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RECORD REFERENCES

CCFF – Complaint Counsel’s Proposed Findings of Fact

CCX – Complaint Counsel’s Exhibit

Dep. – Deposition transcript

ID – Initial Decision

IDFF – Initial Decision Findings of Facts

RX – Respondent’s Exhibit

Tr. – Trial Transcript

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consumers that “biodegradable” plastic would break down completely in a landfill in a reasonably short time (less than five years). Specifically, each of the four surveys in the record shows that significant minorities (and likely majorities) of consumers perceive short timeframes for unqualified biodegradable claims. Moreover, ECM repeatedly tells customers that their plastic could be labeled biodegradable because the additive caused complete landfill breakdown within one or five years.

Even if one were to ignore the clear evidence that consumers understand unqualified biodegradable claims to mean a product will completely break down in a short period, the evidence still overwhelmingly demonstrates that ECM’s implied claim is false and unsubstantiated. At trial, a plastic expert, a landfill expert, and an expert in biochemistry all explained that conventional plastic does not biodegrade at all—let alone in landfills—and mixing in the ECM additive does nothing to change this scientific fact.

Moreover, substantial evidence establishes that ECM’s testing does not substantiate its Implied Claim. Had the ALJ looked to what experts in the field would require to substantiate Respondent’s scientifically causal claims, he would have had to find that Respondent’s substantiation falls dramatically short. Specifically, the evidence overwhelmingly shows that: (1) there is no established mechanism or theory that would lead experts in the field to conclude that ECM’s technology works; and (2) ECM’s testing is neither of the type nor the quality that could substantiate its claims.

903, 907 (D.C. Cir. 1976). The “preponderance of substantial evidence” standards are identical. *Steadman v. SEC*, 450 U.S. 91, 101-102 (1981).

B. Summary of Facts

1. ECM's Deceptive Claims.

ECM made false and unsubstantiated claims to exploit end-consumers' concern about plastics and the environment. (CCFF ¶¶ 14, 17.)

which shows complete biodegradation in any timeframe or biodegradation in landfills at all. (CCFF ¶¶ 449, 454.) Some of ECM's customers are small laboratories that conduct additional tests, but none support ECM's claims. (CCFF ¶ 454.) Unsurprisingly, when sophisticated prospective customers like 3M Corporation conducted their own valid testing, they found no biodegradation at all of the plastic itself. (CCFF ¶ 94.) Moreover, the only study of ECM Plastic published in a peer-reviewed, academic journal also conclusively concluded that the plastic itself does not biodegrade. (CCX-164.) ECM was well aware of these results but hid them from prospective customers, by steering them away from labs that provided negative results and towards labs whose dubious testing protocols provided the semblance of positive results. (CCFF ¶ 99.)

3. ECM Sells the Right to Advertise Plastic Products as Biodegradable.

ECM does not simply sell an additive. Far more importantly, it sells the (purported) ability to make a "biodegradable" advertising claim. (CCFF ¶ 62.) To that end, ECM provides its customers with tools to pass claims to downstream business customers and, ultimately, end-use consumers. (CCFF ¶ 65.) For example, MEC provided a "Certificate of Biodegradability," which claims both to "certify" independent testing to accepted standards and "validate" biodegradable claims. (CCFF ¶¶ 47-48.) MEC also provided the ECM logo, a picture of a green tree with the words "ECM" and "Biodegradable" (CCFF ¶¶ 62-63.) As ECM intended, its customers posted the certificate on their websites, sent it to their own customers, or copied the language verbatim in their ma

The deceptive advertising worked. ECM sold biodegradable additive to about 300 customers. (CCFF ¶ 23.) These customers passed ECM's deceptive claims to millions of consumers who used or purchased "biodegradable" grocery bags, shampoo bottles, Frisbees, golf tees, highlighters, cutlery, and more. (CCFF ¶¶ 24-25.)

4. ECM Ignored Repeated Warnings that its Additive Does Not Work.

ECM's deception did not go undetected. At least two foreign tribunals, the National Advertising Division ("NAD") of the Better Business Bureau, and prospective customers warned ECM that its testing did not support its claims (as that its product was a hoax.) (CCFF ¶ 102-103.) ECM's President, Robert Blair, knew that NAD (three times) as well as French and Italian courts found that customers using ECM's "biodegradable" claims had made false and unsubstantiated claims. (CCFF ¶ 103.) Nonetheless, ECM continued to make them, explaining away credible criticism as bias vendetta. (CCFF ¶¶ 104-106.)

C. Summary of the Argument

The ALJ correctly found that Respondent violated Section 5 by making material false and unsubstantiated efficacy and establishment claims. However, the analysis and findings were critically flawed in numerous respects. First, overwhelming consumer perception evidence as well as ECM's intent show it is more likely than not (a preponderance) that ECM made deceptive implied claims. Second, Complaint **Con** demonstrated by a preponderance of the evidence that ECM's express and implied claims are false and unsubstantiated because ECM Plastic will not—and cannot—biodegrade in a **l** in any reasonably short period of time. Moreover, ECM's radical claims are not supported by the level of testing expected by the relevant scientific community, and these tests are neither of the type nor the quality to come anywhere close to that standard. Complaint **Con**'s proposed relief is necessary to prevent

future violations by a respondent that hastened to make claims despite having been on notice for years that its product is little more than a hoax.

II. QUESTIONS PRESENTED

1. Whether the compelling consumer perception evidence combined with clear intent evidence demonstrate that it is more likely than not that Respondent's "biodegradable" claim and "some period greater than a year" claim implied to reasonable consumers that plastic treated with its additive would completely break down into elements found in nature in a landfill in a reasonably short period of time (i.e., within one or five years) ("Implied Claim").
2. Whether the scientific evidence demonstrating that ECM's additive does not—and cannot—make plastic biodegradable renders ECM's Implied Claim false, and whether this fact, along with the lack of testing required by the relevant scientific community, renders ECM's Implied Claim unsubstantiated.
3. Whether the Notice Order is necessary and appropriate to prevent future violations because ECM knew its claims were false and unsubstantiated, yet continued to make them, and conceal contrary evidence from its customers.

