twenty (20) competent and reliable scientific tests among the 30+ supportive tests offered by ECM.³⁰ Complaint Counsel offer no record basis capable of upending the ALJ's well-reasoned findings and conclusions.

2. ECM's Biodegradable Claims Are Substantiated with Requisite Science

Complaint Counsel argue that no evidence shows ECM's product "could possibly work," while ignoring the 30+ tests that do just that, and the ALJ's evaluation of the testing. *See*, *e.g*. ALJFF ¶1006–1465. The weight of credible evidence in this case proved (1) that ECM's testing met the generally accepted scientific standard for biodegradation testing; (2) that ECM's tests conclusively proved that ECM plastics were biodegradable; and (3) that Complaint Counsel's expert opinions were not supported by testing or peer reviewed science and, in many cases, were contradicted by those experts' own work.³¹

a. The ALJ Identified the Mechanism by Which the ECM Additive Functions

The relevant peer-reviewed literature discussed the means by which proprietary technologies alter conventional plastics and accelerate otherwise slow biodegradation. *See*

³⁰ See, e.g., RPFF ¶¶ 2129–2706.

³¹ Contrary to the characterization of "biofilm formation" in CCOB, ECM never claimed that biofilm formation was equivalent to biodegradation. CCOB at 39–40. The ALJ correctly observed that biofilm formation is a sign that biodegradation may occur and a substantial step toward biodegradation, but biofilm formation is not the sole or indispensable evidence of plastics biodegradation in the record. ALJID at 250–51, 278–79.

ALJID at 230–31; ALJFF ¶915. Experts generally consider plastics non-biodegradable because they are very resistant to biodegradation. ALJID at 247–48. ECM's experts explained how the ECM additive causes plastics infused with it to experience a hastening of biodegradation in two ways: "first, by serving as an attractant for microbial growth within plastics; and, second, by weakening or perturbing the carbon-carbon bonds through weaknesses in the chain or the addition of more weak points in the form of the additive." ALJFF ¶918–19; ALJID at 250, 258. Microbes look for plastic weak points and succeed in enzymatic breakdown of polymers where the ECM additive has reduced bond strength, ALJID at 250–51; because the additive is infused uniformly throughout the plastic, the process of biodegradation involves the entire plastic. ALJFF ¶¶191, 871, 934–35. Those mechanisms of action are supported by the relevant peer reviewed literature, indeed even publications of Complaint Counsel's own witnesses McCarthy and Michel, and by ECM plastic testing and ECM expert opinion in this case. ALJID at 246–51. ECM's experts cited peer-reviewed literature throughout their reports and testimony. ALJFF ¶¶915, 990–94. Complaint Counsel's experts, by contrast, did not support any of their theories with relevant literature or testing, and contradicted themselves and each other. See ALJID at 247-48.

McCarthy never analyzed the ECM test data or performed requisite data analysis. Barlaz was "surprised" that McCarthy dismissed dozens of relevant studies without having actually examined the data. ALJFF ¶1010; ALJID at 275. McCarthy did not test the ECM additive. ALJID at 248–49. McCarthy's opinion that the ECM additive could not alter chemical characteristics of a conventional plastic was contradicted by his own work with biodegradable plastics. ALJ ID at 248–51. The evidence proved that heat melt-compounding the ECM additive into finished plastics "necessarily alters the structure of the plastic." ALJID at 250. The

ECM additive is bonded to and dispersed throughout the finished plastic. ALJID at 249–51. Those methods of creating a "biodegradable" plastic are recognized in the peer-reviewed literature, and in McCarthy's own work. ALJID at 248–51.³²

Plastic manufacturers use the ECM additive at load rates of one percent by weight, equivalent to the percentage of colorant in plastics. ALJID at 249–51 (noting that colorants are generally used in amounts between 0.5% and 2% of the total plastic by weight). *Id.* at 250.³³

