**UNITED STATES OF AMERICA**
**BEFORE THE FEDERAL TRADE COMMISSION**
**OFFICE OF THE ADMINISTRATIVE LAW JUDGES**
**Washington, D.C.**


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| **In the Matter of**<br><br>**ECM BioFilms, Inc.,**<br>**a corporation, also d/b/a**<br>**Enviroplastics International,**<br><br>**Respondent.** | **Docket No. 9358**<br><br>**PUBLIC** |

**RESPONDENT ECM BIOFILMS' REPLY TO COMPLAINT COUNSEL'S POST-TRIAL BRIEF**

Jonathan W. Emord, Esq.
Emord & Associates, P.C.
11808 Wolf Run Lane
Clifton, VA 20124
Ph: 202-466-6937
Fx: 202-466-6938
Em: jemord@emord.com

Peter A. Arhangelsky, Esq.
Eric J. Awerbuch, Esq.
Bethany R. Kennedy, Esq.
Joshua Furman
Emord & Associates, P.C.
3210 S. Gilbert Road, Ste 4
Chandler, AZ 85286
Ph: 202-466-6937
Fx: 602-393-4361
Em: parhangelsky@emord.com, eawerbuch@emord.com,
bkennedy@emord.com

## TABLE OF CONTENTS

# TABLE OF AUTHORITIES

**Cases**

**Statutes**



**Other Authorities**



**Treatises**

**Regulations**

## SUMMARY:

### Complaint Counsel's Failure to State a Prima Facie Case of Deceptive Advertising:

Complaint Counsel's case suffers from a glaring lack of factual evidence essential to satisfy the elements of deceptive advertising under Section 5 of the Federal Trade Commission Act and as explained in FTC and federal decisions. 16 C.F.R. § 3.43 (a) (FTC bears the burden of proof); *see also* 5 U.S.C. § 556 (d); *Sterling Drug, Inc. v. F.T.C.*, 741 F.2d 1146, 1150 (9th Cir. 1984) (same); *Porter & Dietsch, Inc. v. F.T.C.*, 605 F.2d 294, 305 (7th Cir. 1979) (same); *F.T.C. v.* Garvey, 383 F.3d 891, 900 (9th Cir. 2004) ("we put the burden of proving falsity or deception on the FTC"); *FTC v. Tashman*, 318 F.3d 1273, 1283 (11th Cir. 2003) (same). It is that lack of essential facts that overwhelming compels the outcome in this case. It is the presence of facts that ECM's customers were sophisticated plastic manufacturers who independently evaluated the ECM product before purchase that compels the conclusion that they lacked material reliance on representations made by ECM. It is the additional presence of facts that reveal ECM based its biodegradability claims on a reasonable basis, including 37 positive tests of different plastics containing the ECM additive that establishes there to be no deception. Moreover, it is the additional absence of any proof that any consumer ever purchased a plastic product bearing an ECM claim that, together with the other facts, establishes this case to lack any foundation in the public interest. As explained below in point by point rebuttal, the facts and the law warrant dismissal of the complaint, including denial of each charge brought and all relief requested by Complaint Counsel.

### The Sophisticated Customer Defense Applies and Is Dispositive:

In the first instance, the record evidence establishes that ECM's target audience, indeed its only purchasers, is sophisticated, comprised of plastics manufacturers and not of end-use

consumers. (RPFF ¶¶ 296–304). Those sophisticated purchasers perform their own testing and evaluation of ECM's product for six months to two years before making a purchase. (RPFF ¶¶ 433–604). Indeed, most of the thirty seven (37) positive tests of record in this case (twenty eight (28) gas evolution tests) establishing that the ECM additive causes plastics to biodegrade were not commissioned by ECM, but were those of its prospective customers, who endeavored to determine for themselves if a product that interested them was efficacious.[1] In no other FTC case has there been such a clear basis for application of the sophisticated customer defense against a charge of deceptive advertising than in this one. Indeed, when sophisticated customers perform independent, detailed evaluations of products as a basis for determining whether to make a purchase, there is no foundation in materiality for application of deceptive advertising law under Sections 12 and 15 of the Federal Trade Commission Act. *See In re Telebrands Corp.*, 140 F.T.C. 278, 291 (2005).

**ECM Made No Rate Claim, Whether Express Or Implied:**

Complaint Counsel argues that ECM made express and implied "rate" claims for its additive. There is no record evidence that any of the sophisticated purchasers of the ECM product relied on those claims, but there is substantial record evidence that those purchasers relied on their own evaluation and testing of the ECM additive before making a purchase, and there is record evidence, including deposition testimony and survey evidence from ECM's plastic company purchasers, revealing that no purchaser regarded any claim of rate to be material

[1] *See, e.g.*, RX 248; RX 254; RX 263; RX 265; RX 266; RX 268; RX 273; RX 276; RX 392; RX 393; RX 394; RX 395; RX 396; RX 398; RX 399; RX 401; RX 403; RX 402; RX 405; RX 465; RX 467; RX 468; RX 836; RX 838; RX 839; CCX 534; CCX 546; CCX 547; CCX 548; CCX 952.

to a purchase. *See infra* Part III at 134. Moreover, no competent evidence demonstrates that consumers (including any so-called "minority") attribute any set time or rate to the ECM additive or to the biodegradation of any plastic, whether containing that additive or not. Rather, consumers appropriately understand that any biodegradation rates depend on many different factors and, so, give wildly different, inconsistent and variable rate estimates. (RPFF ¶¶ 1330–05, 1310–11, 1315–18, 1333). Moreover, ECM does not market its products to end-use consumers. As the record establishes, not even a significant minority of end use consumers (1) has seen ECM claims; (2) has relied on an ECM claim to make a purchase (there are no "purchases" of ECM products by end-use customers); or (3) has a common understanding of the term "biodegradable" or of the time it takes for any particular piece of plastic to biodegrade. *See infra* Part I(A)(6) at 60.

To the extent ECM ever made a "rate" claim for its biodegradable technology, the record establishes that claims of rate were not material to the purchasing decisions of its plastic manufacturer customers and were discontinued, in any event, in 2012. When made, those claims were predicated on the experiential testing of the additive's inventor, scientists hired by ECM, and ECM's President, were qualified as to any particular piece of plastic (revealing that ambient environmental conditions and the precise kind of plastic, unpredictable in advance, would determine rate at the place of ultimate disposal), and were intended to distinguish the ECM additive from compostable technologies and to assure plastic company customers that the ECM product would have an appropriate shelf life. (RPFF ¶¶ 308, 343). In addition, ECM felt obliged to comply with the FTC's Green Guides' specification, which required it to do the impossible: list a so-called "rate" of biodegradation despite all the uncertainties inherent in that concept. (RPFF ¶¶ 1581–83, 1586, 1588–90, 1644, 1661, 1723).

As discussed in more detail below, the bulk of Complaint Counsel's case against ECM (and industry) is premised on the idea that a "rate" of biodegradation is determinable and is an essential and material element that must be conveyed to consumers of all kinds. But the record in this case does not support that theory, which is scientifically invalid because the "rate" of biodegradation is notoriously impossible to predict with any accuracy. (RPFF ¶¶ 1581–83, 1586, 1588–90, 1644, 1661, 1723). The experts who testified in this case all agree on that point. (RPFF ¶¶ 1581–1605). The survey evidence revealed that end-use consumers understand that point. (RPFF ¶¶ 1330–05, 1310–11, 1315–18, 1333). ECM conveyed that point to its immediate customers. (RPFF ¶¶ 310–12, 320, 377). Only Complaint Counsel still desperately clings (without requisite scientific support) to the notion that a set "rate" of biodegradation is determinable and must be articulated with every claim of biodegradability.

Complaint Counsel mistakenly rely on Dr. Frederick in support of their argument that when ECM referred to its plastics as biodegradable, it necessarily made implied rate claims. Dr. Frederick's work is inherently unreliable and violates every requisite standards for reliable survey work. (RPFF ¶¶ 878–1104). No conclusions can be drawn from Dr. Frederick's Google Consumer Survey because, among other reasons, Dr. Frederick asked only one question per respondent thereby making it impossible to know whether any given response was sincere; has an unknown and unknowable respondent sample; failed to appropriately define his population; used an inherently biased coding rule that was applied by coders—including himself—who were not blinded but were aware of the sponsor and purpose of the research. (RPFF ¶ 878–1104). Dr. Frederick and ECM's expert, Dr. Stewart, do agree on one thing: that the APCO and Synovate surveys are flawed and unreliable, primarily because those surveys use close-ended questions to explore a new area of survey research. (RPFF ¶¶ 818–877). Therefore, Complaint Counsel's

attempt to rehabilitate their implied claim theory through reliance on what Dr. Frederick calls "convergence validity" fails because convergence validity cannot be used to lend credence to three surveys that are each fatally flawed, regardless of whether those surveys yield some results that appear "similar."[2]

Complaint Counsel's convergence validity theory was dismantled at the hearing by Dr. Stewart's evaluation of it and his own survey data—the only sound survey evidence in this case.[3] Dr. Stewart testified, based on the survey he conducted, that no significant minority of consumers share a common understanding of the meaning of the term biodegradable or the rate of biodegradation. (RPFF ¶¶ 1330–05, 1310–11, 1315–18, 1333).

Complaint Counsel's theory of implied deception fails for yet another reason: ECM's customers are not end-use consumers, but are sophisticated plastics companies. (RPFF ¶¶ 296–604). There is no evidence that a single purchase of the ECM additive by any of its actual customers was based on a representation made by ECM; rather, the evidence reveals that purchases were based on independent customer evaluations of the ECM additive, and there is no basis for presuming even an implied deception given the evidence of sophistication and of the long, drawn out evaluation process preceding contract for purchase of the ECM additive. (RPFF ¶ 296–604). Moreover, there is no basis, due to ECM's customers' sophistication, evaluation, and testing of the ECM product in advance of purchase, to presume any of ECM's customers perceived as material to purchase anything beyond the knowledge they themselves acquired from their own independent product evaluations (from their own direct testing, knowledge, and experience), including evaluations of competing technologies. Indeed, if plastic manufacturers

[2] Indeed, the APCO, Synovate, and Dr. Frederick surveys all provide vastly different results. *See infra* at Part I(D) at 64.

[3] *See infra* at Part I(C)(5) at 50.

were to have relied on any statement made by ECM (and there is not one shred of factual evidence to support that conclusion in any single case), the record would have reflected a history of impulse purchases immediately after receipt of specific ECM representations and without the independent expense on independent testing and evaluation. Instead, the record is replete with is record of test after test, critical evaluations, and lengthy communication, written, and, even more extensively, oral between ECM's chief executive and the scientists, engineers, officers, and representatives of plastic companies who were investigating the efficacy and utility of ECM's product in a competitive environment where numerous other options are available. (RPFF ¶¶ 296–432). In short, there are no impulse purchases at issue in this case; no brick and mortar sales or internet purchases. (RPFF ¶¶ 360, 366). There are only sophisticated customer transactions. (RPFF ¶¶ 28, 383, 391, 397, 433–604).

**The Evidence Proves That the Claims ECM Actually Made Are True:**

Complaint Counsel next argues that ECM's biodegradable claims are false and unsubstantiated because ECM's many tests (thirty seven (37) scientific tests and evaluations) were somehow all flawed. Complaint Counsel's scientific theories are unsupported and often contradicted by the peer-reviewed literature, including publications authored by their own expert witnesses. Complaint Counsel categorically ignores 28 gas evolution tests (and at least 9 other qualitative tests) all showing that the ECM technology renders conventional plastics biodegradable. They ignore peer-reviewed literature explaining that conventional plastics can be rendered biodegradable through the use of technologies like the ECM additive, in particular, through melt-compounding polycaprolactone-based additives into the matrix of conventional

plastics.[4] Complaint Counsel has failed to identify any material methodological flaw in those ECM tests. They misrepresented the D5511 standard in an effort to discredit "extension" testing under that protocol (something the D5511 standard permits).[5] Their own witnesses have conducted and accepted the same gas evolution tests to prove biodegradability in plastic products outside of this litigation. (RPFF ¶¶ 1776, 1772, 1775). Furthermore, and most egregiously, Complaint Counsel erroneously has deemed inconclusive tests (lacking any proof as to the cause or source of the failure to biodegrade) to be negative tests (i.e., tests supporting the proposition that the ECM additive did not work), which they are not.[6] For instance, in an effort to show that ECM's product did not work, Complaint Counsel cited to D5511 tests that are considered "invalid" studies under the D5511 standard because they were not properly conducted.[7] That position hoist Complaint Counsel with their own petard because at once through their expert Dr. McCarthy they demand that ECM's testing follow D5511 perfectly or be deemed unreliable[8], yet for its own proof Complaint Counsel relies on testing that materially deviates from D5511 standards.

Most significantly, Complaint Counsel has failed to rebut Dr. Barlaz's critical testimony wherein he proves conclusively that the biodegradation observed in the ECM tests is sourced from the plastic and not solely the ECM additive. (Barlaz, Tr. 2246-65; RX 968 (memorializing

[4] *See infra* at Part II(A)(2) at 75.
[5] *See infra* at Part II(B)(2) at 113.
[6] *See* Complaint Counsel's Post-Trial Brief, at 59–61.
[7] *See infra* at Part II(A)(3) at 83.
[8] Even in this respect, Complaint Counsel's position is inconsistent, because Complaint Counsel simultaneously demands that D5511 be followed and demands that testing proceed until all of the plastic has broken down into elements found in nature, which later point is contrary to the D5511 accelerated testing protocol. *See* Sahu, Tr. 1924; Barlaz, Tr. 2212 (explaining that "it is not practical to try to simulate [the landfill] ecosystem at the time scale in the laboratory"); CCX 84 (D5511 Test permitted tests at temperatures of 52 degrees).

Dr. Barlaz's calculations). Dr. Barlaz's testimony and analysis proved that the ECM tests are competent and reliable evidence of plastics containing the ECM additive biodegrading. He proved that radiolabeled testing is not generally accepted in the scientific community, is not technically feasible, and is unnecessary because gas evolution tests are sufficient to determine that biodegradation occurs in test plastics (the same endpoint carbon-14 tests would provide, even assuming they were feasible). Complaint Counsel essentially ignores that testimony, and certainly offers no tenable rebuttal (nor can they).

Complaint Counsel argues that evidence of some biodegradation cannot support the conclusion that plastics are "completely" biodegradable unless a test ran long enough to show that the plastic completely disappeared. That theory is unscientific and infeasible, as no competent and reliable test is capable of meeting Complaint Counsel's rigid standards. First, no test can precisely mirror the variable landfill environment while providing useful biodegradability data within practical time periods. (RPFF ¶ 1618). Even assuming such a test existed, which it does not, a company would need to perform testing for decades in a closed environment that was nevertheless somehow made to sustain the life of biodegrading biota—an impossible task and an unnecessary burden given the scientific evidence in this case. Second, there is no established understanding or parameters from which to measure "complete" biodegradation. The evidence proves that "biodegradability" is an intrinsic quality of a material, such that a "biodegradable" material will continue to biodegrade as long as the environmental conditions support biodegradation. (RPFF ¶¶ 1621, 1627, 1808, 1891–94). For that reason, Complaint Counsel's own witness (Dr. Michel) understood that a material like cellulose (which is known to be "fully biodegradable") can still be deemed "completely" biodegradable if it biodegrades only to 44% in a test environment. (RPFF ¶¶ 2989–90). The cellulose is

"biodegradable" regardless of whether it stops biodegrading in the lab at 5%, 44%, or 74%, just like ECM's plastics (which have been shown to biodegrade up to 50% in the lab (RX 836)). The material question, therefore, is not whether lab tests show "complete" biodegradation (whatever that term means), but whether the test *plastic* has been shown to be biodegradable.[9] If the plastic biodegrades, then the ECM technology has rendered the conventional plastic intrinsically "biodegradable," and there is no sound science in the record that shows a "biodegradable" plastic ever stops being "biodegradable," only that environments are either hospitable or inhospitable to biodegradation. ECM has conclusively proven through at least 28 gas evolution tests, and additional qualitative tests, that the biodegradation observed in the test reactors is coming from the test plastic infused with the ECM additive. (RPFF ¶ 2129–2706).

**Complaint Counsel's "Priming Effect" Theory Is Unsupported:**

Complaint Counsel offers an unproven theory called the "priming effect" in an effort to discredit dozens of positive ECM tests.[10] The priming effect has never been established, particularly not in anaerobic systems and the plastics substrates involved in this case. (RPFF ¶ 2015–19). Complaint Counsel makes no attempt to support the priming effect with evidence, or to provide any reasonable limitation on or defining parameters for that theory. As explained in detail below, the theory is entirely speculative, and, most importantly, disproven by Dr. Barlaz's

[9] Complaint Counsel's illogical theory is that microbes will somehow digest only the ECM additive (which is melted, mixed, and infused throughout the conventional plastic), and will leave the remaining plastic intact. At once this theory undermines Complaint Counsel's case because it is based on an admission that the additive actually causes biodegradation of the additive and reveals naivete because it ignores the fact that the additive is heat melted into and infused throughout the plastic in the same was as a colorant is in plastic (thereby rendering any biodegradation of the additive to necessarily involve biodegradation of the plastic inextricably intertwined with it).

[10] Complaint Counsel's Post-Trial Brief, at 71, 74.

scientific evaluation of the raw data in the tests establishing ECM's additive to cause biodegradation.[11]

**To the Extent ECM Made Any Rate Claims, Whether Express Or Implied, Those Rate Claims Were Not Material to Any ECM Customer Or Any Consumer:**

Next Complaint Counsel argues that ECM's biodegradable rate statements were material to consumer purchasing decisions. "Materiality turns upon whether those consumers who have drawn the claim from the advertisement and have been misled by it are also likely to have their conduct affected by the misrepresentation." *In re Novartis Corp.*, 127 F.T.C. 580, 691 (1999) (emphasis added). The record demonstrates that ECM's customers never cared about the "rate" of biodegradation as a performance claim. (RPFF ¶¶ 613–707). ECM customers wanted to know if the additive caused "biodegradation" of their specific plastic product. (RPFF ¶¶ 605–704). In contradiction to its rate argument, Complaint Counsel repeatedly concedes that the general "biodegradation" claim was the only claim of importance to ECM's customers.[12]

Moreover, the record proves "rate" had relevance to some ECM prospective customers for but one of three reasons, none of which is a need for ascertaining a specific time for achieving complete break down into elements after customary disposal: (1) to ensure adequate shelf-life of plastic products (i.e., to be sure the additive would not cause plastics to lose their functionality during customer use); (2) to ensure that the technology was actually "biodegradable" as opposed to perhaps recyclable or degradable only; or (3) to comply with the FTC's arbitrary One-Year Rule in the Green Guide Revisions.[13] (RPFF ¶¶ 340, 347, 431, 705,

[11] *See infra* at Part II(B)(2)(d) at 130.

[12] Complaint Counsel's Post-Trial Brief, at 80-82.

[13] *See, e.g., id.* at 80 ("Although consumers probably do not care whether ECM Plastic biodegrades in 'nine months to five years' as opposed to, for instance, 'ten months to six years,'

724–25). None of those concerns is affected if the ECM product takes longer to biodegrade than the so-called "rate" time frame ECM once used.[14] Matters of rate are thus immaterial, because there is no record evidence that ascertaining the precise rate of biodegradation was germane to a customer's purchasing decision.[15]

There are of course many other concerns for a plastic manufacturer seeking to adopt a new biodegradable technology, including, for instance:

- How the technology affects the performance of the finished plastic product (e.g., whether the additive infused plastic bag can hold groceries; can maintain desired color; can have a satisfactory shelf-life; etc.);
- The cost of the additive technology relative to other options (including competing technologies, or no environmental technology at all);
- The ability to manufacture plastics without having to change equipment or methods;[16] and

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there is undisputed evidence that they **do** care whether the product is biodegradable.") (emphasis in original); *see also* CCX 811 (Hong, Dep. at 55) (explaining that some purportedly "biodegradable" products merely degrade, but Island Plastic Bags wants a product that biodegrades).

[14] ECM discontinued the controversial rate claim years in 2012. When it did describe a rate generally, it used many qualifying statements. ECM would discuss these and other issues with its customers over months (sometimes years) of negotiations. Customers would run their own tests of ECM's products to determine whether they wished to make a purchase. *See* RPFF ¶¶ 392-393, 401-412.

[15] There is of course evidence during the six months to two year negotiation process that some ECM customers inquired into the rate of biodegradation, but there is no foundation in fact, and indeed there is evidence to the contrary, that rate was ultimately a basis for any purchase decision. *See infra* Part III at 134.

[16] For example, many ECM customers (like Quest Plastics), manufacture non-biodegradable conventional plastics almost exclusively. (CCX 817 (Bean, Dep. at 22)). But sometimes they want the option to run an isolated "biodegradable" batch for a specific customer order. (CCX 817 (Bean, Dep. at 19) (explaining that a single customer wanted Quest "to find an additive that would make those golf tees biodegradable"). Quest's primary interest is therefore in making a "biodegradable" plastic without having to substantially change its manufacturing

- The ability to recycle the finished biodegradable plastic.

(RPFF ¶¶ 338–40, 344, 387, 395, 401, 404, 408-09, 412, 724).

Indeed, only the truthfulness of the well-supported ECM statement that plastics infused with the additive are "biodegradable" was of concern to ECM's customers in making a purchase.[17] Put simply, there is no basis to conclude that a customer would not have purchased the ECM technology if they thought the product would biodegrade in fifty years as opposed to five. Buttressing the corporate world's absence of concern about rate is the unrebutted testimony from Dr. Barlaz (Barlaz, Tr. 2246–90) affirming that the "rate" of biodegradation in landfills is more environmentally beneficial if slow rather than rapid. (RPFF ¶¶ 1595–1600). The evidence demonstrates conclusively that the ECM additive, **when compared to an untreated plastic**, will biodegrade in a landfill environment (indeed any environment conducive to biodegradation) in a "reasonably short" period of time but that it will do so slowly when compared to compostable technologies.[18]

**The Evidence Establishes That the Complaint Should Be Dismissed:**

Complaint Counsel's notion of deception in this case is an academic fiction, just as is the notion that there is a public interest in protecting sophisticated corporate purchasers from their

process. (CCX 817 (Bean, Dep. at 25) (noting that other products purporting to render plastic biodegradable "didn't seem to fit [Quest's] process, or possibly they were cost prohibitive … They weren't an additive necessarily to the material [Quest] was using. They were a material all by themselves.")). As Quest's designee testified, Quest purchased the ECM additive because it is "usable in [Quest's] process and it seemed to be what [Quest's] customer was looking for," which was "to make his golf tees biodegradable … that [is] putting them in the ground and leaving them there, they'd disappear over time." (CCX 817 (Bean, Dep. at 26)). The ECM additive is attractive for that purpose, and there is no indication that "rate" of biodegradation has anything to do with the transaction.

[17] *See infra* at Part II(B) at 101.

[18] *See infra* at Part II(A)(1)–(3) at 74.

own exercise of informed judgment. There is no evidence to establish that any statement made by ECM was material to a purchasing decision by ECM's actual customers, and there is no evidence to establish that any claim by ECM ever reached even a significant minority of end-use consumers or that, even among the few end-use consumers exposed to the term biodegradation or rates of biodegradation, that any purchased a plastic product based on the claims or otherwise harbored any common understanding or material regard for the claims whatsoever. Indeed, the only record evidence on the point reveals that those end-use consumers who received ECM plastic products did not purchase them, were ordinarily not presented with any statement that the plastic contained an ECM additive or any rate of biodegradability, have no common understanding of biodegradation or rate of biodegradation, and unremarkably have an appreciation for the utility of plastic products while in their possession, but little, if any, material knowledge or interest in the plastic after they have discarded it (thrown it away in the trash). (RPFF ¶¶ 296–739). Significantly, Complaint Counsel introduced no evidence that end-consumers pay any more money for plastics made with the ECM additive than without. There is actually no evidence that consumers purchase plastic containing the ECM additive at all and, certainly, no evidence that they purchase any plastic in reliance on ECM claims. That is a glaring hole in this case, because there is simply no evidence that consumers suffer any economic injury, even if the ECM claims are misleading or false (and they are not).

There are at least 28 independent gas evolution tests that experts in the field (Drs. Sahu, Barlaz, and Burnette) confirm establish that the ECM additive does cause plastics to biodegrade, plus additional qualitative analyses which confirm through other endpoints that ECM plastics are biodegradable anaerobically. (RPFF ¶¶ 2180–2659).

On this record, the only just, factually and precedentially supported conclusion is that Complaint Counsel failed to meet their burdens of production and proof; that the evidentiary record is insufficient to establish deceptive advertising; that no cease and desist order is warranted; and that the case against ECM should be dismissed for want of proof under controlling law and precedent.

**If the Complaint Is Not Dismissed, This Court Cannot Rely on Complaint Counsel's Arbitrary, Capricious, and Unconstitutional Proposed Relief:**

Finally, Complaint Counsel's Proposed Relief is arbitrary and capricious, and would violate the First Amendment to the United States Constitution. The concept of "biodegradability" or a "biodegradable" material is understood broadly by scientists in the field. (RPFF ¶¶ 774–817). ECM has proven that its products are "biodegradable" under the scientific definition of the term used within the relevant scientific community.[19] Yet Complaint Counsel now suggest qualifying language for ECM's "biodegradable" claims. By suggesting qualifying language, however, Complaint Counsel has necessarily conceded that ECM's use of the word "biodegradable" is at worst only potentially misleading (i.e., capable of being rendered non-misleading through addition of claim qualification) and thus subject to First Amendment protection.[20] That is in stark contrast to virtually every other deceptive advertising case brought by FTC wherein the agency has contended that the claims in issue are inherently misleading (i.e., not capable of being rendered non-misleading through the addition of claim qualification). Under the First Amendment, Complaint Counsel (indeed, the FTC) (and not ECM) bear the

[19] *See infra* at Part II(a)(i)-(iii) at 73.

[20] Otherwise, if the speech was misleading or inherently misleading, a qualifier would not be sufficient under the law. *See* ECM's Proposed Conclusions of Law ¶¶ 124–33.

burden to prove that the proposed disclaimers or qualifiers are constitutional under the First Amendment. They cannot shirk that burden, and they cannot subsume that burden under the preponderance of the evidence standard for the lesser law of statutory and regulatory law here in issue. *Pearson v. Shalala*, 164 F.3d 650, 659 (D.C. Cir. 1999) (holding that the government must still meet its burden of justifying a restriction on speech); *National Commission On Egg Nutrition v. FTC*, 570 F.2d 157, 164 (7th Cir. 1977) (explaining that the FTC bears the burden to show that its Orders are consistent with the First Amendment by not prohibiting more conduct than is necessary to prevent deception). Complaint Counsel have not even addressed, let alone proven satisfaction, of that heightened burden of proof (strict scrutiny for scientific speech; intermediate scrutiny for commercial speech). *See Maryland v. Universal Elections, Inc.*, 729 F.3d 370, 376 (4th Cir. 2013) (holding that where government action places differential burdens on speech due to content, it must withstand strict scrutiny analysis); *Police Dep't of Chi. V. Mosley*, 408 U.S. 92, 95 (1972); *Florida Bar v. Went For It, Inc.*, 515 U.S. 618, 623 (1995) (applying at least intermediate scrutiny to restrictions on commercial speech); *Pearson I*, 164 F.3d at 655-56 (same).

An essential requirement in Complaint Counsel's Proposed Order is that ECM state the scientifically impossible, a specific "rate" of biodegradation. That is an impossibility for many reasons. The evidence in this case reveals that predicting or calculating a specific "rate" of biodegradation for slowly degrading materials like plastics is impossible, and no expert in the case provided a means to do so. (RPFF ¶¶ 1581–1605). The rate of biodegradation is inherently variable, fluctuating greatly based on environmental conditions within a landfill, including everything from the moisture content, to the temperature, to the presence of biodegrading biota in surrounding waste. (RPFF ¶¶ 1590, 1593). No test can account for that variability. (RPFF ¶¶

1581–1605). There is therefore no competent and reliable method to satisfy Complaint Counsel's requested Order, and the Order would thus effect an absolute ban on all "biodegradable" claims.

ECM also does not sell to end-consumers; it sells an additive technology to plastics manufacturers. (RPFF ¶ 297). ECM therefore cannot control the qualities and characteristics of the finished plastic. Even assuming it was possible to calculate an accurate "rate" of biodegradation (it is not), ECM cannot determine what the precise rate of biodegradation will be for a product that has yet to be manufactured (with the actual manufacture beyond ECM's control). Complaint Counsel's proposed order would therefore bring about a ban on all "biodegradable" claims by ECM, including a ban on ECM's truthful, non-misleading, and constitutionally protected claim that its product causes plastics to become biodegradable.

Finally, there are many less-speech restrictive alternatives available, including qualifying language that accurately conveys the state of the science without contradicting the science to compel a specific "rate" of biodegradation when no specific rate can be known before customary disposal. For example, the truthful qualification that no precise rate of biodegradation is discernible before customary disposal could be used as a qualification and would not be objectionable to ECM.

**RESPONDENT'S REPLY TO COMPLAINT COUNSEL'S POST-TRIAL BRIEF**

## I. ECM MADE NO DECEPTIVE ADVERTISING CLAIMS

Complaint Counsel argues that ECM made deceptive advertising claims in violation of Section 5 of the FTC Act.[21] However, to prove that an advertisement is false or misleading, the FTC must show (1) the existence of a "representation, omission, or practice," that is (2) "likely to mislead consumers acting reasonably under the circumstances," and that (3) "the representation, omission, or practice is material." *F.T.C. v. Bronson Partners, LLC*, 564 F. Supp. 2d 119, 124 (D. Conn. 2008) (citation omitted). Complaint Counsel must prove each element by a preponderance of the evidence. *See, e.g., In re Adventist Health Sys./West*, 117 F.T.C. 224, 297 (Apr. 1, 1994) (explaining that "[e]ach element of the case must be established by a preponderance of the evidence"); *see also In the Matter of POM Wonderful, LLC*, 2012 WL 2340406, at *171 (F.T.C. May 17, 2012) (noting that "Complaint Counsel has the burden of proving each of the foregoing factual issues by a preponderance of credible evidence").

Complaint Counsel has not meet its burden of proving that ECM violated Section 5 of the FTC Act, in part, because ECM did not engage in any advertising to "consumers." No consumer could possibly be misled by representations allegedly made by ECM if that consumer never saw the representation or, it they did, never made a purchasing decision based on the representations. In addition, to the extent representations made by ECM to sophisticated plastic manufacturers were passed on to consumers, there is no evidence of record that any purchased an ECM additive containing plastic, and the record reflects survey evidence establishing that consumers by an overwhelming rate of 98% think any rate of plastic biodegradation dependent on variables in the environment not knowable before customary disposal. (RPFF ¶¶ 1308, 1311, 1322). Finally, no

[21] Complaint Counsel's Post-Trial Brief, at 26–27.

consumer acting reasonably under the circumstances could be misled by the claim that plastics infused with the ECM additive are "biodegradable," because plastics manufactured with the ECM additive are "biodegradable" based on competent and reliable scientific evidence in the form of 37 tests. *See* ECM RPFF ¶¶ 2133-2659 (gas evolution testing), 2660-2706 (qualitative testing).

**A. ECM Did Not Engage in "Advertising"**

Complaint Counsel argues that ECM "disseminated advertisements."[22] However, because ECM does not conduct any "advertising" at all, ECM did not engage in advertising as defined by law. "Advertising is a form of promotion to anonymous recipients, as distinguished from face-to-face communication. In normal usage, an advertisement read by millions (or even thousands in a trade magazine) is advertising, while a person-to-person pitch by an account executive is not." *First Health Grp. Corp. v. BCE Emergis Corp.*, 269 F.3d 800, 803–04 (7th Cir. 2001).[23] Therefore, an in-person statement by a company's sales team is not "advertising." *Zurich Ins. Co. v. Amcor Sunclipse N. Am.*, 241 F.3d 605, 607 (7th Cir. 2001). Likewise, statements by a company's executive made in-person to other executives cannot be called "commercial advertising or promotion." *First Health Group*, 269 F.3d at 804. Similarly, in order to constitute "promotion," materials must be "disseminated sufficiently." *Coastal Abstract Serv., Inc. v. First Am. Title Ins. Co.*, 173 F.3d 725, 735 (9th Cir. 1999); *Seven-Up Co. v. Coca-Cola Co.*, 86 F.3d 1379, 1384 (5th Cir. 1996) (same).

[22] *Id.* at 27–28.

[23] Black's law definition defines an "advertisement" as "notice given in a manner designed to attract public attention." *See Black's Online Law Dictionary* (2d Ed.), *available at*, http://thelawdictionary.org/advertisement/ (last visited September 25, 2014).

ECM does not engage in advertising as defined in the law. ECM's entire marketing budget is less than $12,000 per year. (RPFF ¶ 300). ECM has no national advertising plan, does not purchase advertisements in any magazine and does not purchase any consumer-type advertising. (RPFF ¶¶ 301–03). ECM does not disseminate information to anonymous recipients, but instead exchanges materials through detailed business transactions with THE representatives of sophisticated plastic manufacturers. (RPFF ¶ 296). Therefore, ECM's customers often become interested in the ECM product through word of mouth from peers in the plastics industry, or as one ECM customer phrased it—"industry osmosis." (RPFF ¶¶ 306, 650–51). Other times, ECM's potential customer hears about the possibility of biodegradable plastic, perhaps from a different customer, and searches for ECM or ECM-like products on the internet. (RPFF ¶ 306). Still, other times, ECM will obtain customer leads at trade shows. (RPFF ¶ 305). Therefore, ECM does not engage in any commercial advertising or promotion to anonymous recipients, but rather disseminates materials about its product to specific and identified corporate representatives and company executives on a person-by-person and company-by-company basis. Almost all of the documents cited by Complaint Counsel in their brief fall within that category of materials given directly to prospective or current customers, but not disseminated to the public at large.

There is thus neither publication targeted to the public of advertising representations nor promotion to the industry through dissemination of materials beyond person to person and company to company exchanges. (RPFF ¶¶ 300–07).

### B. ECM's "Nine Month to Five Year" Statement was Never Intended as a Claim and is not Interpreted as a Claim

Complaint Counsel argues that ECM made four express claims: (1) ECM plastic will biodegrade completely; (2) in nine months to five years; (3) in a landfill; and (4) scientific testing proves these claims.[24] ECM did, of course, make an express claim that plastics made with the ECM additive are "biodegradable." That claim is truthful and non-misleading, particularly under the ASTM and scientific definition, which ECM used to explain its technology. *See* CCX 1. The express claim that plastics containing the ECM additive "will biodegrade completely" and "in a landfill" are backed by competent and reliable scientific evidence, including 28 gas evolution tests, 8 additional confirmatory tests, and detailed foundational science based explanations of the precise mechanisms of action at work. (ECM RPFF ¶¶ 2129-2659).

The record reveals no evidence that any ECM rate claim begot a purchase. Rather, the record reveals that ECM interacts with each prospective customer for a period of between 6 months and 2 years before a purchase is made. (RPFF ¶ 307). The record confirms that ECM's actual customers are sophisticated plastics manufacturers who did not base a purchase of the ECM plastic on rate information. (RPFF ¶¶ 296–725). Nevertheless, the sum total of the interactions between ECM and its customers before a purchase was made establish that Robert Sinclair qualified the rate claim made by ECM by informing his customers that the actual rate of biodegradation for any particular piece of plastic could not be predicted with certainty before customary disposal but was dependent on the final resting place of the plastic after customary disposal, the ambient environmental conditions there and the presence or absence of biodegrading biota. (RPFF ¶¶ 310–11, 320, 377, 421). Customers specifically asked in

[24] Complaint Counsel's Post-Trial Brief, at 28–29.

deposition by Complaint Counsel whether rate was a factor almost to a man answered that it was not even a factor in a purchase, that they were interested in making their plastics biodegradable but did not care how long it took for the products to break down in nature. (RPFF ¶¶ 605–08, 620–25, 636–38, 647, 657–59, 661–66, 677–80, 684–86, 693–95, 704–07, 712–14, 716–19). That makes most sense when one considers the fact that slow biodegradation is actually more beneficial to the environment, produces less greenhouse gas emissions, that rapid biodegradation, as Dr. Barlaz explained. (Barlaz, Tr. 2265-90).

Complaint Counsel repeatedly challenges ECM's use of a "9 month to 5 year" rate claim in their brief[25], which claim was permanently discontinued by ECM in 2012. The nine month to five year estimate arose from the testing experience of the additive's inventor, Patrick Riley, from the independent scientific assessments of Dr. Barber and others, and from the testing experience of Robert Sinclair and ECM CFO Kenneth Sullivan from anaerobic testing of additive containing plastics in sealed drums and from placement of additive containing plastics in garden plots. (RPFF ¶¶ 43–64, 2703). ECM explained to customers the basis for the estimate, that it arose from individual experience, but did not present the estimate as a claim without qualification, expressing over and over again that the time it would take for any specific piece of plastic to biodegrade depended on factors unpredictable before customary disposal, such as the environment at the place of ultimate disposal and the presence there of biodegrading biota. (RPFF ¶¶ 310–12, 320, 377, 1352).

There is no evidence of record that a single ECM customer ever purchased the ECM additive because it would cause the company's plastics to break down in nature within nine months to five years. (RPFF ¶¶ 605–725). The record reflects that in all but a very few

[25] *See, e.g. id.* at 27–29.

instances ECM customers did not communicate to any downstream buyers the nine month to five year estimate and were disabused from using any specific rate of biodegradation by letter from ECM to its customers dated October 5, 2012. (RPFF ¶¶ 380–82).[26]

In addition, Complaint Counsel erroneously argues that ECM claimed that it had testing proving that plastic containing the ECM additive would completely biodegrade in nine months to five years in a landfill.[27] That misrepresents the record evidence. The record reveals: (1) that ECM's customers were sophisticated, plastics manufacturers (RPFF ¶¶ 296, 383, 391–92, 397, 400, 423, 433–604); (2) that ECM interacted with those customers, sometimes in writing and most of the times verbally, over 6 months to 2 years before a purchase was made (RPFF ¶¶ 296, 307); (3) that during that lengthy time interval those customers critically evaluated the ECM product (RPFF ¶¶ 307, 398, 400, 423), were encouraged by ECM to obtain product samples for critical evaluation (RPFF ¶¶ 402, 757), and performed gas evolution biodegradability tests of the additive, including at least 28 independent, positive gas evolution tests that are of record;[28] (4) that those customers depended on their own independent evaluations in making purchasing decisions and did not consider rate of biodegradation a material factor in making a purchase (RPFF ¶¶ 605–725)[29]; and (5) that the net impression conveyed through the sum total of interactions with ECM was that the rate of biodegradation for any particular plastic was dependent on ambient environmental conditions and the presence of biodegrading biota, which could not be predicted in advance (RPFF ¶¶ 310–11, 320, 377, 421).[30]

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[26] *See also* RX 35–77.

[27] Complaint Counsel's Post-Trial Brief, at 29.

[28] *See, e.g.,* ECM RPFF ¶¶ 2129-2659.

[29] It is important to note that the prospective customer testing of the ECM additive is done in a critical vein (companies with many options had to decide which one and, so, they sought best evidence of actual effect, choosing invariably the gas evolution testing method).

[30] *See* ECM's Response to Complaint Counsel's Finding No. 44.

### C. ECM Did Not Make Implied Rate Claims That Its Products Would Biodegrade Within One Year

Complaint Counsel argues that consumers possess an inherent expectation that all "biodegradable" products will completely biodegrade within one year without regard to the nature of the plastic, the disposal environment, or any other obviously relevant variable. The only competent survey evidence of record directly contradicts Complaint Counsel. Based on that flawed supposition, Complaint Counsel then argues that every single "biodegradable" claim which is not qualified is truly an "implied claim" that the product will disappear within one year. Complaint Counsel then asks this Court to find that ECM deceived consumers generally through the straw man of this refuted "implied claim," which in the end is a fiction created entirely by Complaint Counsel.

#### 1. Complaint Counsel's Reliance on "Convergence Validity" to "Prove" that Substantial Numbers of Consumers Understand Biodegradable Claims to Imply a Rate of Within One Year Lacks Merit because "Convergence Validity" Cannot be Used to Lend Credence to Surveys that Are Each Fatally Flawed

Complaint Counsel argues that because three admittedly flawed studies[31] allegedly had "similar" results (they actually have different results), all three studies validate the conclusion that a certain group of consumers had similar beliefs. The theory of "convergence validity" is essential to Complaint Counsel's argument because only through that theory can they somehow credit the flawed assessment of their expert, Dr. Frederick. In short, their theory is that this Court can take three separately flawed surveys, which independently would have little or no credibility or reliability, and then deem each, wherein different methods yielded results that were

[31] Complaint Counsel's Post-Trial Brief, at 32 (arguing that if convergent validity applies at all, then it applies to surveys with "different flaws").

numerically similar to be confirmation that a third, Dr. Frederick's survey, is valid. This argument suffers from classic fallacies of logic. It is a form of circular reasoning, erecting a false tautology, in which Complaint Counsel begins with the conclusion it desires on numbers of people said to believe Complaint Counsel's definition of rate of biodegradation and then proceeds to deem each survey response that supports that definition from each of the three surveys to be proof of the rate's acceptance. The reasoning also fails because it is a classic example of *post hoc ergo propter hoc* illogic that since a question in Dr. Frederick's survey begat a percentage response similar to a percentage response in the APCO survey and a percentage response in the Synovate survey, despite the fact that different questions are involved and different people and methods of survey, nevertheless the notion is that the belief evidenced by each survey question asked is the same as the belief evidenced by the Frederick survey. The illogic is profound because the surveys are of different design, involve different people, and in fact ask different questions.