III. ARGUMENT

A. ECM Made Implied Claims of Complete Biodegradability in a Landfill in a Reasonably Short Period of Time.

An advertisement "convey[s] a claim to consumers, acting reasonably under the circumstances, would interpret the advertisement to contain that message." *Kraft, Inc.*, 114

To show that ECM made the Implied Claim, the Complaint Counsel must prove by a preponderance of the evidence (that it is more likely than not) that a significant minority of consumers understood the advertising to mean that claim. Overwhelming evidence—well beyond a preponderance—establishes that ECM made the Implied Claim.

1. Convergent Results of the Four Studies in the Record Prove Well Beyond a Preponderance that a Significant Minority of Consumers Infer Complete Biodegradation in a Landfill in a Short Time.

Four studies in the record reported on consumer perception of the claim “biodegradable.” Despite different methodologies, each study reached a strikingly similar conclusion: when consumers see an unqualified “biodegradable” advertising claim, they infer a short time for biodegradation.

- f* In 2006, the American Plastics Council (APCO”) conducted a telephone survey, and found that 60% of respondents believe that packages labeled “biodegradable” should biodegrade within one year, 65% believe such packages should biodegrade within four years, and 83% believe such packages will biodegrade in a landfill. (CCFF ¶¶ 194, 195, 209; CCX-890 at 13.)
- f* In 2010, Synovate conducted an Internet panel survey, and reported that 25% of consumers believe that “less than one year” was a reasonable amount of time for a “biodegradable” package to decompose in a landfill, and 45% of consumers believe that “less than five years” was a reasonable amount of time. (CCFF ¶¶ 368, 369, 211.) Seventy-two percent of consumers believe that a package labeled “biodegradable” will biodegrade in a landfill. (CCX-890 at 13.)
- f* In 2014, Dr. Shane Frederick used Google Consumer Surveys (“GCS”) to assess consumers’ understanding of plastic products labeled “biodegradable.” (CCFF ¶¶ 198, 199.) He estimated that 35% believe such products will biodegrade within one year. (CCFF ¶ 200.) Depending on the type of question and the wording, 40-76% understood that such product would biodegrade within five years. (CCFF ¶ 212.) Dr. Frederick found that 42%-64% of consumers believe that plastic products will biodegrade in a landfill,

consumers understand that a plastic product labeled “biodegradable” will break down completely into elements found in nature. (CCFF ¶ 312.)

f In 2014, ECM’s expert, Dr. David Stew

conducted with four distinct methodologies, at different times by four sets of researchers reached similar results.⁷(CCFF ¶ 208.) Converging results from four reasonably reliable and valid studies with different methodologies is powerful evidence that the shared results are accurate. (CCFF ¶¶ 192-193, 208.) Dr. Frederick testified that because of this “convergent validity,” he could conclude with confidence that at least 35% of consumers believe that plastic products labeled “biodegradable” will biodegrade within one year. (CCFF ¶ 200.)

Public and International Affairs at Princeton University, the Massachusetts Institute of Technology’s Sloan School of Business, and Yale University School of Management. (ID 18-19, CCX-890 at 3, Exh. A.) At Princeton, Dr. Frederick worked as a research assistant for Nobel laureate Daniel Kahneman. (CCX-890 at 3, Exh. A.) Dr. Frederick has published extensively in prominent peer-reviewed journals on consumer judgment and decisionmaking, focusing on preferences and cognitive biases (including “nudging”). (ID 19; CCX-890 at 3, Exh. A.) An affiliate with Yale’s Center for Consumer Insights, Dr. Frederick conducts and evaluates hundreds of surveys employing both traditional and newer Internet-based methodologies (such as Google Consumer Surveys). (ID 19; CCX-890 at 4-5, Exh. A.)

⁷ A graphical representation starkly shows their convergence:

	Within 1 Year	Within 5 Years
APCO	60%	65%
Synovate	25%	45%
GCS Study	35%	40-76%
Stewart Survey	33%	58%

⁸ The ALJ found Dr. Frederick’s testimony “less credible” than the testimony of ECM’s expert, Dr. Stewart. (ID 46.) But the ALJ did not actually make any credibility findings. Rather than comm89 Tm -.08998 19.9d T04 1080d T04 1i%Slfu7ro2 0 io.03a4 e9oo(91.9ll)-2fu7ro2 0 io.0i%3

should biodegrade within four years. (CCF# 195, 209.) Additionally, EcoLogic, a manufacturer of an additive similar to ECM's, engaged a survey firm (Synovate) to conduct a 2000-responder Internet panel survey. (CCF# 196.) In that study, 25% of respondents stated that "less than one year" was a reasonable amount of time for a "biodegradable" package to

3. Dr. Frederick's Methodologically-Sound Study Convincingly Demonstrates Significant Consumer Inference of Short Biodegradation Times and Bolsters APCO and Synovate's Similar Conclusions.

The ALJ not only erred in discounting Dr. Frederick's testimony about the convergent validity of the APCO and Synovate studies, but also impugning and ignoring Dr. Frederick's methodologically-sound Google Consumer Surveys (GCS) study. Dr. Frederick's study, on its own, more than meets the legal standard, demonstrating that it is more likely than not that reasonable consumers think an unqualified biodegradable claim means a product will completely biodegrade in a landfill in five years or less. Combined with the APCO and Synovate studies, Dr. Frederick's study presents overwhelming evidence that ECM made the Implied Claim.

Like the APCO and Synovate surveys, Dr. Frederick's survey demonstrates that consumers infer short timeframes from an unqualified biodegradable claim:

- f* For nine of the twelve open-ended questions, more than 50% of respondents understood that a plastic product labeled "biodegradable" would biodegrade

When evaluating consumer perception evidence, the Commission weighs “reliable results from methodologically sound consumer surveys.” *FTC v. Borden*, 382 U.S. 183, 190 (1965), 2013 FTC LEXIS 6 at *45, quoting *Kraft*, 114 F.T.C. at 121. In other words, “[t]he Commission does not require methodological perfection . . . but looks to whether such evidence is reasonably reliable and probative.” *Id.* at *49.