Complaint Counsel's claim that ECM only results in "fragmentation" of plastics lacks record support. The record anaerobic biodegradation tests used methane as a measure of biodegradation—not weight loss. ALJFF ¶1006–42. Thus, Complaint Counsel's so-called "fragmentation" theory is contrived (the methane data proves that the plastic, and not the ECM additive, substantially biodegraded in ECM plastics). ALJFF ¶1006–1465. That test data was confirmed through other methodologies, including, *e.g.*, ASTM D6579 testing of molecular weight averages which confirmed the methane readings within one percentage point. ALJFF ¶1305–11; RX 838 at 73. Barlaz further testified that the amount of methane produced in the test vessels could only have come from biodegrading plastic, as the methane was substantially greater than what could have been attributed to background inoculum or the ECM additive. ALJFF ¶1006-42; ALJID at 263–67. Moreover, plastic biodegradation observed was likely

³² McCarthy's patented invention of a biodegradable polymer is a combination of biodegradable components with conventional polymers like polyesters, which are not generally considered biodegradable. *See* RX 756 at col. 2, lines 10–21.

³³ The colorant example helps illustrate the flaws in Complaint Counsel's argument. If manufactured properly, the ECM additive is dispersed throughout the finished plastic and, so, the additive is available to biota at all points.

underreported because the biota do not finish the additive first.³⁴ Complaint Counsel have no rebuttal to that dispositive evidence and made no attempt to address it in their appeal brief.

b. "Minimum" 60% Conversion and Radiolabeled Testing Are Not Generally Accepted

While Complaint Counsel concede that "the scientific community routinely uses gas evolution tests like the ASTM D5511 to assess biodegradability," they demand what they term a higher standard. CCOB at 40. Their argument is contradicted by their own witnesses. The ALJ identified the flaws in their argument. ALJID at 239–45. For instance, radiolabeled testing is never used, and is impractical, unreliable, and experimental. ALJID at 244–45. When assessing biodegradability of their own plastics, each of Complaint Counsel's experts employed the same gas evolution tests upon which ECM relied. ALJID at 239–45. Barlaz credibly testified that ECM's gas evolution tests were confirmatory tests and were fully sufficient to prove that the ECM additive caused plastics to biodegrade. ALJID at 244–45.

Complaint Counsel's semantic distinctions between "screening" and "confirmatory" testing obfuscate. ECM's supportive tests are not screening, they are "confirmatory" tests.

Complaint Counsel demand "minimum threshold" 60% biodegradation gas-evolution tests and radiolabeled tests. The former involves the same gas evolution tests ECM used. ALJID at 243–45. But Complaint Counsel argue that those tests must reach a specific (and arbitrary) level of 60% biodegradation over a certain period of time to be "confirmatory." CCOB at 42–43. Those levels are completely arbitrary, wholly without a basis in the peer reviewed literature. For instance, the only evidence on this point was McCarthy's unsubstantiated opinion that 60% biodegradation would suddenly become "confirmatory," begging the question why 60% as

³⁴ Barlaz's estimation of biodegradation was intentionally conservative, meaning the additive was actually more effective than reported, ALJID at 266; ALJFF ¶1040, cutting against Complaint Counsel's theories.

opposed to perhaps 50%, 40%, 30%, etc.? ALJID at 244–45. Worse, both McCarthy and Michel deemed other products (including McCarthy's own patented polymer blends) "biodegradable" based on gas evolution tests that never reached anything approaching the 60% mark (and never involved radiolabeled testing). In McCarthy's own biodegradable plastic patent, he deemed the plastics biodegradable when they achieved as little as 14% biodegradation. ALJFF ¶852. ECM had gas evolution test results that reached over 50% biodegradation. ALJFF ¶1046–1465.

Barlaz explained that gas evolution tests confirmed biodegradability of the ECM plastics. ALJID at 266. He analyzed test data and determined the amount of biodegradation that could theoretically have been produced from the ECM additive and background inoculum. ALJFF ¶¶1017–31. He then determined conclusively that the biodegradation recorded must have been sourced from the biodegrading plastic, not the inoculum and not the additive alone. ALJFF ¶¶1036–42. The results were therefore "confirmatory."