"Convergence validity" cannot repair the fatal flaws present in the APCO, Synovate, and Dr. Frederick surveys. Complaint Counsel cited no case law where the Commission or any ALJ recognized that similarity of results in three different individually *flawed* consumer perception studies (here Dr. Frederick's Google Consumer Survey, the APCO survey, and the Synovate survey) negate the significance of those flaws and cause all of the surveys to become reasonably reliable and valid.[32] In *Bristol-Myers*, the Commission made clear that it expected each survey relied upon to comply with the generally accepted standards for competent survey research, emphasizing that it based adjudicatory decisions on surveys that were "reasonably reliable and probative" and "[u]pon thorough and independent examination of the record" to ensure "that the

[32] Complaint Counsel's Post-Trial Brief, at 31.

surveys in question readily meet these standards." *In the Matter of Bristol-Myers Co.*, 85 F.T.C. 688, at *44 (1975). The Commission in *Bristol-Myers* rejected reliance on flawed surveys in its decision. *Id.* The Frederick Survey cannot satisfy the *Bristol-Myers* standard because it was not designed to satisfy those standards; as Dr. Frederick testified, he did not know what those standards were. (RPFF ¶¶ 1085).[33]

In *American Home*, the ALJ stated that, while the surveys he or she relied upon "were neither perfectly nor flawlessly executed, they [were], in general, of the kind and quality normally used by business firms to guide their marketing efforts." *In the Matter of Am. Home Prod. Corp.*, 98 F.T.C. 136, at *90 (1981). Contrary to what Complaint Counsel argues in their brief, the ALJ in *American Home* did not hold that a convergence of flawed survey results made any one or all of the 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. *Id.* *American Home* is inapposite here because Dr. Frederick's survey, as Dr. Stewart well explained, is not of the kind and quality normally used by business firms to support legal policy decisions of the kind at issue in this case. (RPFF ¶¶ 916–17).[34] In addition, the four pieces of evidence Complaint Counsel relies on do not actually reveal similar results.

Both experts agree that the APCO and Synovate surveys are flawed. (RPFF ¶¶ 818–877). Dr. Frederick's survey is so seriously flawed that no valid conclusions can be drawn from it.

[33] *See also* Frederick, Tr. 1190 ("What do you [Dr. Frederick] consider to be the generally accepted survey principles that define a valid survey? What has to be in it in order for the survey to be valid? … ANSWER: I don't have any – I honestly don't have any specific criterion in mind.").

[34] *See also* Stewart, Tr. 2542, 2683.

(RPFF ¶¶ 943–55).[35] Therefore, even if the three surveys obtained similar results (they in fact do not[36]), the convergence validity theory cannot apply here because none of the three surveys satisfies conventions for reasonably reliable and valid survey research; all three surveys are fatally flawed. (*See generally* RPFF ¶¶ 818–1104). By accepting the convergence validity theory based on flawed sources of data, there is too much risk of imposing legally binding obligations on industry based on unreliable (and thus likely incorrect) survey data. Imagine future cases in reliance on Complaint Counsel's precedential theory in which Complaint Counsel or respondents arrive rehabilitate an invalid survey in reliance on additional, equally invalid, ones that just so happen to invite argument that there are certain "similar" results. The exercise invites departure from reason and logic to become institutionalized as the norm.

Dr. Stewart's survey, which is the only survey to meet or exceed the reasonably reliable and valid standard in this case, yields the distinct conclusion that there is no sound basis to conclude that even a significant minority of consumers share a common understanding of biodegradation or a common understating of the rate of biodegradation of plastics. (RPFF ¶¶ 818-1339).

### 2. Survey Research can be Easily Manipulated and therefore Courts must Hold Survey Evidence to Generally Accepted Standards

Complaint Counsel argues that this Court should consider survey evidence that is "not perfect" so long as it is "reasonably reliable and probative."[37] The APCO, Synovate, and Dr. Frederick surveys are not reasonably reliable and probative. *See infra* at Part I(C)(4) at 48. Dr.

[35] *See generally* RPFF ¶¶ 878–1104.

[36] *Cf*. RPFF ¶¶ 824, 871, 1082 (APCO) *with* RPFF ¶¶ 823, 825 (Synovate) and CCX 860 (Frederick, Rep. at 27–45))

[37] Complaint Counsel's Post-Trial Brief, at 33–34.

Frederick's survey, in particular, was manipulated or biased to fit within Complaint Counsel's narrative. Courts have made clear that surveys can be manipulated by experts and that the courts must therefore evaluate surveys to ensure that they are methodologically sound. As one court in the Lanham Act context explained:

> Experts who perform consumer surveys possess technical and linguistic skills that can create valuable tools to assist the courts. However, the court recognizes that experts can use these same skills to structure the language and methodology of a survey to produce the most favorable possible results for a client. Our observations about the language and structure of the survey therefore affect the weight accorded to its statistical results. As courts, particularly in this district, have become more familiar with the use of surveys in Lanham Act claims, we have also become familiar with the subtle ways surveys are structured. Those who believe they can manipulate the structure of consumer surveys to gain a tactical advantage in the courtroom may actually harm their client's strategic position before the finder of fact.

*L & F Prod., a Div. of Sterling Winthrop, Inc. v. Proctor & Gamble Co.*, 845 F. Supp. 984, 995-96 (S.D.N.Y. 1994); *see also New Colt Holding Corp. v. RJG Holdings of Fla., Inc.*, 312 F. Supp. 2d 195, 222–223 (D. Conn. 2004) (quoting *Schering Corp. v. Pfizer Inc.*, 189 F.3d 218, 233–34 (10th Cir. 1999)) (explaining that when parties offer surveys to support statistical inferences, "such inferences can be manipulated through 'artful data collection or presentation' and exacerbated through methodological errors").

Courts must depend on a number of evaluative criteria in order 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 factors 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) (discussing criteria to be considered to determine the admissibility of and weight to be accorded to survey evidence)). Federal courts depend on the Manual for Complex Litigation for guidance on survey evidence. *See, e.g., Nat'l Football League Prop., Inc. v. N.J. Giants, Inc.*, 637 F. Supp. 507, 513–14 (D.N.J. 1986) (citing Federal Judicial Center, *Manual For Complex Litigation*, 116 (5th ed. 1981) (explaining that the proponent of a consumer survey has the burden of establishing that it was conducted in accordance with accepted principles of survey research, i.e., that (1) a proper universe was examined; (2) a representative sample was drawn from that universe; (3) the mode of questioning the interviewees was correct; (4) the persons conducting the survey were recognized experts; (5) the data gathered was accurately reported; and (6) the sample design, the questionnaire and the interviewing were in accordance with generally accepted standards of procedure and statistics in the field of such.").

### 3. Dr. Frederick's Google Consumer Survey Failed to Satisfy Generally Accepted Standards of Survey Research

Complaint Counsel asserts that this Court should base its decision on Dr. Frederick's Google Consumer Survey because it is "reasonably reliable and probative" despite its innumerable flaws.[38] However, no reliable conclusions can be drawn from Dr. Frederick's fatally flawed Google Consumer Surveys. Dr. Stewart explained in detail that Dr. Frederick's Google Consumer Surveys failed to satisfy all seven of the generally accepted principles of

[38] *Id.* at 34–42.

survey research necessary to accept surveys as valid and reliable. In particular, Dr. Stewart found: (1) the survey did not properly choose and define a population because it was not clear what the population was (RPFF ¶ 918); (2) the sample population was not representative of the population, or could not be determined to be representative (RPFF ¶¶ 918–923); (3) Dr. Frederick did not accurately report the data gathered (RPFF ¶¶ 923–26); (4) the data was not analyzed in accordance with accepted statistical principles (RPFF ¶¶ 927–32); (5) the questions that were asked were not clear (RPFF ¶¶ 933–35); (6) the survey was not conducted by unbiased qualified persons (RPFF ¶¶ 936–56); and (7) the process was not conducted to ensure objectivity (RPFF ¶¶ 936–64).

Dr. Frederick readily admitted that he was ignorant of the standards that are used to determine the qualifications of survey evidence before the FTC and in the federal courts. (Frederick, Tr. 1185-87). His survey failed to meet same. (RPFF ¶¶ 878–84). Dr. Frederick is unfamiliar with the Reference Manual on Scientific Evidence, and has no "specific criterion in mind" as to what makes a survey valid.[39] In fact, Dr. Frederick does not "know what other people have written" regarding what constitutes acceptable survey principles that define a valid survey.[40] Moreover, Complaint Counsel drafted substantial portions of Dr. Frederick's expert report, including citations and substantive content. (RPFF ¶¶ 885–94).

Perhaps Dr. Frederick's documented lack of knowledge about what constitutes valid surveys in the litigation context is the reason why he chose to conduct a Google Consumer Survey with no screening questions and with only one question per respondent with an admitted

[39] RX 858 (Frederick, Dep. at 186).
[40] RX 585 (Frederick, Dep. at 186–187).

objective of attempting to find support for the One Year Rule.[41] He chose the Google Survey interface despite the fact that no Google Consumer Survey has ever been relied upon as evidence in an FTC proceeding (or litigation generally), and that its use has never been approved of or validated in any peer reviewed literature.[42] Dr. Frederick's Google Consumer Survey is simply unproven at best.

The methodological and evaluative problems with Dr. Frederick's Google Consumer Surveys are legion. (RPFF ¶¶ 915–1104). There is no way to ascertain the degree to which the sample of respondents used in Dr. Frederick's Google Consumer Surveys are representative of any identifiable population. (RPFF ¶¶ 922, 1090). The sample itself is unknown and unknowable. That is because there is no verification of respondents with Dr. Frederick's Google Consumer Surveys; rather, information on respondents to Dr. Frederick's Google Consumer Surveys is merely inferred by Google from information associated with or that resides on a computer. (RPFF ¶ 1090). Dr. Frederick used no screener questions to assure that he knew who in fact was responding to any particular question and what the age was of the respondent. (RPFF ¶ 1092). He declined to pay the additional fee to include two-part questions that might have provided more direct information about the respondent population. (RPFF ¶ 1091). Dr. Frederick's Google Consumer Surveys included no screening questions whatsoever. (RPFF ¶ 908). By failing to exclude respondents who do not purchase plastic products in the marketplace, Dr. Frederick's Google Consumer Surveys' sample is over-inclusive, and on that

[41] Cost was also another factor. (RX 858 (Frederick, Dep. at 123–5)). This must be especially true because the FTC paid Dr. Frederick a flat fee of $40,000, of which Dr. Frederick was entitled to keep whatever amount he did not spend. (RX 858 (Frederick, Dep. at 8:11–15)). Of the $40k allocated to Dr. Frederick, he profited approximately $32,010, mostly by choosing cheap survey methodologies. (RPFF ¶¶ 899–904).

[42] RX 858 (Frederick, Dep. at 189); RPFF ¶ 903).

ground alone, Dr. Frederick's surveys are irrelevant. *See Water Pik, Inc. v. Med-Systems, Inc.*, 726 F.3d 1136, 1145 (10th Cir. 2013) (affirming the District Court's ruling that the results of a survey "were devoid of any probative value and therefore irrelevant" where the survey's respondents included people who were not potential purchasers of the product at issue, therefore "creating an over-inclusive survey universe"). It is impossible to know whether respondents answers to Dr. Frederick's Google Consumer Surveys were given by those who understood or cared about what was asked, because the single question survey appeared as unexpected pop-ups in front of select news or entertainment content on the web that the respondent desired to access; only upon answering that single survey question would the desired news or entertainment content come to the fore, yet any answer would enable the access to be obtain. (RPFF ¶¶ 988, 991, 1021, 1095, 1138). Consequently, absent any screening, there is no way to confirm whether any respondent answered sincerely or even understood the question. (RPFF ¶¶ 946–48, 1015, 1017).

Fundamentally, Dr. Frederick made no effort to ascertain whether respondents had enough of an understanding of the word "biodegradable" to even fashion a legitimate opinion. We cannot assess whether the respondents were even talking about the same scientific concept or phenomenon when they responded, and that is largely owed to Dr. Frederick's decision to pocket more money by omitting screening questions (which would have added to the cost, reducing Dr. Frederick's fixed fee from the FTC, (Frederick, Tr. 1201-03)).

Google survey generally works by giving internet users access to "premium content" in exchange for answering a question, as opposed to paying for a subscription. Therefore, the questions in Dr. Frederick's survey were, at best, a distraction and barrier to respondents whose objective it is to access information, not complete a survey. (RPFF ¶ 1095). That type of

questioning creates a disinterest bias; a concept alien to Dr. Frederick at the time of his deposition. (RPFF ¶¶ 1095–96). That explains why so many respondents answered Dr. Frederick's survey with nonsensical answers. (RPFF ¶ 1096).

In addition, Dr. Frederick, and his students who acted as his coders, failed to accurately report the data received from the Google Survey. (RPFF ¶¶ 1097–1104). Coding of responses to open-ended questions is an important factor when assessing the validity of a survey. In *Malletier*, the court explained that "the miscoding of even a small number of verbatim responses could have a very significant impact on the survey's overall findings." 525 F. Supp. 2d at 611. *Malletier* went on to quote the Manual on Scientific Research, which states that "[t]wo trained coders should independently score the same responses to check for the level of consistency in classifying responses. When the criteria used to categorize verbatim responses are controversial or allegedly inappropriate, those criteria should be sufficiently clear to reveal the source of disagreements." *Id.* (quoting Shari Seidman Diamond, *Reference Guide on Survey Research*, in MANUAL ON SCIENTIFIC EVIDENCE 2d at 268 (Federal Judicial Center 2000)). Dr. Frederick did not follow the Manual on Scientific Evidence's requirements when coding. Rather, Dr. Frederick rather admits that he and Andrew Meyer, his student, coded most of the responses, that neither he nor Meyer were blinded, and that he, Dr. Frederick, unilaterally resolved disagreements. (RPFF ¶¶ 940–43, 1041–44, 1155).[43]

Dr. Frederick coded nonsensical answers such as "1 nanosecond" and "1 second," coding those absurd responses as "less than one year." (RPFF ¶¶ 1041–44). That might be because, unlike Dr. Stewart's survey which used well-trained coders, Dr. Frederick believes that coders

[43] *See also* Frederick, Tr. 1136 (explaining that he "examined the coding decisions … [and] made different decisions in a few – in some cases.").

only need to be able to read and follow directions.[44] Moreover, Dr. Frederick's survey failed to code accurate and relevant responses such as "don't know" and "it depends." (RPFF ¶¶ 1099–1100). Dr. Frederick also coded answers that did not fit his "bright line rule" which held that only numeric responses were to be coded. (RPFF ¶¶ 1043–44 (coding "forever", "immediately," "minutes," and "never")). Even more troublesome, however, is the fact that Dr. Frederick's supervising coder, Andrew Meyer, was aware that Dr. Frederick's research was sponsored by the FTC and was going to be used by FTC Complaint Counsel against ECM in this case. (RPFF ¶ 1101). Dr. Frederick was likewise aware of that purpose, and yet he did most of the coding work. (RPFF ¶¶ 1034–1104). In short, the coders were not blinded, so bias infected the entire study from the development of questions by Frederick and Meyer to the choice of method to present them to the coding of the results. (RPFF ¶¶ 1034–1104).

In addition, as Dr. Stewart makes clear, even if Dr. Frederick's survey were somehow deemed valid, its results, like Dr. Stewart's survey results, suggest heterogeneity not the degree of homogeneity argued by Complaint Counsel. In other words, there is considerable diversity among respondents in terms of their claimed knowledge about biodegradable products and their views about the time it takes various materials to biodegrade.[45] Therefore, because Dr. Frederick's "survey" is plainly not valid as judged against generally accepted survey principles, and because its results do not prove the existence of any common understanding among consumers about how long a biodegrade product takes to decompose, Dr. Frederick's Google

[44] *See* RX 858 (Frederick, Dep. at 168–169). Based on some of the initial coding disclosed to ECM by Dr. Frederick, it appears that Dr. Frederick's coders were not even able to read and follow directions correctly. (RX 856 (Stewart, Rep. at 13)).

[45] RX 856 (Stewart, Rep. at 13–14).

Consumer Surveys are hopelessly flawed whether viewed alone or in tandem with the results derived from the flawed APCO and Synovate surveys. (RPFF ¶¶ 855, 943, 945, 946, 964).[46]

### a. The Evidence Relied Upon by Complaint Counsel for the Proposition that Google Consumer Survey Is Reasonably Representative of American Consumers Is Not Germane to Dr. Frederick's Actual Survey and Is Rank Hearsay

Complaint Counsel offers five largely irrelevant and hearsay sources to establish that Google Consumer Survey respondents "are both reasonably representative of internet users and American consumers."[47] However, not one of those sources has anything to do with Dr. Frederick or the actual survey he used in this case. None shows that Dr. Frederick's sample was representative of any populations from which his survey allegedly draws inferences. The first line of "evidence" is a report from the Pew Research Center.[48] However, that Pew report contains only unreliable hearsay and is irrelevant without any foundation.[49] None of the data compiled in the Pew report is applicable or bears any relevance to this proceeding because none of the questions analyzed in the Pew report has anything to do with consumers' perceptions of biodegradability.[50] In addition, the report actually comes to a number of conclusions that contradict Complaint Counsel's argument that this report establishes that Google Consumer Survey respondents are both reasonably representative of internet users and American consumers. For example, the report concludes that "[i]t is unknown whether visitors to the network of publisher sites are fully representative of all internet users or what proportion of

[46] *See also* RX 858 (Frederick, Dep. at 151–52).
[47] Complaint Counsel's Post-Trial Brief, at 35–39.
[48] CCX 874.
[49] *See* ECM's Response to Complaint Counsel's Proposed Findings Nos. 227–240.
[50] CCX 874 at 2.

internet users are covered by the publisher network,"[51] that "no meaningful margin of error can be calculated for projecting the results to the internet population,"[52] that Google's "sampling may result in more variation from sample to sample,"[53] that "[e]rrors associated with inferred demographic characteristics can influence the sampling and weighing process, even if these inferred demographic are not used in the analysis,"[54] that "[f]or approximately 30–40% of the users, demographic information is not available,"[55] that "one of the key limitations of the Google Consumer Surveys method" is the fact that "[o]nly one or two questions can be administered to the same respondent,"[56] and that "there can be substantial errors in how individual people are classified using Google' inferred demographics."[57]

The second line of purported "evidence" is a blog post authored by Nate Silver.[58] This blog post is again unreliable hearsay and irrelevant without any foundation.[59] The post is the very same that Dr. Frederick testified he did not know before his expert report was written and included it because Complaint Counsel inserted it into his report. (Frederick, Tr. 1195-96). The blog post, as Complaint Counsel explains, suggests that Google Consumer Surveys was accurate as a polling mechanism for only the 2012 presidential election.[60] Mr. Silver's post about use of some other election survey by Google has no relevance to the actual survey Dr. Frederick performed. Dr. Frederick's own testimony at trial complemented the lack of relevance point

[51] *Id.* at 3.
[52] *Id.*
[53] *Id.*
[54] *Id.*
[55] *Id.*
[56] *Id.* at 4.
[57] *Id.* at 5.
[58] Complaint Counsel's Post-Trial Brief, at 36–37.
[59] *See* ECM's Response to Complaint Counsel's Proposed Findings Nos. 227–240.
[60] Complaint Counsel's Post-Trial Brief, at 36–37.

when he stated, "as the election nears more people are surfing the Web regarding information about the election" and that during the time Dr. Frederick conducted his surveys, there was no national story that riveted public attention and opinion over whether plastics biodegrade.[61] So, even if the Google Consumer Survey mentioned by Nate Silver accurately predicted the 2012 presidential election results, there is no record evidentiary foundation to establish that Dr. Frederick's Google Consumer Surveys were modeled after the ones used by Google to evaluate the 2012 presidential election or, even if they were, whether such replication is appropriate or capable of yielding accurate and reliable results in the context of consumer understanding of the meaning of biodegradability and perception of the rate of biodegradation of plastics. Note well that an election poll requires that the subject make a binary decision on an issue of obvious national import. The election poll therefore presents a polar opposite circumstance from that presented by an open-ended study of consumer impression concerning biodegradability of plastics.

ECM cannot know what Complaint Counsel's third line of evidence is.[62] The paragraph discussing the third line cites to Complaint Counsel's Findings of Fact ¶¶ 248–50 and 252.[63] The paragraph contains no other citations. The cited findings of fact contain no information which supports the stated propositions.[64] ECM therefore cannot respond to this mythical "third" line of evidence.

The fourth line of "evidence" cited by Complaint Counsel is the fact that Dr. Frederick directly communicated with Google representatives purportedly to "confirm the mechanics and

[61] Frederick, Tr. 1340–41.
[62] Complaint Counsel's Post-Trial Brief, at P. 37.
[63] *Id.*
[64] *See* ECM's Responses to Findings of Fact Nos. 248–50, 252.

methodology GCS employs."[65] Despite having two conversations before the hearing, at his deposition and at the time of the hearing, thus after he completed his survey and after he completed his expert report, Dr. Frederick confessed at length to near complete ignorance of how Google Consumer Survey actually works. (RPFF ¶¶ 982–84, 989–92, 1055, 1064–74). For example, Dr. Frederick does not know what percentage of internet users rely on Google Chrome's feature that allows you to browse privately.[66] Dr. Frederick does not know whether Google accepts a response from a user browsing anonymously.[67] Dr. Frederick does not know whether people can access a Google Consumer Survey on a mobile device.[68] Similarly, Dr. Frederick does not know the difference between a static IP address and a dynamic IP address,[69] does not know whether people can access a Google Consumer Survey on a mobile device,[70] is not familiar with dynamic host configuration protocol,[71] does not know how dynamic host configuration protocol assigns IP addresses,[72] does not know what percentage of internet users block cookies,[73] does not know what percentage of internet users mask their identities online,[74] and does not know whether Google accepts a response from a user browsing anonymously.[75] (RPFF ¶¶ 1065, 1068–74). More fundamentally, however, the communications had between Dr. Frederick and Google are nothing but unsupported hearsay, impossible to verify or assess. Complaint Counsel had the ability to support the flawed Google product in its affirmative case,

[65] Complaint Counsel's Post-Trial Brief, at 37–38.
[66] Frederick, Tr. 1334–35.
[67] Frederick, Tr. 1337.
[68] Frederick, Tr. 1329.
[69] Frederick, Tr. 1332.
[70] Frederick, Tr. 1329.
[71] Frederick, Tr. 1333.
[72] *Id.*
[73] Frederick, Tr. 1335.
[74] *Id.*
[75] Frederick, Tr. 1337.

but chose not to despite having full awareness of all Dr. Frederick's methodological fallacies. Asking this Court to "take his word" on Google's reliability is, at this point, beyond the factual record and unreasonable.

Complaint Counsel also mischaracterizes Dr. Stewart's testimony by quoting him out of context in support of their argument that "relying on [Google] a third party to ask questions and gather data from a representative sample" is customary in the survey research field.[76] Dr. Stewart did not testify that it is acceptable to rely on third parties like Google. Rather, Dr. Stewart testified only that a **research organization** or a **research firm** using proper procedures and protocols is operating as a researcher would expect it to operate.[77] But in order for a company to be deemed a research organization or a research firm by professional marketing associations and marketing research professionals, the company must provide a transparent product with sufficient information to adequately evaluate the product. (RPFF ¶¶ 1145–46). The Google Consumers Surveys Dr. Frederick commissioned are not a transparent product, and Dr. Frederick has not provided sufficient information to allow market research professionals to evaluate the product. (RPFF ¶¶ 1144–46). Therefore, Dr. Frederick's Google Consumer Surveys are not of a kind generally accepted as legitimate market research.[78] (RPFF ¶ 1147).

[76] Complaint Counsel's Post-Trial Brief, at 37–38.

[77] Stewart, Tr. 2663–64 ("[I]t's quite common to make an assumption that a **research organization** follows a particular protocol or procedure. Those procedures or protocols are often documented, either verbally or in writing. They can often be observed.") (emphasis added)).

[78] Note well that we have before the Court only what Dr. Frederick actually did, and not whatever survey modality could have been used through Google. The evidence of fault is thus to Dr. Frederick's Google Consumer Surveys in this case and does not support a conclusion that no survey could have been designed for use via Google that would have satisfied the generally accepted criteria for competent survey research. The record is bare of evidence, not germane to this proceeding, concerning whether Google could design such a product for use by those seeking to use a survey before the FTC or in the federal courts.

Complaint Counsel's conclusory assertions to the contrary notwithstanding,[79] there is no record evidence to support the proposition that Dr. Frederick's sample is representative of American consumers or of the relevant population in this case—American consumers who purchase plastic products in the marketplace. (RPFF ¶ 921). As he admitted under cross-examination, he cannot know who in fact has answered any of his Google Consumer Survey questions. (RPFF ¶¶ 1012, 1013, 1075).

### b. Dr. Frederick's Population and Sample in His Google Consumer Surveys Are Unknown and Unknowable

Complaint Counsel argues that even though demographic data about Dr. Frederick's respondents is unknown, Dr. Frederick's overall sample is still "representative."[80] Dr. Frederick's Google Consumer Survey failed to properly choose and define a population; it is not clear what the population was that responded to Dr. Frederick's single survey questions; while it appears to be some subset of the American population, it's not defined by an age and there is no upper or lower bound. (RPFF ¶ 918). Dr. Frederick himself was confused as to who in fact constituted the relevant population for his survey, testifying in one instance that it is "any *adult* that would buy a plastic product" and in another that it is "any *person* who would buy a plastic product" (RPFF ¶ 1008) and in a third that it is "*any adult in the U.S.* who might buy a plastic product."[81]

[79] Complaint Counsel's Post-Trial Brief, at 35–36.

[80] *Id.* at 39–40 (also note that Complaint Counsel fails to state what population Dr. Frederick's sample is supposedly representative of, likely because Dr. Frederick's population is unknown and unknowable).

[81] RX 858 (Frederick, Dep. at 75–76).

Regardless of how Dr. Frederick wanted to define his survey population, Google defined it for him as the "general population in the United States on Google Consumer Surveys Publisher Network." (RPFF ¶ 1010). The population for Dr. Frederick's Google Consumer Survey is therefore defined not by him but by Google, which is not an appropriate way to define a population. (RPFF ¶ 919). In fact, Dr. Frederick admitted that there are "two populations here … the population about which we're trying to draw inferences ... [and] the people who answered the surveys that I posted on Google Consumer Surveys." (RPFF ¶ 1094). Therefore, it is not possible that Dr. Frederick's Google Consumer Survey depended on a defined, relevant population—such as American consumers who obtain plastic in the marketplace—because regardless of who he wanted to survey, Google in fact surveyed the general population in the United States on Google Consumer Surveys Publisher Network, which itself is inadequately defined. (RPFF ¶ 921).

### c. ECM Does Indeed Challenge Dr. Frederick's Questions

Complaint Counsel contends that ECM does not challenge the structure of, or wording of, any of Dr. Frederick's Google Consumer Survey Questions.[82] Not so. ECM challenges the structure of all of Dr. Frederick's questions because Dr. Frederick structured the questions in a way which only allows a single respondent to answer a single question, and because no screening questions were asked of any respondent. (RPFF ¶¶ 908, 946–50, 980–81, 1210–14). The lack of screening questions proves Dr. Frederick's survey invalid, as Dr. Stewart well explained. (RPFF ¶¶ 1210–14). By failing to screen respondents, Dr. Frederick's surveys resulted in a sample that is unknown. (RPFF ¶¶ 1090–94, 1211). That sample is necessarily over-inclusive because it

[82] Complaint Counsel's Post-Trial Brief, at 40.

contains internet users who do not purchase plastics products in the marketplace. *See Water Pik*, 726 F.3d at 1145 (affirming the District Court's ruling that the results of a survey "were devoid of any probative value and therefore irrelevant" where the survey's respondents included people who were not potential purchasers of the product at issue, therefore "creating an over-inclusive survey universe"). Furthermore, Dr. Frederick's lack of screening questions caused his survey to fail to ensure that each respondent had an understanding of biodegradation before answering. (RPFF ¶¶ 908, 1199, 1209). Contrary to Complaint Counsel's argument, the importance of the screening is not to determine whether Consumers' understanding is mistaken or incomplete according to science; rather it's to determine whether the consumer believes he or she has a sufficient understanding of biodegradation to provide a sincere response rather than a random guess. (RPFF ¶¶ 1199, 1209).

Moreover, Dr. Frederick's decision to ask only one question per respondent renders his surveys invalid. When there is only one question asked of a respondent, a researcher cannot know what the response indicates, whether it is a sincere response and whether it is a response that would be subject to qualification if there were a follow-up question.[83] That is especially true where, as here, even the researcher admits some responses to his survey were not given sincerely (he just cannot tell with reasonable certainty which ones).[84]

In addition, the images Dr. Frederick used in his survey questions are not actual images of ECM additive containing plastics in the marketplace, but fictive, invented photo-shopped images created electronically by a person (coder Andrew Meyer's wife (Frederick, Tr. 1265)) who was likely aware of the purpose of the images and of the fact that the FTC was using the

[83] Stewart, Tr. 2606.
[84] Frederick, Tr. 1248–49.

images against ECM. (RPFF ¶¶ 1024, 1049). ECM also faults Dr. Frederick's questions for not specifying the type of plastic to which he refers in each question. (RPFF ¶ 1026). ECM also challenges Dr. Frederick's questions as not clear and misleading.[85]

### d. Dr. Frederick's "Bright Line Rule" Is Evidence of His Own Bias

Complaint Counsel argues that Dr. Frederick properly employed a "bright-line rule" when coding answers to his Google Consumer Survey.[86] However, the bright-line rule Dr. Frederick unilaterally chose to adopt is actually evidence of his intent not to obtain information from consumers, but to provide support for Complaint Counsel and corroborate the APCO survey. To decide which of the 29,000 responses Dr. Frederick obtained in his Google Consumer Surveys to include in the final data, Dr. Frederick supposedly adopted a "bright-line rule" whereby he included respondents' answers only when the respondent's answer contained "both a numeric specification and an accompanying temporal unit."[87] The bright-line rule had the effect of transforming Dr. Frederick's open-ended questions into close-ended questions, by virtue of the fact that any of the 29,000 respondents who answered without both a numeric specification and an accompanying temporal unit were not included in the final data.[88] In other words, Dr. Frederick only "coded" answers that fit into neat categories involving numeric and temporal components, excluding such candid responses like "it depends." Although subjects were not given a limited set of choices, their answers were still limited substantially because they were only coded if they fit within Dr. Frederick's preconceived format.

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[85] RX 856 (Stewart, Rep. at 16).
[86] Complaint Counsel's Post-Trial Brief, at 42–44.
[87] Complaint Counsel's Post-Trial Brief, at 42.
[88] *Id.* at 42–44.

Remarkably, Dr. Frederick erroneously failed to follow his own "bright-line rule" on two instances. First, as Dr. Stewart explained, "[i]n some cases respondents who gave a range [were] not coded at all while in other cases they were assigned the mid-point of the range."[89] Therefore, respondents who provided an answer to Dr. Frederick's survey of, for example, 10-20 years, were sometimes not coded at all and other times were coded as 15 years. Dr. Frederick also coded some answers—in direct violation of his supposed "bright-line rule"—that did not contain both a numeric specification and an accompanying temporal unit. For example, Dr. Frederick readily admitted at trial, without explanation, that he coded "forever," "immediately," "minutes," and "never." (RPFF ¶¶ 1043–44).

Complaint Counsel also argues that Dr. Frederick's failure to code responses who answered "I don't know" is immaterial because, according to Complaint Counsel, there is no reason to believe that people who answer "I don't know" have different beliefs than people who gave specific estimates.[90] As logic dictates, however, there is actually reason to believe that people who answer "I don't know" as a group have a different distribution of views than people who express their view immediately.[91] Dr. Stewart explained that "their distribution would be different because some of those people actually don't know, and so the fact that they don't know will change the overall distribution even if there are a few people who say 'don't know' because they are less certain. But the overall distribution would be quite different."[92]

In a last ditch and futile attempt to show why his coding decisions were appropriate, Dr. Frederick compared the distribution of un-codeable responses containing just the numeric

[89] RX 856 (Stewart, Rep. at 13).
[90] Complaint Counsel's Post-Trial Brief, at 43.
[91] Stewart, Tr. 2668.
[92] *Id.*

specification "1" or "one," without an accompanying temporal unit, with the distribution of codeable responses containing "1" or "one," containing an accompanying temporal unit.[93] Based on that analysis, Dr. Frederick concluded that "the distribution of numbers given without units is very close to the distribution of numbers given with units."[94] Complaint Counsel contends that this "analysis" by Dr. Frederick demonstrates that people who gave uncodeable responses have the same distribution of beliefs as people who gave a codeable response, and that therefore, Dr. Frederick's decision to not code those responses not containing both a numeric specification and accompanying temporal unit does not affect the conclusions that can be drawn from Dr. Frederick's Google Consumer Survey's data.[95] However, this line of "analysis" by Dr. Frederick is completely theoretical, all conclusions drawn from it are wholly inferential, and there is no direct evidence that respondents who replied with "1" or "one" intended to convey any length of time that can be compared to people who responded with both a numerical specification and an accompanying temporal unit.5] It is also possible that "1" was given as a response because it is the first number that comes to respondents' minds, and respondents were merely pressing "1" in order to gain quick access to the desired internet content.[96] Regardless, Dr. Frederick's fatal coding flaw was that he failed to code sincere answers such as "it depends" and "I don't know." (RPFF ¶¶ 1042, 1100).

Lastly, as Dr. Stewart explained, by "ignoring significant portions of the data in computing statistics, you're really misrepresenting the data. If a large number of people are

[93] CCX 865 (Frederick, Rebuttal Rep. at 6)
[94] *Id.*
[95] Complaint Counsel's Post-Trial Brief, at 43–44.
[96] RPFF ¶ 1095; CCX 977 (Dr. Frederick's peer reviewed article, at n. 5 stating that some respondents who answer questions from Google Consumer Surveys "answer randomly to regain access to the webpage as quickly as possible").

uncoded because they gave a response that doesn't fit a desirable structure, you don't report data statistics based only on what was convenient and fit your definition of an appropriate response. You need to report all of the data and the statistics accordingly."[97] Dr. Stewart also explained that "if you're going to compute any statistics, then you need to include those individuals [who provided uncoded answers] within the total sample. You can't ignore them because they didn't give the type of response that you were looking for."[98]

**e. The Results of Dr. Frederick's Survey Questions Reveal that Dr. Frederick's Survey Was Compromised by Disinterest Bias and Protest Responses**

Complaint Counsel argues that there is no credible evidence of disinterest bias in Dr. Frederick's Google Consumer Survey.[99] However, the actual results of Dr. Frederick's survey make clear that his survey was riddled with an incalculable amount of both disinterest bias and protest responses. Dr. Stewart explained the concept of disinterest bias and faulted Dr. Frederick's surveys for suffering from that bias. (RPFF ¶¶ 958, 1096, 2611).[100] Disinterest bias refers to the fact that if people are uninterested in a survey, if they are disengaged, or, even worse, if the survey interrupts an activity that they are more interested in pursuing, they will likely give insincere, random, and often nonsensical responses to simply get past what is essentially an interruption in what they wished to do before being confronted by the survey. (RPFF ¶ 958).

[97] Stewart, Tr. 2602.
[98] Stewart, Tr. 2614.
[99] Complaint Counsel's Post-Trial Brief, at 46–47.
[100] *See also* RX 856 (Stewart, Rep. at 11 n. 7).

A protest or bypass response is a response given by a respondent for the sole purpose of getting past a survey wall. (RPFF ¶ 1136). In an internet survey, where the respondent must enter some information in order to obtain desired content, a protest response can take any number of forms, including what could be interpreted as nominally valid answers. (RPFF ¶1138).

One example of the pervasiveness of disinterest bias and/or protest responses in Dr. Frederick's Google Consumer Surveys is in the responses to the question regarding "9 months to five years." No respondent who actually reads the question and provides a sincere response can provide a response of more than 5 years when the question explicitly states "nine months to five years." Nevertheless, over 20% of respondents provided an answer of more than 5 years.[101]

Other examples of disinterest bias or protest responses include the results to Dr. Frederick's questions 3L through 3P.[102] In those questions, Dr. Frederick asked respondents how long it would take plastic products **without** a biodegradable claim to biodegrade or decompose. The results show that a large percentage of respondents to Dr. Frederick's survey did not seriously consider the questions. For example, between 11% and 16% of respondents to those questions stated that generic plastic products, without any biodegradable claim, will biodegrade in less than one year.[103]

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[101] CCX 860 (Frederick, Rep. at 17).

[102] *Id.* at 33–34.

[103] *Id.;* Given Complaint Counsel's "significant minority" argument, must sellers of non-biodegradable products qualify their products as "non-biodegradable" in order to protect that 11 to 16 percent of American Consumers who apparently believe that regular plastic products are biodegradable in less than one year? *See* Complaint Counsel's Post-Trial Brief, at 30–31. Moreover, even assuming the data was reliable (it is not), this actually proves that consumers are hopelessly confused with respect to plastics generally, in that more than 15% of consumers believe that <u>all</u> plastics biodegrade within one year. Observe that this data squarely contradicts Complaint Counsel's theory on unqualified "biodegradability claims," as the so-called

Perhaps even more troublesome, between 38% and 50% of respondents stated that those products will biodegrade in less than 25 years.[104] In addition, 69% of respondents to Dr. Frederick's survey do not believe that "biodegradable containers" will break down completely into elements found in nature.[105] That data (even assuming it was reliable) would strongly support Dr. Stewart's analysis wherein he explained that consumers are inherently skeptical or uninterested in biodegradable claims, and thus unlikely to materially rely on same. (RPPF ¶¶ 1337-38). Almost that same percentage, 63%, stated that a plastic bucket containing the ECM Biodegradable logo will not completely break down into elements found in nature.[106] Based on the actual responses to Dr. Frederick's survey, it is clear that a large percentage of his respondents provided either protest response, or were subject to disinterest bias.[107]

Complaint Counsel points to the fact that the average response time for respondents in Dr. Frederick's Google Consumer Surveys was 20 seconds as if that was evidence of those respondents reading and providing a sincere response to Dr. Frederick's questions.[108] In reality, when an internet user is faced with a Google Consumer Survey question, like Dr. Frederick's questions, the question pops up in front of, but not completely masking, the desired internet content.[109] A portion of the web site content is still available to the respondent, albeit in the background partially blocked by the pop up question.[110] So, common sense dictates that those anxious to obtain the content would devote at least part of those 20 seconds to reading what is

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significant minority does not even care about "biodegradable"—<u>whatever the product, whatever the claim, they think it disappears in one year</u>.

[104] *Id.*
[105] *Id.* at 37.
[106] *Id.* at 38.
[107] *See generally* CCX 860 (Frederick, Rep. at 27–45).
[108] Complaint Counsel's Post-Trial Brief, at 46.
[109] Frederick, Tr. 1343.
[110] *Id.*

not obscured or is otherwise decipherable from even that portion that is obscured.[111] Moreover, the Google Survey wall is an unexpected encounter for internet users. At very least, common sense dictates that consumers would require a period of time to determine what is displayed in front of them so they can determine whether they even wish to proceed at risk of exposure to malware or other unwanted intrusion. The fact that 20 seconds may elapse truly says nothing about whether the subjects are seriously considering a question.

In addition, as Dr. Frederick admits, any number of things could have happened in the ordinary course of a person using a computer to cause respondents to take on average 20 seconds to answer his questions.[112] So, the fact that the average response time to Dr. Frederick's questions was 20 seconds is not evidence that respondents were thinking about the question. Indeed, that can only be an assumption given that there is no basis in Dr. Frederick's surveys to reveal who actually answered and what distractions or interruptions occurred between the time each visited the site and the time each answered a survey question.