The ALJ’s conclusion that Dr. Fredericks’s survey was not methodologically sound is

were the correct group. (ID 197.) This is wrong,

Dr. Frederick explained that although GCS's demographic inferences are highly reliable in the aggregate, demographic information on individual respondents may be unknown or inaccurate. (CCFF ¶¶ 276-277.) For example, if a user has disabled "cookies," GCS cannot use browsing history to infer gender or age. (CCFF ¶ 277.) Alternatively, as the ALJ noted, GCS's inferences about gender, age, or income could be incorrect if one family member used another's computer. (ID 198.) The ALJ seized on Dr. Frederick's acknowledgment of these imperfections, *id.*, but ignored his testimony that imperfections with respect to individual respondents do not compromise the overall representativeness of the enormous 29,000-respondent sample. (CCFF ¶¶ 271-272, 287.) Tellingly, when Dr. Stewart, ECM's own expert, acknowledged the demographic gaps in his sample, see note 14, he also opined that individual imperfections do not matter if the overall sample is representative. (CCFF ¶ 286.)

iii. GCS's Sampling Is More Representative Than Traditional

Dr. Frederick explained that there are three reasons why GCS is more representative than landline surveys. First, GCS gathers five ~~type~~ demographic information about respondents (age, geographic region, gender, income, and urban density). Landline surveys like Dr. Stewart's only gather two (age and gender) (CCFF ¶¶ 279-280.) This difference is particularly significant because geographic region and urban density can be very useful proxies for respondents' beliefs on many subjects

(after making more than 17,000 calls) to obtain a sample of just 400 respondents. (CCFF ¶ 390; Tr. 2701.) Finally, GCS is more representative than most survey media because it has access to the enormous percentage of the population that uses the Internet (85% in 2013). (CCFF ¶¶ 224-225.) In contrast, only 60% of the American population has a landline, (CCFF ¶ 226), and this group tends to be older and disproportionately white. (CCFF ¶¶ 392, 395.)

And, in fact, Dr. Stewart's survey had precisely this over-representation problem. Fifty-eight percent of Dr. Stewart's respondents were 50 and older, (CCFF ¶ 393), even though

Internet panel surveys, deviating from the

of public debate” but allegedly did not provide such a reasonably representative sample for the questions at issue here. Indeed, this conclusion makes no sense.

Each of these pieces of evidence further supports the reasonable representativeness of Dr. Frederick’s GCS study. Disregarding this evidence, as the ALJ did, improperly holds GCS to a standard of methodological perfection that no one could meet and the law does not require. See POM2013 FTC LEXIS 6, at *49.¹⁶ Accordingly, the Commission should set aside the ALJ’s unsupported findings, and consider the evidence actually presented, which indisputably demonstrates the validity of Dr. Frederick’s GCS sample.¹⁷

b. Dr. Frederick’s Study Asked Appropriate Questions—Including the Central Question in this Case.

The second step in assessing survey methodology is analyzing the appropriateness of the survey’s questions. (ID 189, citing POM, No. 9344, 2013 FTC LEXIS 6, at *49). To ensure the

¹⁶ See also *Stouffer*, 18 F.T.C. at 807 (“A study may be flawed, that is, harbor one or more sources of potential error or bias, and still be probative.”), 114 F.T.C. at 126-27 n.13 (“Although we agree with respondent that the design of the MOR survey questionnaire is not without flaws, and that alternative or additional means could have been used to better minimize the potential for yea-saying bias inherent in using a closed-ended question format, on balance, we find the MOR survey results to be of some probative value.”) *Thompson*, 104 F.T.C. at 796-97 (survey that has “several potential sources of bias” nonetheless deemed to be “reasonably reliable extrinsic evidence”).

¹⁷ Substantial evidence establishes GCS’s representativeness. But, to the extent that the Commission requires additional evidence, it should reverse the ALJ’s improper denial of Complaint Counsel’s Motion For Leave To Call Rebuttal Fact Witness Paul McDonald, GCS Product Manager. Under the Commission’s Rules of Practice, a party may submit rebuttal evidence “as, in the discretion of the Commission or the Administrative Law Judge, may be required for a full and true disclosure of the facts.” 16 C.F.R. § 3.43(d)(1). During trial, ECM,

propriety of his questions, Dr. Frederick asked the relevant question—how much time does it take a plastic product labeled biodegradable to biodegrade—dozens of different ways. (CCFF ¶ 218; CCX-890, App. at 27-37.) The ALJ disregarded this evidence and incorrectly found that the question “design” was not appropriate. (ID. 19) As explained below, the ALJ findings are

biodegradable advertising claim means that product will biodegrade in 100 million years. It is essential to ask about time precisely because it is not necessarily the first thing that pops into consumers' minds.

The ALJ also inexplicably faulted Dr. Frederick's surveys because of their "single-question' design" and alleged lack of open-ended questions. (ID 193-195.) These critiques grossly mischaracterize the actual questions. As his expert report clearly shows, Dr. Frederick asked more than sixty different questions, most of which were open-ended. Compare CCX-890 at 27-36 (open-ended questions) with 37-41 (binary questions). Some questions involved the "ECM Biodegradable" logo, some involved other "biodegradable" logos, and some involved only words. (CCFF ¶ 294.) Significantly, ECM's expert did not challenge the wording or structure of any question Dr. Frederick asked. (CCFF ¶ 288.)

Asking similar questions in different ways to multiple groups of respondents yielded three distinct benefits. First, asking each group a single question enabled Dr. Frederick to avoid influencing respondents' answers to later questions with the phrasing of earlier questions. As discussed *infra* at 29-30, Dr. Stewart's "multiple-question design" study suffered from precisely this flaw, with early questions suggesting a *ability* in biodegradation and priming respondents to be vague when answering questions about ECM's claims. (CCFF ¶¶ 379-386.) Indeed, Dr. Stewart admitted that "information conveyed to respondents earlier in a survey can affect their answers to later questions[.]" (CCFF ¶ 472.)