A radiolabeled test involves marking small portions of a plastic artifact with expensive, radiolabeled carbon (carbon-14). ALJFF ¶828–30. Barlaz wrote the ASTM standard for radiolabeled testing. ALJFF ¶137. Complaint Counsel's discussion of his testimony concerning radiolabeling is demonstrably false and misleading. ALJFF ¶830–32. Barlaz explained that radiolabeled testing is very difficult to achieve in plastic products, and incredibly expensive. *Id.* He explained the many problems inherent in radiolabeled testing. None of the experts in this case has ever used radiolabeling to test plastics for biodegradation. ALJFF ¶841-47. Even locating a manufacturing facility to do radiolabeling of plastics is doubtful. ALJFF ¶834, 837. No record evidence confirms that such testing is practical (or even possible) or that it is more definitive than the gas evolution testing actually performed on ECM plastics. Barlaz testified

that radiolabeled testing was entirely unnecessary, and he would have been surprised if any expert could lay claim to having tested plastics using radiolabeled carbon (in fact, none could). ALJFF ¶832.

Barlaz testified that ECM's tests already confirmed what radiolabeled testing would seek to determine. ALJID at 266; ALJFF ¶831–32. The methane observed in ECM test vessels was substantial enough to conclude that the plastics had degraded. ALJID at 266. In many tests, the amount of methane produced was more than ten times that which could be attributed to the ECM additive, even assuming the most conservative value for the additive's methane potential (and assuming the ECM additive could somehow be metabolized independent of the plastic). ALJID at 265–66. ECM's test data thus conclusively prove the same endpoint that radiolabeled testing would have shown on smaller samples, to wit, that the methane produced in the ECM tests was sourced from the biodegrading plastic. ALJID at 265–66.

Complaint Counsel's experts never performed the relevant statistical analysis of ECM test results and, so, could not opine whether the tests were "confirmatory" at all. ALJFF ¶1010. Complaint Counsel's experts had no response to Barlaz's detailed analysis of the ECM tests, and at least one of those experts—Tolaymat—conceded that Barlaz's statistical analysis was scientifically sound. ALJFF ¶723. The ALJ appropriately rejected Complaint Counsel's unsupported position concerning "confirmatory" testing. ALJID at 243–45.

³⁵ Complaint Counsel offered no record evidence that C14 testing is "routinely used." CCOB at 44. Complaint Counsel could marshal just two citations in the peer review that involved such testing. *Id.* Barlaz and Sahu testified that C14 testing on consumer plastic would be infeasible and unnecessary. ALJFF ¶830–37. Sahu was unable to locate a laboratory capable of both C14 manufacturing and testing. ALJFF ¶834. Manufacturers were generally unwilling to make plastics using radioactive components, and the amount of radioactive carbon necessary to radiolabel an entire plastic product would be prohibitively expensive. ALJFF ¶835–37.

c. ECM's Scientific Proof Satisfies the Scientific Standard

ECM's evidence was the same kind Complaint Counsel's expert witnesses used to evaluate biodegradability of plastics outside of this litigation. ALJID at 240–43. Tolaymat relied on a BMP test (or Biomethane Potential) to assess whether plastics were "biodegradable" in landfills. *See* ALJID at 243, 269–70; Tolaymat, Tr. 239. The BMP test is less representative of landfill conditions than ASTM D5511. Tolaymat, Tr. 237–38. McCarthy used his own modified gas evolution test to measure biodegradability. ALJFF ¶731; ALJID at 242, 244, 283. Michel relied on an ASTM D5511 test to measure plastics biodegradability. ALJID at 242; ALJFF ¶769, 780.

Complaint Counsel argue that, even if gas evolution tests are the industry standard, the ASTM D5511 is not a competent and reliable test because the test does not "simulate" the landfill environment. CCOB at 45. To the contrary, the experts, including even Complaint Counsel's Michel, testified that gas evolution tests are predictive of biodegradation in landfills. ALJFF ¶¶706–11, 758–83; ALJID at 240–45.

Burnette and Barlaz explained that simulated landfill experiments are not appropriate, in part, because landfills are heterogeneous and variable. ALJFF ¶¶793, 796–97. It is "not practical to try to simulate that kind of ecosystem at the time scale in the laboratory." ALJFF ¶¶708, 724 (citing Barlaz, Tr. 2212). A landfill "simulation" is therefore at odds with Complaint Counsel's "minimum threshold" test theory.