#### 4. Both Dr. Stewart and Dr. Frederick Agree that the APCO and Synovate Surveys Are Flawed and Cannot Support Implied Rate Claims

Complaint Counsel asserts that the APCO and Synovate surveys, when "taken together, provide reasonably reliable and valid evidence" to support their contention that consumers interpret the naked term "biodegradable" to mean decompose into elements found in nature "in one year or less."[113] However, both Dr. Stewart and Dr. Frederick agree the APCO and Synovate surveys are flawed; therefore, no valid conclusions can be drawn from them regardless

[111] *Id.*
[112] Frederick, Tr. at 1342–43.
[113] Complaint Counsel's Post-Trial Brief, at 49–50.

of whether they have "similar" results.[114] When beginning consumer perception work in a new area, open-ended questions are essential. (RPFF ¶ 868). Dr. Stewart explained that given the current understanding and state of knowledge with respect to consumer perception of biodegradation, open-ended questions are "much more suitable, much more appropriate, and much more informative, than closed-ended questions." (RPFF ¶ 857). Surveyors must invest in open-ended questions and interviews early in the exploration of a topic like biodegradation to be sure that when they do finally design close-ended questions, they are providing people the full and accurate array of response options. (RPFF ¶ 860). Close-ended questions inherently suggest greater homogeneity within a sample of respondents than may actually exist because close-ended questions exist in a universe with only four or five possible responses. (RPFF ¶ 869).

Dr. Frederick faults the APCO survey for using close-ended questions. (RPFF ¶ 846). According to Dr. Frederick's testimony, the APCO survey is not valid. However, in his expert report, Dr. Frederick concludes the opposite, that the APCO survey is valid. (RPFF ¶ 832). Despite that inherent contradiction, regardless of whether Dr. Frederick believes the APCO survey is valid as a whole, he does believe that the APCO survey, and particularly Question four, is significantly flawed. For example, Dr. Frederick believes that the APCO survey is flawed because of the allocation of response options to Question Four, the use of the word "should" instead of "would" in Question Four, and the fact that the APCO survey employs close-ended questions. (RPFF ¶¶ 836, 838, 846). Dr. Frederick also unequivocally believes that the Synovate survey is invalid. (RPFF ¶ 839). Like Question Four of the APCO Survey, Dr. Frederick faults Question 19 of the Synovate because it uses the word "reasonable" and is close-ended. (RPFF ¶¶ 841–42, 846).

[114] Again, those surveys do not share similar results. *See infra* at Part I(D) at 64.

Dr. Stewart similarly explained that the APCO survey is invalid because it does not provide adequate opportunity for consumers to offer their perceptions of how long it would take for something to biodegrade and because it is inherently biased, offering far more opportunities to select an answer that reflects one year or less than a longer time period. (RPFF ¶¶ 853–54). Dr. Stewart therefore determined that conclusions about people's perceptions of the length of time that biodegradation should require cannot be reliably drawn from the APCO survey. (RPFF ¶ 855). In addition, Dr. Stewart faulted the Synovate survey because it uses close-ended questions when asking about the length of time that biodegradation should occur. (RPFF ¶ 856). In sum, both the APCO and Synovate surveys have "serious limitations," (RPFF ¶ 865), and both experts agree that the surveys are flawed. (RPFF ¶¶ 826, 877).

### 5. Dr. Stewart's Survey Is the Only Valid Survey that Establishes Consumers' Beliefs About Biodegradation

Complaint Counsel argues that Dr. Stewart's survey is not reliable evidence contradicting their theory that some small percentage of Americans share a common understanding that the word "biodegradable" means that a product will decompose into elements found in nature in one year or less after customary disposal.[115] Complaint Counsel is incorrect. Dr. Stewart's reliable survey and uncontroverted testimony establish that consumers have no shared understanding of biodegradable, let alone a specific understanding limited to any specific time or rate of biodegradation.

A survey expert whose work has repeatedly been credited by ALJs of the FTC and the Commission itself, Dr. David Stewart designed a live interview telephone survey in order to

[115] Complaint Counsel's Post-Trial Brief, at 50–54.

determine how consumers who purchase products made from or packaged in plastic actually perceive the meaning of the term "biodegradability."[116] Phone surveys are the most common form of survey used in marketing research. (RPFF ¶¶ 1106–08, 1176–78). The primary reason Dr. Stewart opted for a live telephone interview survey is because he was interested in "meaning." (RPFF ¶¶ 1106–08, 1288). In order to understand what people believe a term means, particularly a term for which little survey research exists, a competent researcher needs a live interviewer appropriately trained to conduct survey research. (RPFF ¶¶ 1108–10). Dr. Stewart's survey also assessed the message that consumers take away from claims made by ECM. (RPFF ¶ 1296).[117] Dr. Stewart's survey used well-designed, non-leading, clear, open-ended questions that allowed actual plastics consumers to answer in their own words and to provide qualifications, contextual information, or other information that established a richer meaning of consumer responses than is typically obtained when only closed-ended questions are posed (or single questions are posed without human interface) in a survey. (RPFF ¶¶ 1293).[118] Dr. Stewart designed and conducted this survey in accordance with well-established principles of survey research offered in litigation, as delineated in the Manual for Complex Litigation. (RPFF ¶ 1289). To that end, the survey defined the relevant population as men and women over the age of 18 in the United States who reported that they had personally purchased a product in the past month that came in a plastic container or was made of plastic. (RPFF ¶¶ 1243, 1292).[119] Unlike Dr. Frederick's sample, Dr. Stewart's sample was representative of the population of those who actually use plastics in the marketplace. From this sample, respondents were disqualified if they

[116] RX 856 (Stewart, Rep. at 15).
[117] *See also Id.*
[118] *See also Id.*
[119] *See also Id.*, at 17.

stated in response to screening questions that they did not have a general understanding of what the term "biodegradable" means. (RPFF ¶ 1209).[120] The actual sampling frame was constructed from a random digit dialing sample obtained from Scientific Telephone Sampling and an age enhanced list was obtained from Survey Sampling, Inc. (RPFF ¶¶ 1236–37; RX 856 at 17). Both of those companies are highly respected, well-known providers of samples for use in survey research. (RPFF ¶ 1242; RX 856 at 17).

Dr. Stewart determined that a sample size of 400 respondents was the appropriate number of participants because that sample size provides, in the worst case, approximately plus or minus 5% of the true population statistics 95% of the time. (RPFF ¶¶ 1231–33).[121] The respondents' answers were accurately reported by well-trained interviewers who had been specifically trained in interviewing methodology, were under the supervision of highly qualified and experienced research supervisors, had been debriefed on the specific requirements and protocol for this survey, and had completed at least one practice interview. (RPFF ¶¶ 1260–63). Importantly, the interviewers were also randomly monitored by supervisors to assure that the interviews were conducted in the prescribed manner. (RPFF ¶¶ 1261–63). These interviewers and their supervisors were blind in the sense that they did not know for whom the survey was being conducted. (RPFF ¶¶ 1251–59).

Once the respondents were appropriately selected from a list of telephone numbers based on an algorithm employed by the Computer-Assisted Telephone Interviewing (CATI) system, interviewers clarified to potential respondents that the call was for research purposes and not telemarketing. (RPFF ¶¶ 1290–91). The interviewers and respondents then went through both

[120] *See also Id.*
[121] *See also Id.*, at 18.

parts of the survey. The first part contained screening questions, a "screener" in the survey vernacular (RPFF ¶¶ 1291–1292), and the second part was the main questionnaire. The screener was used to determine whether the respondent met the screening criteria and was a member of the relevant population. (RPFF ¶¶ 1269–70, 1279, 1292). Those questions ensured that the respondent was over 18, was age and gender representative within the sample, avoided those who work for a manufacturer of plastic products or a waste disposal organization, (RPFF ¶ 1292),[122] ensured that respondents had purchased a product in a plastic container or containing plastic within the past month, and ensured that respondents had a general understanding of the term biodegradable. (RPFF ¶¶ 1196, 1292–94).

Respondents who qualified in the survey sample based on the screen questions were asked a series of substantive questions in the main questionnaire. (RPFF ¶ 1202). All but two of the questions in the main questionnaire were open-ended questions, which have the advantage of allowing respondents to offer answers that are qualified, provide context, or are otherwise nuanced, and which are useful for clarifying terminology by gauging the meanings of words and for informing variability among respondents. (RPFF ¶ 1293).

The questions in the main questionnaire were clear and not leading. (RPFF ¶ 1278). The first few questions asked respondents about their perceptions of biodegradability generally. (RPFF ¶ 1294). For example, Q4 asked, "If something is biodegradable, how long do you think it would take for it to decompose or decay?" (RPFF ¶ 1295). The next set of questions asked the respondents to indicate in their own words what claims adapted from claims used by ECM mean to them. (RPFF ¶ 1295).

[122] This exclusion was justifiable on the ground that these respondents would have atypical knowledge of the issues, and therefore would not be representative of the larger population. (RX 856 (Stewart, Rep. at 19–20)).

The survey was conducted by qualified persons following proper procedures. Dr. Stewart himself personally designed the survey. (RPFF ¶ 1320). A well-known survey research agency, California Survey Research Services (CSRS), coordinated interviewing and data tabulation. (RPFF ¶ 1325). The field work for the survey cost $37,500. (RPFF ¶ 1297). In addition, the survey was pre-tested by conducting a small pilot study, which confirmed that no changes to the survey design were necessary. (RPFF ¶ 1298). The coding of the responses to the open-ended questions was carried out by experienced staff members at CSRS who were double-blinded, and the codebook used was suggested by CSRS and approved by Dr. Stewart. (RPFF ¶¶ 1257–59, 1299). The coders themselves were blind to both the sponsor and the purpose of the survey (i.e., they were double blinded). (RPFF ¶¶ 1253–59). All verbatim responses were coded independently by two coders and any disagreements were resolved in discussion. (RPFF ¶ 1257).

#### a. There Is No Evidence that Dr. Stewart Designed His Survey to Create Confusion

Complaint Counsel argues that Dr. Stewart designed his survey to create confusion. Complaint Counsel cited their proposed findings of fact ¶¶ 380–833.[123] Those findings of fact, however, with the exception of some editorial comment by Complaint Counsel, merely regurgitate the questions Dr. Stewart asked in his survey. Those findings provide no evidence at all that Dr. Stewart intended to confuse his respondents, or that Dr. Stewart actually did confuse any of his respondents. Complaint Counsel offers no evidentiary support (i.e., expert testimony

[123] Complaint Counsel's Post-Trial Brief, at 51–52.

or documents) in support of their argumentative position. Complaint Counsel did not cite any responses from Dr. Stewart's respondents showing that they were confused with any question.

Furthermore, Complaint Counsel misrepresents Dr. Stewart's testimony regarding the purpose for asking questions in the order that he did.[124] As Dr. Stewart testified at hearing upon Complaint Counsel's intimation of an intention to drive responses to the answers obtained, his questions and sequencing was specifically designed to avoid influencing responses and to invite the full spectrum of response from those who professed some knowledge of the term "biodegradation."[125]

**b. Dr. Stewart's Survey Was Both Psychographically and Demographically Representative**

Complaint Counsel argue that Dr. Stewart's "Study was psychographically and demographically unrepresentative." Complaint Counsel cited their Findings of Facts ¶¶ 400–07, 409.[126] Findings of Fact ¶¶ 400–05, however, are "intentionally left blank."[127] Therefore, ECM cannot properly respond to Complaint Counsel's conclusory argument that cited findings of fact that do not exist. However, for purposes of responding to Complaint Counsel's argument, ECM will assume that Complaint Counsel inadvertently forgot to renumber their citations in their Post-Trial Brief, and will also assume that the findings of fact citations in the Post-Trial Brief correspond to the findings of fact in Complaint Counsel's initial proposed findings of fact.[128]

[124] *Id.* at 52.
[125] Stewart, Tr. 2812–13.
[126] *Id.* at 53–54.
[127] *See* Complaint Counsel's Proposed Findings of Facts and Conclusions of Law, at ¶¶ 400–05.
[128] It appears to ECM that after Judge Chappell issued his order requiring Complaint Counsel to reformat their Proposed Findings of Fact that Complaint Counsel renumbered their proposed findings of fact, in addition to reformatting them. However, Complaint Counsel did

As for demographic representativeness, there is no evidence that Dr. Stewart's survey was not demographically representative. In fact, Dr. Stewart explained, regarding his survey, that "the data we have makes clear that we have a representative sample on key demographic characteristics …"[129] Dr. Stewart also explained that his survey, regarding demographics, was "broadly representative."[130] Dr. Stewart included screening questions that specifically allowed him to "capture information about gender and about age category which allowed [Dr. Stewart] to make a determination of the degree to which [Dr. Stewart was] representing those demographic characteristics within the survey." [131] He also used a random-digit dialing sampling "to assure a more representative sample." [132] Furthermore, it is precisely because Dr. Stewart is aware that landline surveys tend to represent older Americans that Dr. Stewart used an age-enhanced sample and also set age quotas to ensure "that each of the various age categories was well-represented in the sample."[133]

The only support for Complaint Counsel's argument that Dr. Stewart's survey was not psychographically representative is from Dr. Frederick, who stated that telephone surveys generally are "probably not psychographically representative."[134] Dr. Frederick provided no support for that opinion, nor did he tie that broad statement to Dr. Stewart's specific survey. Dr. Frederick merely speculated in an unbridled fashion about a potential for problems in a telephone survey; he did not offer any proof that, indeed, Dr. Stewart's survey suffered from the problems

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not properly revise their citations in their post-trial brief to correspond to the new numbering of their proposed findings of fact.

[129] Stewart, Tr. 2587.
[130] Stewart, Tr. 2572; *see also* Stewart, Tr. 2543 ("the sample was representative").
[131] Stewart, Tr. 2551.
[132] Stewart, Tr. 2541.
[133] Stewart, Tr. 2546, 2551.
[134] Frederick, Tr. 1391.

he theorized. Dr. Frederick gave the example that the psychographic characteristics of respondents to a telephone survey "would likely differ in their attitudes toward technology, for instance. I would expect that they would have less familiarity with, maybe less positive attitude, towards, you know, technology, cellular devices, web browsing, so forth."[135] That was it, just Dr. Frederick's unsubstantiated opinion and nothing more.

Complaint Counsel has therefore supplied no credible evidence that Dr. Stewart's survey was not psychographically representative. Furthermore, even assuming *arguendo* that psychographic differences exist between the general population and the population who partake in telephone surveys, Complaint Counsel has supplied no evidence that those differences relate in any way to views on biodegradation or biodegradable products or are in any other respect material to assessment of Dr. Stewart's survey.

Dr. Stewart explained that it was unlikely that people willing to participate for free in a telephone survey have different psychological profiles than the population of American consumers at large where data is collected "over several weeks and during all parts and all days."[136] Dr. Stewart's survey collected data over the course of approximately five weeks and during all parts of the day.[137]

### c. Complaint Counsel Mischaracterizes the Structure and Results of the Manufacturer Pilot Study

Complaint Counsel incorrectly represented that ECM defined the pool of respondents in the manufacturer pilot study and that, based on patently flawed interpretations of ASTM testing

[135] *Id.*
[136] Stewart, Tr. 2709.
[137] RX 609.

standards, Complaint Counsel is also incorrect that the manufacturer pilot study adds evidence that ECM's sophisticated plastic manufacturing customers understand biodegradation to happen within a year.[138] Regarding the structure of the manufacturer pilot study, ECM never "elected" not to run a full scale manufacturers study. Rather, "[b]ecause it was a pilot, [ECM and Dr. Stewart] set a limit of twenty hours of calling, and [they] were able to reach and talk with twenty—with ten individuals in those twenty hours."[139] In addition, ECM provided Dr. Stewart with a list of 200 customers in order to conduct the manufacturer pilot survey.[140] Complaint Counsel has provided no evidence that ECM "defined" this pool of companies at all, as opposed to providing Dr. Stewart with a complete list of all of ECM's customers with contact information available.[141]

Complaint Counsel also mischaracterizes the results of the pilot study by claiming that "3 of the 10 respondents gave either responses that they understood biodegradation as something that happens in less than a year or referenced tests that are run for less than a year."[142] The referenced tests are not ones that are confined to less than a year. In fact, ASTM D5511 "shall be run until no net gas production is noted for at least five days from both the positive control and the test substance reactors," and can theoretically be run for an indefinite amount of time, including exceeding one year.[143] Indeed, ECM customers have elected to run D5511 studies for years. (*See, e.g.*, RX 836; RX 838). As for ASTM D6400, that protocol "covers plastics and products made from plastic that are designed to be composted under aerobic conditions … to

[138] Complaint Counsel's Post-Trial Brief, at 54.
[139] Stewart, Tr. 2588.
[140] Stewart, Tr. 2637–39.
[141] Stewart, Tr. 2637–39.
[142] Complaint Counsel's Post-Trial Brief, at 54.
[143] CCX 84.

establish the requirements for labeling of materials and products, including packaging made from plastics, as 'compostable in aerobic municipal and industrial composting facilities.'"[144] So Complaint Counsel's argument here is flawed because ASTM D5511 can be run for more than one year, and ASTM D6400 is not used to assess biodegradability at all, but only compostability under active aerobic systems (which would not include landfills).

Moreover, as Dr. Stewart testified, the results of the manufacturer survey revealed that not even companies that purchase the ECM additive have a common understanding of the term "biodegradation" or common expectation as to rate of biodegradation. (RPFF ¶ 1343). The actual responses to question 6 from the customers that were surveyed reveal that their understanding of biodegradation is nuanced and guided by both the FTC's faux definition and relevant scientific standards.[145] Question 6 of Dr. Stewart's Manufacturers Survey was "how would you define biodegradability?"[146] One response said "using ASTM 6400…or ASTM D5511." Another respondent defined "biodegradable" as "something that would break down according to the ASTM 6400 standards."[147] Another answer stated that "[the] classical definition is the breakdown of the chemical components." That answer reflects the ASTM D883-12 definition of biodegradation very closely. Another customer responded that Biodegradation is "[b]ased on what resins specs dictate."[148] One customer also lamented that the definition of biodegradation is "a joke right now."[149] Therefore, the manufacturers pilot survey provides some evidence that ECM's customers, like consumers, have a nuanced definition of

[144] CCX 91.
[145] RX 849 at 5.
[146] *Id.*
[147] *Id.*
[148] *Id.*
[149] *Id.*

"biodegradation," and also that their definition is well informed by FTC guidelines and relevant scientific standards.

### 6. Dr. Stewart's Survey Confirms that Not Even a Significant Minority of End-Use Consumers Have a Single Definition of Biodegradation or Expectation as to the Rate at Which ECM Plastics Will Biodegrade

Complaint Counsel argues that Dr. Stewart's survey reveals a significant minority of consumers understand "biodegradable" to mean within one year.[150] That argument is flawed. After an assessment of all responses to his survey, Dr. Stewart concluded that there is no sound basis to find that even a significant minority of consumers share a common understating of the rate of biodegradation. (RPFF ¶¶ 1308, 1311, 1317). Critically, Dr. Stewart testified that his survey revealed no consumer awareness of ECM and not even a significant minority of consumers shared any common understanding of biodegradation. (RPFF ¶¶ 1303, 1313). Ninety-eight percent of respondents in Dr. Stewart's survey thought rate of degradation was dependent on variable environmental factors. (RPFF ¶¶ 1311). The results also made very clear that the vast majority of consumers have an understanding that the process of biodegradability is highly varied and that it is not often a rapid process. (RPFF ¶ 1333). Furthermore, 98% of respondents believe that different types of products take different amounts of time to biodegrade, decompose, or decay. (RPFF ¶¶ 1308, 1311, 1322).

Because Dr. Stewart asked multiple questions of his respondents (instead of one isolated question), he was able to develop a clearer understanding of what consumers actually think "biodegradable" means. Thus, while a certain percentage of consumers gave a temporal range

[150] Complaint Counsel's Post-Trial Brief, at 48–49.

when asked for same, those individuals also understood that the rate would necessarily depend on the kind of material and the disposal conditions. (Stewart, Tr. 2581; RX 856 (Stewart, Rep. at 26)). That clear finding shatters Complaint Counsel's blind allegiance to "rates" of biodegradation as the *sine qua non* of consumer promotional claims. Therefore, Dr. Stewart's survey and analysis demonstrate a need to fully understand *why* consumers select temporal ranges, and whether those ranges are at all significant to consumer impression of the biodegradable claims. Furthermore, the fact that some select few consumers (erroneously) believe that a plastic product can biodegrade within one year in a landfill is legally irrelevant because that impression is either (1) entirely **unreasonable** based on the science; or (2) expressly made contingent on the receipt of more information about the product and disposal conditions.

As for Dr. Stewart's questions which incorporated ECM's claims, Dr. Stewart found that a common response included a lack of understanding, expressions of confusion, expressions of skepticism or disbelief, or a simple restatement of the claim. (RPFF ¶ 1337). That lack of understanding, confusion, and skepticism make it highly unlikely that these claims would be of any material significance to an end use consumer, even if the claims were directed right at that consumer (which, of course, they were not). (RPFF ¶ 1338). In sum, Dr. Stewart's survey clarified that two of three criteria required for a finding of deception, a false belief attributable to actions of the marketer and that the claim be material to consumers, are not present in ECM's alleged advertising. (RPFF ¶ 1339).

As compared to the flawed surveys conducted by APCO, Synovate, and Dr. Frederick, when a consumer perception survey of biodegradability "is properly designed, the questions are

appropriately asked and provide a wide latitude of opportunities for response," such as Dr. Stewart's survey, "it produce[d] a different result."[151]

### 7. Complaint Counsel's Inexpert Manipulation of Dr. Stewart's Data Is Grossly Inappropriate

Complaint Counsel cherry picked and misconstrued Dr. Stewart's data to conclude that "Dr. Stewart's data establishe[d] that substantial numbers of consumer understand 'biodegradable' to mean within one year."[152] Dr. Stewart asked the question: "If something is biodegradable, how long do you think it would take for it to decompose or decay?" (RPFF ¶ 1295). Complaint Counsel, in their calculations, assert that 206 respondents gave "codeable estimates" in response to that question.[153] Complaint Counsel does not define "codeable estimates."[154] However, it appears that Complaint Counsel defines "codeable estimates" in the same or similar manner as Dr. Frederick defined "codeable responses" in his surveys—responses that offered a temporal response limited to a rate or time of biodegradation. Then, using only those responses Complaint Counsel unilaterally decided were "codeable estimates," Complaint Counsel concluded that of those "codeable estimates," 33% gave "estimates of one year or less."[155] Complaint Counsel was forced to manipulate Dr. Stewart's survey data in this manner because Complaint is aware that Dr. Stewart's survey is the only valid survey at issue in this litigation and because Complaint Counsel could not simply ignore the fact that Dr. Stewart's data, interpreted in a valid manner, obliterates Complaint Counsel's theory that any significant

[151] Stewart, Tr. 2617–18; Response to Complaint Counsel's Finding No. 261.
[152] Complaint Counsel's Post-Trial Brief, at 48–49.
[153] *Id.* at 48.
[154] *Id.*
[155] *Id.*

minority of consumers interpret "biodegradable" to mean decompose into elements found in nature within any set time frame, let alone a time frame of less than one year.[156]

Contrary to Complaint Counsel's claim that only 206 of Dr. Stewart's respondents provided "codeable estimates" in response to that question, all 400 of the respondents to Dr. Stewart's survey provided "codeable estimates," and Dr. Stewart in fact coded all 400 responses.[157] Based on an appropriate evaluation of all the data in his survey, Dr. Stewart concluded that consumers have a very nuanced understanding of biodegradability; that the process of biodegradation is one that can vary quite substantially depending on the material, the context, where the item is disposed of, and the size of the product; that the word "biodegradable" means to decay or destruct, and in general terms that the process of biodegradation is one whereby the product breaks down in some way; that there is great agreement that the amount of time something takes to degrade depends upon factors such as the material, the context, and the environment; that Americans have a shared understanding of the word "biodegradable" only to the extent that it means to break down; that Americans do not hold a shared belief as to the amount of time a biodegradable substance takes to biodegrade; that Americans recognize significant time variances in decomposition; and that there is little evidence that their understanding of the term biodegradability is restricted to decomposition processes that occur within one year or less (RPFF ¶¶ 1303–05, 1311, 1315, 1317, 1336).

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[156] This flawed and egregious method of manipulation is the same process used by Dr. Frederick to bias his survey data. *See supra* at Part I(C)(3)(d) at 42. Dr. Frederick erroneously ignored (or failed to code) all responses that did not fit neatly into his mold by including a numerical and temporal value. *Id.* That obviously would exclude reasonable answers like "it depends on the product." *Id.* Complaint Counsel's manipulation of Dr. Stewart's data is patently flawed for the same reasons discussed *supra* at Part I(c)(7) at 62. Notably, Dr. Stewart vehemently disagreed with that approach, and testified that it was improper. (Stewart, Tr. 2782–83).

[157] RX 846, at 20–21.

Unlike Complaint Counsel, Dr. Stewart appropriately analyzed all of the data acquired in response to his surveys in reaching his conclusions. One of the fundamental tenants of acceptable survey research is the requirement that the data be analyzed in accordance with accepted statistical principles. (RPFF ¶ 916). It is not appropriate to ignore certain data that is unfavorable. (RPFF ¶¶ 929, 961–63). Ignoring data is the same as not reporting it accurately. (RPFF ¶ 926). By ignoring a large portion of the data—nearly half—Complaint Counsel is misrepresenting the data. (RPFF ¶ 928). Therefore, by choosing to form conclusions based on only half of the data collected in Dr. Stewart's survey, Complaint Counsel is violating a fundamental tenant of survey research. Further, regarding the entire line of questioning during the portion of Dr. Stewart's cross-examination wherein Complaint Counsel was manipulating his data, Dr. Stewart made it clear that he had "an objection to the whole exercise,"[158] and that he "object[ed] to what [Complaint Counsel was] doing with the data," explaining that "[i]t's an inappropriate use of the data that [Dr. Stewart] collected."[159]

### D. Complaint Counsel's Reliance on "Convergence Validity" Lacks Merit under Accepted Survey Principles and the Results of the Surveys Compared Are in Fact Dissimilar

Complaint Counsel erroneously equates four pieces of disparate evidence to conclude "that between 25% and 60% of consumers believe that 'biodegradable' means 'biodegrade within one year or less.'"[160] The four pieces of evidence do not support the notion that consumers interpret the word "biodegradable" on a package to mean that the package will biodegrade within any specific time frame, let alone in a time frame of one year or less. That is

[158] Stewart, Tr. 2783.
[159] Stewart, Tr. 2782–83.
[160] Complaint Counsel's Post-Trial Brief, at 30.

because a closed-ended question, or even an open ended question, that solicits a specific **rate of biodegradation** presupposes the very response that a specific rate is sought after or appropriate, when, indeed, the appropriate investigation must first ascertain whether the consumer understands what biodegradation means and has any presumption that the process is cabined by set times. (RPFF ¶¶ 857, 860, 868–69, 1106, 1110, 1128). In short, if you ask a person in a survey to identify a rate of biodegradation, that person will likely specify a time even if, in truth, the person does not know what biodegradation means or, even if he or she does, does not have any foundation for thinking any specific time appropriate. (RPFF ¶¶ 867, 1209, 1277). Consequently, to understand what meaning actually exists, Dr. Stewart screened survey respondents to see if in fact those respondents had any understanding of what the term biodegradation meant and, only then, whether they in discussing the term construed it to mean that a set time applied. He found that consumers have no common understanding of the term biodegradation and share no common understanding as to the time it would take for plastics to biodegrade. Rather, 98% of them responded that the amount of time would vary based on the kind of plastic involved and other environmental factors. (RPFF ¶¶ 1300–03).

As discussed *supra* at Part I(C)(1) at 23, Dr. Frederick and Complaint Counsel argue that if studies flawed for different reasons reach the same conclusion, then those studies' flaws should be overlooked because of the concept Complaint Counsel refers to as "convergence validity." While Dr. Frederick testified regarding convergence validity, that testimony has no support in the peer-reviewed literature. (RPFF ¶ 192). In addition, Dr. Stewart explained in common sense terms why the concept of convergent validity as used by Dr. Frederick is invalid. (PPFF ¶¶ 968, 969). Dr. Stewart explained that if two surveys (or more) are each flawed and

reflect similar results, the similar result is just evidence that the two surveys could be flawed in the same manner. (RPFF ¶ 968–69).

Complaint Counsel, in attempting to avoid Dr. Stewart's logical explanation of convergence validity, argues that the surveys conducted by APCO, Synovate, and Dr. Frederick do not share the same flaws, but remarkably concedes that they have **different** flaws.[161] However, all three surveys do in fact have at least one flaw in common—they all compel respondents to answer with a rate or time of biodegradation, thus biasing the studies in favor of a set time in response. Both the APCO and Synovate surveys employed closed-ended questions, forcing respondents to choose from a limited set of specific time response options. (RPFF ¶¶ 1113, 1115, 1117, 1124, 1127, 1128). Both Dr. Frederick and Dr. Stewart agree that the APCO and Synovate surveys are flawed because they ask closed-ended questions which required respondents to provide a set rate or time of biodegradation. *See supra* at Part I(C)(4) at 48.

Similarly, Dr. Frederick's coding caused the open-ended questions in his survey to become closed-ended because only answers that provided a set rate or time of biodegradation were deemed worthy and thus included for analysis in Dr. Frederick's data, and when he did code that information, he funneled the responses into categories. Dr. Frederick asked about 60 single questions to about 29,000 respondents on Google Consumer Surveys, never more than one question per person.[162] Some of the questions allowed respondents to type in any answer they wanted.[163] Only a fraction of those responses, however, were actually counted in the final

[161] Complaint Counsel's Post-Trial Brief, at 32 (emphasis in original).
[162] *Id.* at P. 35; Frederick, Tr. 1059.
[163] Frederick, Tr. 1215–16 (Dr. Frederick explaining that for some of his questions, he required respondents to answer with only a numeric value).

data.[164] To decide which responses to include, Dr. Frederick adopted a "bright line rule" whereby he included respondents' answers only when those answers contained "both a numeric specification and an accompanying temporal unit."[165] The bright line rule had the effect of transforming Dr. Frederick's open-ended questions into close-ended questions, by virtue of the fact that any of the 29,000 respondents who answered without both a numeric specification and an accompanying temporal unit were not included in the final data.[166]

So, just like respondents in the APCO and Synovate surveys, only respondents who answered with a rate or time of biodegradation were included in Dr. Frederick's survey data. Therefore, the APCO Survey, Synovate Survey, and Dr. Frederick's Google Consumer Surveys all share that major flaw: each one allowed respondents to answer questions about biodegradation and biodegradability only with set rates or time of biodegradation. So, Dr. Stewart's explanation of convergence validity, that when multiple flawed surveys produce similar results those similar results likely reflect that the flawed surveys shared the same flaw, aptly described the convergence of *invalidity* occurring in Dr. Frederick's assumptive analysis of the combination of APCO, Synovate, and Frederick surveys.

Dr. Stewart's explanation of the invalidity of Dr. Frederick's convergence theory is further supported by Complaint Counsel's inappropriate use of Dr. Stewart's own survey. Complaint Counsel argues that "of 204 respondents who gave specific estimates about how long an unspecific material would take to biodegrade, 33% estimated within one year."[167] However, all 400 respondents responded to Dr. Stewart's survey, and Dr. Stewart coded all 400

[164] CCX 863 (Dr. Frederick's concatenated data demonstrating that many responses were not coded and counted in the data).

[165] Complaint Counsel's Post-Trial Brief, at 42.

[166] *See, e.g., id.* at 42–44.

[167] *Id.* at 32.

responses.[168] If he had not, and he had instead excluded large sections of relevant data (almost 50% of responses), then his survey would be similarly flawed and unreliable, and it could not become a basis for convergence analysis. By manipulating Dr. Stewart's data, Complaint Counsel is again, like in the APCO, Synovate, and Dr. Frederick surveys, only considering responses that provided a specific rate or time of biodegradation. Complaint Counsel has essentially picked out of a crowd only those responses that mesh with their case theory. Therefore, Complaint Counsel's use and interpretation of all four pieces of evidence (included Dr. Stewart's data) to demonstrate that a substantial minority of consumers interpret "biodegradable" to mean biodegrade within one year all suffer from the same flaw—they only consider responses by consumers who provided a rate or time of biodegradation, and ignore responses by consumers who does not understand "biodegradable" to be a process defined by any specific time or rate of biodegradation.

Notwithstanding the fact that Complaint Counsel's interpretation of the consumer perception evidence is flawed, Complaint Counsel is wrong when arguing that the APCO, Synovate, Dr. Frederick, and Dr. Stewart surveys all yield similar results.[169] Dr. Frederick testified in a conclusory fashion that APCO Survey and the Synovate Survey reached similar conclusions.[170] However, the APCO and Synovate surveys come to completely different conclusions. The relevant question of the APCO survey was "If a package is labeled 'biodegradable,' what should be the maximum amount of time that it should take for that package to decompose?"[171] Sixty percent of respondents to the APCO survey chose one of the

[168] RX 846, at 20–21.
[169] Complaint Counsel's Post-Trial Brief, at 31.
[170] Frederick, Tr. 1059 (stating that the results "are almost identical").
[171] CCX 860 (Frederick, Rep. at 9).

four answers—out of six total— that contained a time span of one year or less.[172] The relevant question of the Synovate Survey was "What do you believe is a reasonable amount of time for a 'biodegradable' plastic pack to decompose in a landfill?"[173] Twenty Five percent of respondents selected the answer of one year or less.[174] The 25% in the context of the Synovate Survey and 60% in the context of the APCO Survey are "not similar" in any respect. Plainly, 60% is roughly 240% higher than 25%.

Similarly, Complaint Counsel fails in its attempt to paint Dr. Stewart's and Dr. Frederick's surveys as yielding similar results. Dr. Stewart explained that the results of his survey produced "quite different results" from Dr. Frederick's Survey.[175] While Dr. Frederick concludes, based on his consumer polling, that 35% of consumers believe plastic products labeled biodegradable will biodegrade within one year,[176] Dr. Stewart concluded that consumers recognize significant time variances in decomposition, that there is little evidence that their understanding of the term biodegradability is restricted to decomposition processes that occur within one year or less, and that the vast majority of consumers have an understanding that the process of biodegradability is highly varied and that it is not often a rapid process. (RPFF ¶¶ 1333, 1336). Indeed, a whopping 98% of those surveyed thought that "there are differences in the amount of time it takes for different types of products to biodegrade, decompose, or decay."[177]

[172] *Id.*
[173] *Id.* at 11.
[174] *Id.*
[175] *See* ECM's Response to Finding No. 261.
[176] Complaint Counsel's Post-Trial Brief, at 32.
[177] RX 846, at 21.

## II. ECM'S CLAIMS ARE TRUTHFUL AND NON-MISLEADING

Concerning the scientific proof of efficacy, Complaint Counsel ignores whole categories of positive, relevant data in favor of select data points. ECM's representation that products containing its additive are biodegradable within a reasonable period of time after customary disposal is truthful and non-misleading. That representation is supported by a wealth of competent and reliable scientific testing, and confirmed by credible expert analyses which Complaint Counsel have not rebutted with credible evidence. By contrast, Complaint Counsel's various arguments that ECM's additive is not efficacious are unsupported by record evidence, are unscientific, and reflect a lack of understanding of the scientific issues and testimony. *See* Compl. Counsel's Amend. Post-Trial Br. at 54-75.

Complaint Counsel ignores the material significance of thirty-seven (37) positive tests in the record (including twenty-eight (28) gas evolution tests). Those tests, which ECM experts Dr. Burnette, Dr. Sahu, and Dr. Barlaz evaluated, were ones they consistently testified to be competent and reliable and dependent upon scientifically valid and accepted measures. Complaint Counsel's experts have inconsistently (and in conflict with themselves, RPFF ¶¶ 1353-1580 (Dr. McCarthy); RPFF ¶¶ 2707-2885 (Dr. Tolaymat)) demanded varying kinds of scientific proof other than the gas evolution tests accepted in the peer-reviewed literature as necessary and sufficient to determine if plastics are biodegradable (even accepted in that literature by Complaint Counsel's own experts outside of this litigation). (RX 756 (McCarthy's gas evolution standard); RX 164 (Michel's D5511 test); RX 906 (Tolaymat's BMP test)). Complaint Counsel's experts deviated from accepted testing norms and their own reliance outside of this litigation by demanding tests with durations beyond those commonly accepted in

the accelerated gas evolution testing, that would require individual tests to run for decades, far longer than it would take for even cancer drugs to go from concept through clinical trials and to market.[178] Complaint Counsel has cited hypothetical grounds for calling into question ECM's testing evidence, such as their reliance on the "priming effect" theory, without offering any proof of a priming effect in the test environments presented and without any peer reviewed scientific evidence to support the notion that the priming effect exists in the anaerobic environment.

Indeed, all of Complaint Counsel's posited grounds for questioning ECM testing are theoretical (not based on peer reviewed publication, any actual testing, or any scientific testing analyses) and, as discussed below, those grounds lack a reasonable basis (or defining parameters) under which this Court could responsibly rule. Instead, in an attempt to show that ECM's product is inefficacious, Complaint Counsel has relied on inconclusive studies that include no analysis of the actual causative factors responsible for a lack of biodegradation and that often appear affected by factors that call into question either the manufacture of the test plastic, the suitability of the test plastic, or the extent to which the test environment remained hospitable for microbial life and biodegradation processes. Critically, Complaint Counsel does not defend the integrity or reliability of those studies on the points in issue but instead deems them dispositive because the purported results mirror Complaint Counsel's desired outcome in this case. This Court must depend upon reliable evidence, and Complaint Counsel has offered none, certainly none that can suffice to rebut the 37 positive studies by independent laboratories, establishing that the ECM additive causes plastics properly manufactured to biodegrade.

[178] *See, e.g.*, Frequently Asked Questions, The University of Arizona Cancer Center, m azcc.arizona.edu ("[m]any standard treatments used today are the result of past clinical trials, which involve a strict and rigorous, multi-step process that takes eight years on average to complete"), *at* http://azcc.arizona.edu/patients/clinical-trials/faq (last visited Sep. 25, 2014).

In short, Complaint Counsel's scientific case against ECM is not supported by the record before this Court. Beyond the fact that Complaint Counsel's experts depend on speculation in the absence of credible evidence, those experts also suffer from obvious and profound credibility issues. They have mouthed Complaint Counsel's narrative (many times admitting to being given the language to communicate by Complaint Counsel).[179] One testified falsely and against his own peer-reviewed publication that the scientific definition of "biodegradable" was interchangeable with the definition Complaint Counsel gave the expert, which definition mirrored the one contained in the Green Guides (i.e., McCarthy, Tr. 486-87). Another testified without basis that all supportive science favoring the biodegradability of ECM's product is categorically insufficient proof yet admitted to having never performed any specific review of that science (Tolaymet, Tr. 296, 317-322). A third testified that a single per respondent question from individuals who cannot be specifically identified proves that a significant minority of consumers think biodegradable products are those that completely break down into elements in nature within one year after customary disposal yet admitted that the survey was designed without any understanding of the criteria required for a valid survey, and that study coding that must be blinded under that criteria was not blinded and was performed instead by those aware of the results desired by Complaint Counsel (Frederick, Tr. 2596-98, 2904). A fourth admitted that the sole study he relied upon to call into question ECM's 37 tests showing biodegradation involved a test plastic made by an ECM competitor (the method of manufacture and chain of custody of which was left unproven) and paid for by that competitor, which study had been published in a peer reviewed journal without disclosure of the commercial funding source,

[179] *See* Frederick, Tr. 1191-92; McCarthy, Tr. 487.

against that journal's policy, and without any scientific analysis whatsoever to determine the actual causative reason for a failure of biodegradation (Michel, Tr. 2925-28, 2939-42).

By contrast, ECM has proven by at least a preponderance of the evidence that its technology works and that its claims are truthful (proving that through testimony explaining in detail the mechanism of action, the tests performed, the reliability of the tests performed, and the detailed foundation for expert conclusions that the tests are competent and reliable proof of biodegradation).

We address each of Complaint Counsel's arguments concerning the efficacy of the ECM additive seriatim.

### A. ECM's Express and Implied Claims Are Truthful and Non-Misleading

Complaint Counsel erroneously argues that ECM's experts conceded that ECM's biodegradation claims are false. That charge is belied by the evidence of record. Complaint Counsel identified four scientific claims in their charging document, the Complaint:

- ECM plastics are biodegradable, *i.e.*, will completely break down and decompose into elements found in nature within a reasonably short period of time after customary disposal;
- ECM Plastics are biodegradable in a landfill;
- ECM Plastics are biodegradable in a stated qualified timeframe; and
- ECM Plastics have been shown to be biodegradable, biodegradable in a landfill, or biodegradable in a stated qualified timeframe under various scientific tests including, but not limited to, ASTM D5511.

**(**Complaint, Dkt. No. 9358, at 8). The evidence proves that only representations of "biodegradability" were material to the plastics manufacturers who purchased the ECM product,

not claims of rate. Moreover, the evidence fails to prove that a single consumer purchased an ECM additive containing plastic, let alone did so predicated on an ECM claim appearing on the plastic.