Second, Dr. Frederick's questioning mimicked the varying ways ECM's "biodegradable" claims reach consumers—e.g., via a biodegradable label, an eco-friendly label that mentions "biodegradable," or the "ECM biodegradable" logo. Compare CCX-890, App. at 27-30 ("biodegradable" label) with App. at 30-31 (eco-label) with App. at 31, 36, 38, 40, 41, 43, 44

(ECM logo). By contrast, Dr. Stewart's study did not ask respondents about the "ECM Biodegradable" logo, any other biodegradable logo—or any biodegradable labeling at all. (CCFF ¶ 353.)

Third, asking each question in different ways to different groups enabled Dr. Frederick to have confidence in the results. As Dr. Frederick explained, arriving at the same result despite asking questions in different ways is an indication of the "robustness" or "convergent validity" of the results. (CCFF ¶¶ 291-92.)

c. There Is No Credible Evidence of "Disinterest Bias."

When courts and the Commission assess survey questions, they consider whether questions were asked to minimize bias. (ID 189, *COM*, No. 9344, 2013 FTC LEXIS 6, at *49.) Completely misunderstanding the evidence, the ALJ found that the GCS study was tainted with a "disinterest bias." (ID 192.)

Dr. Frederick explained that any "disinterest bias"—Dr. Stewart's notion, borrowed from a Google competitor's blog post, not any academic literature (CCFF ¶¶ 329-330)—did not materially affect the reliability of the survey results, for several reasons. First, the number of obviously disinterested "protest" responses (e.g., "go away") was minimal—less than 1% of an enormous sample (N>20,000) (CCFF ¶ 324.) Second, there is no reason to believe that this one

¹⁸ Contrary to the ALJ's findings, the absence of "screening questions" did not undermine the reliability of Dr. Frederick's study. (IDFF 47-48.) The ALJ disregarded evidence that screening questions can do as much harm as good, so it is reasonable not to use them. For example, screening respondents, as Dr. Stewart di

percent's views are different from the remaining 99%.) (Tellingly, Dr. Stewart did not contradict this point. (CCFF ¶ 325.) Third, there is no greater reason to disbelieve the genuineness of the 99% of facially meaningful answers simply because respondents wanted access to Internet content than there is in telephone survey, where respondents may answer in order to conclude the conversation, to have someone to talk to, or for any other reason. (CCX-890 at 5.) Finally, Google takes steps to validate respondents' willingness to provide meaningful answers by periodically asking questions with obvious answers, (e.g., how many states are there in the United States?), and ensuring that persons who respond incorrectly do not receive future surveys. (CCFF ¶ 326.)

In fact, Dr. Frederick explained that the 1% of "protest" answers provides evidence of the validity of the remaining 99% of answers. (CCFF ¶ 331.) Obviously, "protest" was an option—but an option that 99% of respondents did not elect. The fact that average response times were generally above 20 seconds suggests that the 99% gave thoughtful answers. (CCFF ¶ 332.) In fact, as Dr. Frederick testified, and Dr. Stewart conceded, a question which the consumer gives a response after 20 seconds much better replicates the actual consumer experience when confronted with a "biodegradable" claim on store shelf than a telephone interview taking twelve minutes. (CCFF ¶ 336.) Finally, even if some respondents took 20 seconds or more because they were distracted by another activity (as the ALJ posited (ID 193)), as Dr. Frederick explained, with respect to most respondents, "I wouldn't make any sense . . . for someone to see a question, to sit there and do nothing, then key in a nonsense response [after] 22 seconds" when he or she could do so immediately. (CCFF ¶ 333.)

- d. Dr. Frederick Correctly Analyzed the Results of His Study in Bias-Minimizing Ways.

The final step in assessing the soundness of survey methodology is considering whether the survey results are analyzed correctly. (ID 189, ~~CONF~~)

(CCFF ¶ 315.) Dr. Frederick explained that he uses this “bright line” rule to avoid any “value judgments [by the coders] about which responses are ‘too inaccurate’ to count.” (CCFF ¶ 313.) For example, without the rule, a coder would have to make a value judgment about whether to include an answer such as “10 days,” which could be either an absurd or a genuine response. With the rule, such problematic value judgments are not necessary.; (see also CCFF ¶ 341

case. (CCFF ¶ 353.) Instead, he asked: “If something is biodegradable, how long do you think it would take for it to decompose or decay?” (CCFF ¶ 354.) In other words, ECM avoided eliciting consumers’ understanding about how quickly a plastic product advertised as “biodegradable” would biodegrade.

Nonetheless, over half (206) responded with a number and unit of time. (CCFF ¶ 355.) Of these 206, 33% gave estimates of one year or less and 58% gave estimates of five years or less. (CCFF ¶¶ 210, 355.) The ALJ faulted Complaint Counsel for considering 206 of the 400 responses. (ID 214-215.) However, responses without number and unit of time are irrelevant. See supra at 25. Nevertheless, even improperly considering all 400 responses, ECM’s survey still supports Complaint Counsel’s point. Seventy percent of respondents estimated less than a year and nearly 30% estimated five years or less. (Tr. 2790-91.) In other words, Dr. Stewart’s results, like the results of APCO, Synovate, and GCS, show that significant minorities (and

“biodegradable in some period greater than a year” claim means²² After respondents had already answered several questions about biodegradation²² Dr. Stewart’s researchers asked a final series of questions. (CCFF ¶ 379.) First, they asked: “Do you think that there are differences in the amount of time it takes for different products to biodegrade, decompose, or decay?” (CCFF ¶ 380.) Unsurprisingly, almost everyone (98%) answered affirmatively. (CCFF ¶ 381.) Next, those 98% were asked to expound on those differences: “What differences exist in the time for different types of products to biodegrade, decompose, or decay?” (CCFF ¶ 382.) Immediately after, respondents were asked to give their impressions of claims similar to ECM’s. (CCFF ¶ 383.)