By contrast, "scientists agree that it is perfectly acceptable to extrapolate whether a material is biodegradable, including in a landfill, from accelerated lab test data." ALJID at 278; ALJFF ¶¶717–31. That is in no small measure because "biodegradability" is an intrinsic property of a material. ALJFF ¶688; ALJID at 239. If a material is "biodegradable," then it will

biodegrade whenever environmental conditions favor biodegradation. *Id.*; ALJFF 733–40. Tolaymat agreed that biodegradation tests are customarily "accelerated" to show an effect within reasonable time constraints. ALJFF ¶723. In biodegradation testing scientists accelerate tests by (1) increasing moisture content, and/or (2) increasing temperature. ALJFF ¶722, 732. Elevated moisture and temperature both increase the rate of biological activity in the test vessels. *Id.* At 52 degrees Celsius and 60% moisture, the ASTM D5511 test mimics conditions found in landfill microenvironments. ALJID at 242, 279; ALJFF ¶778.³⁶ But changes to temperature and moisture in a D5511 affect only the <u>rate</u> of biodegradation, not whether the plastic is biodegradable. ALJID at 280; ALJFF ¶738. Mesophilic and thermophilic bacteria metabolize carbon sources using the same pathways and enzymatic activity, just at different rates. ALJFF ¶733–40. ECM plastics biodegrade in mesophilic, thermophilic, anaerobic, and aerobic conditions. RPFF ¶¶2129–2706. The evidence does not support Complaint Counsel's theory that an ECM plastic is biodegradable in an ASTM D5511 test, but not in a landfill. ALJID at 223–24, 276–85.

d. ECM's Test Data Was Competent and Reliable

ECM produced 30+ gas evolution studies involving ECM-infused plastics against negative controls (i.e., untreated, conventional plastics known to degrade very slowly).³⁷ Those tests included anaerobic (e.g., ASTM D5511, BMP) and aerobic conditions (e.g., ISO 14855, UNI EN 14046). ALJFF ¶¶1006–1465. Results of those 30+ tests revealed biodegradation of the ECM plastic. ALJFF ¶¶1041–43; RPFF ¶¶1899–1933, 1964–2037, 2129–2659. Biodegradation observed in ECM's many positive tests was sufficient to conclude that the plastic

 $^{^{36}}$ When testing ECM plastics, Eden labs reduced moisture content to more closely resemble landfill averages. ALJFF $\P1055$.

³⁷ The ALJ credited at least twenty of those competent and reliable studies. ALJID at 263, 284; ALJFF ¶1006–1465.

polymer, and not just the ECM additive, had biodegraded substantially. ALJFF ¶1023, 1040–43; ALJID at 262–66. The accuracy of those results was confirmed by D6579 testing that compared molecular weights of the negative control versus the test plastic after biodegradation testing. ALJID at 266. ECM further confirmed the anaerobic biodegradability of its plastics through qualitative analyses. ALJFF ¶982–86; 1423–24; RPFF ¶1305, 1607, 2660–706. It confirmed that its plastics were intrinsically biodegradable when compared to untreated plastics. ALJID at 266; ALJFF ¶1040–43.

Complaint Counsel argue that the ALJ should have credited "criticisms regarding the reliability of ECM test data." CCOB at 46. The ALJ carefully considered the criticisms offered below and found them unsupported. ALJID at 267–75. The witnesses never developed their "criticisms" in testimony, or supported their positions with peer-reviewed literature, their own test data, or with an analysis of ECM test data. ALJID 267–75. The ALJ found that the criticisms were based on speculation not scientific evidence. For instance, Complaint Counsel's "priming effect" theory lacked scientific support either in the peer reviewed literature or in testing data. ALJID at 282–84. Complaint Counsel's own witnesses never accounted for a so-called "priming effect" in their own research, and the ASTM standards do not mention a priming effect. ALJFF ¶866–69. The ALJ noted that, "[a]Ithough Complaint Counsel has the burden of proof on its position that any test results showing biodegradation are likely the result of the