### 1. ECM's Experts Testified that ECM's Biodegradable Representations Are Truthful and Non-Misleading

ECM's plastic manufacturer customers were not naïve concerning their plastics propensity to break down after disposal and understood that the "rate" of biodegradation was dependent on many factors that included characteristics of the plastic itself, and the environmental conditions of disposal (which also vary tremendously from site to site, and within each site).[180]

Those perceptions are consistent with ECM's expert testimony. Drs. Barlaz and Sahu both testified that predicting "rates" of biodegradation in landfills is nearly impossible, because the rates depend on so many factors, almost all of which are beyond ECM's control. (Sahu, Tr. 1768-70; Barlaz, Tr. 2282). ECM cannot control the specifics of the plastics manufactured by customers. It cannot control or predict the amount of other additives or impurities in finished plastics. It cannot predict the final molecular weights of the plastics. (Sahu, Tr. 1828-1836, 1886; RX 855 at 27 (Sahu Rep.)). ECM manufactures additives, not plastics. (*See, e.g.*, Sinclair, Tr. 758-60). ECM infused plastics go through multiple manufacturers and sub-manufacturers before ever reaching an end-consumer or landfill site. (Sinclair, Tr. 707–08; RX

[180] *See, e.g.,* RX 681 at 61 (ECM Website capture). ECM explained on its website that "Plastics with our additive behave like sticks, branches or trunks of trees. Due to this fact, we do **not guarantee any particular time** because the time **depends on the same factors** that the biodegradation of woods and most other organic materials on earth depend—**ambient biota and other environmental conditions**." (RX 681 at 61) (emphasis added).

471). ECM cannot control the moisture content, temperature, microbial populations, location of disposal, and method of disposal for ECM-infused plastics. So when before 2012 ECM communicated to customers its 9 months to 5 year estimate, it necessarily qualified that estimate by explaining that for any particular plastic the rate of biodegradation was dependent upon the environmental conditions present at the place of ultimate disposal and the presence of biodegrading biota, both of which cannot be discerned before disposal takes place. *See, e.g.,* RX 681 at 61.

ECM's experts thus testified that the primary analysis was whether the ECM plastic is "intrinsically biodegradable," particularly in comparison to untreated plastics without the additive. (Barlaz, Tr. 2217-21; Sahu, Tr. 1848-49). ECM's experts testified that competent and reliable evidence proved that ECM plastics were intrinsically biodegradable and would biodegrade in landfills. (Barlaz, Tr. 2219; Sahu, Tr. 1752-54, 1926-27, 1943-44; *see also* Barber, Tr. 2027). Therefore, because ECM's representations about biodegradability are backed by competent and reliable scientific evidence the sufficiency of which is accepted by the three leading experts who testified for ECM, there is not a preponderance of evidence necessary to prove that the four "biodegradable" claims are legally actionable as deceptive under governing law and precedent. 16 C.F.R. § 3.43 (a) ("Counsel representing the Commission . . . shall have the burden of proof, but the proponent of any factual proposition shall be required to sustain the burden of proof with respect thereto.").

### 2. ECM's Additive, Which Is Melted into and Fused with the Base Plastic, Chemically Alters the Conventional Plastic

Complaint Counsel argues that conventional plastics are not biodegradable because they "have not been around long enough for microorganisms to develop the ability to digest them."

CC Brief at 57. Complaint Counsel further argues that the ECM plastic is a "physical blend" that "does not alter the chemical structure of the plastics" and, so, the ECM additive does not make the plastic biodegradable. Record evidence proves that Complaint Counsel's theories are wrong on both points.

First, ECM's experts presented many scientific papers discussing the biodegradability of conventional plastics. (Sahu, Tr. 1848-59; RX 855 at 24-40; Burnette, tr. 2426-29; RX 854 at 16-22). Although conventional plastics biodegrade very slowly, they still biodegrade. (RX 855 at 40).[181] The concept of accelerating that natural biodegradation through the introduction of biodegradable additives is not novel.[182] Complaint Counsel offered no support for the claim that microbes have not evolved to biodegrade plastics, aside from speculation from their experts lacking peer reviewed journal support. Dr. Sahu addressed the point, however, and cited to peer reviewed scientific literature revealing specific proof that, indeed, conventional plastics do biodegrade. The peer reviewed literature Dr. Sahu cited shows conventional plastics are biodegraded by many types of microbes in the environment. (Sahu, Tr. 1858-59; RX 855 at 24-40 (citing peer-reviewed literature)). In the end, even Complaint Counsel's expert Dr. Tolaymat conceded that, over time, every plastic biodegrades. (CCX 893 at ¶ 73 (Tolaymat Rep.) ("given enough time … anything will biodegrade") (emphasis original).

Moreover, Dr. Sahu explained that in fact microbes do evolve to biodegrade substances previously alien to them, reciting that microbes can and have evolved rapidly to digest novel substrates:

[181] Dr. McCarthy conceded that conventional plastics are biodegradable and that peer reviewed literature has shown conventional plastics to be biodegradable. (McCarthy, Tr. 573-76, 577; RX 841 (McCarthy, Dep. at 115)).

[182] *See, e.g.*, RX 854 at ¶¶ 59-61 (Burnette Rep.).

> I'll give you probably, the one that comes readily to mind is organochlorine pesticides. These are synthetic chemicals. You may have heard about DDT, for example, widely used before as an insecticide, and so on, even an antimalarial compound and not used anymore, at least in this country.
>
> But there is traces of DDT, which hasn't been around that long, the same hundred years or less, and DDT is present in the environment and routinely biodegrades. That means there are biological organisms that attack DDT and convert it to subsequent compounds and ultimately to different gases.
>
> So the point is, even synthetic compounds that are not that old, so to speak, are susceptible to biological attack quite readily.

(Sahu, Tr. 1879-81).

Second, Complaint Counsel's theory that the ECM additive does not chemically alter the conventional plastic conflicts with the scientific record, including Complaint Counsel's own expert's work. The ECM additive alters the chemical characteristics of a plastic, just as a color additive does, and just as Dr. McCarthy's own patented biodegradable technologies do. The errors in Complaint Counsel's argument are evident from an analysis of Dr. McCarthy's writings published before he was retained as a witness in this case. (RX 756; RX 928).[183] Dr. McCarthy himself has manufactured "blends" of biodegradable plastics melt-compounded with conventional plastics to create finished "biodegradable" blends that supposedly did alter the chemical characteristics of the conventional plastic (according to Dr. McCarthy). (McCarthy, Tr. 543-548; RX 928).

Dr. McCarthy inconsistently argues in this case that "copolymers" and blends (like his technology) are chemically altered materials, while plastics blended with ECM additives are simply independent "physical" mixtures of two materials. (McCarthy, Tr. at 387). Dr. McCarthy testified that the ECM additive would not alter the chemical characteristics of the

[183] Complaint Counsel relied on Dr. McCarthy's opinion as the sole support for the point that ECM's additive "does not alter the chemical characteristics" of the plastics.

conventional plastic unlike his "co-polymer" technology identified in his '199 Patent, which he claimed was fully biodegradable. (RX 928; RX 756). But Dr. McCarthy also described in his '199 Patent how he created those "blends" relying on the exact same manufacturing processes used when introducing ECM additives into plastics. (RX 928 at column 6). Dr. McCarthy does not employ some complex or sophisticated manufacturing or chemical process to create a chemically altered product. Rather, he simply melts a biodegradable component with a conventional plastic, just as ECM's manufacturers do. According to Dr. McCarthy in sworn statements made to the USPTO:

> **Standard melt processing equipment and processing conditions can be used to prepare the new blends.** Examples of polymer melt processing equipment that can be used to make the new blends include melt mixers (Banbury mixer), blenders, **extruders for sheet, film, profile and blown-film extrusion**, vulcanizers, calenders, and spinnerets for fiber spinning, molding, and foaming.

(RX 928 at column 6) (emphasis added). In that section, Dr. McCarthy described the method by which one makes a "biodegradable blend" involving a conventional plastic with a biodegradable component, whereby the blending process alters the chemical characteristics of the plastic (and that process is exactly the same manufacturing process ECM's customers use). (RX 928; RX 756; Sahu, Tr. 1813-17). In other words, Dr. McCarthy melts the two ingredients together using the same type of equipment that ECM uses, and from that he gets a chemically altered biodegradable plastic.[184]

[184] While testifying at the hearing Dr. McCarthy claimed that "blends" of polycaprolactone (PCL) based materials would not be biodegradable because the PCL is not "miscible" with conventional plastics. (McCarthy, Tr. 409-411). Dr. McCarthy appears to acknowledge that an "immiscible" blend is good for biodegradation, he concedes that the ECM additive would form an "immiscible" blend, but then he somehow posits a completely unsupported theory that an immiscible blend of the ECM additive would leave the additive completely concentrated at the surface. It is important to note that this theory is contradicted in the peer-reviewed literature, and not supported in Dr. McCarthy's own testimony. Dr. McCarthy

Complaint Counsel (or Dr. McCarthy) never explained, nor could he rationally, why a plastic that **was** a chemically altered composition would be created through certain manufacturing processes used by Dr. McCarthy to make his blends, but not when the ECM additive is similarly melt compounded into a plastic using the identical manufacturing methods. Like Dr. McCarthy's "invention," the ECM additive is a biodegradable component that is melted together and then fused with the conventional plastic at high temperatures using "standard melt processing equipment and processing conditions" including, e.g., "extruders for sheet, film, profile and blown-film extrusion." (*c.f.* RX 928 at column 6, *with* Sahu, Tr. 1813). According to Dr. McCarthy's own work, therefore, the ECM additive would necessarily alter the chemical structure of the plastic through melt compounding, which is obviously a denaturing process.

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failed to fully explain his testimony in that regard, and he failed to mention that he had authored a contradictory paper in 1997 wherein he specifically addressed the "reactive compatabilization of **biodegradable blends** of poly(lactic acid) and **poly(e-caprolactone)**." *See* RX 944 (emphasis added). In that paper, Dr. McCarthy discussed the performance of physical and reactive blends of PLA/PCL with various PCL concentrations. (RX 944 at 162). In Figure 13 (RX 944 at 168), Dr. McCarthy shows that the so-called "physical" blend of PLA and PCL was enzymatically biodegradable, which means that Dr. McCarthy's theory on "physical" blends is again contradicted by his own work, even assuming that theory had validity.

Furthermore, the peer-reviewed literature has also rejected Dr. McCarthy's theory, as scientists have explained that "blending" is a common and acceptable means to make a biodegradable product: "[c]ompared to copolymerization method, blending may be a much easier and faster way to achieve the desired properties." (RX 932 at 3731) (Tokiwa, Y., et al., "Biodegradability of Plastics," *Int. J. Mol. Sci*. 2009, 10, 3722-3742)). Tokiwa, et al., explain that the "formation of miscible blends especially with non-biodegradable polymers can slow down or even inhibit the degradation of the biodegradable components," meaning that immiscibility is preferable, and immiscible blends are biodegradable. (RX 932 at 3731). Again, Dr. McCarthy's testimony does not match his own work and the work of other scientists who published in the peer-review. *See also* RX 940 (McCarthy, S, "Advances in Properties and Biodegradability of Co-Continuous, **Immiscible**, Biodegradable, Polymer Blends") (emphasis added)); RX 925 at 647-48, Gisha, E & Pillai, C.K, "Biodegradable Polymers—A Review on Recent Trends and Emerging Perspectives" (discussing production of "biodegradable polymer blends," including polyethylene materials, through the addition of materials like PCL).

When the ECM additive is melted into the plastic, it necessarily alters the structure of the plastic, as Dr. Burnette opined in his testimony: "When the ECM additive is added to the plastics mixture, you perturb the plastics mixture, not necessarily in a way that violates the integrity or the quality of the product, but as I explained earlier, enzymes look for points of weakness… If there is a way to take a bond that is already favorable, it would be to further reduce that bond strength." (Burnette, Tr. 2436; RX 854 at ¶¶ 45, 57, 59 (Burnett Rep.)). Dr. Sahu explained that the ECM additive is uniformly melted throughout the plastic, and it becomes part of the entire plastic matrix. (Sahu, Tr. 1813-14). The blended plastic is one homogenous, new material. *See, e.g.*, RX 756 at column 6 (describing manufacturing methods to make a blended polymer); Burnette, Tr. 2436; Sahu, Tr. 1813-14. As Dr. Sahu explained, the additive:

> goes into the blend uniformly no matter whether it has got a high or low [weight] distribution. It is just that it will be present along with this varying chain lengths of original polymers that were there in the plastic and as they have cooled down and formed these crystalline and amorphous regions.

(Sahu, Tr. 1814).

Dr. Sahu explained that the process of "blending" the additive with the plastic resin involves heat blending so that the two components become one:

> [S]o the carrier is melting, the additive is melting, and then they are literally mixed together. They're compounded. And then the melt as it's cooling is then further processed to make the article, in this case the bag or whatever, whatever article is going to be made from that compounded melt basically, subject to thermal action.

(Sahu, Tr. 1816).

Dr. Sahu compared the ECM additive to colorants, which are usually introduced into plastics at a 0.5 to 2% load rating (just like the ECM additive). (Sahu, Tr. 1818-19). Thus, aside from the fact that Dr. McCarthy's own writings say that the plastic is chemically altered by this manufacturing process (RX 756 at column 6), a new plastic material is indeed created by the heat

blending of the additive with the plastic resin. Consider a colored plastic product that might be in one's home (e.g., a red water bottle, a blue plastic coffee mug, a black plastic television), and ask whether those products look like two separate components (i.e., a plastic and a distinct color additive), or whether they look like one uniform material. Even when those plastics are cut into pieces, the plastic remains one uniform color inside. That is also how the ECM additive is dispersed within the plastic; the additive becomes one with the plastic, and it is uniform throughout.[185]

Complaint Counsel's position thus rests on a false premise, revealing in part the erroneous further foundation for Complaint Counsel's rejection of the many tests that show the ECM additive is efficacious. *See, e.g.*, RX 248; RX 254; RX 263; RX 265; RX 266; RX 268; RX 273; RX 276; RX 392; RX 393; RX 394; RX 395; RX 396; RX 398; RX 399; RX 401; RX 403; RX 402; RX 405; RX 465; RX 467; RX 468; RX 836; RX 838; RX 839; CCX 534; CCX 546; CCX 547; CCX 548; CCX 952. Complaint Counsel has erroneously argued that the ECM additive is a separate component of the plastic that can be excised or eaten from the plastic as an individual component without affecting the plastic, which is an unsupported and invalid premise.

Complaint Counsel is incorrect that the mechanism of action for the ECM additive is not defined. Drs. Sahu and Burnette explained the mechanism of action in detail: that the ECM additive, when melted uniformly throughout the plastic, creates weak points in the conventional plastic that can be broken down by enzymatic digestion, identifying the precise kinds of microbial life, microbial colony formation on plastic (so-called biofilms) and enzymes

[185] Note that the ECM additive is melted into the plastic at the same load rates as most color additives would be. (Sahu, Tr. 1818-19). So looking at a piece of colored plastic is a reasonable means to project the way in which the ECM additive is dispersed throughout the final plastic (assuming the final plastic is manufactured properly).

responsible for that degradation. (Sahu, Tr. 1866-67; RX 855 at 27; Burnette, Tr. 2435-37). The ECM additive serves as an attractant that helps bacteria develop, mature, reproduce, and thus metabolize the additive along with the conventional plastic into which the additive is integrated. (Burnette, Tr. 2435-37; Sahu, Tr. 1810-11, 1853, 55). The presence of biofilms on the plastic surface helps facilitate that process, and food sources in the ECM additive promote biofilm formation and development. (Sahu, Tr. 1863-64; RX 855 at 27). The biological digestion of the substrate (plastic and additive) continues indefinitely as the biota slowly peel back layers of plastic and continue to find the ECM additive which is melted throughout the plastic material. (RX 855 at 27-28; Sahu, Tr. 1863-65). Indeed, because the additive appears throughout the plastic (and not just on the surface), the plastic is completely biodegradable, and biodegradation of the plastic substrate would continue until completion. (Sahu, Tr. 1864-65).

ECM's expert opinions were supported by evidence in the peer-reviewed literature. For instance, Gisha and Pillai (2011) explained that the "insertion of weak links" into a polyethylene polymer would promote biodegradability. (RX 925 at 647-49).[186] Tokiwa, et al. explained in 2009 that PCL-based materials are readily biodegradable. (RX 932 at 3727) (Tokiwa, Y., et al., "Biodegradability of Plastics," *Int. J. Mol. Sci*. 2009, 10, 3722-3742)). By reference to the body of scientific literature, Tokiwa, Y., et al., specifically addressed polycaprolactone (PCL) blends and explained that "blends of PCL and LDPE [and others] retained the high biodegradability of PCL" after blending. (RX 932 at 3731). Here, again, the authors explained that "it seems that the higher the miscibilitiy of PCL and conventional plastics, the harder the degradation of PCL on their blends" by certain microbes. (RX 932 at 3731). The manufacture of immiscible

[186] Note well that the Gish and Pillai 2011 article was published in a journal that Dr. McCarthy edited and reviewed. (McCarthy, Tr. 511-12).

biodegradable blends is therefore well-supported by the peer-reviewed literature (including Dr. McCarthy's own work), and theories of viscosity or surface effect are not relevant or discussed as a viable concern.[187]

### 3. Tests Prove That ECM's Additive Creates Biodegradable Plastics, and Complaint Counsel Has Not Rebutted that Evidence

Complaint Counsel argued that "tests show no biodegradation of ECM plastic." CC Amend. Post-Trial Br. at 59. That argument is contradicted by a very large volume of documentary and testimonial evidence in the record. *See, e.g.,* RPFF ¶¶ 1964-2009, 2129-2706. Dr. Morton Barlaz, a recognized authority in the field of biodegradation and waste decomposition, testified that the tests of record prove conclusively that plastics manufactured with the ECM additive were anaerobically biodegradable. (Barlaz, Tr. 2246-65; RX 968 (Dr. Barlaz's sample statistics)). He did not equivocate, qualify, or otherwise refrain from delivering that direct opinion. (Barlaz, Tr. 2166-2346). Indeed, Dr. Barlaz calculated the maximum amount of biodegradation that could theoretically be sourced from the ECM additive alone. (Barlaz, Tr. 2253-55). He compared that theoretical yield to the amount of biodegradation recorded in the various laboratory tests. (Barlaz, Tr. 2256-57; RX 968). He proved that the amount of biodegradation was far more than anything the additive could have produced independently (including any so-called "priming effect," which remains an unsupported theory). (Barlaz, Tr. 2265). He and ECM's other experts testified that the overwhelming majority of tests in the record proved (note that word proved, not suggested or indicated) that ECM plastics were

[187] In ECM's positive gas evolution tests, presence of biodegradation far in excess of the ECM additive is further proof that a so-called "surface effect" is not supported by the test data.

anaerobically biodegradable. (Barlaz, Tr. 2264-65; Sahu, Tr. 1752; Burnette, Tr. 2373). The testimony is strong, presented without reservation.

None of Complaint Counsel's experts looked at the data from the tests in the record. (Tolaymat, Tr. 316-17, 320-21; McCarthy, Tr. 654; Michel, Tr. 2966). None of Complaint Counsel's witnesses performed statistical analyses to determine the amount of biodegradation that could be attributed to the additive alone (a crucial fact necessary to understanding the scientific testing). Dr. Tolaymat conceded that Dr. Barlaz's methodology was scientifically sound and appropriate. (Tolaymat, Tr. 304-08). Dr. Tolaymet never evaluated Dr. Barlaz's statistical analyses, and never contradicted Dr. Barlaz's opinion on the testing. (Tolaymat, Tr. 316-21). None of Complaint Counsel's witnesses did. (Tolaymat, Tr. 316-17, 320-21; McCarthy, Tr. 654; Michel, Tr. 2966). Instead, Drs. McCarthy and Tolaymat excluded entire categories of testing on the basis that they did not perfectly match the landfill environment. (Tolaymat, Tr. 243; CCX 891 at 15 (McCarthy Rep.)). That decision to ignore gas evolution testing is not consistent with generally accepted science, which science favors accelerated gas evolution testing as predictive of biodegradation of plastics in landfills. (Sahu, Tr. 1924 (explaining that accelerated testing is generally accepted); Tolaymat, Tr. 244 (conceding that accelerated testing is appropriate)). Indeed, Dr. McCarthy's own peer-reviewed science outside of this litigation relies upon gas evolution testing as predictive of biodegradation, including in landfills; to be sure, the '199 patent for a biodegradable plastic that he swore an oath to before the United States Patent and Trademark Office stands for that same proposition (because it too rests the claim of biodegradation on gas evolution testing). (RX 756).

Dr. Barlaz was "surprised" by Complaint Counsel's experts' categorical rejection of gas evolution testing on the basis that it did not perfectly match the landfill environment, and thought

the position scientifically disingenuous. (Barlaz, Tr. 2247). Dr. Michel, Complaint Counsel's rebuttal witness, never reviewed the studies at all. (Michel, Tr. 2965–66; CCX 895 (Michel, Rebuttal Rep.)). He based his entire opinion of the ECM additive on the one test he performed, ignoring the totality of the scientific evidence, including more the 37 other tests in the record that support ECM's claims. (Michel, Tr. 2965–66; CCX 895 (Michel, Rebuttal Rep.)).

Instead of having its experts perform a proper review of the record and address directly the conflicting testimony of ECM's experts, Complaint Counsel selectively cited portions of Dr. Barlaz's testimony out of context, and in ways that misconstrue Dr. Barlaz's entire scientific opinion. *See* CC Amend. Post-Trial Br. at 59-60. Complaint Counsel went so far as to write that "Dr. Barlaz's report offers no opinion on the biodegradability of ECM's Plastics." *Id.* at 60. The statement is false; Dr. Barlaz's report did discuss his review of the scientific testing. *See* RX 853 at 14. He explained his opinion directly to Complaint Counsel. (CCX 943 (Barlaz, Dep. at 136-41)). And, of course, he testified during the hearing that competent and reliable scientific evidence proved ECM plastics were biodegradable. (Barlaz, Tr. 2241-65; RX 968). Put simply, Complaint Counsel has no tenable response to Dr. Barlaz's direct testimony, and they attempt none in their briefing or proposed findings, preferring instead to deny that Dr. Barlaz even stated what he did:

> I went back to the data and tried to summarize some, not all of it, but some of it and looked at the data on methane generation from the test substrate and methane generation from the inoculum that would be the background methane.
>
> In tests—in lab reports where the triplicate data was reported—were reported—excuse me—I could calculate a—I could perform a T-test, which is a statistical test, to answer whether there was a statistically significant difference between the methane generation in the reactor with the test substrate and the methane attributable to the inoculum alone. And in many cases I found that their results were significant, and that would suggest that there was anaerobic biodegradability.

(Barlaz, Tr. 2247-48; RX 968 (memorializing Dr. Barlaz's statistical analyses). Dr. Barlaz also calculated the amount of methane that could possibly have been attributed to the additive:

> What I did then … is calculate the volume of methane in milliliters per gram of additive. And I calculated with my assumptions you would get 933.3 milliliters of methane per gram of carbon…
>
> And of course what I could do then is say okay, that means that if you had a gram of additive … [w]hat I did with that was then, you know, look at the methane yield from the inoculum and the mass—excuse me—the methane yield from the substrate and the mass of additive sued to say, look, you know, if 900 ml of that was attributable to the additive, is there still evidence of biodegradation.

(Barlaz, Tr. 2252-54; RX 968 (displaying Dr. Barlaz's calculation for the methane content of the ECM additive in the "summary" spreadsheet tab). Dr. Barlaz also calculated the total amount of methane production possible from the ECM additive using Dr. McCarthy's own projections, and found that using Dr. McCarthy's own assessment of the additive, the test results would actually have been more persuasive than Dr. Barlaz's original calculations would suggest. (Barlaz, Tr. 2254-55). Dr. Barlaz clearly explained the mathematical calculations that prove convincingly that the biodegradation observed in test reactors came from the *plastic* and not the additive. (Barlaz, Tr. 2254-58; RX 968 (at the "summary" spreadsheet).

#### 4. The Few Tests Relied on by Complaint Counsel Are Inconclusive and Fail to Prove Causality

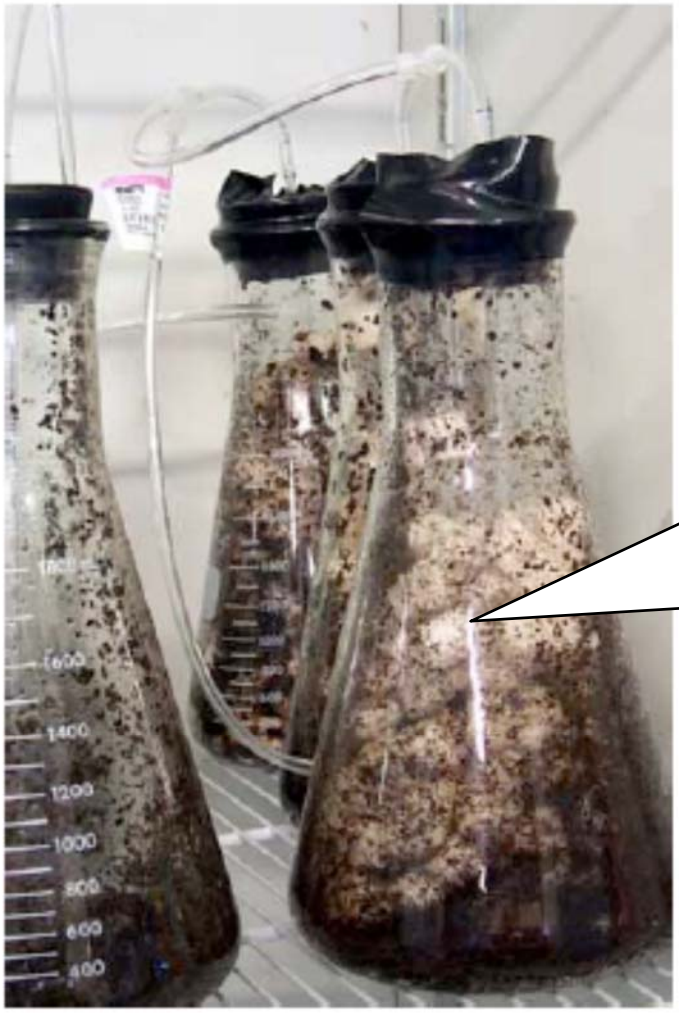
Complaint Counsel next tries to discredit the ECM technology by referencing a select few inconclusive (but not negative) tests (out of a body of at least 52 tests relevant to this case). *See* CC Amend. Post-Trial Br. at 61. ECM's experts testified that many variables could influence the outcome of a gas evolution test, and that an inconclusive test is expected in light of them and must be examined and assessed to determine what, if anything, those tests reveal,

particularly in the presence of so many favorable tests that prove the ECM technology works. (Sahu, Tr. 1938-39; Barlaz, Tr. 2272-73; Burnette, Tr. 2443). The tests Complaint Counsel cited support that expert testimony, because none of them includes an evaluation of the actual cause for the failure of biodegradation and most of them have flaws.[188] The flaws in those studies, ironically, were far more substantial than any of the immaterial and specious criticisms Complaint Counsel launched against ECM's laboratory tests.[189] Consider the tests that Complaint Counsel relied on to argue that the ECM additive is inefficacious. At least three of those tests are actually "invalid" under the D5511 standard because evidence reveals that the test environments were insufficient to test biodegradation (i.e., the positive control did not reach 70% within the allocated period of time).[190] Several tests failed to report essential information about the plastic or the methane production in the anaerobic test environment.[191] Several tests showed negative biodegradation in the test sample, revealing a high likelihood that the plastic contained components inhibitory to biodegradation (which the testing laboratories recognized).[192] Other tests used equipment and test designs that made accurate testing nearly impossible (including failure to even contact the test plastics with the inoculum).[193] So while Complaint Counsel categorically dismisses every single ECM study, they deemed adequate the following studies:

[188] *See, e.g.* CCX-174-CCX-176; CCX-156; CCX-157; CCX-163; CCX-169-CCX-171; *see also* ECM's Responses to Complaint Counsel's Proposed Findings of Fact No. 174.
[189] *See* ECM's Responses to Complaint Counsel's Proposed Findings of Fact No. 174.
[190] *See* CCX 174; CCX 175; CCX 157.
[191] *See* CCX 174; CCX 175; CCX 176; CCX 170; CCX 171.
[192] *See, e.g.,* CCX 171 (showing -4.4% biodegradation); CCX 156; CCX 164.
[193] *See* CCX 174.

CCX 174; Stevens Ecology, 2008 Test of FP International's Loose Fill Product (Invalid Test):

Complaint Counsel cited this 2008 laboratory test as evidence that the ECM product did not perform in a gas evolution test. At the outset, to the extent the laboratory claimed to follow the D5511 test protocol, the test is not a valid test under the standard. The D5511 standard specifically says that "[f]or the test to be considered **valid**, the positive control must achieve 70% biodegradation within 30 days." (CCX 84 at 3 ¶ 11.2.1.1) (emphasis added). That requirement is to ensure that the test environment is viable enough to actually measure biodegradation. None of the test procedures in CCX 174 produced the 70% value within the 30 day period and, so, by letter of the standard the tests are invalid. Furthermore, it is obvious to the naked eye why those tests reported little biodegradation. Consider the test environment as pictured by the laboratory on page 9 of CCX 174 (aerobic test):




Observe the test plastic foam peanuts are not even touching the inoculum and, therefore, almost all of the test plastic is not exposed to biota. (CCX 174 at 9).

Figure 2. Thermophilic Composting Apparatus

The image clearly shows that the test materials are not even contacting the inoculum that contains the microbes responsible for biodegrading material. The laboratory recognized that problem, and decided to remedy that major design error by simply shaking the vessels every now and then:

> [T]his arrangement introduced a potential difficulty, **since most of the test material in treatments T was not in contact with the compost inoculum**. To alleviate this, and to ensure even aeration, the vessels were physically agitated each day.

(CCX 174 at 9) (emphasis added).

Neither Complaint Counsel nor their experts attempted to explain how this type of test could be valid when the inoculum is not even in continuous contact with the test material, and whatever contact occurs is constantly broken by agitating the test material. In fact, Complaint Counsel's witnesses gave no testimony at all concerning these tests on which Complaint Counsel now relies. Note well, however, that this obvious design error did not stop Complaint Counsel from relying on the test as evidence against ECM, even though Complaint Counsel simultaneously ignored dozens of positive ECM gas evolution tests that were conducted reasonably and competently, according to ECM's experts (Sahu, Tr. 1895-96, 1926-27; Barlaz, Tr. 2219; Burnette, Tr. 2373; *cf.* Tolaymat, Tr. 295 (rejecting ECM studies "no matter how well conducted")).

Finally, as with almost all of the tests that Complaint Counsel relied on to suggest that the Additive does not work (and unlike many of the ECM gas evolution tests in the record), the laboratories never reported critical information such as the total methane produced in the various test reactors. *See generally* CCX 174. Because methane is the primary endpoint in assessing biodegradation during anaerobic tests, the absence of that information makes any analysis of the test impossible. ECM cannot determine, for example, and Complaint Counsel cannot rule out, whether negative test results are owed to one of the three triplicate test vessels failing, which would downward bias the other two test vessels which might have showed substantial evidence of biodegradation.[194]

[194] The gas evolution tests are run in triplicates, and the amount of biodegradation is ordinarily calculated based on an average of the three test vessels. (Tolaymat, Tr. 300-303).

CCX 175; Stevens Ecology 2008 Biodegradation Testing of Plastic Film Product (Invalid Test):

As with CCX 174, this Stevens Ecology anaerobic testing failed to reach 70% biodegradation of the positive control within 30 days and, so, the test is considered invalid under the D5511 test protocol. (CCX 84 at 3 ¶ 11.2.1.1). The laboratory also never reported total methane production from the vessels, nor provided methane reports as a percentage of total gas, making an assessment of the biodegradation results impossible. *See generally* CCX 175. The laboratory did not provide the final data showing the numbers for total gas, and reported no data (statistics, totals, anything) for the anaerobic testing. (CCX 175 at 15-19). Moreover, the laboratory designed and used the following contraption to measure gas totals:

Figure 7. Gas volume totalizers.

Makeshift "gas totalizers" apparently manufactured out of PVC tubing are evidently not even of the same size. There is no evidence that the contraptions are validated or proven effective/accurate. (CCX 175 at 17).

(CCX 175 at 17). There is no evidence or discussion in the record supporting the competence or accuracy of this testing method, how this system works, or how the laboratory could calibrate

same.[195] The use of this collection system is definitely not permitted by the ASTM D5511 standard. (CCX 84; RX 356). Recall that Complaint Counsel's expert, Dr. Tolaymat, criticized ECM's tests because the laboratories had used a graduated cylinder to record gas totals. (Tolaymat, Tr. 206). Dr. Tolaymat considered that practice imprecise, and rejected ECM studies as a result, even though the ASTM D5511 standard itself calls for the use of a graduated cylinder for that purpose. (Tolaymat, Tr. 206; CCX 84 at 2 ¶ 6.1 (requiring the use of an "inverted graduated cylinder or plastic column")). Complaint Counsel also criticized Northeast Laboratories' use of metal canisters during biodegradation testing instead of glass vessels. (CCX 891 at 34). ECM put fact witnesses forward (NE Labs) to describe the use of metal canisters, and ECM's experts testified that the canisters were acceptable and did not affect the data. Complaint Counsel, by contrast, makes no attempt to explain or justify the use of Stevens Ecology's makeshift "gas totalizers," or explain whether those devices are generally accepted in the scientific field to yield accurate results. Complaint Counsel does, however, rely on the questionable Stevens Ecology test as evidence that ECM's product does not work.

CCX 156; Collection of Emails between Non-Parties (Incomplete Document):

This so-called "test" of an ECM product is actually just a series of email reports sent between OWS Labs and a nonparty. The piecemeal reports submitted through email do not disclose the methane content of the test vessels or the triplicate data. (CCX 156). Note, however, that the laboratory reports a negative amount of biodegradation in the test vessel over

[195] The makeshift plastic columns do not even appear to be a uniform length in the picture.

the short duration test. (CCX 156 at OWS001640). In other words, the test article actually inhibited biodegradation when compared with the blank and the positive control.

That data, if accurate, proves that ECM's experts are correctly concerned with manufacturing issues inherent in the test plastics, or the formula of the test plastic itself. *See, e.g.,* Sahu, Tr. 1815-17, 1931-39; Sinclair, Tr. 761-64. Dr. Sahu, for example, explained that plastics sometimes include impurities or components that are antimicrobial. (Sahu, Tr. 1828-30, 1835-36). There is no record evidence to rule out this concern in the case of the OWS laboratory reports cited by Complaint Counsel.

Complaint Counsel has conceded that the ECM additive is biodegradable. *See, e.g.,* CCX 891 at 24. In fact, Complaint Counsel suggested (erroneously) that positive data from ECM tests is simply owed to the ECM additive biodegrading and nothing else. *See* Complaint Counsel's Amended Post Trial Brief at 1 ("the ECM additive is itself biodegradable"). Even assuming, *arguendo,* that Complaint Counsel is correct and biodegradation in positive tests comes only from the additive (which Dr. Barlaz conclusively disproved when he showed that the amount of biodegradation present in the many positive tests he reviewed must have come from the plastic and not the additive), a laboratory should expect to see the ECM additive biodegrade in every test involving an ECM additive. If the laboratory records negative amounts of biodegradation showing that the test article inhibited biological activity, that data strongly suggests at the very least that (a) the ECM additive was not present in the test plastic (Sinclair, Tr. 787-790); (b) the test plastic contained other components that are antimicrobial or inhibitory of biodegradation (Sahu, Tr. 1828-30, 1835-36); (c) the ECM additive was not properly manufactured in the test article, either due to burning or scorching (Sinclair, Tr. 762, 787-790; Sahu, Tr. 1815); or (d) the lab environments for the various test plastics were not biologically conducive to biodegradation

testing (Barlaz, Tr. 2274; Burnette, Tr. 2388-90). Without at least exploring those possibilities, let alone proving an actual cause for the lack of biodegradation, a result of the kind seen in CCX 156 is inconclusive and highly suspect. For good reason, ECM's experts explained that these inconclusive tests do not outweigh the many positive tests in the record. (Sahu, Tr. 1938-39; Burnette, Tr. 2442; Barlaz, Tr. 2272-73).

Complaint Counsel presented no fact witness testimony whatsoever either at the hearing or through depositions concerning this and other similar studies. Thus, without any sponsoring witness, the significant flaws and questions with these inconclusive tests have been left unaddressed.

CCX 157; OWS 2010 Biodegradation Test for Covidien (Invalid Test):

As with other tests discussed here, the OWS test marked CCX 157 is not a "valid" test under the D5511 standard because the test environment plateaued prematurely, demonstrating that the environment was not competent to permit assessment of biodegradability. (CCX 157 at ECM114737). The test never reached the minimum 70% biodegradation for the positive control, as required by the test standard. (CCX 84 at 3 ¶ 11.2.1.1; RX 356 (same)). Furthermore, the test environment ostensibly plateaued, even for the cellulose control, around the sixth day of testing, which strongly suggests that the test was not conducive to protracted biodegradability testing. (Burnette, Tr. 2401-02, 2412-13, 2442-43; Barlaz, Tr. 2272-73). Nonetheless, even despite those evident flaws, the ECM test article revealed 3.9% biodegradation within the very short window where the test environment was biologically active. (CCX 157 at ECM114737). That percentage of biodegradation is consistent with ECM's other favorable tests that eventually revealed substantial, consistent, and ongoing biodegradation of the test sample when the

environment remained viable over time. (*See, e.g.*, RX 838). Finally, the test reported as CCX 157 included none of the data necessary to evaluate the tests themselves. The laboratory included no data concerning the methane production in the anaerobic test, except to characterize the methane composition as a total percentage. (CCX 157 at ECM114737-39). The laboratory provided no gas readings or triplicate data. There is no information as to the nature of the plastic or the load rating of the ECM additive.

Complaint Counsel presented no fact witness testimony, either at the hearing or through depositions, concerning this and any other matter at issue. Thus, without any sponsoring witness, the significant flaws and questions with these documents remain unanswered and prevent the court from finding the information reliable.

CCX 163; OWS 2009 Biodegradation Test for Masternet:

This test demonstrated a biodegradation of -3.7% in the test article, meaning that the test plastic inhibited biodegradation. ECM reiterates and restates the same concerns with this OWS test as with the others cited and relied on by Complaint Counsel. Note, however, that this test serves a critical purpose because, as with other tests discussed here, **it validates expert opinion concerning the need to investigate inconclusive testing**. (Burnette, Tr. 2442; Sahu, Tr. 1938-39). ECM's experts testified that many variables can influence an inconclusive test. (Burnette, Tr. 2442; Sahu, Tr. 1938-39). Dr. Sahu explained that many plastics can contain additives (e.g., colorants), impurities, or manufacturing errors (e.g., scorching of the additive) that, unbeknownst to the manufacturer, might negate the effect of the ECM additive. (Sahu, Tr. 1828-1836, 1938-39). The presence of those impurities and additives is more likely in the type of low-grade plastics that ECM customers would use to create products like garbage bags and other items

intended for disposal (when compared with, e.g., medical devices and other plastics applications that demand higher grade materials). (Sahu, Tr. 1878-79). This study (CCX 164) shows that the test plastic actually inhibited the biological activity in the test vessel. The study authors specifically observed:

> The biodegradation percentage was slightly negative, this is because the background activity in the test reactors was slightly less than in the test reactors. **This could point to some kind of inhibition**, but probably not a severe toxicity.

(CCX 164 at ECM113623) (emphasis added). Note that OWS did not include a negative control in its tests and, so, it is impossible to determine whether that inhibitory effect was also observed in an untreated plastic. (*See generally* CCX 164). These flaws eliminate this test as a sufficiently reliable basis upon which the Court can depend. Moreover, like the other tests, even if credited, the results are merely inconclusive and not proof that the ECM additive containing plastic is not biodegradable. Evidence of that kind requires a scientific evaluation to determine the actual cause of the absence of biodegradation in the test, which evaluation was not performed in any of the tests relied on by Complaint Counsel.

CCX 169; OWS Letter to Gary Hellinger:

ECM objects to the use of this document as evidence against ECM. Certainly, the document is not a "test" as described by Complaint Counsel in their brief at Page 61 and, so, the use of this document and its description is misleading and improper. The document marked CCX 169 is a review of several other test documents and materials provided to OWS Labs by Gary Hellinger of Gary Plastic Packaging Corp, a nonparty. (CCX 169). The document states on the first page that it is a "review of the several documents, reports and statements on biodegradation of ECM MasterBatch pellets." (CCX 169 at 1). The document does not include

any original test data considered by OWS, nor does it include any of the statements and marketing materials relied on by OWS in its review letter. (CCX 169). The document is not Bates numbered and, so, the origins of the actual exhibit are uncertain. Moreover, Complaint Counsel presented no testimony (either at the hearing or through depositions) from a sponsoring witness that could explain the contents of this document. The document is therefore unreliable hearsay, and should be treated as such by the Court.