It was entirely predictable, given the order of the questions, that a high percentage of respondents would answer “it depends” rather than giving a timeframe²³ Thus, the fact that such high percentages of respondents gave the same answers as respondents in the other three studies is particularly significant. In fact, ECM’s own study supports the conclusion that a significant minority (and likely majorities) of consumers believe that biodegradation happens within a reasonably short period of time.

showing that an advertiser intended to make particular claims can help demonstrate that the alleged claim was in fact conveyed to consumers. *POM*, No. 9344, 2013 FTC LEXIS 6, at *51. *Accord Novartis Corp.* 127 F.T.C. 580, 683 (1999) (“[E]vidence of intent to make a claim may support a finding that the claims were indeed made. *Telebrands* 140 F.T.C. at 304 (finding support that claims were made in part by evidence that respondents intended to convey the challenged claims). *Thompson* 104 F.T.C. at 791 (“Thompson intended to make these claims . . . [and] [t]herefore, it is reasonable to interpret the ads as making them[.]”).

There is overwhelming evidence that including unqualified “biodegradable” claims,

substantiated its claim by demonstrating ECM Plastic to be more susceptible to the biodegradation process. In reaching this result, however, the ALJ grossly misunderstood the scientific testimony. Substantial evidence shows that ECM's claim that ECM Plastic biodegrades in any meaningful way is both false and unsubstantiated.

1. The ALJ's Interpretation of Biodegradable Renders ECM's Implied Claims Meaningless.

The ALJ found that an unqualified biodegradable claim does not convey that the product will biodegrade "completely" or in any specific time period. Instead, he contends, based on his interpretation of the "scientific" meaning of the term, ECM's Implied Claims conveyed nothing more than the ability of ECM Plastic to undergo a biodegradation process that has no clearly defined end-point. (ID 247-248.)

This interpretation is absurd. Because things biodegrade eventually (given hundreds of millions of years), this definition would permit marketers to advertise every product as "biodegradable," including conventional plastic. If ECM's customers had this understanding, they would have no reason to buy the Additive; they would simply label their conventional plastic "biodegradable" without the extra expense. Of course, neither consumers (as explained supra 6-30) nor scientists share this understanding. At a minimum, ECM's unqualified claim must convey something more than the inherent ability of things to eventually biodegrade. It must convey at least a fundamental change in the biodegradable properties of conventional plastic that is meaningful and relevant to consumers. Although the ALJ never makes a specific finding that ECM Plastic is less resistant to biodegradation than conventional untreated plastic, including in a landfill, he appears to implicitly recognize this point by finding ECM substantiated the legally irrelevant scientific definition. As discussed below, incontrovertible scientific evidence contradicts this finding.

2. ECM Plastic Cannot Be Biodegradable.

ECM's claim that the ECM Additive can ~~change~~ the fundamental non-biodegradable nature of conventional plastics ~~is~~ completely at odds with ~~the~~ overwhelming, well-established scientific opinion. In finding otherwise, the ~~ALJ~~ incorrectly failed to evaluate the type of substantiation the relevant scientific community ~~would~~ consider appropriate. Instead, he relied heavily on the opinions of scientists who are not ~~experts~~ in relevant fields of study. However, the evidence demonstrates a strong scientific consensus that conventional plastics are not biodegradable. Accordingly, the scientific community requires a high level of substantiation to

evidence.²⁴ However, he critically failed to determine “the amount of substantiation experts in the field believe is reasonable.”

The ALJ relied heavily on the testimony of two ECM experts, Drs. Sahu and Burnette, neither of whom has relevant expertise, and rejected the testimony of extremely qualified relevant experts and the consensus of the relevant scientific community. Compare IDFF 122-130 (Sahu) and 140-143 (Burnette) with IDFF 107-111 (McCarthy) and IDFF 117-121 (Michel).

Dr. Sahu is a general-purpose environmental law consultant, without experience, training,

Environment (IDFF ¶ 109.) Moreover, he has authored or co-authored more than a hundred publications about polymer or plastics engineering, including peer-reviewed articles on biodegradable blends. (IDFF ¶ 110.) Not surprisingly, a number of the papers cited by ECM's so-called experts relied on materials written or co-authored by Dr. McCaskey, e.g. RX-360 at 9; RX-365 at 1; RX-581 at 14; RX-584 at 12.)

Dr. Michel explained that his whole career has involved polymer conversion in compost systems and anaerobic digesters. (Tr. 2836.) He has a Ph.D. and M.S. in Chemical Engineering from Michigan State University. (IDFF ¶ 119.) For the past 25 years, Dr. Michel has conducted research on the biodegradation of plastics, bioplastics, biofoams, and natural fiber materials in anaerobic digesters, composting systems and in soil. (IDFF ¶ 119.) Dr. Michel has authored over 40 peer-reviewed publications in the areas of composting and anaerobic biodegradation of polymers. (IDFF ¶ 119.) Since 2007, he has served as the Editor of Compost Science and Utilization Journal, an international peer reviewed scientific journal, and as an Associate Editor for the Biological Engineering division of the American Society of Agricultural and Biological Engineers. (IDFF 120.) Importantly, Dr. Michel is author of the only published, peer-reviewed scientific literature evaluating whether ECM Plastic is biodegradable. (CCX-880.) Notably, this peer-reviewed paper found that ECM Plastic does not biodegrade in any environment. (CCX-880.)

The ALJ made no findings that either Dr. McCarthy or Dr. Michel based their opinions on anything other than their scientific knowledge. Nor did he explain why he failed to give

biodegradable, mixing 1% biodegradable additive can weaken the plastic and increase

has yet to occur.”). Conventional plastic polymers are composed primarily of polymer chains with molecular weights typically ranging from the hundreds of thousands to millions. (CCX-891 ¶ 30.) Their enormous average molecular weight makes them inherently extremely difficult to break down. (CCFF ¶ 9.)

Microorganisms secrete enzymes that adhere to the surface of organic materials and cause fissures in the molecular chain (also called hydrolysis). (CCX-891 ¶ 22.) These cleavages make long-chain molecules shorter, resulting in the release of carbon and energy (heat). (CCX-891 ¶ 22; see also RX-584 at 4-5.) It is widely accepted that known microorganisms do not secrete enzymes that can bind to commercial conventional plastics.²⁶ (See CCX 891 ¶ 22, ¶¶ 32-35 and ¶ 74; RX-581 at 1 (“Plastics are resistant against microbial attack, since during their short time of presence in nature evolution could not design new enzyme structures capable of degrading synthetic polymers”); RX-584 at 4 (same).)