³⁸ Complaint Counsel also asked the ALJ to rely on inconclusive tests that were egregiously flawed. Some of those tests were actually "invalid" under the ASTM D5511. *See*, *e.g.*, ALJID at 256–57. In others, the laboratory had failed to even contact the test material with the inoculum. *Id.* at 256. Of course, Complaint Counsel introduced no fact witnesses concerning those tests.

priming effect, in its proposed findings of fact, Complaint Counsel does not offer a single proposed finding on the priming effect." ALJID at 283. 39

Complaint Counsel flatly misrepresent the record by stating that "Barlaz acknowledges that the priming effect and abiotic degradation can result in overestimation of biodegradability potential." CCOB at 46. In fact, Barlaz testified to the contrary, that he had seen no credible evidence that a priming effect could influence ECM's test results, and he had seen no such effect in other laboratory tests involving polycaprolactone-based materials. ALJFF ¶866–68. Indeed, Barlaz described the priming effect as "quite speculative as a way to shoot down a test." ALJFF ¶866. Complaint Counsel never rebutted that testimony, or Barlaz's analysis of test data, which they ignored completely in their appeal brief.

VI. A STRONGER REMEDY IS UNJUSTIFIED, ARBITRARY, AND CAPRICIOUS

Complaint Counsel's argument for a stronger remedy is inextricably intertwined with their flawed scientific theories. Complaint Counsel's proposed remedy would violate the First Amendment by imposing a prospective speech ban, a cease and desist order, on truthful commercial speech. *New.Net, Inc. v. Lavasoft*, 356 F. Supp. 2d 1071, 1084 (C.D. Cal. 2003) (citing *Ohralik v. Ohio State Bar Ass'n*, 436 U.S. 447, 456 (1978)); *Gibson v. Texas Dep't of Ins.—Div. of Worker's Compensation*, 700 F.3d 227, 235 (5th Cir. 2012).

Without evidentiary support, Complaint Counsel argue that ECM "exploited consumers' environmental consciousness." CCOB at 47. The ALJ found "no evidence of economic harm to

³⁹ Additionally, Complaint Counsel argued that ECM's tests lacked "statistical analyses" which therefore "invalidated the results." CCOB at 47. But Complaint Counsel ignore the fact that NE Labs provided raw data for its tests, ALJFF ¶1371, and that Barlaz performed the statistical analyses himself, determining that the tests had statistically significant positive results based on low t-statistics. ALJFF ¶1011–15. Complaint Counsel's experts had that same data but chose to ignore it. ALJFF ¶1010.

ordinary consumers; Respondent has no prior violations; and there is no issue of transferability." ALJ ID at 309. Complaint Counsel have not rebutted those findings and conclusions.

Complaint Counsel erroneously argue that ECM "knew about five different adverse adjudications regarding the efficacy of ECM Plastics." CCOB at 48 (referencing NAD and foreign decisions); ALJID at 307 at n.62. The fact that ECM rightfully believed in its technology should not be held against it. Those so-called "adverse adjudications" were not United States judicial proceedings and involved downstream clients, not ECM; none applied FTC standards of decision; and none included the testing, peer reviewed science, and expert opinion evaluated by the ALJ in this case. ALJID at 307 n.62. The so-called "adverse" NAD decision involving FP International actually recognized that

[T]the advertiser provided support that its own plastic product, because of its additive, will degrade at a faster rate than conventional petroleum-based plastics and . . . provided a scientific bases for the theory that its product will degrade more rapidly than conventional ... plastics in specified anaerobic conditions.

See CCX 28 at 15.