CCX 170; 2007 Aerobic Biodegradation Test of Plastic Bag Under Composting Conditions:

As with many of the other inconclusive (but not provably negative) tests relied on by Complaint Counsel in its brief, no testimony is presented from fact witnesses or experts concerning the contents of the document. The study authors provided no data from the study that would be necessary to verify the testing method used or determine the amount of biodegradation recorded in the study. (CCX 170). For example, unlike ECM's supportive gas evolution tests, this OWS test did not report total gas volume data, provide percentages of carbon dioxide, or provide information concerning the calculation of the theoretical gas yields from the sample. (CCX 170). OWS reported no information concerning the test plastic itself, including, for example, the load rating of the ECM additive, or if the ECM additive was even involved. (CCX 170). Nothing in the test report identifies the ECM additive. Put simply, Complaint Counsel had the burden to support its documentary record with competent supportive testimony or, at the very least, a more robust recitation of facts, particularly where the documents have major information gaps. They have failed to do so.

More significantly, however, is Complaint Counsel's attempt to discredit ECM tests by relying on inconclusive tests that not only fail to identify and evaluate the actual cause of test failure but also suffer from serious methodological flaws.

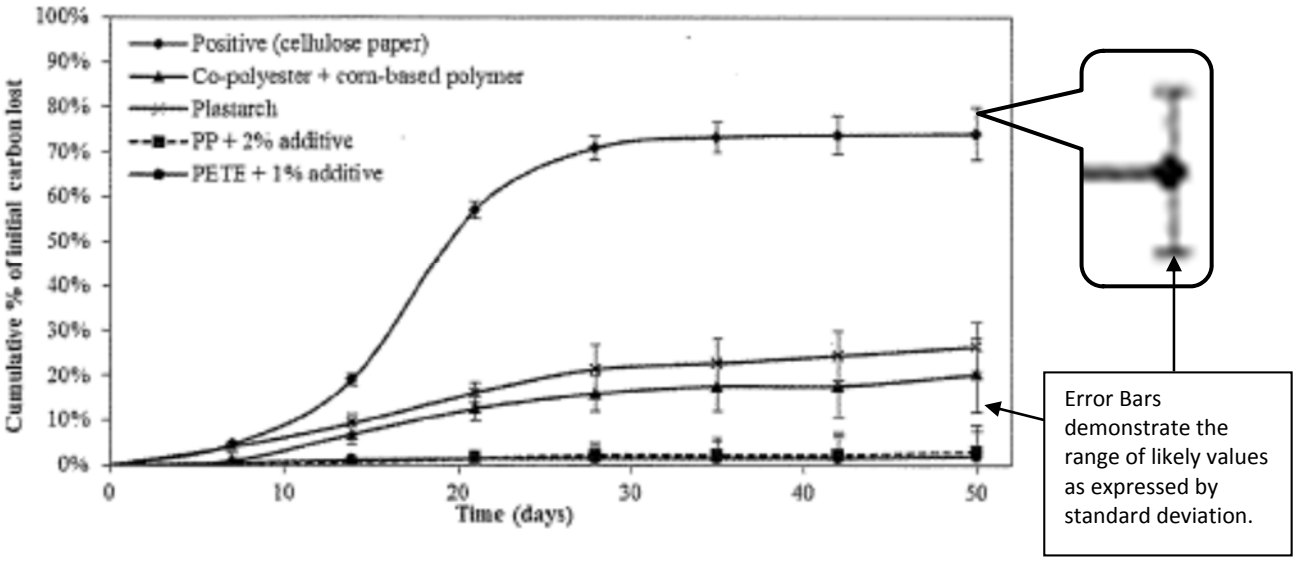
CCX 171; OWS 2012 Anaerobic Biodegradation Study for Shields:

ECM reiterates all previous concerns noted above with the OWS laboratory testing, including the lack of supporting data, particularly the absence of any methane data. (CCX 171). This test also failed to use a negative control, which is significant because the reported biodegradation in the sample vessel was -4.4%, meaning that the test plastic actually *inhibited* rather than promoted biodegradation. (CCX 171 at ECM114222). The test therefore reveals a high likelihood that the plastic contained a component that was inhibitory of biodegradation, or that the test plastic containing the ECM additive was not properly manufactured. (Sahu, Tr. 1828-1836, 1938-39). Complaint Counsel did not support this document with any fact witness or expert testimony of any kind (at deposition or at the hearing). The document is therefore **unreliable hearsay**, and should be discounted as such. Moreover, even if credited, it is at best inconclusive because it, like every one of the studies cited by Complaint Counsel as support for its position, fails to include any identification of or scientific evaluation of the actual cause for test failure.

CCX 164; Dr. Michel's 2012 OSU D5511 Test of Various Plastics:

Complaint Counsel is incorrect that this test produced "no biodegradation," as the test revealed 3.1% biodegradation as an average of the test vessels. (CCX 164). In fact, the data projected in Dr. Michel's test report demonstrates a progressive, steady increase in

biodegradation of the ECM test plastic over time, until the entire laboratory system failed around the 30 day mark. (CCX 164 at 2590 (showing system-wide plateau)). When factoring the *error bars* that report the statistical range in the data points, it is obvious that every test vessel, including the cellulose (cellulose has been shown in other tests to biodegrade beyond 90%), plateaued right around the exact same time in the test—at about 30 days—which would be an extraordinary coincidence if that system-wide plateau did not relate to the environmental conditions in the test:




(CCX 164 at 2590). The range of likely error (as reflected in the error bars) is clearly large enough around days 40-50 to swallow any slight uptick in biodegradation that might mask the obvious plateau in the system. In fact, based on a projection of the deviations (again, error bars), the test appears likely to have lost vitality in all systems, but particularly the "co-polyester and "plastarch." (CCX 164 at 2560).[196] ECM's experts explained, and Dr. Michel agreed, that the plateau in a test environment means that the test is simply no longer capable of sustaining

[196] Note that for many ECM tests, Dr. Barlaz ran statistical analyses and verified that the data points were statistically significant. (Barlaz, Tr. 2246-65; RX 968).

biodegradation testing. (Sahu, Tr. 1931-32; Burnette, Tr. 2401-02; Michel, Tr. 2959). Unlike a landfill environment, the closed-system laboratory tests cannot sustain life over the prolonged period necessary to maintain biodegradation testing. (Burnette, Tr. 2401-03). It is therefore impossible to determine, based on CCX 164 alone, whether the ECM test plastic would have continued to biodegrade had the test systems not collapsed at the 30 day mark. Furthermore, Dr. Michel performed no statistical analysis to determine if the percent of biodegradation was more than what would be sourced from the ECM additive during the period when the test was actually viable.

Dr. Michel does not report his raw data in CCX 164. (CCX 164). He does not report methane levels, percentages of total gas composition, or triplicate data. (CCX 164). That absence of data would have precluded the peer reviewers from assessing the accuracy of his test. (Michel, Tr. 2940 (conceding that peer-reviewers never saw Dr. Michel's data)). Dr. Michel performed this test on behalf of an ECM competitor who was not a long-time ECM customer, did not manufacture the product with ECM's assistance, and thus had no experience manufacturing plastics with the ECM additive. (Michel, Tr. 2931-32). The risk that the ECM additive was not properly included in test plastic is high. *See* Michel, Tr. 2933-36 (testimony showing that Dr. Michel never determined whether the product was properly manufactured with the ECM additive, that he received no certificate of ingredients regarding the samples, and that he did nothing to verify whether the additive was properly incorporated in the plastic by the ECM competitor). In addition, Dr. Michel did not investigate beyond his inconclusive test result to identify the actual cause for test failure. (Michel, Tr. 2961-62). For those and many other reasons articulate by ECM's experts, the presence of one or few inconclusive biodegradation tests do not outweigh or diminish the clear, competent, and reliable scientific evidence showing

that ECM plastics are anaerobically biodegradable in more than two dozen favorable tests. (*See, e.g.,* RX 248; RX 254; RX 263; RX 265; RX 266; RX 268; RX 273; RX 276; RX 392; RX 393; RX 394; RX 395; RX 396; RX 398; RX 399; RX 401; RX 403; RX 402; RX 405; RX 465; RX 467; RX 468; RX 836; RX 838; RX 839; CCX 534; CCX 546; CCX 547; CCX 548; CCX 952).

### B. ECM Has a Reasonable Basis for Its Representations

Complaint Counsel argues on page 61 of their brief that ECM lacked a reasonable basis for its claims. Lack of a reasonable basis depends on proof by at least a preponderance of the evidence,[197] but in the presence of 37 positive test results, only a smattering of several inconclusive tests, and no negative tests, there simply is not a preponderance of the evidence to prove the absence of a reasonable basis. Complaint Counsel offers two arguments: First, that ECM's testing is not methodologically sound; and, second, that ECM's testing does not show products infused with the ECM additive will "completely" biodegrade. Both arguments are unsupported by the record. ECM has a reasonable basis for its claims, which are scientifically proven by 37 positive test results. It has established the mechanisms of action present through competent and reliable scientific testimony and peer reviewed literature support. Application of each *Pfizer* strongly favors ECM.

#### 1. ECM Possesses Competent and Reliable Scientific Evidence for Its Representations Based on Application of the *Pfizer* Factors

ECM's representations to its customers, plastics manufacturers, present no risk of harm to consumers, and Complaint Counsel has offered no evidence of a consumer injury (actual or

[197] *In the Matter of POM Wonderful LLC,* 2012 WL 2340406, at *257 (F.T.C. May 17, 2012).

potential). Consumers do not purchase ECM plastics. (Sullivan, Tr. 695-96; Sinclair, Tr. 758-59). Consumers receive an ECM plastic as part of packaging materials, as a grocery bag, etc.[198] There is no evidence in the record that an end-consumer has ever made a purchase of ECM plastics, or that an end-consumer ever considered a "biodegradable" claim before purchasing. Furthermore, even assuming, *arguendo*, that ECM's claims are false, there is no risk to the consumer; no harm or loss in value of the product; and no risk to the consumer health or safety. Application of the *Pfizer* factors demonstrates that the level of substantiation required for ECM's "biodegradable" claims is not high. Put simply, if the standard for substantiation under *Pfizer* is "high" in this case (as Complaint Counsel suggests), then there is no case where the standard would be anything but "high." Nevertheless, ECM possesses 37 positive tests (including 28 positive gas evolution tests) that Drs. Sahu, Barlaz, and Burnette have testified rely on generally accepted scientific testing methods (gas evolution testing) and are competent and reliable scientific evidence that substantiate the claims ECM has made. *See* ECM RPFF ¶¶ 2133-2659 (gas evolution testing), 2660-2706 (qualitative testing). That is a "high" level of scientific proof, because the standards can only get as rigid as the generally accepted scientific standards permit. In this case that level of proof is gas evolution testing sufficient to show that the plastic substrate biodegrades, which ECM possesses in spades. Moreover, ECM has a direct and detailed explanation for how the additive is fused with the plastic resin, and the mechanisms of action which facilitates biodegradation of same, which is supported by expert testimony from a microbiologist and biochemist (Dr. Burnette), a world-renown environmental scientist with expertise in biodegradation (Dr. Barlaz), and an environmental engineer and material scientist

[198] *See, e.g.,* CCX 810 (Blood, Dep. at 13)); Sahu, Tr. 1813; Sinclair, Tr. 758-59, 764-67; Sullivan, Tr. 703-04, 707.

(Dr. Sahu). Each of those experts cited to peer-reviewed literature establishing the mechanisms and results to be well-accepted. In short, by any reasonable measure, whether the standard is set low or high, ECM meets it.[199]

### a. The Level of Substantiation is Not High for Claims That Have No Bearing on The Health or Safety of Consumers

Complaint Counsel incorrectly argued that the first and second *Pfizer* factors favor a high degree of substantiation in this case, however the type of claims here at issue are of little significance to end-consumers, and are readily investigable (and have indeed been independently evaluated) by ECM's immediate customers. By "high" level of substantiation, Complaint Counsel suggests that companies must complete carbon-14 testing that shows "complete" biodegradation. That level of proof is nowhere supported by scientists in the field, and has not been adopted by Complaint Counsel's own witnesses outside of this case. ECM does, in fact, possess a "high" level of substantiation, as it has shown through twenty eight (28) positive gas evolution studies (plus at least nine (9) supportive qualitative tests and imaging) that various forms of plastic manufactured with the ECM additive are completely anaerobically biodegradable. *See* ECM RPFF ¶¶ 2133-2659, 2660-2706.

There is no evidence that ECM's claims presented a risk of injury or illness to consumers, or impacted the products functionality for end-consumers that may have used the ECM plastics. In fact, Dr. Barlaz testified that, from an environmental standpoint, more slowly biodegrading products are preferable to those that biodegrade quickly. (Barlaz, Tr. 2284-90; RX 854 at 12).

[199] As explained *infra* Part II(B)(1)(3) at 107, radiolabeled testing has not been proven competent and reliable based on generally accepted scientific evidence, in part, because the evidence revealed that this kind of testing is not feasible for plastic materials, is unreliable for same, and is never used by scientists in the field.

So if ECM's product actually take longer to biodegrade than compostables, it would actually benefit the environment by decreasing greenhouse gas emissions. (Barlaz, Tr. 2283-90; RX 967). There is no evidence of an economic injury, because no consumer has predicated a purchasing decision based on claims they do not see until after purchasing other goods.

Complaint Counsel argues that a "high level of substantiation" is required under the *Pfizer* factors because, according to Complaint Counsel, "consumers are not in a position" to evaluate the evidence of biodegradability. *See* CC Amend. Post-Trial Br. at 62. But who are the "consumers" that Complaint Counsel references? ECM sells only to plastics manufacturers.[200] Those manufacturers are certainly in a position to evaluate the claims of biodegradability. In fact, almost all of the laboratory testing in the record was developed by ECM customers who commissioned independent testing to evaluate the ECM product before opening accounts.[201] ECM's customers participated in detailed pre-contract negotiations and independent product evaluations lasting between 6 months and 2 years, and even evaluated competing technologies, before choosing the ECM additive. (Sullivan, Tr. 703-06, 710; Sinclair, Tr. 763, 764-67, 772-74; RX 131; RX 132).

From an end-consumer standpoint, ECM's claims are of the most innocuous kind because there is no evidence in the record that consumers would be affected by the claims in any material respect (whether the claims are true or false). Consumers do not make purchasing decisions based on the claims; the technology does not affect the usability of the plastic product; and the rate of biodegradation is not relevant to the environmental concerns in landfills (except to the

[200] *See infra* at Part V(A)(2) at 165.

[201] *See, e.g.*, RX 248; RX 254; RX 263; RX 265; RX 266; RX 268; RX 273; RX 276; RX 392; RX 393; RX 394; RX 395; RX 396; RX 398; RX 399; RX 401; RX 403; RX 402; RX 405; RX 465; RX 467; RX 468; RX 836; RX 838; RX 839; CCX 534; CCX 546; CCX 547; CCX 548; CCX 952; *see also* ECM RPFF ¶¶ 296-604.

extent that slower biodegradation is better than faster). Put simply, if the level of substantiation for these types of claims is "high," then there is no advertising claim that would require less than a "high" degree of substantiation, and the first two *Pfizer* factors are essentially nullified or predetermined in every case.

### b. There is No Evidence of Any Harm or Potential Harm to Consumers

Complaint Counsel argues that the third and fourth *Pfizer* factors weigh in favor of a high level of substantiation, however they have failed to identify any palpable or material harm to consumers should the claims be false or misleading. With respect to those third and fourth *Pfizer* factors, there is no evidence to warrant a "high" level of substantiation as Complaint Counsel argued. There is no evidence in the record of an injury (economic, physical, etc.) to any end-consumer, and the lack of any record support for Complaint Counsel's argument on pages 63-64 of their brief is revealing. For instance, Complaint Counsel argues that based on ECM's claims, "consumers are likely to replace environmentally-beneficial practices such as recycling with disposal of 'biodegradable' plastic in a landfill." CC Amend. Post-Trial Br. at 63 (providing no citation to the record). That statement is illogical and unsupported by the record. One of the principal benefits to using the ECM plastic over technologies like bioplastics is the fact that ECM plastics remain recyclable. (Sinclair, Tr. 767). Thus, for plastics that are already recyclable, use of the ECM additive does not change that characteristic, and the "recyclable" logo could still appear on the plastic bottle. (Sinclair, Tr. 767 (explaining that ECM plastics are recyclable to the extent the plastic would be recyclable without the addition of the ECM additive)). Complaint Counsel's theory that consumers would suddenly shift their practices to

disposing recyclables in the waste stream, rather than recycling the *still recyclable* plastic as they always have, is conjecture, entirely unsupported by the record.

Second, there is no evidence in the record that consumers have ever paid more for products made with ECM plastics. Here Complaint Counsel relies on Dr. Frederick's faulty dataset to suggest that consumers "would be willing" to pay more for environmentally friendly plastics. But that data says nothing, of course, about whether consumers ever *have* paid more for ECM plastics. Again, consumers never actually buy ECM plastics—they receive them as ancillary packaging items next to the item they actually did purchase. (Sinclair, Tr. 785-86; *see also* CCX 811 (Hong, Dep. at 10-11, 112); RX 471).

There are several examples of an ECM plastic appearing for sale (e.g., a shampoo bottle, etc.), and those products may have used a "biodegradable" logo or an unqualified claim. But the record reveals no record evidence showing that consumers were asked to pay more for those products, or that those consumers ever made purchasing decisions based on the environmental claims appearing on same. Dr. Frederick's data, even if reliable (it is not), only suggests what consumers said under hypothetical situations and in the absence of any context. To the extent Complaint Counsel's position had any merit, it would have been simple to gather data showing what consumers paid for certain biodegradable items versus what conventional, non-biodegradable products sold for. That evidence is lacking.

Finally, Complaint Counsel's argument that "false claims of biodegradability … undercut faith in truthful claims" is generic and not substantive. This generic argument concerning faith in truthful claims, even if supported by record evidence (it is not), applies with equal force to every instance of alleged deception and, so, it is not a distinction with substance that should tip the balance of *Pfizer* factors in any one direction.

### c. Complaint Counsel is Attempting to Require Scientific Substantiation Through Carbon-14 Testing, Which is an Unreliable Departure From Generally Accepted Testing, is Infeasible, and is Unnecessary

Complaint Counsel's final argument under the *Pfizer* factors posits that carbon-14 radiolabeled testing should be used by industry to prove biodegradability claims. Complaint Counsel cited to their rebuttal expert's flawed and unsupported "estimate" for such testing, even though Dr. Michel never addressed the major testing limitations that ECM's experts each identified.[202] However, this arguments tips against Complaint Counsel because radiolabeled testing (1) is never used by scientists in the field; (2) is not generally accepted by scientists as necessary to prove biodegradation; (3) is not practical; (4) is not scientifically necessary to prove biodegradation; (5) is not used by Complaint Counsel's own experts McCarthy and Michel in testing for biodegradability; and (6) is overly burdensome and costly.

Put simply, radiolabeled testing has never been required to prove biodegradation claims or test for biodegradability. There is no evidence in the record that any expert or company has ever relied on carbon-14 testing to demonstrate biodegradability. Several researchers at major research institutions have, on rare occasions, turned to radiolabeled testing, but only because the anticipated amount of biodegradation was not substantial enough to use conventional test methods.[203]

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[202] *See* Michel, Tr. 2968-69; CCX 895 (Michel Rebuttal Rep. at Appx. 2). Dr. Michel provided no substantive information concerning his "estimate" other than an approximation (his own) of the cost for materials and lab time. Dr. Michel did not provide evidence that any company could make the radiolabeled material, or give an estimate for same. (Michel, Tr. 2968-69). He has never conducted radiolabeled testing of plastic polymers, and he never testified that the scientific community requires same. (Michel, Tr. 2820-2998).

[203] *See, e.g.*, RX 855 at 24-40 (Sahu Rep.) (citing papers by Albertsson, A-C, et. al.).

Radiolabeled testing suffers from impracticalities that limit use of the method. (Sahu, Tr. 112-347; Barlaz, Tr. 2244-2246). For instance, there is no record evidence of a company or laboratory successfully polymerizing a plastic test product with sufficient radiolabeled carbon to generate a reliable test. (Sahu, Tr. 1897-1905). Unlike other testing (like pharmaceuticals), to test plastic biodegradability, the entire test sample would need to be radiolabeled (except the ECM additive, of course), because only then can the laboratory measure the presence of radiolabeled carbon. (Sahu, Tr. 1903-1905 (explaining that it would be impossible to radiolabel only the crystalline sections of a polymer); Barlaz, Tr. 2244-45). If only a small amount of carbon-14 was included in the test plastic, then the laboratory could generate a false negative if, for instance, a majority of the plastic biodegraded, but not the minute amount that was radiolabeled. The cost of acquiring the amount of radiolabeled carbon necessary to make a test plastic would be astronomical, however. (Sahu, Tr. 1904). Then the lab needs to find a company that can polymerize the radiolabeled plastic, which is a substantial challenge. (Sahu, Tr. 1898-1902). The manufacturer must also make the plastic in a way that does not combine the radiolabeled carbon with the additive, and there is no evidence in the record showing that is possible during the melting process used to combine the ECM additive. (Barlaz, Tr. 2244-45). As discussed *supra* at Part II(A)(2) at 75, the ECM additive is *melted* into the conventional plastic, and the materials are mixed together along with other additives. (Sahu, Tr. 1813). There is no evidence from Dr. McCarthy or Dr. Michel showing that the carbon-14 would not migrate during that heat-intensive manufacturing process. There is no evidence suggesting that a test plastic radiolabeled in that way would be at all representative of the finished ECM test plastic that is not radioactive. There is no evidence of a laboratory that could successfully overcome these hurdles to produce a testable product. (*See, e.g.*, Sahu, Tr. 1898-1902). There is, however,

considerable testimony from ECM's experts revealing that the radiolabeled test is infeasible, impractical, and unnecessary. (Sahu, Tr. 1794-95, 1897-1905; Barlaz, Tr. 2243-2246).

Dr. Barlaz explained that the radiolabeled test is unnecessary particularly where, as in this case, gas evolution data clearly shows biodegradation of the test plastic (and not the additive alone). (Barlaz, Tr. 2243-46). Here, the methane data revealed the same information that the carbon-14 test would show, to wit, that biodegradation was observed coming from the test plastic. (Barlaz, Tr. 2243-46, 2246-65; RX 968). Dr. Barlaz proved that the amount of biodegradation observed in the test vessels could not have possibly come from the ECM additive. (Barlaz, Tr. 2246-65; RX 968). Dr. Barlaz also disproved the priming effect argument. (Barlaz, Tr. 2277-2280). His testimony on those points was not rebutted or even addressed by any of Complaint Counsel's witnesses.

Significantly, Dr. Barlaz is one of the lead scientists who drafted the ASTM's standard for radiolabeled testing. (Barlaz, Tr. 2223). Although Dr. Barlaz played a substantial role designing that test standard, even he testified that it is wholly impractical. (Barlaz, Tr. 2243-46). Dr. Barlaz testified that he would be "surprised" if any expert had performed radiolabeled testing, that it was not generally accepted in the relevant scientific community as necessary to show biodegradation of materials, and that a carbon-14 test does not "buy[] you anything] in these plastics tests." (Barlaz, Tr. 2243-46). He confirmed that manufacturing polymers with carbon-14 is difficult. (Barlaz, Tr. 2244-45). He also testified that sellers of radiolabeled materials recommended by Complaint Counsel had sold Dr. Barlaz an incorrectly labeled compound some years ago, and that error had impacted Dr. Barlaz's tests. (Barlaz, Tr. 2321-22). That experience (which involved cellulose polymers only), affirms ECM's expert testimony concerning the difficulty in manufacturing properly radiolabeled materials for testing. There still

remains no evidence in the record of any company having used a properly radiolabeled material to test for biodegradability of a plastic.

There is also no evidence that any of Complaint Counsel's witnesses has ever used radiolabeled testing. (McCarthy, Tr. 359-680; Michel, Tr. 2906; Sahu, Tr. 1895; Tolaymat, Tr. 112-347). Meanwhile, each of those witnesses have tested for biodegradability, and, when they did, they chose to run the same type of tests that ECM and its customers have performed (gas evolution testing). (Sahu, Tr. 1894-95; Michel, Tr. 2907; Tolaymat, Tr. 238-39; RX 928). A radiolabeled test would be experimental, not generally accepted. *See* Sahu, Tr. 1905 (explaining that radiolabeled testing is not industry standard); Barlaz, Tr. 2246 (same).

Finally, Complaint Counsel simply ignores the realities of ECM's supply chain. ECM does not manufacture plastics, it sells plastic additives. (Sullivan, Tr. 695-96; Sinclair, Tr. 758-59). Thus, Complaint Counsel's argument is really that every ECM customer should pursue radiolabeled testing—not ECM alone—and that also every similar company that sells additives in competition with ECM, as well as bioplastic manufacturers, etc. That is obviously a tremendous burden on industry to perform test methods that have never been established, are not required by the relevant scientific community, are unnecessary to reveal whether the plastic is truly biodegradable and are no better in establishing biodegradability than generally accepted gas evolution testing.

#### d. Scientists in the Relevant Fields Demand the Type of Proof That ECM Has Supplied

Complaint Counsel argues that scientists in the field require a "high" level of substantiation for biodegradation claims, however that argument has no legs and tips in ECM's favor because: (1) all of the scientists in this case have agreed that the gas evolution testing of

the type ECM presented is generally accepted in the field as competent and reliable scientific evidence of biodegradation; (2) Complaint Counsel's own experts have relied on gas evolution testing to evaluate biodegradation of plastics, including in the peer-reviewed literature and in the '199 patent; (3) Complaint Counsel has failed to rebut or address ECM's expert testimony confirming that ECM's additive technology works; (4) Complaint Counsel's alleged criticisms of ECM's testing are specious, based on inconclusive rather than negative tests, and contradicted by the documentary and testimonial record.

Each of Complaint Counsel's experts has relied on the very same type of gas evolution testing as ECM to prove biodegradability claims in the past. (Sahu, Tr. 1894-95; Michel, Tr. 2907; Tolaymat, Tr. 238-39; RX 928). Dr. Tolaymat testified that the BMP test would be competent and reliable to demonstrate biodegradable claims, even though the BMP test is "dramatically" different from a landfill environment, and certainly far less representative of a landfill than the ASTM D5511 test. (Tolaymat, Tr. 238). Dr. Tolaymat accepted that "accelerated" testing as appropriate to measure anaerobic biodegradability under realistic time-frames without having to test a product over many decades to determine intrinsic biodegradability. (Tolaymat, Tr. 247-50). ECM's experts similarly explained that decades long testing (endorsed by McCarthy in his expert report (CCX 891 at ¶¶ 81-83), but not followed by McCarthy in any of his own biodegradability testing outside of this case (*e.g.*, RX 756) under real-time conditions is wholly impractical, because tests would need to be conducted for so very long. (Barlaz, Tr. 2217-18), and because accelerated testing is generally accepted and used in the scientific community as predictive of landfills. (Sahu, Tr. 1924-27).

In context with biodegradability testing, researchers "accelerate" the tests in three generally acceptable ways: (1) increase moisture; (2) increase temperature; and/or (3) add

nutrients to the inoculum (e.g., BMP testing). (Sahu, Tr. 1924-26; CCX 84 (ASTM D5511); CCX 86 (ASTM D526); CCX 91 (ASTM D6400)). Every test before this Court involved increased moisture levels (including those relied upon by Complaint Counsel). Many tests also included increased temperatures (including those relied upon by Complaint Counsel). (*See* CCX 84 (ASTM D5511); *see, e.g.*, RX 838; RX 403; RX 396; RX 393; RX 394; RX 401; CCX 548; CCX 714 at 15; CCX 175 at 15; CCX 157 at ECM 114736). The point is to accelerate microbiological activity in ways generally accepted by scientists to yield results predictive of longer term landfill conditions. (Sahu, Tr. 1924). That practice is generally accepted in this field by scientists and industry. (Sahu, Tr. 1924- 27; Barlaz, Tr. 2212). ECM's experts testified that increased temperatures affect the "rate" of biodegradation in the test, not alter a substance from a non-biodegradable state to a biodegradable one or vice versa. (Barlaz, Tr. 2228; Burnette, Tr. 2430-31; Sahu, Tr. 1844). ECM's tests also included negative controls proving that, even with increased temperatures, the conventional plastic without the additive did not biodegrade at all. In short, ECM's experts testified that the "accelerated" tests were competent and reliable, and routinely relied on by experts in the field (including Complaint Counsel's own experts).

Finally, Complaint Counsel's citation to prior consent orders is in error. *See* CC Amend. Post Trial Br. at 65. Prior consent orders that were entered outside of the crucible of litigation have no relevance. Complaint Counsel ought not be permitted to bootstrap their fraudulent scientific theories into this proceeding by reference to other cases where the parties lacked the financial ability, incentive, or will to defend themselves or present a complete record.

### 2. ECM's Testing is Competent and Reliable, and Complaint Counsel has not Supported with Sound Scientific Evidence the Charge that those Tests Are Materially Flawed

Complaint Counsel has not presented any scientifically valid basis for calling into question the 37 positive evaluations (28 positive gas evolution studies), demonstrating the ECM's additives effectiveness in biodegrading plastics. As explained in detail below, Complaint Counsel's criticism of Dr. Barber's Environ tests contradicts the testimony of their own experts. When viewed with the totality of the evidence presented, Dr. Barber's Environ data actually confirms that greater body of scientific evidence showing that the ECM additive causes plastics to biodegrade. Second, Complaint Counsel offers no record support for criticisms of ECM's gas evolution test data. The testimony of Complaint Counsel's experts revealed the startling fact that none had actually examined the test data, performed an assessment of the data quality, or bothered to consider Dr. Barlaz's expert opinion concerning the data. (Tolaymat, Tr. 316-17, 320-21; McCarthy, Tr. 654; Michel, Tr. 2966). Dr. Michel testified concerning Drs. Sahu and Burnette *only*, and Dr. Michel based his entire opinion concerning the efficacy of the ECM additive on just two tests in the record (his own and the Environ BioPVC test), while disregarding or ignoring more the 28 positive independent gas evolution tests on ECM additive containing plastics. (Michel, Tr. 2965-66; CCX 895 (Michel Reb. Rep.).

Complaint Counsel criticizes three categories of testing, the Environ tests, Eden Laboratories gas evolution testing, and Northeast Laboratories testing. We address each of those points below seriatim:

**Dr. Barber's Environ Testing Supports ECM's Biodegradability Claims and Was Not Materially Flawed:**

Complaint Counsel argues that "weight loss" is an "inherently unreliable" endpoint for biodegradation testing. *See* CC Amend. Post-Trial Br. at 66. However, Complaint Counsel's own expert, Dr. Tolaymat, disagrees, having testified that weight loss is an acceptable endpoint, and that it was the *only* viable endpoint that one could use during his suggested *in situ* landfill testing of plastic products; Dr. McCarthy too has relied on weight loss as a valid measure. (Tolaymat, Tr. 279-80; McCarthy, Tr. 583-84 (conceding that his prior work involved biodegradation assessments based on weight loss)). Dr. Tolaymat's opinion is not credible because, among other issues, he testified inconsistently throughout. *See* ECM RPFF ¶¶ 2707-2885. He ultimately agreed, however, that weight loss can be a valid endpoint under certain circumstances. (Tolaymat, Tr. 279-80). Dr. McCarthy has also relied on "weight loss" as an endpoint in his biodegradation testing. (McCarthy, Tr. 540-42, 858, 583-84; RX 942).

Second, ECM's experts testified that the loss of chloride ions in the Environ BioPVC test unquestionably indicates that the molecule had biodegraded. (Sahu, Tr. 1912-13; Burnette, Tr. 2415-16). Complaint Counsel chooses to examine this endpoint separately, as though the free chloride data came from an independent test; it did not. The point of the Environ test was to examine different complementary endpoints (i.e., weight loss and free chloride combined) to draw conclusions from the scientific data as a whole. (Barber, Tr. 2055-56). In conjunction with the evidence of weight loss, Dr. Barber proved that the plastic itself biodegraded by measuring the presence of free chloride ions in solution. (Barber, Tr. 2056). The free chloride ions could only have come from the BioPVC test material. (Sahu, Tr. 1912-13; Tolaymat, Tr. 285 (noting that the ECM additive "shouldn't" contain polyvinyl chloride); ECM RPFF ¶¶ 2823-2825). The

presence of free chloride is a detection method accepted to confirm biodegradation of plastics. (Sahu, Tr. 1912-13; Barber, Tr. 2053-56; Burnette, Tr. 2415-16).

Dr. Tolaymat conceded that the presence of free chloride ions would be evidence that the BioPVC had biodegraded, *provided* the ECM additive did not contain chloride. (Tolaymat, Tr. 285-85). Based on Dr. McCarthy's assessment of the ECM additive (CCX 891 at 24 n.17), it does not contain any molecules made with chloride. Complaint Counsel now argues (by mischaracterizing Dr. Burnette's testimony) that the loss of chloride does not necessarily mean the carbon-carbon backbone has been broken. Dr. Burnette testified that the loss of PVC did not, in theory, mean the carbon-carbon chain was broken, but he explained that breakage of the backbone was in reality unavoidable, certain to occur. (Burnette, Tr. 1415-18). Furthermore, he testified that the hydrolysis reaction required would mean "we have broken the backbone of the carbons." (Burnette, Tr. 2417). At his deposition, Dr. Burnette extemporaneously sketched the morphology of the PVC molecule and depicted the various changes to chemical bonds that would occur while PVC lost its chloride group (HCL group). (RX 840 (Burnette, Dep. at 129) (discussing Burnette Exh. 6)). He explained that "decades" of research shows that the result is a breakage of the carbon-carbon bonds. (RX 840 (Burnette, Dep. at 129)). He testified that "I don't think I could draw you another mechanism where the chlorine would be lost and the carbon-carbon bond would still be intact." (RX 840 (Burnette, Dep. at 129)).

At the hearing, Dr. Burnette testified that the loss of chloride from the PVC molecule is a "textbook example" of the molecule breaking down, and that it was a "fundamental of

biochemistry." (Burnette, Tr. 2418). Dr. Sahu agreed that the loss of chloride would indicate that the PVC molecule was breaking down. (Sahu, Tr. 1912-13).[204]

**Northeast Laboratories ("NE Labs") Gas Evolution Testing Supports ECM's Biodegradability Claims and Was Not Materially Flawed:**

At the outset, none of ECM's experts doubt the utility of the D5511 test protocols. Each testified that the D5511 tests were competent and reliable measures of intrinsic biodegradability in anaerobic landfills. (Sahu, Tr. 1895-96, 1926-27; Barlaz, Tr. 2219; Burnette, Tr. 2373). Observe that Complaint Counsel frequently inserts the word "complete" to modify their criticisms of test protocols, e.g., by arguing that the ASTM test does not support "claims of *complete* biodegradation…" CC Amend. Post-Trial Br. at 68 (emphasis added). Complaint Counsel's experts have never explained, however, precisely what level of evidence would support a claim of "complete" biodegradation, other than testing for decades on end under conditions that perfectly mirror landfills until the plastic disappears entirely. That test, of course, is impractical for any laboratory.

Although Complaint Counsel cites no expert opinion concerning or peer reviewed science supportive of the supposed "flaws" they contend exist, ECM addresses each point below:

Complaint Counsel argued that NE Labs was not audited and held no certifications. Although it is true that NE Lab's *biodegradable* testing group was not audited, the rest of NE Labs was audited by state and federal authorities. (Johnson, Tr. 1559-60). NE Labs passed its audits, and it holds several certifications relevant to sensitive testing areas. (Johnson, Tr. 1558-

[204] Dr. Grossman (ECM's proffered expert), if permitted to testify, would have explained that Dr. McCarty's testimony was grossly in error, such that he suspected a miscommunication on the scientific points. (RX 971).

59). NE Lab's chemistry lab is audited. (Johnson, TR. 1558-59). That chemistry lab performs services for the biodegradation laboratory during the biodegradation testing. (Johnson, Tr. 1560-61 (explaining that NE Labs' chemistry lab assists biodegradability testing by performing titrations, instrument work, and report writing). Regardless, whether NE Labs is audited is not a substitute for proof of invalidity of the specific tests performed, is highly speculative in that the absence of an audit is not the same as an audit failure, and has no bearing on the accuracy or reliability of NE Labs' tests. Complaint Counsel has not produced evidence that the auditing of biodegradation labs is common, that its own experts' labs were audited, or that other biodegradation labs are audited.

Complaint Counsel argues that NE Labs did not maintain anaerobic conditions throughout "extension" testing. There is no evidence that NE Labs testing was anything but anaerobic. The percentage of biodegradation recorded in the test environments is based on methane production. (Barlaz, Tr. 2188, 2246, 2261-62). Methane can only be produced by an anaerobic system. (Barlaz, Tr. 2188). The presence of oxygen either destroys or severely limits an anaerobic system. (Barlaz, Tr. 2277). Thus, even assuming the NE Labs tests were aerobic at times, the amount of *anaerobic* biodegradation would be minimized as oxygen kills off the anaerobes. Moreover, there is no indication from the test data, and Complaint Counsel provides no documentary evidence of any kind and no testimony, showing that the tests did not remain anaerobic. All relevant tests consistently produced methane during the course of the tests, which proves the systems were anaerobic.[205] Because the amount of biodegradation in the D5511 test

[205] *See* RX 248; RX 254; RX 263; RX 265; RX 266; RX 268; RX 273; RX 276; RX 392; RX 393; RX 394; RX 395; RX 396; RX 398; RX 399; RX 401; RX 403; RX 402; RX 405; RX 465; RX 467; RX 468; RX 836; RX 838; RX 839; CCX 534; CCX 546; CCX 547; CCX 548; CCX 952.

is calculated based on methane production, which is exclusive to anaerobic systems, there is simply no evidence to support Complaint Counsel's theory that aerobic conditions either existed or factored into the data. Complaint Counsel fails to acknowledge that NE Labs sparged its canisters with Nitrogen (an inert gas that does not affect biodegradation testing) after re-inoculating. (Johnson, Tr. 1573-74; Barlaz, Tr. 2276). No evidence explains whether NE Labs re-inoculated its canisters in the ECM testing, but, if it did, the use of Nitrogen gas to sparge canisters clearly maintained an environment that produced methane gas (and was thus anaerobic). *Id.* ECM's expert testimony confirmed that NE Labs' practice of re-inoculating was not problematic. (Barlaz, Tr. 2276)

Complaint Counsel argued that the ASTM D5511 test does not allow for extension testing beyond "the 30-day period of the test." CC Amend. Post-Trial Br. at 69. That is false and misleading. The D5511 standard does not include a time limitation on testing, contains no "30-day" limitation, and expressly authorizes continued testing provided the test environment is still viable. (RX 356 at 3 § 11.2.1.2) (stating, "The incubation time shall be run **until** no net gas production is noted for at least five days from both the positive control and the test substance reactors.") (emphasis added).

Complaint Counsel argues that the NE Labs test protocol setup by Dr. Bill Ullmann had never been independently re-evaluated. That is not relevant to the reliability of NE Labs' testing. Dr. Ullmann was a well-credentialed and established researcher. (Johnson, Tr. 1562). He was the former director of the State of Connecticut's Public Health Laboratory, and he held a Ph.D. in microbiology. (Johnson, Tr. 1562). He was well qualified to design NE Labs' biodegradation testing.

Complaint Counsel argues that NE Lab's use of inverted cylinders and metal paint cans prevented NE Labs from identifying "small leak[s]" in the system. That criticism reveals Complaint Counsel's misapprehension of test bias because, if anything, a "small leak" in the system would downward bias the results of the test by failing to record methane that was generated by the inoculum.[206] That point notwithstanding, there is no evidence that any leakage occurred in the vessels, which are run in triplicate so the laboratory can determine if the data recorded is an outlier. (RX 356). Dr. Barlaz's statistical t-tests (t-statistic) were designed to identify the standard deviations and determine statistical anomalies. (Barlaz, T. 2247-49, 2263-64). He determined that the data shows statistical significance, meaning that the fluctuations between triplicate test vessels was not extraordinary. (Barlaz, Tr. 2259-61, 2263-64; RX 968). NE Labs also pressure tested its vessels to measure against leakage before testing. (Johnson, Tr. 1567-68). Furthermore, the D5511 test standard (which Complaint Counsel's Dr. Michel promoted in his testimony) specifically requires the use of inverted cylinders to measure gas totals. (RX 356).