Existing microorganisms can ingest polymers with a molecular weight below 500, where they can be “depolymerized” and used for energy (also known as mineralization). (CCX-891 ¶ 86; CCX-892 ¶ 12; RX-584 at 4.) Over time (perhaps millennia), new microorganisms may evolve that can either secrete enzymes that break down high molecular weight plastic or perhaps even ingest conventional plastics—but such a claim is speculative and far distant. Until then, conventional plastic will be broken into much shorter chains through abiotic processes before it will biodegrade. Unaided by chemical or mechanical means, this process could span tens of thousands of years. See CCX-895 at 12 (“without these abiotic and chemical and physical modifications, the extent of plastic biodegradation is essentially nil.”).) Even chemical and

²⁶ Some microorganisms secrete enzymes that can break down naturally occurring polymers, like starch and cellulose, and some synthetic polymers that closely resemble them. (CCX-891 ¶¶ 33-34; CCFF ¶ 8.)

mechanical processes may not enhance ultimate biodegradability. (CCX-891 ¶¶ 26-27 (“[A]lthough degradation (or disintegration) may change the plastic’s physical form, it does not involve microorganisms, nor does degradation necessarily mean that the plastic will degrade into natural elements.”); see also CCX-895 at 12.)

b. There Is No Scientific Basis to Believe ECM’s Purported Technology Could Possibly Work.

Dr. McCarthy explains that there is no reason to believe that ECM’s purported technology could possibly work. (CCX-891 ¶¶ 64-65; CCX-892 ¶¶ 15-16.) The ECM Additive is a pelletized, mostly synthetic biodegradable polymer that is added to the hopper when a plastic is melted down to be formed into sheets or molds. (CCFF ¶¶ 129-131; Dr. 1813.) ECM recommends that its customers add a small concentration, about 1%, of its Additive to the non-biodegradable conventional plastic, much as they would add a colorant. (CCFF ¶ 129-131.) ECM contends that its Additive promotes the formation of a biofilm that can produce enzymes capable of biodegrading conventional plastic. (CCX-4.)

As Drs. Michel and McCarthy explain, physically blending 1% additive to conventional plastic cannot accomplish the reduction in molecular weight necessary to enhance biodegradability. (CCX-891 ¶ 74; CCX-895 at 13.) Therefore, conventional plastic is no more susceptible to biodegradation after blending than it was before. (CCFF ¶¶ 130-131.)

Despite this clear evidence, the ALJ adopts Dr. Sahu and Burnette’s opposite citations to the scientific literature about blends of non-conventional plastics, and mistakenly finds that ECM’s Additive could change the recalcitrance of conventional plastic. But none of the scientific literature demonstrates this. Rather, these articles clearly show that blending even large proportions—30 times the amount of ECM Additive—at best facilitates fragmentation. (RX-925 at 13) (“[a] large amount of starch of the order of 30% by volume needs to be blended

drainpipes, “[b]ut they’re not breaking down the pipe itself. If they would be breaking down the pipe itself, then you wouldn’t be using those materials to make the pipe. . . their understanding of biofilms, just because a biofilm forms that is biodegrading the material to which it’s attached, is incorrect.” (Tr. 2865.) ECM’s own expert, Dr. Burnette, concedes that the presence of a biofilm does not indicate microorganisms are using the plastic as a food source. (CCFF ¶ 179.)

In short, there is no known, or plausible theoretical, mechanism that could cause the ECM Additive to work. At best, and there is no evidence of this, it may help the plastic fragment and possibly expose some of the very small pieces of shorter chains of conventional plastic to biological agents. But even accepting this unsupported assumption, the Additive still does not alter biodegradability in any meaningful way. (CCFF ¶ 132.) The conventional plastic remains chemically unaltered. ECM Plastic still consists of 99% chemically unaltered conventional plastic, which could take as long, or longer, to biodegrade. (CCFF ¶ 133.)

c. ECM Does Not Have Tests the Relevant Scientific Community Would Require to Support its Extraordinary Claim that ECM Plastic Is Biodegradable in a Landfill.

The ALJ improperly concluded that because the scientific community routinely uses “gas evolution tests” like ASTM D5511 to assess biodegradability, and some tests showed biodegradation rates above the 1% load rate of the ECM Additive, it must be efficacious. The scientific community demands more than minimal methane production in anaerobic conditions to support ECM’s unorthodox claim that the ECM Additive renders conventional plastic biodegradable after disposal. Instead, before labeling that a material (not already known to be biodegradable) is “biodegradable” in a waste stream, scientists would require both screening and confirmatory tests. ECM’s substantiation includes no confirmatory testing. (CCX-891 ¶¶ 44-45;

¶ 67.) Moreover, the ASTM D5511 screening test for ECM Plastic were neither well-controlled nor well-designed studies (See infra at 46-47.) Consequently, the data from ECM's screening level tests does not support even claim that ECM Plastic is "intrinsically" biodegradable, let alone a claim of complete, or even substantial, decomposition in a landfill.

- i. Recalcitrant Non-Biodegradable Materials Require Confirmatory Testing to Establish Biodegradability in a Waste Stream.

Experts in the field require competent and reliable scientific evidence for ECM's biodegradability claims in the form of appropriately-analyzed results of independent, well-designed, well-conducted, well-controlled testing. (CCFF ¶ 135.) The testing should use the appropriate plastic application, load rate, incubation, test conditions, and sample weight, over an appropriate duration of time. (CCFF ¶ 135.)