ECM's decision to change disclaimer language in 2012 reflected an attempt to comply with scientifically implausible governmental standards, not a nefarious plot to deceive customers (of which there is no evidence). Complaint Counsel directly misrepresented the record evidence by stating that "ECM was well aware" of certain negative test results and "hid them from prospective customers." CCOB at 4 (referencing Dr. Michel's study and 3M's testing). In fact, Complaint Counsel were actually <u>sanctioned</u> by the ALJ for <u>withholding</u> Dr. Michel's study in

discovery.⁴⁰ Mr. Sinclair testified at the time that he had never seen the document, and no evidence proves or suggests otherwise. CCX 819 (Sinclair Dep. at 367).⁴¹

Complaint Counsel did not support their demand for broader fencing-in relief, which apparently involves imposition of a heightened—and scientifically implausible—standard on prospective ECM speech. Complaint Counsel's proposed order included mandatory disclaimer language rejected by the experts in this case and the ALJ. The so-called "One Year Rule" featured in Part I(A) and 4(A)–(B) of the Proposed Order is unscientific and unsupported by competent survey evidence. No expert in this case could explain how to reliably substantiate a claim concerning the "time to complete decomposition" or the "rate and extent of decomposition" required by Part I(A)(ii)(a)–(b) and 4(A)–(B) of the Proposed Order. Because nothing reliably biodegrades completely within one year in a landfill, not even a tree trunk, a banana, or an orange, the Proposed Order would create a categorical bar on biodegradable claims, effectively censoring out of the marketplace ECM's useful, environmentally friendly biodegradable technology.

That relief would violate the First Amendment and redound to the detriment of the environment. It would impose a prior restraint on truthful speech without reliance on obvious, less speech restrictive alternatives (such as a qualification that there is no known precise rate of biodegradation). *See Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999); ALJID at 304–06;

⁴⁰ See Order, supra note 12.

⁴¹ Complaint Counsel had a copy of Michel's study well before filing its Complaint against ECM. Michel had been retained as an FTC consulting witness since at least 2012. Complaint Counsel withheld Michel's evidence from ECM. Michel's 2012 testing was directly responsive to ECM's discovery requests, but Complaint Counsel did not timely supply it. *See* Order, *supra* note 12. (sanctioning Complaint Counsel for discovery violations). Complaint Counsel never designated Michel as an expert witness in the case, although they clearly intended to use him as a rebuttal witness. With considerable hubris, Complaint Counsel ask for relief against ECM on the false rewritten history that ECM "hid" Michel's study from customers. CCOB at 4.

PUBLIC DOCUMENT Docket No. 9358

RPCL ¶67. The ALJ found because landfills present such varied environmental conditions, any

projection of a precise biodegradation "rate" is scientifically impossible. ALJID at 240, 277-78;

ALJFF ¶566-607, 629-32, 30-40. None of Complaint Counsel's experts could support a "rate"

qualification. ALJID at 239-40; ALJFF ¶¶712-14, 952. Barlaz testified that there is no

generally accepted method to determine that "rate" in landfills. ALJFF ¶¶713, 724.

VII. **CONCLUSION**

For the foregoing reasons, the Commission should affirm the ALJ's decision finding

ECM's express biodegradable claim substantiated by competent and reliable scientific evidence,

affirm his decision that no claims in issue were reasonably implied, and deny Complaint

Counsel's appeal, and take no action against Respondent ECM Biofilm pled for in the

Complaint.

Respectfully submitted,

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DATED: March 25, 2015

52

CERTIFICATE OF SERVICE

I hereby certify that on March 27, 2015, one original and twelve copies of Respondent ECM BioFilms' Brief in Answer to Complaint Counsel's Appeal, were mailed via UPS Second Day Air:

Donald Clark, Secretary Federal Trade Commission 600 Pennsylvania Ave., NW, Room H-159 Washington, DC 20580

I hereby certify that this is a true and correct copy of Respondent ECM BioFilms' Brief in Answer to Complaint Counsel's Appeal, and that on March 31, 2015, I caused the foregoing to be served **electronically** to the following:

The Honorable D. Michael Chappell Administrative Law Judge 600 Pennsylvania Ave., NW Suite 110 Washington, DC, 20580

Donald Clark 600 Pennsylvania Ave., NW Suite 172 Washington, DC 20580

I hereby certify that this is a true and correct copy of Respondent ECM BioFilms' Brief in Answer to Complaint Counsel's Appeal, and that on March 31, 2015, I caused the foregoing to be served electronically to the following:

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