Complaint Counsel argues that NE Labs used canisters that might rust during testing. There is not one shred of evidence in the record that NE Labs had that type of problem with any tests of ECM additive containing plastics, and the testimony from NE Labs established that rust corrosion was a very rare anomaly. (Johnson, Tr. 1566-67 (explaining that NE Labs had never had a problem with leakage resulting from rust or otherwise)). Again, Dr. Barlaz examined the statistical data to determine whether certain vessels had an observable variance that would render

[206] If Complaint Counsel intended to argue that a small leak would introduce oxygen, then that argument is equally unsupported and illogical. The D5511 test is a positive pressure system, which is why it expels gas that is eventually collected and measured. (RX 356). A small leak would not involve the ingress of external gases but, rather, it would permit the pressurized system to expel gas through other channels.

data not statistically significant and found none. (Barlaz, Tr. 2247-50; RX 968). Complaint Counsel also ignores NE Labs' testimony wherein their laboratory director stated that they switched to lined paint cans that would have no risk of corrosion. (Johnson, Tr. 1565-66). Dr. Barlaz had no issue with the use of the metal canisters (i.e., the cans ordinarily used for paint but here simply the cans). (Barlaz, Tr. 2276). NE Labs explained that they use several materials, including a silicone sealant, to ensure that the vessels remain airtight. (Johnson, Tr. 1567-68). NE Labs and Dr. Barlaz both explained that the presence of methane indicates that no leakage in the test system occurred. (Johnson, Tr. 1566-67 (explaining that if oxygen was "getting into the can, then you won't be producing methane"); Barlaz, Tr. 2276 ("[y]ou either have a leak in your system or you don't have a leak in your system … [a]nd the fact that they were getting methane generation from their positive controls indicates to me that they have an ability to make a gas-tight system out of a metal can").

Finally, Complaint Counsel mischaracterizes the factual record by suggesting that NE Labs' IR machine had an error rate of 20%. The testimony was that the error rate is as low as 1% or less for the higher amounts of methane generated in the ECM tests. (Johnson, Tr. 1586-87). In other words, for very low amounts of methane recorded, the error rate may be higher (as much as 20%). But for larger amounts of methane the error rate diminishes considerably. Again, any precision considerations would of course apply to all vessels tested, including the positive and negative controls, and the inoculum blank. Thus, variance in the readings would apply to the inoculum blank, which would be factored by Dr. Barlaz's statistical t-test calculations across the triplicate test data. (Barlaz, T. 2247-49, 2263-64; RX 968).[207]

[207] ECM notes that there is no evidence in the record (testimonial or otherwise) discussing the precision of analytical laboratory equipment used by Dr. Michel in his study, or in the few other studies upon which Complaint Counsel has relied. *See, e.g.*, CCX 164.

Significantly, Complaint Counsel fails to acknowledge that at least one NE Labs' test was validated by supporting testing of molecular weights under ASTM D6579. (RX 838 at 73 (8/1/2012 Report)). NE labs had measured the total biodegradation of the sample at 17% through gas evolution testing, and the difference in molecular weights of the sample vs. the untreated plastic (negative control) was 16% at the end of the one year test. *Id.* That additional data point obtained through the D6579 molecular weight testing confirms the accuracy of NE Labs' gas evolution data, and also soundly discredits any claim that biodegradation could be the result of a "priming effect."

**Eden Laboratories ("ERL") Gas Evolution Testing Supports ECM's Biodegradable Claims and Was Not Materially Flawed:**

Complaint Counsel's criticisms of the Eden Laboratories testing are, like those of NE Labs, unfounded in record evidence and science, and none go to the reliability or accuracy of the tests themselves. For instance, although ERL did not report standard deviations, it did report triplicate data in its final reports, and it reported detailed findings concerning the amount of biogas produced in the studies. *See* RX 248; RX 839; RX 403; RX 402; CCX 548; CCX 546; CCX 534; CCX 547. ERL's "update" reports, which note the progress of studies (instead of full reports that would issue at the end of a study, or upon request by a customer), do not include all of the information relevant to the studies, but that is not an indication that the data is unreliable. *See* Poth, Tr. 1475; RX 403; CCX 548; CCX 546; CCX 534; CCX 547. Based on a review of the gas production totals, Dr. Barlaz assessed whether the data was reliable based, in part, on the methane ratios recorded in the test vessels versus the inoculum blanks. (Barlaz, Tr. 2248-51). Dr. Barlaz explained that the ratios themselves left him confident that the tests revealed the amount of biodegradation to be considerably more than what could have been produced by the

ECM additive alone. (Barlaz, Tr. 2249; RX 968). The ratios of biogas were consistent with ECM's other positive test results. *See* ECM RPFF ¶¶ 2217-2625. Dr. Barlaz testified that:

> [F]rom those ratios alone I have every reason to believe that the tests suggest a significant methane generation that could be attributable to the substrate, which suggests that the substrate was undergoing anaerobic biodegradation and conversion to methane.

(Barlaz, Tr. 2249).

Dr. Barlaz further testified that he had visited Eden Laboratories in an unrelated trip before this case began. (Barlaz, Tr. 2274). He had reviewed ERL's testing model and procedures, and he was satisfied that ERL was operating a sound test. (Barlaz, Tr. 2274-75).

Complaint Counsel suggests that ERL "adjusts biodegradability percentage of positive control to 100%," and claims that is a "flaw" in the test. Not so. ERL may have provided a so-called "adjusted" calculation as Complaint Counsel argued, but it also provided the unadjusted percentage without any additional calculations, e.g., the pure percentage of biodegradation based on the loss of methane from the test vessel.[208] ECM relies on that pure "percent biodegraded" number in this case, rendering the criticism of the adjusted number immaterial. *See, e.g.*, RX 968. There is thus no basis to suggest that ERL's adjusted number calculation affected the test results, affected ECM's experts' opinion of the tests, or affected the underlying data.

Indeed, ECM's experts testified that the studies were competent and reliable. (Burnette, Tr. 2438-39; Barlaz, Tr. 2219; ECM RPFF ¶¶ 1766-1809).

[208] *See, e.g.*, RX 403 at 1 (listing "Percent Biodegraded (%)" immediately above "Adjusted Percent Biodegraded (%)").

### a. The Demand that ECM Show Evidence of "Complete" Biodegradation, as Opposed to Intrinsic Biodegradability, is Not Scientifically Warranted to Prove Biodegradability

Complaint Counsel argues that ECM must have testing that actually shows a plastic "completely" biodegraded in a laboratory environment before it can claim that plastics made with its technology are "completely" biodegradable. ECM proved that plastics made with its additive are completely biodegradable. *See* ECM's RPFF ¶¶ 1629-70, 1699-1765, 1964-2009, 2129-2706. Complaint Counsel was unable to produce any evidence contesting Dr. Barlaz's analysis of the test data, which was based on testimony concerning the amount of methane that could feasibly be sourced from the ECM additive versus the amount of methane recorded in the test vessels. (Barlaz, Tr. 2246-65). So Complaint Counsel shifts to another position and argues that, although the ECM products may be "biodegradable," they are not "*completely*" biodegradable, whatever the word "completely" might mean to Complaint Counsel (Dr. Michel thinks it means 44% biodegradation in a test, (Michel, Tr. 2961); Dr. McCarthy said in his report that it means 60%, but in his '199 patent he found 14% sufficient, and in at least one of his papers, he found 5% enough, (RX 756)).

There is no scientific support in the record corroborating Dr. McCarthy's theory in his report (albeit contradicted by his own '199 patent and his peer-reviewed writings, (RX 756)) that a biodegradation study "must show at least 60% biodegradation" to establish that a product will completely biodegrade. Dr. McCarthy provided no citation for that premise in his report, which is what Complaint Counsel relies on as authority. (*See generally* CCX 891). He did not himself require a 60% threshold in gas evolution testing before declaring materials "biodegradable" at amounts less than 60%. (McCarthy, Tr. 558–560; RX 928). There is no peer reviewed scientific literature setting a gas evolution test threshold of 60% biodegradation before the test article can

be deemed biodegradable. (Sahu, Tr. 1793). In fact, Dr. Michel testified that an article which biodegrades to 44% would be considered fully biodegradable in a gas evolution test. (Michel, Tr. 2961). Dr. McCarthy labeled a substrate "biodegradable" after observing just fourteen percent (14%) biodegradation in a gas evolution test. (Sahu, Tr. 1894; RX 756 at 11). Dr. McCarthy also labeled plastics biodegradable upon evidence of only 5% biodegradation in a study that last only 5 seconds. (RX 969; McCarthy Tr. 644-646).[209] Dr. McCarthy's 60% threshold is thus incompetent and entirely arbitrary, capricious, and lacking in scientific support.

### b. The Only Relevant Inquiry is Whether the ECM Additive Causes Plastics to Be Intrinsically Biodegradable

Complaint Counsel repeatedly argues that because ECM never produced a test showing that a plastic "completely" biodegraded, ECM cannot claim that plastics would be "completely" biodegradable, even though the scientific record proves that "biodegradability" is an inherent or intrinsic characteristic of a material. The record evidence demonstrates that the phrase "totally" or "completely" biodegradable is a highly subjective and amorphous phrase, in part, because biodegradation is a process and not a clearly identified goal. (Barber, Tr. 2069). It is precisely because a plastic infused with biodegradable elements, shown to biodegrade by a statistically significant amount, is accepted as being ultimately fully biodegradable that scientists like McCarthy define in the peer-reviewed literature (and in McCarthy's own submission to the U.S. Patent and Trademark Office) that amounts of biodegradation of varying levels, including 5%, 14%, and more all under 100%, all support the conclusion that the plastic is biodegradable. (RX 756; RX 969; McCarthy Tr. 644-646).

[209] RX 969 may have been inadvertently omitted from the joint exhibit list, but it was entered as an exhibit without objection. *See* McCarthy, Tr. 644-45.

For instance, Complaint Counsel's own witness (Dr. Michel) explained that a product which biodegrades 44% would be considered "fully" biodegradable. (Michel, Tr. 2960-61). He also noted that cellulose (a material that is indisputably "fully biodegradable"), could be fully biodegraded at just 74%. (Michel, Tr. 2955, 2992). So what, then, is a "fully" or "totally" biodegradable substance? Complaint Counsel has offered no record evidence on that point. If there was a set percentage deemed necessary to reach that conclusion, Complaint Counsel had every incentive to present the evidence at trial through its experts but it did not. Dr. Michel clearly intended to define "completely" biodegradable by reference to the ability of a product to biodegrade. (Michel, Tr. 2961). ECM scientists, by contrast, look to the totality of the scientific evidence to conclude that the ECM additive renders plastics intrinsically biodegradable, meaning that if left in an environment where biota are present they will inevitably biodegrade until they are nothing more than residue, indistinguishable from common dirt. (*See, e.g.,* Sahu, Tr. 1943-44; Barlaz, Tr. 2274). It is only because of a determination that a plastic is "intrinsically biodegradable" that scientists in the literature, including Complaint Counsel's own scientists on this point, can deem a plastic in an accelerated gas evolution test "biodegradable" despite the fact that only a small percent of the plastic during the time of the test biodegraded (e.g., 3% in the case of Dr. McCarthy. (RX 756 ('199 Patent) (observing biodegradation of PLA, a known biodegradable substance, of only 3% in anaerobic composting tests over 20 days)).

Drs. Barlaz and Sahu, by contrast, have explained directly that biodegradability is an intrinsic characteristic of the material. (Sahu, Tr. 1924-26; Barlaz, Tr. 2217-19; *see also* Barber, Tr. 2027). Dr. Barlaz used the example of copy paper, which could degrade differently under certain conditions (or not at all), but is indisputably "biodegradable" if or when that material is placed in an environment suitable for biodegradation:

> Q: So to what extent, if any, would changes in temperature and moisture influence intrinsic biodegradability of a material?
>
> A: Well they wouldn't. In other words, this piece of paper is bone dry and it's – I don't know what temperature is in here – maybe its 70-71 degrees, but it's bone dry (indicating). It's not going to biodegrade if I hold it up here for the next hundred years. But this piece of paper is biodegradable. It's an intrinsic property of this paper that it's biodegradable.
>
> So the moisture and temperature would begin to put this piece of paper in a system where biodegradation is favored. And when we do biodegradability testing, obviously we're having to create an environment in which biodegradation can occur if the material is biodegradable.

(Barlaz, Tr. 2218-19).[210]

Complaint Counsel argues that "extrapolation" of biodegradation test data is inappropriate, but they misunderstand the testimony concerning extrapolation of "rate" data. For instance, ECM would agree that you cannot extrapolate the "rate" of biodegradation easily from a lab test environment into the landfill. (Barlaz, Tr. 2282). That is because too many variables exist that might increase or decrease that "rate" of biodegradation over time. (Barlaz, Tr. 2282; Sahu, Tr. 1769-71). The "rate" could thus vary, and it would be near impossible to predict with precision. Indeed, the product may not biodegrade at all if disposed in a sterile environment (imagine a piece of plastic soaked in bleach cleaner), nor would *any* biodegradable substance under those conditions. Indeed, the inability to measure rate precisely in a landfill is exactly why

[210] Dr. Barber similarly testified about "inherent" biodegradability, explaining the relevant question:

> Is the material itself biodegradable and would it biodegrade completely at the -- at some point in time, given the proper conditions to support biological activity, including microbes, water, pH, nutrients, all the things necessary to support biological activity.

(Barber, Tr. 2027).

Complaint Counsel's Proposed Order in this case is so arbitrary, capricious, unconstitutional, and unsupported by the record. *See infa* at Part VI(3) at 189.

By contrast, scientists agree that it is perfectly acceptable to extrapolate "biodegradability" into the landfill based on accelerated lab test data. (Sahu, Tr. 1864-65; Burnette, Tr. 2437-40; Barber, Tr. 2057 ("there's no reason that I understand that the microbes would not continue to attack those base polymers until it was completely biodegraded"). Dr. Barlaz explained that testing over long periods of time to show complete biodegradation would be impractical and unnecessary. (Barlaz, Tr. 2212). He explained that the central question was whether the material is "intrinsically biodegradable" because, if the product biodegrades, then it will do so as long as environmental conditions support biodegradation. (Barlaz, Tr. 2217-21; *see also* Sahu, Tr. 1848-49). Dr. McCarthy contradicted his own expert report when he testified that indeed you can "extrapolate" biodegradability through incomplete testing. (McCarthy, Tr. 558–59; Contrast with RX 891 (McCarthy, Rep. at 15)). That is what he unwittingly proposed in his report by suggesting that 60% biodegradation (which is <u>not</u> 100%) is sufficient to show a completely biodegradable substance (McCarthy, Tr. 558–59; RX 891 (McCarthy, Rep. at 15)) and functionally established in his peer-reviewed writings outside of this case where he has accepted 5%, 14% and other amounts of biodegradation in accelerated lab tests to be sufficient proof that a plastic is biodegradable. *See, e.g.*, RX 756 (McCarthy '199 Patent).

Finally, Complaint Counsel has misinterpreted the concept of causation expressed by ECM's experts concerning biofilm formation. ECM's experts conceded that the presence of a biofilm does not necessarily indicate that the microorganisms are using the plastic as a food source, but the formation of biofilms is a considerable step towards the ultimate biodegradability of plastics. (RX 855 at 27; Burnette, Tr. 2406-09). ECM has not maintained that a Biofilm is

*evidence of biodegradation*, but rather, that the biofilm is one step in a larger process that leads to inevitable biodegradation. (RX 855 at 27 (Sahu Rep.); Burnette, Tr. 2408-10).

ECM's experts have agreed on the mechanism of action for the ECM additive. Dr. Sahu explained that the additive is fused within the plastic through melt-compounding, where it then creates weaknesses in the conventional plastic susceptible to enzymatic attack. (Sahu, Tr. 1813-15. The ECM additive is an attractant and food source for microbes and fungi that each produce enzymes known to biodegrade plastics. (Sahu, Tr. 1848-53; Burnette, Tr. 2435-37). The enzymatic processes reduce the chain lengths of the polymers into more easily digestible lengths (Sahu, Tr. 1809-11), and also expose additional weakness or chain endings that can be broken down by the biota. (Sahu, Tr. 1831, 1865-67; Burnette, Tr. 2438-39). The point is to both reduce the plastic chains while attracting further biodegradation as the additive serves as a food source and attractant for additional biota. (Sahu, Tr. 1831, 1865-67; Burnette, Tr. 2438-39).

### c. The Preponderance of Unrebutted Scientific Evidence Shows that Plastics Infused with the ECM Additive Will Biodegrade in Landfills

Complaint Counsel argues that the tests run at 52 degrees Celsius somehow have no bearing on the biodegradability of a plastic in a landfill and, so, ECM's testing performed at higher temperatures has no relevance to the landfill. That argument is a red-herring, as it was rejected by ECM's experts and no rebuttal testimony has called into question those experts' analyses. First, ECM's experts explained that the elevated temperature in the D5511 test only affect the "rate" of biodegradation, and does not call into question whether the test plastic is biodegradable in a landfill. (Barlaz, Tr. 2228; Burnette, Tr. 2430-31 (explaining that mesophilic and thermophilic bacteria function at different temperatures and pace, but use common and universal mechanisms of action to gain access to food sources); Sahu, Tr. 1844 (stating that, at a

fundamental level, there is no difference in the way thermophilic bacteria metabolize waste versus the way mesophilic bacteria metabolize waste). Second, at least one test conducted under mesophilic temperatures (37 degrees Celsius) demonstrated statistically significant biodegradation of the ECM additive infused test plastic that was continuing at the time the test was terminated and was consistent with ECM's other positive tests. *See* CCX 952; Barlaz, Tr. 2269-72). Third, the experts explained that landfill temperatures fluctuate considerably, and that there are areas within landfills (and anaerobic digesters) that reach or exceed 57 degrees Celsius (the temperature of the D5511 test). (Sahu, Tr. 1842-44; Barlaz, 2207-08). Fourth, Complaint Counsel has no factual basis to conclude that anaerobic bacteria which survive at the hotter temperatures are not similar to bacteria that operate at lower temperatures. ECM's experts testified that while the bacteria are different in that they work faster; they are very much the same in all relevant areas (e.g., metabolic processes and function). (Burnette, Tr. 2430-31). ECM's experts testified that there are also mesophilic bacteria in landfills that would degrade plastics, and those bacteria would not be represented in the thermophilic systems, meaning that the D5511 tests may not actually capture all of the biodegradation that occurs in landfills. (Burnette, Tr. 2431-32). All ECM experts testified that the D5511 tests conducted by ECM customers were competent and reliable evidence to establish that ECM infused plastics will biodegrade in landfills. (Burnette, Tr. 2438-39; Barlaz, Tr. 2219; RPFF ¶¶ 1766-1809). Complaint Counsel's expert witness conceded that the ASTM D5511 test could produce data of biodegradability in landfills, just not the "rate" of biodegradability, which, as stated *supra* at *124* at Part II(B)(2)(b) at **Error! Bookmark not defined.**, is impossible to predict: "ASTM D5511

… can provide data about anaerobic biodegradation, but it … cannot provide data about the **rate** of biodegradation in a typical landfill." (CCX 893 at ¶ 77) (emphasis added).[211]

### d. Complaint Counsel has no Support for the Mythical, Undefined, and Scientifically Disproven Priming Effect Theory

Complaint Counsel's final argument involves reliance on the "priming effect," a theoretical proposition never shown in the peer reviewed literature to exist in an anaerobic environment and disproven by the record evidence. At the outset, Complaint Counsel styles its argument: "No evidence of biodegradation **above** the priming effect." CC Amend. Post-Trial Br. at 74. Complaint Counsel has never, however, attempted to explain how much biodegradation occurs within the "priming effect," or where the imaginary line of the priming effect begins or ends. That point notwithstanding, the "priming effect" argument is unsupported and flawed for at least five reasons.

First, Dr. Barlaz proved that the amount of biodegradation observed in many of the ECM tests was substantially more than any biodegradation that could be attributed to the ECM additive alone. (Barlaz, Tr. 2175). Simply put, based on weight, there is only so much methane that the additive can produce. (Barlaz, Tr. 2252-58). Dr. Barlaz compared that value to the amount of biodegradation recorded in the test vessels. (Barlaz, Tr. 2252-58). He concluded that many tests showed biodegradation of the *test plastic* in very substantial amounts, sometimes more than fifteen (15) times the amount that could be attributed to the ECM additive. (RX 836; RX 968; Barlaz, Tr. 2252-58). Furthermore, as explained *supra* at Part II(B)(2) at 113, at least one of the

[211] The ASTM D5511 standard was designed by scientists to assess biodegradability of plastics materials under a variety of conditions. Even Dr. Tolaymat conceded that D5511 can assess intrinsic anaerobic biodegradability. (CCX 893 at ¶ 77).

NE Labs' gas evolution tests was supported by additional testing of molecular weights under ASTM D6579 (Standard Practice for Molecular Weight Averages and Molecular Weight Distribution). (RX 838 at 73 (8/1/2012 Report)). NE Labs had calculated 17% biodegradation of the test sample through methane production. *Id.* NE Labs also measured a molecular weight differential of 16% between the test sample and the untreated plastic at the end of the test period. *Id.* That evidence proves that the molecular weight loss from biodegradation occurred solely from the test plastic, and not from some speculative "priming effect" as Complaint Counsel now argues.

Second, Dr. Barlaz's calculation was a conservative figure, in part, because he assumed that the ECM additive could be consumed *first* before the plastic substrate would also be consumed. (Barlaz, Tr. 2252-54). That scenario is logically implausible, because the ECM additive is dispersed throughout and within the test plastic, meaning that most of the additive is unavailable to the microorganisms until the plastic is first digested and peeled back. (Sahu, Tr. 1813-14).

Third, Complaint Counsel did not rebut Dr. Barlaz's dispositive testimony. Instead they argue that the "ECM additive is highly biodegradable" and, so, it might be likely to stimulate the inoculum and create a priming effect. *See* CC Amend. Post-Trial Br. at 75. However, again, Complaint Counsel has never bothered to explain how much of a "priming effect" might be seen even for rapidly biodegradable substances, and if that effect is even significant, assuming (again) that the ECM additive can be separately digested from the plastic. That theory is also dispelled by the scientific evidence. For example, Complaint Counsel has cited inconclusive tests of the "ECM" plastic that revealed no biodegradation at all. *See, e.g.*, CCX 156; CCX 163; CCX 171. If the ECM additive was included in the test plastic, and the "priming effect" was as significant

as Complaint Counsel suggests,[212] we would expect to see a priming effect in all studies of record. Thus, the absence of a "priming effect" in the inconclusive tests leads to one of only two conclusions: (1) either the ECM additive was not included properly in the test plastic (in which case the test is invalid); or (2) the priming effect is a myth.[213]

Fourth, none of the biodegradation tests performed by any of the experts on either side of this case controlled for the "priming effect," which, if it were more than a polemic, certainly such controls would have been used. Moreover, none of the testing standards mention the priming effect. If the priming effect was significant enough to swallow more than 20% biodegradation (as Complaint Counsel brazenly argues), then surely the scientific community would at least acknowledge that possibility when designing a test for biodegradable materials. In fact, none of the ASTM biodegradation test standards (e.g., ASTM D5511, D5526, D6400, etc.) require laboratories to consider or account for a priming effect. *See* CCX 84 (D5511); CCX 87 (D5526); CCX 91 (D6400). They do not even mention it, which should be reason enough to be highly skeptical of a priming effect theory of the magnitude Complaint Counsel and Dr. McCarthy posit.

To support his own biodegradation testing, Dr. McCarthy designed a gas evolution biodegradation test which was memorialized in his '199 Patent. (RX 756 at columns 9-12).

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[212] They suggest, for instance, that the priming effect could be responsible for producing more than 45% biodegradation of a plastic sample, which would be well over 15 times the amount of biodegradation that could be attributed to the ECM additive. (RX 836; RX 968; Barlaz, Tr. 2252-58).

[213] Complaint Counsel has also argued that the ECM additive is as biodegradable as cellulose and, so, the priming is somehow relevant. *See* CC Amend. Post-Trial Br. at 75-76. That argument lacks any support, however, because there is no indication that even cellulose produces a priming effect. The very limited information in the peer review concerning the existence of any "priming effect" has been seen with **glucose** and in aerobic systems, not cellulose in anaerobic systems, and even then the priming effect is not that substantial. (Sahu, Tr. 1889; Barlaz, Tr. 2279). Glucose is basically sugar.

Although his test reflected results similar to ECM's test data (e.g., 3%,14%, 20%, 40%, etc.), Dr. McCarthy never mentioned, accounted for, or controlled for a "priming effect" in his testing. (RX 756 at columns 9-12). Dr. Michel performed D5511 testing to assess biodegradability of substances, and he never mentioned, accounted for, or controlled for the alleged "priming effect" in his testing. *See generally* CCX 164.

Consider that Dr. McCarthy recorded 14% biodegradation using his gas evolution test for polylactic acid (PLA) over a test period of 45 days, and PLA is a substance he declared was completely biodegradable. (RX 756 at column 11; RX 756 at 2; McCarthy, Tr. 376). Dr. McCarthy did not discount that evidence in any way based on the priming effect, and that was under **aerobic** testing conditions, where a priming effect, if it existed, would be prevalent. (RX 756; Barlaz, Tr. 1888-89, 2278). Yet, in one D5511 test, the ECM additive produced over 17% biodegradation under anaerobic conditions, and Complaint Counsel discounts the entire study because, according to them, the data could have been the elusive priming effect in action. *See* RX 838 at 6 (6/13/2011 Report).

The "priming effect" also lacks support in the peer reviewed literature, particularly in anaerobic systems, as ECM's experts explained. (Barlaz, Tr. 2277-78; Sahu, Tr. 1888-89). Each of ECM's expert witnesses explained that the priming effect was mythical or illusory and had no relevance. (Sahu, Tr. 1888-89; Barlaz, Tr. 2278-79; Burnette, Tr. 2400). Dr. Barlaz specifically testified that the ECM additive was mostly composed of polycaprolactone (PCL) and in Dr. Barlaz's own research the amount of degradation solely from PCL is not significant enough to stimulate background methane production or a "priming effect." (Barlaz, Tr. 2279-80). Dr. Barlaz described Dr. McCarthy's priming effect theory as "quite speculative." (Barlaz, Tr. 2280-81). He also testified that the amount of biodegradation observed in the ECM tests is much

higher than any reasonable interpretation of a priming effect theory and, so, the so-called "priming effect" is not logical. (Barlaz, Tr. 2280).

Finally, Dr. Barlaz testified that his *statistical* calculations would not, in fact, account for possible irregularities in the tests, but he elsewhere testified that he saw no such irregularities that would limit the reliability of the ECM tests, and his statistical model does account for methane production (an exclusively anaerobic characteristic). (Barlaz, Tr. 2275-76).

## III. TO THE EXTENT ECM MADE ANY RATE CLAIMS, THOSE RATE CLAIMS WERE NOT MATERIAL TO PURCHASING DECISIONS

### A. To the Extent ECM Made any Rate Claims, those Rate Claims Were Not Material

Complaint Counsel argues that any rate claim made by ECM, whether express or implied, is presumptively material because those claims "directly relate to the product's central characteristic," that is, that the ECM additive makes plastic biodegradable.[214] However, rate claims in this case, whether express or implied, are not presumptively material because competent survey evidence shows that both ECM's target audience and end-use consumers do not consider rate of biodegradation directly related to the fact of biodegradation. *See supra* Parts I(C)(5)-(6) at 60.

The FTC applies a presumption of materiality to "(1) express claims; (2) implied claims where there is evidence that the seller intended to make the claim; and (3) claims that significantly involve health, safety, or other areas with which reasonable consumers would be concerned." *Kraft, Inc. v. F.T.C.*, 970 F.2d 311, 322–23 (7th Cir. 1992). The first situation applies "[w]here the seller knew, or should have known, that an ordinary consumer would need

[214] Complaint Counsel's Post-Trial Brief, at 76–77.

omitted information to evaluate the product or service, or that the claim was false," and, in such a circumstance, "materiality will be presumed because the manufacturer intended the information or omission to have an effect." *Matter of Cliffdale*, 103 F.T.C. 110, at *49 (1984). The second situation applies "when evidence exists that a seller intended to make an implied claim." *Id.* The third situation can apply when the advertisement concerns information that "pertains to the central characteristics of the product or service." *Id.*

Complaint Counsel argues broadly that "ECM's claims directly relate to the product's central characteristics, [so] they are presumptively material."[215] The assertion is contrary to the record evidence in several respects. The evidence reveals the target audience to be sophisticated plastics manufacturers, not lay consumers. (RPFF ¶¶ 433–604). As such, they know well what affects the central characteristics of their products. (RPFF ¶¶ 397–401). There is not one shred of evidence that any of them presumed that their plastics infused with the ECM additive could predictably result in complete biodegradation within a specific amount of time. Indeed, to the contrary, the tests those companies actually performed aimed at discerning whether the products were intrinsically biodegradable, and resulted in different quantitative amounts of biodegradation based on the kind of plastic tested, and gave no proof beyond intrinsic biodegradability, i.e., no proof of any specific rate. (*See generally* RPFF ¶¶ 2129–2706). To be sure, those manufacturers were concerned that their products infused with the ECM additive not biodegrade too quickly, like the oxo-degradables and bioplastics, to which they objected because they biodegraded on the shelf and, thus, interfered with consumer use. (RPFF ¶¶ 340, 343–47, 705, 724, 1696). It is therefore demonstrably the case that the customers of ECM sought products that would not biodegrade within a short period of time and, rather, expected biodegradation to occur over an

[215] Complaint Counsel's Post-Trial Brief, at 77.

unspecified significant length of time and only after customary disposal. (RPFF ¶¶ 605–08, 620–25, 636–38, 647, 657–59, 661–66, 677–80, 684–86, 693–95, 704–07, 712–14, 716–19).

Complaint Counsel makes no other argument as to why any of ECM's claims are material, *i.e.* that the claims are express claims, that ECM intended to make implied claims, or that the claims involve health, safety or other areas with which reasonable consumers would be concerned.[216] As Complaint Counsel inconsistently, but tellingly, admits, "the additive's central (and only) characteristic is that it purportedly makes plastic biodegradable."[217] Complaint Counsel presents no specific argument that explains with evidence and reason why ECM's rate claims, if any, should be deemed presumptively material under any the circumstances recited in precedent.[218] There is no basis to conclude a single ECM customer purchased the ECM additive based on a claim of rate.

None of the three situations in which the FTC can presume materiality apply to ECM's rate claims. The first situation does not apply. ECM's statements regarding "nine months to five years" were never intended as an unqualified express claim to be taken in isolation. (RPFF ¶ 308). ECM always explained that the rate of biodegradation for each specific plastic was dependent on many variables, including disposal conditions. (RPFF ¶ 310). ECM explained to customers that it had seen products biodegrade in less than nine months in some conditions, however, conditions might result in biodegradation in far more than five years. (RPFF ¶ 311). The time frame was predicated on the specific experience of the additive's founder Patrick Riley,

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[216] *Id.* ("Because ECM's claims directly relate to the product's central characteristic, they are presumptively material … ECM's attempt to rebut the presumed materiality associated with the product's central characteristic falls short.").

[217] *See* Complaint Counsel's Post-Trial Brief, at 77; 80 (stating that "there is undisputed evidence that [consumers] **do** care whether the product is biodegradable") (emphasis in original)).

[218] *Id.* at 76–77.

ECM President Robert Sinclair, and ECM CFO Kenneth Sullivan along with the position of scientists commissioned by ECM to test biodegradability of the additive, including Dr. Barber and Dr. Litt, and qualified as dependent on environmental conditions present at the site of disposal and the presence of biodegrading biota. (RPPF ¶¶ 45–64, 312, 2703). Thus, the rate claim, taken in isolation, was never intended to be an express claim and never conveyed as an unqualified claim.

The second situation does not apply. Complaint Counsel provides no evidence that ECM ever intended to make an implied rate claim. In fact, the evidence makes clear that ECM's intent throughout its correspondence with customers was to disclaim any specific rate of biodegradation for any specific article of plastic. The only record evidence on that point shows that ECM intended their discussions of "rate" only to distinguish its product from competing technologies claiming to satisfy short-term compostability standards. (RPFF ¶ 308). ECM's marketing materials also make clear that ECM did not intend to make any implied rate claims—explicitly stating that the rate of biodegradation depends on a multitude of factors, none of which is predictable in advance of disposal.[219] ECM always explained the actual rate of biodegradation for each specific plastic to customers as an approximation that is, of course, subject to numerous disposal conditions. (RPFF ¶ 310–12). Since the FTC revised the Green Guides, ECM's only rate claim now is the truthful claim that plastic containing the ECM additive will biodegrade in some timeframe greater than one year. (RPFF ¶ 317). ECM's website even explains:

> The basic concept is that biodegradation is a natural process that occurs around the world but at various speeds due to various conditions. Plastics with our additives behave like sticks, branches or trunks of trees. Due to this fact, we do not guarantee any particular time because the time depends on the same factors

[219] *See infra* at Part III(C) at n. 232.

> that the biodegradation of woods and most other organic materials on earth depend – ambient biota and other environmental conditions.[220]

Finally, ECM was aware that its customers were primarily concerned with shelf-life and other properties affecting the performance of plastics containing the ECM additive and, so, the purpose of any discussion on "rate" was to assuage customer concerns that the ECM plastics survive in the market to function as intended—not to disappear quickly. (RPFF ¶¶ 340–44, 705, 724).[221]

Lastly, the third situation does not apply. As Complaint Counsel admits, the central characteristic of the ECM additive is its ability to cause ECM-containing plastic to become "biodegradable," without regard to any rate of biodegradation.[222] The record is replete with evidence that ECM's customers purchased the ECM additive not because it guaranteed biodegradation by any specific time but because it was easily integrated into the plastic manufacturing process, did not negatively affect the plastics' primary features, and rendered the final plastic product intrinsically biodegradable. (RPFF ¶¶ 320, 321, 329–33, 337–48, 359, 395, 431, 605–725).[223] That is why the overwhelming majority of products containing the ECM additive contain no claim at all or claim simply that the product is "biodegradable," but not biodegradable within any specific time. (RPFF ¶ 739). To be sure, the ECM certificate of

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[220] RX 681, at P. 3.

[221] *See also* CCX 5(document authored by ECM wholly devoted to explaining to potential customers the fact that plastic containing the ECM additive will have the same shelf life as plastic not containing the ECM additive, but that plastic containing the ECM additive, like a piece of wood, will biodegrade at once it is exposed to constant contact with other biodegrading materials).

[222] *See* Complaint Counsel's Post-Trial Brief, at P. 77 (conceding that "the additive's central (and only) characteristic is that it purportedly makes plastic biodegradable"); P. 80 (stating that "there is undisputed evidence that [consumers] **do** care whether the product is biodegradable") (emphasis in original)).

[223] *See also infra* at Part III(D)(2) at 152.

biodegradability likewise certifies intrinsic biodegradability but makes no certification as to rate. (RPFF ¶¶ 320, 1348, 1350–52). Therefore, the totality of record evidence overwhelmingly confirms that claims of rate were not material to ECM's plastic manufacturing customers or, for that matter, to the general public. (RPFF ¶¶ 605–725, 728–30, 1331, 1338, 1339).

There are many other concerns for a plastic manufacturer seeking to adopt a new biodegradable technology, including, for instance:

- How the technology affects the performance of the finished plastic product. That analysis involves and assessment of whether the additive influences tensile strength of the material; whether the additive impacts shelf-life or durability; or whether the additive will influence the performance of other additives like colorants; etc.
- The cost of the additive technology relative to other options. That analysis involves an assessment of whether the cost of the ECM additive fits within a business' margins, or whether other competing technologies are more cost effective. For many companies, the expense of additional technologies might outweigh the need to make "environmentally friendly" products at all. ECM is attractive to manufacturers because it can be incorporated in finished products at lower load rates, making the influence on cost bases lower.
- The ability to manufacture plastics without having to change equipment or methods.[224] Other technologies may produce products that more rapidly

[224] For example, many ECM customers (like Quest Plastics), manufacture non-biodegradable conventional plastics almost exclusively. (CCX 817 (Bean, Dep. at 22)). But sometimes they want the option to run an isolated "biodegradable" batch for a specific customer order. (CCX 817 (Bean, Dep. at 19) (explaining that a single customer wanted Quest "to find an additive that would make those golf tees biodegradable"). Quest's primary interest is therefore

biodegrade, but changes to equipment or manufacturing components add significant expense, which for certain companies may not be worth the cost.

- The ability to recycle the finished biodegradable plastic. Unlike other technologies, plastics made with the ECM additive usually remain recyclable because the ECM technology is incorporated at lower load ratings.

(RPFF ¶¶ 338–40, 344, 387, 395, 401, 404, 408-09, 412, 724). Indeed, with all those more paramount and practical concerns, arguing that the "rate" of biodegradation (which is inherently unknowable and speculative for any specific piece of plastic) is material to the purchasing decision is a leap in conflict with the factual record. The "rate" of biodegradation is something that becomes relevant (if at all) long after an end-use consumer has discarded the product. But the consumer must first use the product and be satisfied with its functionality. For instance, if the consumer's plastic grocery bag tears in the parking lot before reaching the car, then a claim about rapid biodegradation or "biodegradability" will be no consolation. Thus, aside from the record support, common sense dictates that ECM's customers are primarily concerned with the practical questions partly outlined above.

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in making a "biodegradable" plastic without having to substantially change its manufacturing process. (CCX 817 (Bean, Dep. at 25) (noting that other products purporting to render plastic biodegradable "didn't seem to fit [Quest's] process, or possibly they were cost prohibitive … They weren't an additive necessarily to the material [Quest] was using. They were a material all by themselves.")). As Quest's designee testified, Quest purchased the ECM additive because it is "usable in [Quest's] process and it seemed to be what [Quest's] customer was looking for," which was "to make his golf tees biodegradable … that [is] putting them in the ground and leaving them there, they'd disappear over time." (CCX 817 (Bean, Dep. at 26)). The ECM additive is attractive for that purpose, and there is no indication that "rate" of biodegradation has anything to do with the transaction.

### B. To the Extent ECM Made any Representations Of Rate, and to the Extent those Representations Were Material in any Single Case, ECM Rebutted that Presumption of Materiality

Complaint Counsel argues that ECM failed to rebut the presumption of materiality because ECM failed to provide evidence that rate claims are not directly related to the additive's central characteristics. However, ECM has supplied sufficient evidence to meet the low hurdle of rebutting a presumption of materiality.

A respondent can rebut the presumption of materiality with extrinsic evidence. *See In the Matter of Pom Wonderful LLC*, 2012 WL 2340406 (F.T.C. May 17, 2012). As explained in *POM Wonderful* and *Novartis*:

> A respondent can present evidence that tends to disprove the predicate fact from which the presumption springs (*e.g.*, that the claim did *not* involve a health issue) or evidence directly contradicting the initial presumption of materiality. This is not a high hurdle. Unless the rebuttal evidence is so strong that the fact finder could not reasonably find materiality, the fact finder next proceeds to weigh all of the evidence presented by the parties on the issue. *See id.* at 516 (noting that after the presumption drops out, "the inquiry ... turns from the few generalized factors that establish [the presumption] to the specific proofs and rebuttals ... the parties have introduced").

*Id.* at *235.