The scientific community generally uses three tiers of tests to determine whether biodegradation of plastic occurs. First, an initial screening test, such as ASTM D5511, can show whether any biodegradation is occurring (whether any component of the test material is biodegrading).²⁹ Second, level-1 confirmatory tests can determine whether the conventional

²⁹ As further explained in the leading treatise on solid waste:

Screening-level evaluations of materials do not provide definitive evidence of biodegradation. [] The possibility of overestimation of biodegradation potential exists if the "priming effect" occurs [] If material transformations are due to microbial attack on additives [] rather than mineralization of a polymeric component of material, or if material is exposed to microbial cultures that are not representative of the environment in which the material will be disposed. Alternatively, the presence of pro-oxidants or starches in a material may facilitate major physical changes (i.e., disintegration) that could be misinterpreted as evidence of complete biodegradation []. Weight loss and tensile strength changes may be due to partial hydrolysis or abiotic hydrolysis caused by interaction of the polymer with the medium. Thus, more definitive biodegradation tests simulating the environment in which the polymer will ultimately reside are required to

plastic is in fact biodegrading and whether and to what extent it will biodegrade under specific (e.g., real-world) conditions. Third, ~~we~~¹⁻², field-scale tests that ~~are~~^{in situ} can be used to evaluate whether biodegradations ~~and~~^{adverse environmental effects} (CCX-891 ¶ 43³⁰; see also CCX-945 at 65-66 (Barlaz waste ~~cell~~^{site} discussing a three ~~field~~^{field} approach to assessing biodegradability of plastics); RX-767 (same).)

Thus, screening tests, like the ASTM D5511 ~~one~~^{one} cannot establish the extent or rate of biodegradation in specific disposal ~~and~~^{and} conditions. (CCX-891 ¶ 44; CCFF ¶ 13~~9~~³⁹; see also CCFF ¶ 175.) To substantiate its claims regarding the purported biodegradability of ECM Plastics in landfills and the role of the ECM Additive, ECM must have both screening and confirmatory tests. (CCX-891 ¶ 45; see also CCX-945 at 72.) Confirmatory ~~test~~^{testing} is essential to establish that the conventional plastic itself is biodegrading and whether and to what extent it will biodegrade under real-world disposal conditions. (See CCFF ¶¶ 147-148; CCX-891 ¶¶ 44-45.)

For example, in a source cited by Dr. Sahu, ~~the~~ ~~source~~ explains, “[a] demonstrated potential of a material to biodegrade does not say anything about the time frame in which this occurs, nor the ultimate degree of degradation.” (RX-584 at 2-3.) If degradation rates are slow, or degradation is incomplete, the polymer will accumulate in ~~the~~ environment. (RX-584 at 2-3.) Therefore, scientists have adopted a ~~definition~~ of biodegradable that includes “specified periods of time, specific disposal pathways, and ~~standard~~ test methodologies.” (RX-584 ~~see also~~ RX-767 (describing same criteria); ~~see also~~ RX-787 at 1 (same); CCX-945 at 72 (same); RX-776 at 11 (same).)³¹ Dr. Michel reiterates this concept in ~~his~~ peer-reviewed published paper and his expert report. (CCX-895 at 11; CCX-880 at ~~11~~ 10). McCarthy explained that the ASTM is currently implementing a standard ~~specific~~ for biodegradable plastics under anaerobic conditions, which would require treated ~~plastic~~ ~~to~~ reach 60% biodegradation in 18 months. (CCX-891 ¶ 56.) Thus, a minimum threshold of biodegradation in a specified time and disposal condition is one commonly accepted standard for assessing biodegradability.

(2) Radiolabeling

Alternatively, the relevant scientific community would accept radiolabeling (C14 tests). (CCFF ¶ 455.) Radiolabeling involves tagging ~~carbon~~ isotopes of carbon, C14, to a high-molecular weight plastic, such as polyethylene, before conduc

945 at 72-73.) Radiolabeling is particularly useful for technologies where the observed biodegradation would happen over a period of years. (CCX-945 at 72-73; CCX-895 at 12.)

Drs. Michel and Barlaz likewise explained that to “obtain accurate evidence of biodegradation” a C14 test is necessary. (See CCX-895 at 12; Tr. 2224.) Indeed, Dr. Barlaz has not only performed C14 tests, but wrote an ASTM specification on how to do so. (CCX-943 (Dep. 67).) In fact, Dr. Barlaz testified that C14 tests are “well-suited” to “very, very small amounts” of biodegradation, and for slowly degrading materials. (Tr. 2244.)

The ALJ erroneously rejected C14 tests “as the industry standard or reasonably required by any expert in the field.” (ID 244.) However, C14 is routinely used for unorthodox claims that conventional plastic can undergo biological transformation. See, e.g. Eastman Study (Tr. 650-51; CCX-841, Dep. 149-151); and Albertsson Study (CCX-897-898). ECM conducted neither confirmatory test, despite ample opportunity and ability to do so.

³² If a C14 test shows sufficient biodegradation of the high-weight conventional plastic component, it could substantiate a claim that the Additive increases a plastic’s susceptibility to biodegradation in a landfill. If it were to show 60% biodegradation of the plastic, it could substantiate a rate claim.

³³ ECM has known for years that ASTM D5511 tests are insufficient to support its claims (see, e.g. CCX-963 at 5-6), and since at least 2008, C14 tests would provide the requisite substantiation in the scientific community. (CCX-310 (email from American Radiolabeled Chemicals to A. Poje explaining how it would prepare C14 labeled polyethylene for a test of ECM Plastic conducted under ASTM D6776); CCX-311 (email from A. Poje to Dr. Barlaz discussing conducting a radiolabeled test under ASTM D6776); CCX-314 (Email from Moravek Biochemicals to A. Poje providing a quote for the synthesis of radiolabeled polyethylene.) Dr. Michel (who has practical experience conducting C14 tests and whose university is licensed to conduct such tests) testified that “it would be a rather straightforward matter to mix ECM additive with ¹⁴C labeled polyethylene” and would not have been prohibitively expensive. (CCX-895 at 15, 23.)

- ii. ASTM D5511 Does Not Rise to the High Level of Substantiation Required by the Scientific Community.

The relevant scientific community ~~do~~ not consider ASTM D5511 adequate substantiation to support ECM's unorthodox claims.

- (a) To Substantiate its Claims, ECM Must Test Under Typical Landfill Conditions.