ECM has met the low hurdle of rebutting any presumption that ECM's representations of rate were material, and established by a preponderance of the evidence that the claims were not material. ECM's CEO and CFO testified extensively that from his interactions with customers he understood they did not think rate of biodegradation was a central characteristic of the ECM additive. For example, Mr. Sinclair, ECM's President and CEO, testified to the fact that the ECM certificate of biodegradability, given to each ECM customer, contains no rate claim, (RPFF ¶ 320), that ECM's customers are not concerned with the rate of biodegradability, (RPFF ¶ 321), and that ECM customers are interested in a "biodegradable" product that can work with their

manufacturing systems, because the plastic has to serve a function foremost, (RPFF ¶ 331). Furthermore, Complaint Counsel's assertion that Mr. Sinclair only testified at his deposition, but not at the hearing, that ECM used the "nine months to "five years" claim only to distinguish the ECM additive from faster-degrading compostable material is in error. He testified consistently at deposition and at hearing to that point.[225]

Similar to Mr. Sinclair, Mr. Sullivan, ECM's CFO, testified at deposition and at hearing that the ECM customer is primarily interested in the ECM Additive because it provides a cost-effective method to produce a biodegradable product in the modern, environmentally friendly market and that ECM customers are primarily concerned with how their product will perform (i.e. maintain its other attributes) after the addition of the ECM additive.[226]

ECM's marketing materials no longer contain the nine month to five year statement. (RPFF ¶¶ 314, 376). ECM permanently discontinued the statement in 2012. There is no evidence that ECM lost business from abandoning the former rate claim. Moreover, contrary to Complaint Counsel's assertion, ECM's marketing materials never "emphasized" the nine months to five years statement.[227] Rather, the statement, in the instances where ECM made it, was either one of a number of bulleted statements in a document, or one sentence on a document containing many paragraphs. For example, in support of their argument that ECM emphasized the nine month to five year statement, Complaint Counsel cite to three documents.[228] On the first one, CCX 3, the nine month to five year statement is merely one bullet point out of many describing the features of the ECM additive.[229] The second document, CCX 6, contains just one sentence

[225] Cf. Sinclair, Tr. 768 to CCX 818 (Sinclair, Dep. at 77–79).
[226] Cf. Sullivan, Tr. 696, 709 to CCX 820 (Sullivan, Dep. at 56–57).
[227] Complaint Counsel's Post-Trial Brief, at P. 82.
[228] *Id.*
[229] *See* CCX 3.

stating the time frame, and contains many more sentences explaining how plastic containing the ECM additive can biodegrade, and that "[a]ll sorts of factors determine the amount of microbes available in the soil and the soil conditions determine the rate of degradation."[230] Lastly, CCX 7 is a nine page marketing brochure wherein ECM stated only on the sixth page and in one bullet the nine month to five year statement.[231] Moreover, the totality of the evidence reveals that on the ECM web site and in ECM communications to its customers it actually emphasized the point that for any particular piece of plastic made by a manufacturer with the additive, the rate of biodegradation for that plastic depended on numerous environmental variables not predictable in advance of disposal.[232]

### C. In Context, The Net Impression Of The 9 Months To 5 Years Statement Is Defined By The Concurrent Qualification That The Rate Of Biodegradation For Any Specific Plastic Made By A Manufacturer Is Dependent Upon Numerous Environmental Variables Not Predictable In Advance Of Disposal

Complaint Counsel points to few instances out of hundreds of thousands of documents as evidence that ECM's statements regarding rate of biodegradation were material claims.[233] However, in evaluating alleged claims in advertising, the Commission looks to the "net impression" derived, not to an interpretation of the gist or sting of the language attributable to the

[230] CCX 6.

[231] CCX 7, at P. 6.

[232] *See, e.g.* CCX 5 ("The basic concept is that biodegradation is a natural process that occurs around the world but at various speeds due to various conditions. Plastics with our additives behave like sticks, branches, or tree trunks. Due to this fact, we do not guarantee any particular time because the time depends on the same factors that the biodegradation of woods and most other organic materials on earth depend – ambient biota and other environmental conditions …"); CCX 6 ("All sorts of factors determine the amount of microbes available in the soil and the soil conditions determine the rate of degradation."); CCX 11 (same); CCX 19, at P. 10 (same); RX 135 (collection of e-mails)).

[233] Complaint Counsel's Post-Trial Brief, at 77–79.

language alone and out of context. *F.T.C. v. Wash Data Ress.*, 856 F. Supp. 2d 1247, 1272 (M.D. Fla. 2010). The nine months to five years statement must be interpreted in context of the overall pre-purchase customer interactions and correspondence had by ECM.[234]

In this case, the nine month to five year statement was the subject of various written and verbal exchanges ECM had with customers in which repeatedly ECM explained that for any individual piece of plastic made by a manufacturer the rate of biodegradation was ultimately dependent on numerous environmental variables, which are themselves not predictable in advance of disposal. Moreover, the audience receiving these messages weighs heavily in assessment of the "sting" of the communication. *Schering-Plough Healthcare Prods., Inc. v. Schwartz Pharma, Inc.*, 547 F. Supp. 2d 939, 943 (E.D. Wisc. 2008). In that regard, the recipients were all sophisticated plastics manufacturers, very familiar with the tensile strength, use, and disposal characteristics of the plastics they produce. (RPFF ¶¶ 296–98, 300–04, 396, 386, 388–401, 408–09, 433–604). Those customers evaluated the ECM additive, integrated the additive into production samples of their own plastic, and evaluated and tested the additive containing plastics—doing all of this before purchasing the additive. (RPFF ¶¶ 408–09). Consequently, to the extent that they were even aware of the 9 months to 5 years statement, they

[234] *See* ECM's Proposed Conclusion of Law No. 40 ("In reviewing allegedly false and misleading statements, courts are to read the statements in their entirety and in context to determine whether they are actionable." *Schering-Plough Healthcare Prods., Inc. v. Schwartz Pharma, Inc.*, 547 F. Supp. 2d 939, 943 (E.D. Wisc. 2008) (citing *Southland Sod Farms v. Stover Seed Co.*, 108 F.3d 1134, 1139 (9th Cir 1997) ("[w]hen evaluating whether an advertising claim is literally false, the claim must always be analyzed in its full context")); *Castrol, Inc. v. Pennzoil Co.*, 987 F.2d 939, 946 (3d Cir. 1993) ("in assessing whether an advertisement is literally false, a court must analyze the message conveyed in full context"); *Schwarz Pharma, Inc. v. Breckenridge Pharm., Inc.*, 388 F.Supp. 2d 967, 976 (E.D. Wis. 2005) ("To determine whether a particular representation is literally false, it must be analyzed with its full context")). "In addition, the specific audience is part of the context that must be considered in deciding whether a statement is literally false." *Schwarz*, 388 F.Supp. 2d at 976.

were possessed of direct evaluative information that became their source of reliance, rendering the 9 months to 5 years statement one without a "sting" in light of the fact that the customers' purchasing decision depended on their own independent evaluation. *See Terra Securities ASA Konkursbo v. Citigroup, Inc.*, 450 Fed. App'x 32, 34 (2d Cir. 2011) (reliance by the plaintiff on representations made by the defendant was unreasonable where the plaintiff was sophisticated, conducted no independent investigation, and had "available the means of ascertaining the truth").

Additionally, Dr. Stewart testified that, from a consumers' perspective and from the plastic manufacturers' perspective, the rate of biodegradation was not material. (RPFF ¶¶ 1332–38). Similarly, based on the limited data in the manufacturers pilot survey, Dr. Stewart testified that that data showed that among those 10 respondents there is substantial variation in opinions about how quickly a biodegradable product should take to decompose. (RPFF ¶ 1343). Therefore, ECM presented "evidence that tends to disprove the predicate fact from which the presumption springs"—to wit, that rate of biodegradation is a central characteristic of the ECM additive. *Pom Wonderful*, 2012 WL 2340406, at *235.

### D. A Preponderance of the Evidence Demonstrates that Rate of Biodegradation of Plastic Containing the ECM Additive Was Not Material to ECM's Sophisticated Plastic Manufacturer Customers and Not Material to End-Use Consumers

In approximately one page of text, Complaint Counsel suggests that, regardless of presumption, the evidence establishes that ECM's rate claims, whether express or implied, are material to both ECM's customers and to consumers.[235] A preponderance of evidence, however,

[235] Complaint Counsel's Post-Trial Brief, at 81–82.

clearly demonstrates that rate of biodegradation is immaterial to ECM's customer and end-use consumers.

Once a respondent has presented evidence that tends to disprove the predicate fact from which the presumption of materiality springs, "the fact finder next proceeds to weigh all of the evidence presented by the parties on the issue" of materiality. *Pom Wonderful*, 2012 WL 2340406 at *235.

In order to determine whether an advertisement is material, "[t]he basic question is whether the act or practice is likely to affect the consumer's conduct or decision with regard to a product or service." *Cliffdale Assocs., Inc.*, 103 F.T.C. 110, at *45 (1984)). "In other words, [information that is material] is information that is important to consumers." *Id*. at *49. As the Seventh Circuit stated, "[a] claim is considered material if it involves information that is important to consumers and, hence, likely to affect their choice of, or conduct regarding, a product." *Kraft, Inc. v. F.T.C.*, 970 F.2d 311, 322 (7th Cir. 1992) (internal quotations and citations omitted); *see also F.T.C. v. Colgate-Palmolive Co.*, 380 U.S. 374, 391 (1965) (citing *F.T.C. v. Raladam Co.*, 316 U.S. 149, 152 (1942)) ("when the Commission finds deception it is also authorized, within the bounds of reason, to infer that the deception will constitute a material factor in a purchaser's decision to buy"). In sum, "[m]ateriality turns upon whether those consumers who have drawn the claim from the advertisement and have been misled by it are also **likely to have their conduct affected by the misrepresentation**." *In re Novartis Corp.*, 127 F.T.C. 580, 691 (1999) (emphasis added).

### 1. A Preponderance of the Evidence Demonstrates that Rate of Biodegradation of Plastic Containing the ECM Additive Is Not Material to ECM's Customers

Evidence in the form of hearing testimony from Mr. Sinclair and Mr. Sullivan, deposition testimony from ECM customers, and evidence from documents in the record consistently demonstrate that ECM's customers' conduct was not affected by ECM's rate representations, to the extent that ECM even made any rate representations. As noted above, Mr. Sinclair and Mr. Sullivan testified extensively that ECM's customer simply did not care about the rate of biodegradation and did not purchase the ECM additive predicated on a need for the plastic to biodegrade by any specific time. *See supra* at Part III(B) at 141. Rather, Mr. Sullivan and Mr. Sinclair testified that ECM's customers purchased the ECM additive because it rendered plastic containing the ECM additive intrinsically biodegradable as defined by ASTM and scientific standards, (RPFF ¶¶ 320, 321, 341, 357, 358, 359, 387, 431), because it was a cost-effective alternative to bioplastics, (RPFF ¶¶ 322, 328, 330, 333, 336, 338, 345, 387), and because it did not alter the other properties of the plastic needed to assure its utility in the market. (RPFF ¶¶ 329, 331, 332, 335, 341, 343–45).

Mr. Sinclair's and Mr. Sullivan's testimony is complemented by the deposition testimony of ECM's customers. For example, one ECM customer, BER Plastics, never even thought about how long it would take plastic containing the ECM additive to biodegrade. (RPFF ¶ 605). That is probably because BER Plastics' customers only wanted a product that they could call biodegradable and environmentally sensitive, and did not themselves care about rate of biodegradation. (RPFF ¶ 607–08). Similarly, Dispoz-o/D & W Fine Pack purchased the ECM additive because they wanted a "green product that [they] could bring to the marketplace" not because it would biodegrade within any specific time. (RPFF ¶ 620). Dispoz-o also understood

only that their product containing the ECM additive "would degrade over a period of time" not that it would biodegrade within any specific time. (RPFF ¶ 624).

Down to Earth Organic and Natural chose to purchase plastic bags containing the ECM additive because those bags biodegrade with or without oxygen, because of the price as compared to compostable products, and because using plastic bags containing the ECM additive would further their purpose of cherishing the land and living in health and harmony. (RPFF ¶¶ 636, 638). Like the other companies, Eagle Film Extruders, Inc. and their customers only wanted blown film amended with the ECM additive because they wanted to sell an environmentally-friendly biodegradable product. (RPFF ¶ 647). In none of these cases did the customer base its purchasing decision, in whole or part, on the notion that the additive containing plastic would biodegrade in the environment by any set time.

Flexible Plastics and their customers use the ECM additive because they want to sell a more environmentally friendly plastic bag. (RPFF ¶¶ 658, 662). It was important to Flexible Plastics that any additive they added to their bags would not dramatically change their pricing. (RPFF ¶ 659). FP International and their customers simply wanted products that lessen their impact on the environment and give them a market advantage. (RPFF ¶¶ 677–80, 685). Plainly, FP International's customers do not care how long it takes ECM amended plastics to biodegrade, so long as it takes less time than non-amended conventional plastics. (RPFF ¶ 684). Kappus Plastic Company and their customers also purchased the ECM additive because they wanted a product that was biodegradable and more environmentally friendly. (RPFF ¶¶ 693–95). Quest Plastics, Inc. chose to purchase the ECM additive because it is usable in their manufacturing process, was not cost prohibitive, and rendered golf tees biodegradable. (RPFF ¶ 706). ANS Plastic Corporation's customers were interested in a biodegradable or "green" product because

they wanted to be "green." (RPFF ¶¶ 712–13, 720). ANS Plastic Corporation's customers never asked about the rate of biodegradation for ECM amended products, and only wanted to know whether they were buying a biodegradable bag. (RPFF ¶¶ 717, 718).

Note well that despite almost twenty fact depositions in this case, many of which involving ECM customers, there is no evidence in the testimonial record that ECM customers were influenced in their purchasing decisions by the "rate" claims in any way.

Furthermore, documentary evidence proves that "rate" of biodegradation was not a basis for ECM's customers' purchasing decisions. Rather ECM's customers explained that they based their purchasing decisions on a number of factors other than rate. For example, ECM customers based their purchasing decisions on their understanding of the additive's ingredients.[236] Documentary evidence also shows that ECM customers, as backed by the deposition cited above, purchased the ECM additive because it caused plastic to generally become more environmentally friendly.[237] ECM customers also wanted to ensure that the additive was safe for food products.[238] ECM customers also wanted to make sure that the additive would be easily incorporated into the manufacturing process.[239] Further, just as Mr. Sinclair testified, documentary evidence shows that ECM customers were concerned with the shelf life of plastic containing the ECM additive (meaning that they did not want it to rapidly biodegrade but to biodegrade only after the plastic was discarded for customary disposal).[240]

Complaint Counsel undergirds its rate claim materiality argument on a single piece of evidence, a communication log referencing an e-mail correspondence between Mr. Sinclair and

[236] RX 126.
[237] RX 128.
[238] RX 129.
[239] RX 130.
[240] RX 133.

one customer or potential customer of ECM.[241] That lone communication log,[242] between Mr. Sinclair and "Westchem Group," lacks any foundation. The Court cannot know who "Westchem Group" is, what question Mr. Sinclair was purportedly responding to when he purportedly wrote that "Lots of people get hung up on how long" (wherein Mr. Sinclair is obviously speaking colloquially), or *why* people were supposedly hung up on how long in that unknown context.[243] Moreover, the single log entry is but one interaction among many, and there remains nothing of record to rebut Mr. Sinclair's statement that in his discussions with customers he emphasized that for any particular piece of plastic made by them the rate of biodegradation was dependent on numerous environmental factors that could not be predicted in advance of customary disposal. (RPFF ¶¶ 310–312; 320).

Complaint Counsel's other "evidence" is similarly unreliable hearsay without foundation.[244] The few e-mails to and from ECM and its customers and/or potential customers were cherry picked by Complaint Counsel from more than 100,000 pages of e-mail communications ECM produced during discovery. (RPFF ¶ 30). Furthermore, it is impossible to know, without testimony regarding those e-mails, what ECM's customers actually meant when asking questions about rate of biodegradation, why they cared (if they cared at all) about rate of biodegradation, or whether, in the end, rate factored into their actual purchasing decisions because in no instance do those communications express that rate was a basis for a purchase. *See*

[241] Complaint Counsel's Post-Trial Brief, at P. 78.

[242] CCX 423, at P. 9.

[243] The Court ruled at the hearing that all content in these communications logs is hearsay because that content is not even entered by Mr. Sinclair, but, in this case, by someone with the initials "ML." Chappell, Tr. 856; CCX 423, at P. 9 (initials on right side of the entry).

[244] *See* Complaint Counsel's Post-Trial Brief, at P. 78–79, n. 119, n. 120.

*Lozano v. Ashcroft*, 258 F.3d 1160, 1166 n. 6 (10th Cir. 2001) (reasoning that, because a document is hearsay, the court cannot know the basis for the content in the document).

Moreover, the testimony reveals the pre-purchase interactions with customers to be lengthy, covering 6 months to 2 years, and to be multifaceted, involving not only written communication but also more extensive verbal exchanges. (RPFF ¶¶ 307, 1681, 1679). Random excerpting of single sentences from such complex interactions does not, absent more, establish that indeed a purchase, if had at all, arose in part or whole based on the sharing of rate information as opposed to the many other factors discussed (that, of course, is particularly true here where the testimony of customers, the testimony of ECM principals, and other documentary evidence cited above reveal rate not to have been material to purchasing decisions). *See supra* at Part III(D)(1) at 147. A few statements in emails offered for the truth of the matter despite their hearsay content are no counterweight for the direct in-court testimony of witnesses,[245] the deposition testimony of customers in response to Complaint Counsel questioning, (RPFF ¶¶ 605–725), the competent survey evidence from Dr. Stewart,[246] and the other documentary evidence demonstrating that ECM's customers did not base purchasing decisions on the rate of biodegradation of plastic containing the ECM additive.[247]

ECM Customers explained that in making a purchase they were concerned with shelf-life and product durability rather than the specific time it takes for the product to fully biodegrade. (RPPF ¶¶ 340, 705, 724). In fact, customers only made requests of information on the time it takes ECM plastics to fully biodegrade in the context of regulatory compliance inquiries. (RPFF ¶ 725). If not for the FTC and the Green Guides making rate of biodegradation a legal concern,

[245] *See supra* at Part III(D)(1) at 147.
[246] *See supra* at Part I(C)(5) at 50; *supra* at Part I(C)(6) at 60.
[247] *See supra* at Part III(D)(1) at 147.

there is no evidence that any ECM customer would have cared about the rate of biodegradation at all, and there is no evidence, not even the excerpted emails, that demonstrate a single purchase decision was predicated on the accuracy of rate information. (RPFF ¶¶ 605–725).

### 2. A Preponderance of the Evidence Demonstrates that Rate of Biodegradation of Plastic Containing the ECM Additive Is not Material to End-Consumers

First and foremost, there is no evidence that any consumer ever changed their conduct based on any rate claim made by ECM, and therefore, ECM's rate claims, if any were even made, cannot be material to consumers. *See Kraft, Inc. v. F.T.C.*, 970 F.2d at 322 (explaining that "a claim is considered material if it involves information that is important to consumers and, hence, likely to affect their choice of, or conduct regarding, a product"); *In re Novartis Corp.*, 127 F.T.C. at 691 (emphasis added) (holding that "materiality turns upon whether those consumers who have drawn the claim from the advertisement and have been misled by it are also **likely to have their conduct affected by the misrepresentation**").

In fact, Complaint Counsel failed to even argue in their Post-Trial Brief that any consumer changed his or her conduct because of any of ECM's representations, let alone because of any alleged ECM implied or express rate claims.[248] Complaint Counsel argued in their opening statement, and presumably will argue at closing argument, that one example of consumers changing purchasing decisions because of ECM's claims is that on "Earth Day" 2009, Down to Earth "debuted its [ECM] biodegradable grocery bag" and broke sales records that day.[249] However, Down to Earth did not break sales records that day because of it offered plastic

[248] *Id.* at 76–82.
[249] Johnson, K. Tr. 23, 33.

bags containing the ECM additive; rather, Down to Earth broke sales records that day because they had a storewide sale and offered 30% off on over 50 of their best-selling items. (RPFF ¶¶ 498, 500).

Second, there is no evidence that any consumer ever purchased, knowingly or unknowingly, any plastic containing the ECM additive in any form. (RPFF ¶¶ 731–34). For example, Complaint Counsel cited to the fact that Island Plastic Bags manufactured about 10 million plastic bags containing the ECM additive.[250] However, Island Plastic Bags only sells to distributors or retailers, and not consumers. (RPFF ¶¶ 560, 564, 565). One such company that Island Plastic Bags sold plastic bags containing the ECM additive to is Triple F, which then sold those bags to Down to Earth Organic and Natural. (RPFF ¶ 501). However, no consumer ever purchased a plastic bag containing the ECM additive from Down to Earth; rather, like the typical grocery store, the bags were simply given to consumers after check out, at a time when those consumers have already made their purchases of other products (e.g., groceries). (RPFF ¶ 641). Therefore, because there is no evidence that a consumer ever purchased an item containing the ECM additive, any claim by ECM cannot be material to any consumers' purchasing decision.

Furthermore, Dr. Stewart testified that no significant minority of American consumers imply any rate claim when they see just a "biodegradable" claim. (RPFF ¶ 1305). Dr. Stewart explained that 98% of consumers understand that rate of biodegradation depends on a multitude of factors. (RPFF ¶¶ 1300–02, 1310). Dr. Stewart also explained that no significant minority of American consumers share a common understanding of biodegradation or a common understanding of the rate of biodegradation. (RPFF ¶¶ 1317, 1331). Therefore, even assuming, *arguendo*, that some consumers did alter their conduct because of "biodegradable" claims on

[250] Complaint Counsel's Post-Trial Brief, at P. 79.

certain products, those consumers did not alter their conduct because they believed that the products with a "biodegradable" logo on them would biodegrade in any specific time. (RPFF ¶¶ 1300–06, 1310–13, 1315–17, 1336–39).

The fact that consumers rarely saw a rate of biodegradation is also evidence that consumers could not have based their conduct on any rate representations ECM made to its plastic manufacturer customers, to the extent ECM made any rate representation at all. In the few instances of record where evidence exists of consumers receiving a representation initially made by ECM, the end-customer is provided with a naked "biodegradable" claim and not a rate claim, which "biodegradable" representation is the only one ECM has in its certificate of biodegradability. (RPFF ¶ 319). In that minority of instances where any representation appears on a plastic product made by a company that has made the product with an ECM additive, the overwhelming majority of such advertisements do not mention or focus on rates of biodegradation. (RPFF ¶ 739). To the extent that Complaint Counsel found instances where consumers did see a rate claim, Complaint Counsel provided no evidence that the product in issue reached any set number of consumers, reached even a significant minority of consumers, or caused a single consumer to change any conduct based on the rate claim.[251]

The Down to Earth example is again pertinent here, because the Down to Earth Bags are among the few instances where Complaint Counsel provided the court with proof that a finished product (sold in a single chain of grocery stores in Hawaii) contained a rate claim; however, Complaint Counsel provided no evidence that consumers shopped at Down to Earth because they gave away bags bearing that rate claim at check out. Furthermore, even if the fact that Down to Earth provided consumers with plastic bags containing the ECM additive affected those

[251] *Id.* at 79–80.

consumers' purchasing decisions, there is no evidence that consumers shopped at Down to Earth because of the rate claim on the bag, as opposed to the fact that bag is intrinsically biodegradable.

In other words, the want of proof is so profound, with proof of a purchase predicated on a rate claim so dependent on evidence not of record, that the mere fact of the Hawaiian grocery stores' use of a plastic bag bearing a rate claim is without probative value under the factors for decision. Even were it otherwise, evidence of customers of one grocery store chain in Hawaii making purchases of products based on rate claims on plastic bags given them at the time of purchase does not prove that even a significant minority of consumers nationwide made purchases predicated on rate claims.

Adrian Hong is the Marketing Director of Down to Earth, the company that provided bags to Down to Earth through Triple F. (RPFF ¶¶ 487, 501). His testimony supports Mr. Sinclair's testimony that ECM and its customers used the nine month to five year statement to differentiate itself from competing technologies, not as proof of a prediction that any specific piece of plastic would completely disappear in the environment within any set time. When asked why Down to Earth placed the nine month to five year claim on their plastic bags, Mr. Hong testified that Island Plastic Bags "want[ed] people to know, you know, how [the bag] breaks down and what it breaks down into."[252] When asked why Island Plastic Bags wanted people to know that, Mr. Hong testified that its:

> Because people – there's a lot of people that say they're degradable or they say they're green, and really all they're using is recycled plastics, they aren't using anything that break down the plastics into, you know, water, carbon dioxide and stuff like that. So we want people to know how it does that so that they feel like this is an actual technology that is biodegrading, it's for real.[253]

[252] CCX 811 (Hong, Dep. at 54).
[253] *Id.* at 55.

Mr. Hong's testimony makes clear that Island Plastic Bags, and by extension Down to Earth, placed the rate on the plastic bags only because they wanted to ensure that customers and consumers understood that the bags actually break down. No one, not the consumer receiving the bag, not the company providing the bag, and not the company producing the bag, cared at all the specific time within which any particular bag would break down; rather they just cared that the bags were not merely made from recyclable materials and that the bags would actually biodegrade.

### E. Complaint Counsel's Erroneous Dismissal of Scientific Immateriality

Complaint Counsel argues that "whether 'nine months to five years' is irrelevant to a landfill expert with a Ph.D. in environmental engineering says nothing [about] the claim's relevance to ECM's customers or consumers."[254] Complaint Counsel's argument fails to appreciate the significance to materiality analysis of the fact that rate of biodegradation is in the end immaterial from an environmental science perspective. The absence of materiality from an environmental science perspective supports ECM's public interest defense.[255]

Because there is no evidence that any consumer suffered any legally cognizable injury as a result of any claim made by ECM, (RPFF ¶¶ 731–34), the fact that there is also no harm to the environment if plastic containing the ECM additive take longer than nine months to five years to biodegrade in a landfill demonstrates that absolutely no harm to anyone or the environment resulted from any claim of rate made, whether express or implied.[256] Indeed, to the contrary,

[254] Complaint Counsel's Post-Trial Brief, at P. 81.
[255] *See* ECM's Post-Trial Brief, at 195–200.
[256] *See id.*

longer rather than shorter periods of biodegradation in a landfill are preferable environmentally because they result in fewer harmful greenhouse gas emissions.[257]

## IV. ECM DID NOT PROVIDE ITS CUSTOMERS WITH THE MEANS AND INSTRUMENTALITIES TO MAKE A RATE CLAIM

Complaint Counsel contends that ECM provided its customers the means and instrumentalities to deceive end-use consumers by providing its customers the means to make an economically beneficial claim.[258] Complaint Counsel makes this argument despite the evidence showing that only two end-use products contained rate claims, and those products were not purchased by end-use consumers.[259] Complaint Counsel further states that ECM provided its customers with its logo, certificate of biodegradability, and marketing materials; thus ECM provided the means to pass its claims on to end-use consumers.[260] However, the materials that Complaint Counsel identified do not support the proliferation of rate claims, and instead support mere unqualified "biodegradable" claims.[261]

### A. No Product Containing a Rate-Claim was Ever Purchased By an End-Use Consumer

Complaint Counsel argues that it is "self-evident" that ECM's "claims" provide economic value solely because they can be passed down the distribution chain, eventually reaching end-use consumers.[262] However, Complaint Counsel never addressed the fact that rate

[257] RX 853 (Barlaz, Rep. at 3 ("Our research has shown that slower biodegradability is better for the environment as it allows for more complete capture of the $CH_4$ that is produced.")).
[258] Complaint Counsel's Post-Trial Brief, at 83-84.
[259] *See, e.g.*, Complaint Counsel's Proposed Finding of Fact ¶ 36.
[260] Complaint Counsel's Post-Trial Brief, at 84-86.
[261] *See infra* at Part IV(B) at 159.
[262] Complaint Counsel's Post-Trial Brief, at 83-84.

claims were not passed down the chain to even a significant minority of end-use consumers.[263] In fact, ECM's "nine month to five year" language (discontinued approximately three years ago) has almost never made its way to the end-use consumer level, and invariably, the end-customer is provided with an ECM containing product that bears no claims at all or, if a claim is made, it is ordinarily a naked "biodegradable" claim, which is the only claim ECM has in its certificate of biodegradability. (RPFF ¶ 739). Even among the numerous examples cited in Complaint Counsel's Proposed Finding No. 36, only two products that could potentially be seen by an end-use consumer (but not purchased) contain any rate claim.[264] Thus, the nine months to five years statement was not passed on to even a significant minority of end-use consumers and has not been shown in a single instance to be the basis of a purchasing decision (the bags in issue were given away, not sold). Therefore, according to Complaint Counsel's own evidence of record, the "nine months to five years" timeframe provides no economic value. Said differently, the alleged rate claim has not been shown in fact or in reason to be material to a single purchase by a single end-use consumer.[265]

There is no evidence in the record showing that any consumer ever purchased any product containing any reference to ECM, any biodegradable claim, or any rate claim.[266] In fact, the evidence shows just the opposite: end-consumers did not purchase plastics containing the ECM additive but were given them and were, if exposed at all to a representation, almost invariably shown a "biodegradable" claim containing no rate. (RPFF ¶ 319). Complaint Counsel provided evidence that a rate claim was placed on only two products that *reached* (but

[263] *See* Respondent's Response to Complaint Counsel's Proposed Finding of Fact ¶¶ 25, 36.

[264] Complaint Counsel's Proposed Finding of Fact ¶ 36.

[265] *See supra* at Part III(D)(2) at 145.

[266] *See Id.*

were not purchased by) end-use consumers.[267] CCX 44 and CCX 45 are images of plastic grocery bags produced by Island Plastic Bags and CCX 134 is a plastic popcorn bag. Those products are not actually end-use consumer products, instead they are products sold to retailers and ultimately given away by retailers to an extreme minority of end-use consumers. There is no evidence to suggest that consumers base their popcorn purchasing decision on the characteristics of the popcorn bag, or choose the groceries they buy based on the type of bags given them at check-out. Indeed, the evidence—not to mention common sense—supports the conclusion that consumers choose popcorn and grocery store items primarily based on the characteristics of the specific popcorn and other foods and because of price considerations of those items, such as sales on popular products.[268]

### B. ECM Provided Its Customers With the Means and Instrumentalities to Make a "Biodegradable" Claim, Not a Rate Claim

Complaint Counsel argues that ECM provided customers the means to make a "biodegradable" claim. As Complaint Counsel points out, ECM provided its customers with a logo, certificate of biodegradability, and informational material.[269] Not one of those documents would enable the plastic manufacturer customer of ECM to have a means to represent that its specific plastic infused with the ECM additive would biodegrade in the environment by any specific time. Of those materials, only the ECM logo was intended by ECM to reach the retail/end-use consumer level, and that logo contains no rate information at all.[270] The logo, as

[267] CCX 44–45; CCX 134.
[268] *See supra* at Part III(D)(2) at 152.
[269] Complaint Counsel's Post-Trial Brief, at 84–86.
[270] *See* Complaint Counsel's Proposed Findings of Fact, ¶¶ 25, 64 (note that there is no evidence that these products were purchased by end-use consumers or placed in retail stores for consumers to buy); CCX 44-45.

described by Complaint Counsel, merely contains a green tree with the wording "ECM" and "Biodegradable."[271] The logo contains no rate claim.[272] To the extent that Complaint Counsel contends that the word "biodegradable" in the ECM logo contains an implied rate claim, *supra* at Part I(C)(6) at 60 explains that no significant minority of consumers interprets the word "biodegradable" to mean decompose into elements found in nature within one year, let alone any specific time frame.

Furthermore, the ECM certificate of biodegradability, which was disseminated to every ECM customer, originally contained no rate claim.[273] Instead, that version of the certificate claimed that:

> This Certificate and the Ecological Assessment of ECM Plastic report, along with Scanning Electron Microscope and other studies that have been conducted since the publication of the Ecological Assessment, all of which use a one percent loading rate of the ECM MasterBatch Pellets rather than the higher additive levels used earlier, have been presented to [COMPANY NAME], and may be used by it to validate its claims to the biodegradability and environmental safety of plastic products that it manufactures that are made consistent with the manufacturing guidelines for uses of ECM MasterBatch Pellets presented to it by ECM BioFilms, Inc.[274]

However, after the 2012 revision of the green guides, ECM understood that a "biodegradable" claim would be considered deceptive by the FTC unless the product completely biodegraded into elements found in nature within one year of customary disposal. (RPFF ¶¶ 316–17). From that point forward, ECM placed an asterisk on the "biodegradable" claim in its Certificate of Biodegradability, indicating that the plastic product "biodegrades in any biologically active environment (including most landfills) in some period greater than a year."[275]

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[271] Complaint Counsel's Post-Trial Brief, at P. 84.
[272] CCX 8; CCX 13.
[273] CCX 18.
[274] CCX 18.
[275] CCX 14.

That statement was intended to, and did, make clear that the "biodegradable" claim in the Certificate of Biodegradability was not based on the Green Guides' definition of biodegradability, but instead was in accordance with the scientific definition of biodegradability.

Furthermore, in case there was any doubt as to how ECM was defining degradable and biodegradable, every "Certificate of Biodegradability" ECM issued contained the ASTM definition of "degradable plastic" and "biodegradable plastic." For example, the 2011 version of the certificate biodegradability defined "degradable plastic" and "biodegradable plastic" as defined under ASTM D1991:

> A Degradable Plastic is defined (ASTM D1991) as a plastic that is designed to undergo a significant change in its chemical structure under specific environmental conditions resulting in a loss of some properties that may vary as measured by standard test methods appropriate to the plastic and the application in a period of time that determines its classification. A Biodegradable Plastic is defined as a degradable plastic in which the degradation results from the action of naturally occurring microorganisms such as bacteria, fungi, and algae.[276]

(RPFF ¶ 320). Similarly, more recent versions of ECM's Certificate of Biodegradability contain an identical definition of degradable plastic and biodegradable plastic, as defined by ASTM D883-12.[277] ASTM is a highly respected scientific organization whose definition of "biodegradable" is widely accepted in the scientific community. (RPFF ¶¶ 790, 792–94, 1450). That definition does not include a claim of rate. (RPFF ¶ 320).

Finally, there is no evidence that the informational material that Complaint Counsel identifies ever reached the end-use consumer level, or that claims contained therein were ever disseminated to consumers[278] That material was always intended to be exchanged exclusively

[276] CCX 18.
[277] CCX 14.
[278] Tr. 1-3005.

with sophisticated plastics manufacturers, and to the extent that the material contained a rate representation, that representation was intended to distinguish ECM amended plastics from their rapidly degrading competitors. (RPFF ¶¶ 300–04, 308). The evidence also demonstrates that to the extent ECM made any rate representations, they were made in the context of complex and lengthy business transactions and were accompanied by considerable information explaining that biodegradation rates vary based on numerous environmental factors not capable of being predicted before customary disposal.[279] Notwithstanding, the fact remains that no ECM customer and no end-use consumer ever made any purchasing decision because of a rate representation made by ECM, whether express or implied.[280]

## V. ECM'S SOPHISTICATED CUSTOMERS ARE NOT MISLED OR DECIEVED BY ECM'S TRUTHFUL "BIODEGRADABLE" CLAIMS

### A. ECM's Customers Have a Highly Sophisticated Understanding of ECM's Claims

Complaint Counsel argues that ECM's "sophistication defense" fails for two reasons: (1) that under *Pantron I*, sophistication of the customer is irrelevant to interpretation of ECM's "express, objective claims," and (2) that ECM's customers are only sophisticated in plastic manufacture, not biodegradation, and therefore lack the resources or knowledge to evaluate ECM's technology.[281]

[279] See *supra* at Part I(B) at 20.
[280] *See supra* at Part III(D)(2) at 152.
[281] Complaint Counsel's Post-Trial Brief, at 86-87.

### 1. The Sophistication of ECM's Customers Is Dispositive because Complaint Counsel Alleges that ECM Made Implied Claims

Complaint Counsel's argument that the sophistication of ECM's customers is irrelevant under *Pantron I* is incorrect. In *Pantron I*, the court stated that when a case involves "*express* objective product claims," the court need not consider the reasonableness of the consumer's interpretation. *F.T.C. v. Pantron I*, 33 F.3d 1088, 1096 n.21 (9th Cir. 1994) (emphasis in original) (quoting *In re Thompson Medical Co.*, 104 F.T.C. 648, 788–89 n.6 (1984)).

However, Complaint Counsel has only alleged that four "claims" at issue are express (and each of those, relating to whether the ECM additive renders plastics containing the additive biodegradable, is demonstrably true based on the science of record).[282] Complaint Counsel has alleged that ECM's "biodegradable" claim is an unqualified claim that carries with it an *implied* "less than one year claim," and that ECM's disclaimer that ECM amended plastics would biodegrade in biologically active environments in some period greater than a year is a qualified implied claim.[283] The "biodegradable" claim is an express claim because no significant minorities of consumers understand that "biodegradable" necessarily denotes any rate of biodegradation. (RPFF ¶ 1305).[284] However, assuming *arguendo* that "biodegradable" contains an implied rate claim, the sophistication of ECM's customers is relevant because it goes to how those customers interpreted the "biodegradable" claim and ECM's qualified claim of greater than one year.

ECM does not dispute that the following claims are express objective claims: (1) ECM amended plastic will fully biodegrade; (2) in a landfill; and (3) scientific testing proves these

[282] Complaint Counsel's Post-Trial Brief, at 28-29.
[283] *Id*. at 29-30.
[284] *See also supra* at Part III(d)(2) at 152.

claims. Those claims are truthful and not misleading, backed by a reasonable basis in competent and reliable scientific evidence of record.[285] However, ECM never made an express claim regarding the rate of biodegradation. ECM's "nine months to five years" statements were not claims, but were instead points of discussion during the lengthy negotiation process between ECM and its sophisticated customers. (RPFF ¶¶ 307-08, 310–12). ECM's customers do not take a significant manufacturing decision, like amending their plastics' composition with ECM's additive, lightly. (RPFF ¶¶ 1679, 1681). The negotiation process often begins with the exchange of information, including manufacturing methodology, ECM's biodegradability tests, and cost assessment. (RPFF ¶¶ 296, 349, 352, 354). Next, customers will often run product trials to determine the manufacturing logistics and to test performance of the product with the additive. (RPFF ¶¶ 355, 401, 404, 408). Many customers will then perform their own biodegradability testing. (RPFF ¶¶ 402, 405–07, 410, 428).

During these steps, ECM maintains open lines of communication with the potential customer and encourages customers to obtain samples of the additive to manufacture test samples of their plastics. (RPFF ¶¶ 402-03, 413, 420, 422, 425, 429, 432). These discussions will often involve, as most sales do, differentiating ECM's product from competing technologies. (RPFF ¶ 308). ECM often expressed the nine month to five year general timeframe in an effort to explain that ECM's additive is not a "poof it's gone" system and that it is very different from oxo-degradable or compostable technologies that customers may be considering which plastics companies have found objectionable because they biodegrade during periods of customer use before customary disposal. (RPFF ¶¶ 334, 341–47, 378). Furthermore, ECM's customers understood that biodegradability of any specific plastic made was dependent on numerous

[285] *See generally supra* at Part II at 70.

factors, that no specific timeframe could be determined, and that the timeframe would vary from product to product. (RPFF ¶¶ 374, 377-79, 416–19, 421, 467, 553). Therefore, in the context in which ECM made the nine months to five years statement, the nine months to five years statement cannot reasonably be considered a claim. It was instead a point of reference for discussion of material elements in the negotiation process; a point of reference qualified by the largely unremarkable fact known to the industry that for any specific plastic the rate of biodegradation is dependent on numerous environmental factors not predicable before the time of customary disposal.

### 2. ECM's Customers Are Sophisticated Plastics Manufacturers with the Resources to Conduct Their Own Product Evaluation, Testing and Interpretation of Testing Results

Contrary to Complaint Counsel's contention, whether ECM's customers are themselves ultimate "experts" in biodegradability is not dispositive of whether they are sophisticated companies capable of assessing the validity of ECM's technology. Indeed, whether the President of a plastic manufacturing company has a Ph.D. in biochemistry and plastics engineering has no bearing on whether that President has access to such people, consults with them, or otherwise depends upon them in determining the utility of a plastics product. The President of such a company is ordinarily incapable of causing the manufacture of a complicated product like a plastic for a particular use, yet is able to do so through the employ, directly or indirectly, of those with the academic training and experience sufficient to make the complicated product. Most of ECM's customers employ scientists of varying disciplines, often including a plastics engineer. (RPFF ¶¶ 416–18). In addition, ECM's customers have often inquired about ECM's testing methodology, results of testing, and certifications. (RPFF ¶ 426). That information is ordinarily

evaluated by those with detailed knowledge of the plastics they produce, including the tensile strength and viscosity of those plastics, the market longevity of those plastics, and the degradability of those plastic. *See* RPFF ¶¶ 296-604.

ECM's customers are larger than ECM. (RPFF ¶ 394). ECM customers are large enough to have entire regulatory departments. (RPFF ¶ 424). ECM's customer revenues also far exceed, multiple times over, ECM's annual revenues.[286] For example, Island Plastic Bags has an average annual revenue of $6.8 million, Dispoz-o had a 2008 revenue of $83 million, D&W Fine Pack had a 2009 revenue of $120 million and a 2013 revenue of $424 million, and Down to Earth Organic and Natural had an approximate annual revenue of $30 million from 2008 to 2013. (RPFF ¶¶ 452–54, 489, 568). Therefore, every ECM customer has the resources to conduct their own testing because an ASTM D5511 biodegradability test is relatively cheap, usually starting at around $2,000.[287] For many ECM customers, deciding whether to test a product for biodegradability is just another operational decision in the course of determining which competing additive is best suited to achieve that customers marketing and environmental objectives. (RPFF ¶ 428).

In fact, ECM customers did perform their own biodegradability testing of their plastics infused with samples of the ECM additive. (RPFF ¶¶ 410–11, 549–50, 2242, 2257, 2457, 2478, 2507, 2524, 2550, 2559, 2581, 2603). Of the dozens of tests offered into evidence by ECM, only the McClaren/Hart report was not performed by ECM customers. (RPFF ¶¶ 2133–2659). Thus, it is wholly incorrect to suggest that all of ECM's customers relied principally or exclusively on

[286] CCX 820 (Sullivan, Dep. at 96–97) (Discussing CCX 749 and CCX 750 which show ECM annual revenue from 2009 to 2013, which ranges from approximately two million dollars to three and a half million dollars).