The finding that ASTM D5511 simulates landfill conditions is simply wrong.³⁴ The ALJ found that the ASTM represents a microcosm of conditions potentially found in some landfills. (IDFF 778.) However, ECM's sales spanned the U.S., its promotional materials are available nationally through ECM's website, and there was no limitation or qualification of the claim with respect to disposal conditions. See (IDFF ¶¶ 4, 9, 14, 23, 32, 37, 53, 78 (ECM's customers' locations); CCFF ¶¶ 24-25 (reached millions of consumers); IDFF ¶ 206 (advertises through website); IDFF ¶¶ 245-246, 258 (claims convey "typical landfill" generally'); CCFF ¶ 112.) ECM represented that ECM Plastic biodegrades in landfill conditions available to all consumers, and thus must substantiate efficacy in the landfills used by those consumers. ASTM D5511 does not replicate the temperatures and moisture levels typical of U.S. landfills.

Landfills are anaerobic, highly heterogeneous waste containment systems. (IDFF ¶ 570; CCX-893 ¶ 20.) Drs. Tolaymat and Barlaz, the only two experts in solid waste management, both testified that typical landfills operate in the mesophilic temperature range, e.g., 37°C. (CCX-

³⁴ The ASTM D5511 test protocol clearly explains that "it is not intended to resemble any

943, Dep. 69.) In contrast, ASTM 511 tests are conducted at 52°degrees.

¶ 155; Tr. 2279.) Consequently, the test results do not effectively correlate the result (positive methane production) with a particular cause (biodegradation of conventional plastic versus other potential factors). (CCFF ¶¶ 139-140.)

Additionally, Drs. McCarthy and Tolaymat identify several other flaws specific to the tests conducted that make the data inherently unreliable. The two most significant are the lack of statistical analyses and undocumented deviations from the protocol that likely invalidated the results. (CCFF ¶¶ 142-143.)

C. Substantial Record Evidence Supports a Stronger Remedy.

The ALJ's proposed remedy eliminates those portions of the Order that would (1) require Respondent to substantiate unqualified biodegradability claims

campaign for nearly a decade, passing items to hundreds of business customers and millions of end-use consumers. (CCFF ¶¶ 23, 24, 52, 65, 139) *Stouffer*, 118 F.T.C. at 812-13 (“extensiveness” of deceptive ad campaign enhances seriousness of violations), *Kraft*, 114 F.T.C. at 140 (“size and duration of [response to] misleading advertising campaign” compound seriousness of violations). Third, ECM told customers that testing proved its claims (CCFF ¶¶ 44-45), even though conventional plastics do not biodegrade in a period anywhere close to five years or less, and ECM’s “proof” had gross flaws, *supra* at 32-49. See *Schering Plough Corp.*

IV. PROPOSED ORDER

4. "Competent and reliable scientific evidence" shall mean tests, analyses, research, or studies that have been conducted and evaluated in an objective manner by qualified persons, that are generally accepted in the profession to yield accurate and reliable results, and that are sufficient in quality and quantity based on standards generally accepted

9. Unless otherwise specified, “respondent” sha

IT IS FURTHER ORDERED that respondent, and its officers, agents, representatives, and employees, directly or through any corporation, partnership, subsidiary, division, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any product, package, or service in or affecting commerce, shall not provide to others the means and instrumentalities with which to make, directly or indirectly, expressly or by implication, including through the use of endorsements or trade names, any false, unsubstantiated, or otherwise misleading representation of material fact regarding any environmental benefit.

III.

IT IS FURTHER ORDERED that respondent shall, for five (5) years after the last date of dissemination of any representation covered by this order, maintain and upon request make available to the Commission for inspection and copying:

- A. All advertisements, labeling, packaging and promotional materials containing the representations specified in Parts I and II;
- B. All materials that were relied upon in disseminating the representations specified in Parts I and II;
- C. All tests, reports, studies, surveys, demonstrations, or other evidence in its possession or control that contradict, qualify, or call into question the representation, or the basis relied upon for the representation, including complaints and other communications with consumers or with governmental or consumer protection organizations; and
- D. All acknowledged receipt of this order obtained pursuant to Part IV.

IV.

IT IS FURTHER ORDERED that respondent shall deliver a copy of this order to all current and future subsidiaries, current and future principals, officers, directors, and managers, and to all current and future employees, agents and representatives having responsibilities relating to the subject matter of this order. Respondent shall secure from each such person a signed and dated statement acknowledging receipt of this order and a copy of this order.

other action that would result in the emergence of a successor entity; the creation or dissolution of a subsidiary, parent, or affiliate that engages in acts or practices subject to this order; the proposed filing of a bankruptcy petition; or a change in the business or corporate name or address. Provided, however, that with respect to any proposed change in the corporation about which respondent learns less than thirty (30) days prior to the date such action is to take place, respondent shall notify the Commission as soon as practicable after obtaining such knowledge.

Unless otherwise directed by a representative of the Commission in writing, all notices required by this Part shall be filed to Debrief@ftc.gov or sent by overnight courier (not the U.S. Postal Service) to: Associate Director for Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Mail Stop M-8102B, Washington, DC 20580. The subject line must begin: "ECM BioFilms, Inc., File No. _____."

VI.

IT IS FURTHER ORDERED

Respectfully Submitted,

/s/ Katherine Johnson

Katherine Johnson

Elisa Jillson

Dated: February 27, 2015

Federal Trade Commission
Bureau of Consumer Protection
Division of Enforcement
600 Pennsylvania Ave., N.W., CC-9528
Washington, D.C. 20580
Telephone: (202) 326-2185; -3001
Facsimile: (202) 326-3259

Counsel Supporting the Complaint

CERTIFICATE OF SERVICE

I hereby certify that on February 27, 2015, I used a true and correct copy of the foregoing to be served as follows:

One electronic copy to the

Notice of Electronic Service for Public Filings

I hereby certify that on February 27, 2015, I filed via hand a paper original and electronic copy of the foregoing Complaint Counsel's Appeal Brief, with:

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Chief Administrative Law Judge
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I hereby certify that on February 27, 2015, I filed via E-Service of the foregoing Complaint Counsel's Appeal Brief, with:

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