[287] RX 873 (Ullman, Dep. at 73); RX 876 (Poth, Dep. at 14).

ECM's testing (that is false and contrary to the record), or that any ECM customer was not capable of understanding or evaluating the results of the biodegradability studies that they themselves had conducted (that again is false and contrary to the record). Indeed, the fact witnesses at hearing from the two main labs that performed the testing solicited by ECM customers testified that they explained their communication of findings in those tests to those customers.[288]

Furthermore, ECM customers have shown sophistication by "shopping around" within the additive market. (RPFF ¶ 412). ECM customers have performed biodegradability tests not only on ECM amended plastics, but also on plastics amended with competitors' additives. (RPFF ¶ 412). Others, such as Down To Earth Organic and Natural, investigated ECM and its additive for nearly a year before deciding to purchase ECM amended plastics. (RPFF ¶¶ 492–96). Such sophisticated purchasing behavior is in stark contrast to the fictive representation presented by Complaint Counsel of hapless, scientifically handicapped customers dependent on ECM for their understanding of the product's characteristics. Clearly, each of ECM's customers was sophisticated and proved that sophistication by their purchasing behavior, involving lengthy periods of evaluation, sample product acquisition for critical testing, and critical testing of manufacturing feasibility and of product characteristics in their own corporate labs or in independent scientific labs. (RPFF ¶¶ 307, 354-55, 393, 401-12).

Complaint Counsel contests that a potential customer, 3M Company, decided not to purchase the ECM added because 3M Company, unlike ECM's customers, is sophisticated.[289] To support that contention, Complaint Counsel notes that 3M conducted biodegradability testing

[288] Poth, Tr. 1475-81; Johnson, Tr. 1571-76
[289] Complaint Counsel's Post-Trial Brief, at 87–88.

on the ECM product.[290] If biodegradability testing is the measure of sophistication, then we may rightly conclude that ECM's other customers are highly sophisticated, because they too conducted biodegradability testing of additive samples infused into their own plastics. (RPFF ¶¶ 406-07, 410–12). In fact, nearly every biodegradability test in evidence was conducted by an ECM customer, all independent of ECM. (RPFF ¶¶ 2129–2706). Complaint Counsel only identifies one other factor in its determination that 3M is sophisticated, unlike all of ECM's customers: that 3M concluded that ECM's additive does not render its plastics biodegradable.[291] The validity of 3M's biodegradability testing cannot be ascertained because we have no record evidence of it,[292] but 3M's determination that the ECM product is not efficacious is contradicted by the weight of the scientific evidence.[293] Therefore, Complaint Counsel appears to suggest that because 3M conducted its own testing *and* that testing supported Complaint Counsel's position in this case, that 3M is sophisticated. That reasoning is entirely circular and completely misguided and backwards, and "3M's story"—untested by cross examination—sheds no light on whether ECM's customers were actually capable of conducting testing and interpreting scientific results. It is indeed odd for Complaint Counsel to elevate 3M as a gold standard without ever having called a single witness from 3M at the hearing.

Complaint Counsel further contends that Dr. Stewart's pilot study supports the contention that ECM customers are unsophisticated.[294] In support of that proposition, Complaint Counsel states that 37.5% of the customers questioned believed that biodegradation would happen within

[290] *Id.*
[291] *Id.*
[292] No individual with knowledge testified about the performance of the 3M test either at deposition or the hearing.
[293] *See supra* at Part II(a)(3) at 83.
[294] Complaint Counsel's Post-Trial Brief, at P. 88.

one year, making them essentially indistinguishable from end-use consumers."[295] Several profound flaws infect Complaint Counsel's argument. First, Complaint Counsel fails to cite to the record in support of that contention, instead relying on footnote 147 which merely explains Complaint Counsel's own misguided coding of the survey answers to generate this fictitious 37.5%[296] statistic.[297] Complaint Counsel is not its own expert and would have at least been required to present expert testimony on this point were it to rely, as it does, on the argument in its findings and conclusions. Of course, Complaint Counsel did not adduce any testimony on this point from any of its own expert witnesses.

Second, the actual responses to question 6 from the customers that were surveyed reveal how much more sophisticated their understanding of biodegradation is than an end-use consumer.[298] Question 6 of Dr. Stewart's Manufacturers Survey was "how would you define biodegradability?"[299] One response said "using ASTM 6400…or ASTM D5511."[300] Another respondent defined "biodegradable" as "something that would break down according to the ASTM 6400 standards."[301] It is absurd to think that an end-use consumer would give such a response, referencing an industry standard by name. The surveyed customers referenced ASTM protocols from memory to express how they determined whether something is biodegradable. Another answer that illustrates sophistication was "[the] classical definition is the breakdown of the chemical components." That answer reflects the ASTM D883-12 definition of

[295] *Id*.
[296] Note that Complaint Counsel's math appears to be incorrect, 3 of 10 would be 30%, not 37.5%.
[297] Complaint Counsel's Post-Trial Brief, at n. 147.
[298] RX 849 at 5.
[299] RX 848 at 5.
[300] RX 849 at 5.
[301] *Id*.

biodegradation very closely, and illustrates an offhand response far superior to the average end-use consumer's responsive expressions.[302]

Third, Complaint Counsel disingenuously "coded" these responses to produce a finding that "37.5% of the customers questioned believed that biodegradation would happen within one year."[303] To reach that conclusion, Complaint Counsel coded responses that referenced ASTM standards as "less than one year." Nothing in those ASTM standards requires complete biodegradation within one year.[304] Finally, Dr. Frederick and Complaint Counsel both argue (contradicting Complaint Counsel's sophistication argument) that the study had far too small of a sample size for any meaningful conclusions to be drawn.[305] Complaint Counsel cannot have it both ways. The appropriate conclusion to be drawn from all of the record evidence concerning ECM's actual plastic manufacturer customers is that those customers have a very sophisticated appreciation of plastics, plastics functionality, and plastics biodegradation, certainly an appreciation that is informed by education, experience, and expert advice that is not present among end-use consumers.

The weight of the evidence clearly shows that ECM customers were large, highly sophisticated companies with a thorough grounding in plastics composition, plastics engineering, the scientific standards generally accepted that govern biodegradability, and the science of biodegradability. Furthermore, the evidence shows that these companies did, in fact, have the resources to perform their own testing, whether internally or by contract, did perform that testing, and did receive expert evaluations of test results. It is also clear that ECM's customers

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[302] ASTM D883-12.

[303] Complaint Counsel's Post-Trial Brief, at P. 88.

[304] *See supra* at Part II(b)(2) at 113.

[305] Complaint Counsel's Post-Trial Brief, at P. 88; CCX 865 (Frederick, Rebuttal Rep. ¶ 17).

understood that the market ECM competes in is highly competitive and contains ready alternatives to ECM's technology. The companies shopped around and used their ample resources to ensure their investment in ECM's technology was not imprudent. Thus, ECM's customers were not in a position to be deceived because they depended on their own richly informed evaluations as predicates in making purchasing decisions, and they made those purchasing decisions in a transparent, competitive market environment.

### B. ECM's "Biodegradable" Claim Is Clear and Unambiguous, and ECM's Customers Understand that Biodegradation Rate Is Inherently Unpredictable

#### 1. ECM's Dissemination of Truthful, Non-Misleading Information and Open Lines of Communication with its Customers Was Sufficient to Eliminate Confusion, if any Existed

Complaint Counsel argues that ECM's dissemination of truthful, non-misleading information to its customers was not capable, as a matter of law, of eliminating any confusion or deception that may have existed due to prior communications.[306] That is speculative nonsense contradicted by record evidence. Even assuming *arguendo* that any deceptive claims were made (which the record does not support), ECM's relationship with its customers is distinguishable from those in the case law cited by Complaint Counsel because in none of the cited cases was the exclusive customer a sophisticated buyer. These distinctions destroy Complaint Counsel's analysis at its foundation.

In *In re Chrysler Corp.*, Chrysler released a series of magazine and newspaper advertisements containing a gas mileage claim that was determined to be deceptive, and during

[306] Complaint Counsel's Post-Trial Brief, at P. 88.

the same period, released separate advertisements that contained limiting language resulting in the determination that the claims were true. *In re Chrysler Corp.*, 87 F.T.C. 719, at *8–9 (Apr. 13, 1976). The court explained that "the public has a right to expect each of respondent's advertisements to be equally free of deception," and for this reason determined that the accurate advertisements were not sufficient to cure the deception in the inaccurate advertisements. *Id.* at *19. In *Removatron*, the respondent, through magazine advertisements aimed at consumers, claimed that its product would permanently remove unwanted hair. *Removatron Int'l Corp. v. FTC*, 884 F.2d 1489, 1491–93 (1st Cir. 1989). Some of the advertisements were properly qualified and non-deceptive, but the court found that each advertisement must stand on its own merits. *Id*. at 1496–97.

In both of those cases the consumer and the respondent had no relationship beyond a one-way communication, *via advertisements,* from company directly to consumer. *See generally In re Chrysler Corp.*, 87 F.T.C. 719; *Removatron Int'l Corp.*, 884 F.2d 1489. As a result, there was no avenue for clarification of a claim beyond the consumer reading the advertisement. This lack of communication actually compounds the risk of confusion for the reader because the consumer reading the advertisements does not know which advertisement supersedes which or if the message being conveyed is to be read in conjunction instead of in lieu of the prior message.

Furthermore, courts have consistently held that when the parties to a business transaction "have a close working relationship" there is less likelihood of confusion. *John Crane Prod. Solutions, Inc. v. R2R and D, LLC*, 861 F. Supp. 2d 792, 801 (N.D. Tex. 2012). In fact:

> [c]ourts have found that the sophistication of the potential purchasers alone is enough to find that there is no likelihood of confusion even when all of the other digits [in the trademark context] weigh in favor of such a finding. *See, e.g.*, *Perini Corp. v. Perini Constr.*, 915 F.2d 121, 128 (4th Cir.1990) (reversing summary judgment because district court did not consider how sophistication

> of purchasers of construction services affected analysis, even though all other digits weighed in favor of finding likelihood of confusion).

*Id.* at n. 16.

ECM has long-term, two-way relationships with its customers that span a period of 6 months to 2 years before a purchase is made. (RPFF ¶¶ 384, 388, 414, 458). ECM's customers regularly inquire about ECM's product, manufacturing processes, and scientific studies. (RPFF ¶¶ 420–21, 423, 426). ECM regularly informs its customers of changes in FTC regulatory guidelines and developments in biodegradability science, and ECM answers any questions that its customers may have regarding its additive. (RPFF ¶¶ 380–82, 420-22, 425, 429). ECM encourages its customers to obtain test samples before a purchase, and ECM customers obtain those samples and test their own plastic products once infused with the ECM additive, all before ever making a purchase for market use. (RPFF ¶¶ 401-04). Furthermore, because ECM's customers are far more sophisticated than the end-use consumers in *Chrysler* and *Removatron*, the likelihood that a clarifying statement during the course of communication could eliminate any confusion is much higher than a consumer reading a curative ad and having no experience or independent means to evaluate the product before making a purchase.[307] Therefore, to the extent that any confusing or misleading information existed in an ECM communication with its customers, subsequent corrective, truthful communications eliminate that misleadingness. Indeed, given the sophistication of the ECM customers, the assumption that they were ever confused at all on any material point of purchase from ECM's conveyance of information is

[307] "Context can often be important in discerning the message conveyed and this is particularly true where, as here, the target of the advertising is not the consuming public but a more well informed and sophisticated audience." *Sandoz Pharms. Corp. v. Richardson-Vicks, Inc.*, 902 F.2d 222, 229 (3d Cir. 1990) (emphasis added) (citation and internal quotation marks omitted).

unfounded in the record, dubious, and contrary to precedent which defines the sophisticated customer as presumptively impervious to the kind of deception that occurs with lay consumers. *Perini Corp. v. Perini Constr.*, 915 F.2d 121, 128 (4th Cir.1990); *Oreck v. U.S. Floor Sys., Inc.*, 803 F.2d 166, 173 (5th Cir. 1986) ("because these persons are buying [vacuums and extraction machines] for professional and institutional purposes at a cost in the thousands of dollars, they are virtually certain to be informed, deliberative buyers").[308]

### 2. ECM's Only "Claim" has Been a Clearly Stated "Biodegradable" Claim

ECM has always claimed that infusion of the ECM additive into conventional plastics at a 1% or greater load by mass renders such plastics "Biodegradable" as defined by the ASTM. (RPFF ¶¶ 320, 745–48, 760, 765, 1346). "Biodegradable" is an express, objective claim that is literally true, backed by a reasonable basis of competent and reliable scientific evidence. The results of testing performed by ECM customers and by ECM itself, the opinions of expert Drs. Barlaz, Sahu, and Burnette, and the peer reviewed scientific evidence of record all support this conclusion.[309]

Complaint Counsel alleges that ECM's statements regarding biodegradation rate (*i.e.* nine months to five years) were rate claims.[310] Complaint Counsel further asserts that these purported claims created confusion in ECM's customers despite concurrent statements explaining that biodegradation rates are approximations and that actual rates for any particular piece of plastic infused with the ECM additive were dependent upon numerous environmental factors, none of

[308] *See also* ECM's Proposed Conclusions of Law ¶¶ 43-58 (Explaining that increases in customer sophistication are associated with a commensurate decrease in the risk of confusion or deception, and therefore, the sophisticated purchaser requires less protection.)

[309] *See generally supra* at Part II at 70.

[310] Complaint Counsel's Post-Trial Brief, at P. 89.

which are determinable in advance of customary disposal.[311] In *Removatron*, the court explained that the "tendency of the advertising to deceive must be judged by viewing it as a whole, without emphasizing isolated words or phrases apart from their context … The impression created by the advertising, not its literal truth or falsity, is the desideratum...." 884 F.2d at 1496 (citation omitted). In many of ECM's marketing materials, on its website, and in email correspondence, the nine months to five years timeframe is merely one statement among many others that should not be taken "apart from [its] context." *Id*. ECM did not discuss biodegradation rate in a vacuum, instead ECM often discussed rate with its customers while explaining its technology and distinguishing it from competitors. (RPFF ¶¶ 334, 340, 343, 354). Furthermore, ECM's materials containing the nine months to five years statement always contained many other statements as well, including the representation that the actual rate of biodegradation was the result of numerous environmental factors, which factors are not known in advance of customary disposal.[312]

Additionally, ECM competes with compostable plastics, replacement resin manufacturers, oxo-degradables, and bioplastics. (RPFF ¶¶ 323–35). All of those products have different (and, to ECM's customers, undesirable) characteristics including shelf-life, structural integrity, cost, and rapid degradation rates. (RPFF ¶¶ 323–41). Therefore, when ECM stated a nine months to five years timeframe, it often did so in an attempt to distinguish itself from faster degrading products like compostables. (RPFF ¶ 308).

Unlike the advertising in *Removatron* where the only relevant context was contained within the four corners of the advertisement, ECM's entire body of communication with its

[311] *Id*.
[312] *See supra* at Part V(B)(1) at 171.

customers is relevant to determine context and net impression.[313] ECM's customers spent 6 months to 2 years communicating with ECM prior to deciding to purchase the additive. (RPFF ¶¶ 307, 355). ECM customers evaluated and tested samples of the additive in their own plastics before deciding to purchase the additive. (RPFF ¶¶ 404-07). Numerous emails, phone calls, meetings, and information exchanges occurred during the 6 month to 2 year timeframe, covering everything from engineering feasibility to impact on product performance to intrinsic biodegradability.[314] When taken as a whole, it is clear that ECM intended to convey, and did properly convey, that ECM's additive makes conventional plastics "biodegradable" without affecting shelf-life or product performance, and that the timeframe of this biodegradation process for any single plastic is dependent on variable disposal conditions, the knowledge of which is not discernible until after customary disposal. Thus, the only actual claim made is that ECM's additive makes products "biodegradable."

Moreover, Complaint Counsel's statement that "Dr. Barlaz explains this range is off by decades if not centuries" is supported by a citation to footnote 45 of Complaint Counsel's Post-Trial Brief.[315] Footnote 45 however lends absolutely no support for the representation of Complaint Counsel.[316] Instead, that footnote discusses Professor Frederick's testimony with respect to testing methodologies for investigating consumer behavior.[317] Therefore, the

[313] *Castrol, Inc. v. Pennzoil Co.*, 987 F.2d 939, 946 (3d Cir. 1993) ("in assessing whether an advertisement is literally false, a court must analyze the message conveyed in full context"); *Shering-Plough Healthcare Prods., Inc. v. Schwartz Pharma, Inc.*, 547 F.Supp. 2d 939, 943 (E.D. Wisc. 2008) ("In addition, the specific audience is part of the context that must be considered in deciding whether a statement is literally false.").

[314] *See supra* at Part V(B)(1) at 171.

[315] Complaint Counsel Post-Trial Brief, at 89.

[316] *Id.* at n. 45

[317] *Id.*

representation made by Complaint Counsel should be stricken or disregarded for lack of evidentiary support.

### 3. The End-Use Consumer Is not the "Relevant Audience"

Complaint Counsel argues that because ECM "intended (and insisted)" that its customers pass its claims down the distribution chain, ultimately to end-use consumers, that the end-use consumer is ECM's relevant (or target) audience.[318] Complaint Counsel incorrectly cites *Removatron* to support this contention.[319] In *Removatron*, the manufacturer of the hair removal machine sold the machines to hair salons. 884 F.2d at 1491. Those salons then offered hair removal services using this machine to customers who paid for the service. *Id*. The manufacturer of the product provided hair salons with advertisements to place in print media or around their salons. *Id*. The court determined that the "relevant audience" as it related to Removatron's advertising claims was clearly the end-use consumer because Removatron provided material that was intended to be displayed to consumers and printed in consumer targeted media. *Id*. at 1497.

There are two distinctions in the case *sub judice* that are dispositive. First, there is no evidence in the record that a single end-use consumer ever purchased an ECM amended plastic product, while in *Removatron* the sole purpose of the product was to provide a paid-for service to end-use consumers.[320] (RPFF ¶¶ 732–34); *see generally Id*. Second, unlike in *Removatron*, ECM's marketing material was never provided to or directed at end-use consumers, and to the extent that a handful of consumers allegedly viewed ECM's website, it is of no consequence

[318] *Id.* at 89–90.
[319] *Id.*
[320] ECM's Response to Complaint Counsel's Proposed Finding of Fact ¶¶ 25, 36, 67.

because none could make a direct purchase of the ECM additive. (RPFF ¶¶ 366, 369, 735). There is no evidence that a single ECM brochure or flyer ever ended up in the hands of an end-use consumer, whereas in *Removatron* consumers were routinely exposed to the respondent's advertisements.[321] *Removatron*, 884 F.2d at 1491. Most importantly, unlike in *Removatron*, there is no evidence that an end-use consumer saw ECM marketing material and made a decision based off of that marketing material.[322] Therefore, the end-use consumer is clearly not ECM's "relevant audience" because ECM did not provide marketing material to consumers and there is no evidence that any end-use consumer ever changed his or her behavior based on ECM claims or marketing material.[323] (RPFF ¶¶ 728, 730).

Assuming *arguendo* that the "relevant audience" is the end-use consumer, end-use consumers were ordinarily not exposed to any claims made by ECM on plastic products containing the ECM additive but in the few instances of record where a product bears such a claim it is almost always a naked "biodegradable" claim, not a rate claim.[324] Also, there is no evidence that any claim or advertisement was material to any consumer decision, and, in particular, to a purchasing decision.[325]

[321] Tr. 1–3005.
[322] *See supra* at Part III at 134.
[323] *Supra* at Part III(A) at 134.
[324] *See supra* at Part III(D)(2) at 152.
[325] *See id.*

#### 4. ECM's Customers Understand that Biodegradation Rates are Difficult to Predict and Any Stated Ranges were Mere Approximations, Subject to a Multitude of Variables Dependent on the Environment after Customary Disposal

First, Complaint Counsel argues that ECM's own customers' understanding of ECM's claims demonstrates that ECM's qualifying statements were ineffective.[326] To support this conclusion, Complaint Counsel suggests that ECM customers testified at deposition that they believed the nine months to five year timeframe was literally true.[327] Complaint Counsel cites to their Statement of Facts Section III *generally* in support of this contention.[328] However, Complaint Counsel's Statement of Facts Section III lends no support for the sweeping conclusion Complaint Counsel makes.[329] That section never discusses ECM customers' interpretation of statements of rate.[330] Instead it addresses the alleged dissemination of ECM marketing and informational material, and ECM's alleged approval and editing of customer marketing material and claims.[331] Therefore, Complaint Counsel has failed to support the statements of fact upon which its argument is based with evidence in the record, and the argument on that basis collapses because of a false foundation.

Second, there is ample evidence in the record that ECM's customers understood the variable nature of biodegradation times. (RPFF ¶¶ 421, 425). Complaint Counsel argues that ECM provided marketing material to all of its customers and that this marketing material contained statements of rate.[332] Complaint Counsel further alleges that ECM's "qualifications

[326] Complaint Counsel Post-Trial Brief, at P. 90.
[327] *Id.* at P. 90.
[328] *Id.* at n. 152–53.
[329] *Id*. at 19–21.
[330] *Id*.
[331] *Id*.
[332] *Id.* at P. 85.

were rare," and thus do not "rise to the prominent and unambiguous level required by law."[333] Yet ECM's information exchanged with its sophisticated customers contained the so-called "qualifications" that Complaint Counsel suggests were rarely conveyed.[334] For example, one of these ECM marketing materials that Complaint Counsel regularly refers to in its Brief states unambiguously:

> The basic concept is that biodegradation is a natural process that occurs around the world but at **various speeds** due to **various conditions**. Plastics with our additives behave like sticks, branches or trunks of trees. Due to this fact, **we do not guarantee any particular time because the time depends on the same factors** that the biodegradation of woods and most other organic materials on earth depend – ambient biota and other environmental conditions…[335]

An identical statement is posted on the ECM website.[336] The marketing sheet in CCX 5 further explains that while "petrochemical plastics would normally take hundreds or thousands of years or even longer to 'biodegrade;' with our additives, these same plastic formulas biodegrade in a hundredth of that time or less."[337] A stated range of hundreds or thousands of years, or even longer, is so broad that it accurately conveys the vast ambiguity inherent in biodegradation time. Furthermore, a hundredth of thousands of years is clearly greater than five years. Thus, taken as a whole,[338] these statements are plainly meant to convey that ECM amended plastics biodegrade markedly faster than untreated plastics, but slower than compostable technologies.

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[333] *Id*. at P. 90.
[334] CCX 5; CCX 6; CCX 15; CCX 19 at 9–10; CCX 20.
[335] CCX 5.
[336] RX 681 at 61.
[337] CCX 5.
[338] *Removatron I*, at 1496 ("The tendency of the advertising to deceive must be judged by viewing it as a whole, without emphasizing isolated words or phrases apart from their context … The impression created by the advertising, not its literal truth or falsity, is the desideratum....").

The evidence also shows that rate of biodegradation time was not material to ECM customers.[339]

## VI. THE ORDER SOUGHT BY COMPLAINT COUNSEL IS ARBITRARY, CAPRICIOUS, AGAINST THE PUBLIC INTEREST, AND IN VIOLATION OF THE FIRST AMENDMENT

Complaint Counsel's Proposed Order is unsupported and unconstitutional, as it would imposed heightened requirements as a condition precedent to protected speech by ECM that are not supported by the record in this case, or within the law. The Proposed Order is unconstitutional under the First Amendment, and Complaint Counsel cannot meet their burden to show that their proposed disclaimers are a reasonable fit.

### A. The Notice Order Is Vague and Ambiguous, and Impossible to Satisfy

In its Proposed Order, Complaint Counsel uses vague, ambiguous, and undefined terminology. Complaint Counsel requires proof of "complete" biodegradation, but they make no effort to define that terminology, let alone integrate it into the gas evolution testing which is the industry standard. As discussed *supra* at Part II(B)(2)(a) at 123, the concept of "complete" biodegradation is based on a misunderstanding of the science which focuses instead on intrinsic biodegradability. Gas evolution testing evaluates that intrinsic biodegradability, which can be shown, as ECM's experts and McCarthy in his own peer reviewed publications and patents reveals, based on even small percentages of the plastic biodegrading in the accelerated gas evolution tests. So it is that McCarthy accepted amounts ranging from 3% to 14% in his peer reviewed journal articles and in his '199 patent as evidence sufficient to prove a plastic

[339] *See supra* at Part III(D)(1) at 147.

"biodegradable." *See, e.g.*, RX 756; RX 969 (measuring biodegradation for very short periods of time). As Complaint Counsel posits it, "complete" biodegradation is an entirely illusory phenomenon because it is not capable of demonstration in the gas evolution testing environment that is the industry standard. Moreover, it is unscientific, because, as stated above, biodegradation is dependent upon numerous environmental factors that are triggers to biodegradation. A plastic infused with an additive that renders the plastic biodegradable will biodegrade until the plastic is but residue dependent upon ambient environmental conditions and the presence of biodegrading biota. It is for that reason that Complaint Counsel's own witness testified in regard to gas evolution testing that material could be considered "fully" biodegradable even when it stops biodegrading in test vessels at 44% or 72%. (Michel, Tr. 2954, 2961). To be sure Dr. McCarthy accepted as fully biodegradable plastics that biodegraded in lab testing at 3%, 5%, and 14%, without need for proof of 100% biodegradation in the lab. What, then, would be the definition of "complete" biodegradation for ECM Plastics if divorced form the science? We need not guess, as Complaint Counsel has offered no evidence of any kind establishing scientifically sound criterion on which to rely, and Complaint Counsel bears that burden. *See, e.g., National Commission On Egg Nutrition v. FTC*, 570 F.2d 157, 164 (7th Cir. 1977) (explaining that the FTC bears the burden to show that its Orders are consistent with the First Amendment by not prohibiting more conduct than is necessary to prevent deception).

Aside from the definitional issues, Complaint Counsel has offered no evidence concerning how a company like ECM could ever set any specific *rate* or timeline for biodegradation that would not be deceptive in light of the fact that, as ECM's historic qualifications make clear, rate is entirely dependent upon numerous environmental variables. Yet a central point in Complaint Counsel's brief is that "If ECM cannot determine the time to

complete degradation, it can make qualified claims about the rate and extent of biodegradation shown in **valid**, properly controlled and conducted, scientific tests." CC Amend. Post-Trial Br. at 93 (emphasis original). But Complaint Counsel's own witnesses were unable to explain how a company could reliably test for rate, or offer any example of a "valid" test to show rate given the inherent uncertainties in the landfill environment. The evidence shows that landfill environments are highly variable in the rates of biodegradation from one location to the next, and even within points in a single landfill. (*See* ECM's RPFF ¶¶ 1582, 1640-44). The moisture levels, temperature, and surrounding materials (e.g., foods, waste, paper, wood, yard clippings, etc.) will vary dramatically within the same landfill. *See* ECM RPFF ¶¶ 1582, 1640-44, 2065, 2807). That variability makes it impossible to draft any single figure for rate of biodegradation. Even a conservative "rate" is impossible, because the same article may biodegrade almost not at all on one side of a landfill, and rapidly on another. (ECM RPFF ¶¶ 1581–1605, 1723). In fact, Dr. Tolaymat testified evasively when asked how a company might prove a "rate" of biodegradation." (Tolaymat, Tr. 219-21). He was unable to point to any test or evidence that might be sufficient to show a "rate" of biodegradation, or satisfy Complaint Counsel's proposed qualifiers, even when specifically questioned on the content of Complaint Counsel's Proposed Order. (RX 851 (Tolaymat, Dep. at 120)).

For his part, Dr. McCarthy never provided a test or method that can establish the rate of biodegradation in a landfill, although he did explain that the "rate" can vary even within the same plastic article, going faster in amorphous regions and slower in crystalline regions. (McCarty, Tr. 477). Dr. Barlaz, also explained that there was no uniformly accepted method to extrapolate rate data from the laboratory scale to field-scale landfills. (Barlaz, Tr. 2282) (explaining that it is "very, very difficult to measure rates at either—at field scale for individual

components or for bulk waste, so all we have is the lab"). Thus, there remains no evidence in the record that would suggest how a company could plausibly satisfy Complaint Counsel's Proposed Order; all competent evidence of record confirms that providing a "rate" claim is scientifically infeasible.

Complaint Counsel also ignores the realities of ECM's supply chain. ECM is a manufacturer of a plastic additive that is introduced into finished plastics. (CCX 818 (Sinclair, Dep. at 120); RX 371; RX 656; RX 681). While ECM knows much about its customers' products, ECM ultimately exercises no control over the type and kind of products that its customers manufacture. *See, e.g.,* Sinclair, Tr. 707-08; RX 471. ECM cannot control, for example, whether its customers manufacture a thin plastic grocery bag or a toilet seat. Quite obviously, the "rate" of biodegradation for those two materials will differ substantially because the products have very different characteristics, including mass, density, etc. (Sahu, Tr. 1828-1836, 1886; RX 855 at 27 (Sahu Rep.); McCarthy, Tr. 392)). ECM's experts testified that there are many, many variables that factor into the potential rate of biodegradation for a plastic, many of those variables involve the specific characteristics of the finished plastics, and still many other variables involve the environment where that plastic is ultimately disposed. (Sahu, Tr. 1828-1836, 1886; RX 855 at 27 (Sahu Rep.)). Predicting any reasonable "estimate" for the rate of biodegradation simply cannot be done by ECM, who is only the additive manufacturer, or by anyone else for that matter.

Based on the foregoing discussion, the resulting effect of Complaint Counsel's Proposed Order would prevent ECM from making any biodegradable claim and depriving its customers of the scientifically valid statement that the ECM additive makes plastics biodegradable. Because there is no generally accepted method to test for (or calculate) the "rate" of biodegradation in

landfills, and ECM has no control over the finished plastic, ECM scientifically cannot produce a "competent and reliable" test or claim that would be acceptable under the Proposed Order. If the Proposed Order requires tests that are "generally accepted in the profession to yield accurate and reliable results," then evidence that no such standard exists to show "rate" of biodegradation in landfills reveals that Complaint Counsel's Proposed Order (which requires a "rate" be stated in advertising) is the equivalent of an absolute prior restraint and is arbitrary and capricious, and unsupported by any facts or testimony.

### B. Complaint Counsel's Requested Relief Is Not in the Public Interest

Complaint Counsel's Proposed Order is not in the public interest, in part, because it is intended to promote "rapidly" degrading substances that can completely biodegrade within one year. Complaint Counsel's Proposed Order would limit "biodegradable" claims to just two separate claims: (1) unqualified claims where the plastic completely disappears within one year; or (2) qualified claims when the manufacturer can prove a specific "rate" of biodegradation. For the reasons discussed *supra* at Part (II)(B)(1)(c) at 107, specific "rate" claims are scientifically infeasible, particularly for a company like ECM which manufacturers additives and not plastics. Thus, Complaint Counsel has offered a clear pathway to industry only for those products that can completely biodegrade within one year, thus imposing an absolute prior restraint on use the term "biodegradable" in advertising for all additives that cause plastics to biodegrade within periods longer than a year. That approach violates the First Amendment because it bars truthful claims of biodegradation for companies that sell additive and plastics that biodegrade in periods greater than a year. Moreover, Complaint Counsel's Order effects the creation of a new national environmental policy at odds with the National Environmental Policy Act's goal of reducing greenhouse gases. *See* 42 U.S.C. § 6901; RX 967. As uncontroverted record testimony in this

case reveals, rapidly degrading plastics contribute to greenhouse gas emission levels higher than slowly degrading plastics. *See* ECM RPFF ¶¶ 1593-1605.

Complaint Counsel bases the proposed Order solely on misapprehension of consumer impression (not science) allegedly reflecting what a small minority of consumers would *expect* from a plastic product marked "biodegradable." Even assuming that the consumer survey evidence on which it relies was competent, the minority of consumers themselves are scientifically wrong on two crucial points. First, they are wrong that products can ever reliably biodegrade within one year in a landfill. (ECM RPFF ¶¶ 804-805). Second, they are wrong that "rapidly" degrading materials are environmentally beneficial.[340]

Dr. Barlaz testified that the rate of biodegradation in landfills is largely irrelevant. (Barlaz, Tr. 2283–84; RX 853 (Barlaz, Dep. at 12). Because the residence of waste in a landfill is intended to be infinite, if a material is biodegradable, then it would not matter from a landfill science perspective if that material biodegrades within ten years or many more years. (RX 853 (Barlaz, Rep. at 12); Barlaz, Tr. 2283–84). In fact, products that would very rapidly biodegrade in landfills present environmental concerns because the methane released during that short and rapid biodegradation would not be captured by landfill operators. (Barlaz, Tr. 2284–85).

Methane is produced when products biodegrade. (RPFF ¶¶ 1813, 1840). Methane is a powerful greenhouse gas emission that contributes to climate change. (Barlaz, Tr. 2285). As methane gas increases in the atmosphere, it contributes to warming of the atmosphere, which most environmental scientists believe damages the planet. (Barlaz, Tr. 2286). The EPA's Landfill Methane Outreach Program (LMPO) has an express mission to reduce greenhouse gases

[340] In other words, the thought that rapid degradation is best just because the material is "gone" is not scientifically valid.

emitted from landfills. (RPFF ¶ 2877). Landfills remain one of the largest man-made sources for methane emissions on the planet. (RX 967). Yet EPA regulations do not require landfill owners to install gas collection systems until five years after waste burial. (Barlaz, Tr. 2285).

If a product biodegrades completely within one year, that product will not take up space in a landfill, but the methane produced will not be captured and will have less desirous environmental consequences than simply storing the product in a landfill for a longer period of time. (Barlaz, Tr. 2285–86). Thus, through critically acclaimed research published in the peer-reviewed literature, Dr. Barlaz demonstrated that based on decay rates the slower a product biodegrades in a landfill environment, the better that product is for the environment after disposal. (Barlaz, Tr. 2287–88). Dr. Barlaz explained:

> The reason we make products is for people to use them, not to throw them in a landfill… What we're trying to do here is ask, given the fact that waste exists and waste is generated, what's the best thing to do with it and what's the best way to design a product, without impending its functionality, to minimize environmental impact."

(Barlaz, Tr. 2288). Complaint Counsel has offered no evidence that contradicts or rebuts that logical conclusion, which reveals the entity into which Congress by statute has vested exclusive jurisdiction over environmental policy, EPA, to be in direct opposition to the policy position effected by Complaint Counsel's biodegradation definition, limiting the claim of biodegradation to biodegradation of plastics within one year after customary disposal. *Compare* RX 967 (LMOP citing methane emissions as problematic greenhouse gases), *and* RPFF ¶¶ 1593–1605 (rapidly biodegrading products present a risk of increased methane emissions), *with* 16 C.F.R. § 260.8(c) (promoting rapidly degrading materials under mistaken theory that physical disappearance is, by itself, the only environmental objective).

Complaint Counsel's Proposed Order is not in the public interest for still another reason: there is no evidence of actual or threatened consumer injury anywhere in the record. Complaint Counsel argues that the "Proposed Relief is needed to stop ongoing deception," and they cite the "seriousness" of violations. Notably, however, they fail to identify any risk of harm to the public based on those claims. In fact, there is no risk of economic, physical, or environmental injury. First, end-use consumers never purchase the ECM plastic. *See supra* at Part III(D)(2) at 152. There is no evidence that they make purchasing decisions based on the ECM claims and, so, there is no risk of economic injury. Second, the consumers are not put at physical risk, and the plastic products (intended for disposal) have no performance issues within the usable lifetime of the product. (Sahu, Tr. 767, 785 (explaining that the shelf-life and usable-life will not be negatively affected by infusion of the ECM additive); RX 13). Finally, as discussed *supra* at Part II(B)(1)(a) at 103, the record reveals that, even if ECM's claims were incorrect, a slower degrading product would benefit the environment more than a rapidly degrading product. (Barlaz, Tr. 2283-90; RX 853 at 12).

Finally, there is no indication that ECM or its officers have not genuinely held a belief in the efficacy of their technology, and with good reason. The testimony shows that even in the earlier years, ECM's personnel were buoyed by positive experiences derived from expert opinion based on testing (e.g., Dr. Barber's testing) and their own sealed drum anaerobic and garden aerobic tests. (CCX 818 (Sinclair, Dep. at 63-69); CCX 820 (Sullivan, Dep. at 8-9); Sullivan, Tr. 725–728; Sinclair, Tr. 755–56). ECM had received expert reports from several qualified scientists, including Dr. Barber, wherein the scientists concluded that the technology rendered plastics biodegradable. (*See, e.g.*, RX 254; RX 269; RX 270; RX 271; RX 275). Finally, ECM repeatedly received positive tests from its customers. In 2012, when the FTC revised its Green

Guides, ECM alerted its customers and informed them that claims should fit within the Green Guide revisions. (RX 35-RX 77). Those facts reveal a company that operated in good faith and attempted to meet the FTC's onerous restrictions, even though they were not scientifically valid.

### C. The Order Violates the First Amendment

Complaint Counsel's Proposed Order must be constitutional under the First Amendment. The Federal Circuit Courts of Appeal have held that the First Amendment requires the FTC to prove that its remedial orders are necessary to prevent deception. *See National Commission On Egg Nutrition v. FTC*, 570 F.2d 157, 164 (7th Cir. 1977) ("The First Amendment does not permit a remedy broader than that which is necessary to prevent deception); *Beneficial Corp. v. FTC*, 542 F.2d 611, 618 (3d Cir. 1976); *Warner-Lambert Co. v. FTC*, 562 F.2d 749, 760 (D.C. Cir. 1977). Complaint Counsel's Proposed Order would restrain substantially more speech than is necessary to prevent a minority of consumers from having a misimpression of biodegradable claims.

*Pearson I* held that the First Amendment requires agencies to "allow" advertising claims that are potentially misleading (as opposed to inherently misleading) unless those agencies meet a strict First Amendment burden of proof for claim suppression. *See Id*. at 656. *Pearson I* determined that an agency cannot constitutionally censor claims through prior restraint (there a prior restraint by rule for claims that did not meet an impossibly high "significant scientific agreement" standard and by comparison, here, a prior restraint by order for claims that do not meet an impossible to achieve specifically identified rate of biodegradation or biodegradation of plastics that occurs in periods greater than a year) unless the agency can establish with empirical evidence that the claims are *inherently* misleading (i.e., incapable of being rendered non-misleading through the addition of reasonable disclaimers). *See id*. at 655. Because ECM's

truthful unqualified "biodegradable" claim is, at worst, potentially misleading (and that potential is theoretical, it having not been proven by Complaint Counsel), the Order proposed by Complaint Counsel cannot constitutionally be imposed. We reiterate, as was stated in the opening brief, ECM has qualified its biodegradation claim from the start in its dealings with customers and is willing to accept any reasonable qualification on biodegradation, e.g., the rate of biodegradation varies dependent upon numerous environmental factors.

By suggesting a set of qualifiers, Complaint Counsel concedes that the claims in issue are, at worst, only potentially misleading (capable of being rendered non-misleading through the addition of claim qualification) and not inherently misleading (incapable of being rendered non-misleading through the addition of claim qualification). *See infra* at Part VI(C)(3) at 197 (listing potential alternative qualifiers that are less speech-restrictive the Complaint Counsel's proposal). Complaint Counsel cannot show, however, that its onerous, unattainable, and scientifically infeasible qualifiers are the "least restrictive" means to achieve its goals of preventing consumer deception (e.g., consumer deception that does not present a risk of injury to the consumer or environment). A burden on speech need not be a complete prior restraint in order to compel constitutional assessment under the commercial speech standard. *See, e.g., Alliance for Natural Health U.S. v. Sebelius*, 786 F. Supp. 2d 1, 24 (D.D.C. 2011) ("the FDA cannot require a disclaimer that simply swallows the claim . . .").

To be sure, Complaint Counsel's disclaimers themselves would propound deception by denying the corporate purchasers of the ECM product access to speech from ECM concerning the biodegradation effects of the ECM additive, including its greater benefit for the environment effected by slow biodegradation (i.e., of greater than a year's duration). Non-disclosure of information material to a purchase is a form of deception. *See, e.g., Meade v. Cedarapids, Inc.*,

164 F.3d 1218, 1222 (9th Cir. 1999); *Andolsun v. Berlitz Sch. of Languages of Am., Inc.*, 196 A.2d 926, 927 (D.C. Cir. 1964); *Restatement (Second) of Torts* § 529. Under Complaint Counsel's proposed order, that deception would be mandated by law.

### 1. The Claim "Biodegradable" is Truthful Speech that is, at Worst, Only Potentially Misleading and Therefore Subject to First Amendment Protection

"Potentially misleading speech" is that speech which can be rendered misleading connotation through use of a reasonable qualification or disclaimer. *See Bates v. State Bar of Arizona*, 433 U.S. 350, 376 (1977); *see also Peel v. Attorney Registration and Disciplinary Com'n of Illinois*, 496 U.S. 91, 110 (1990) ("A state may not … completely ban statements that are not actually or inherently misleading…").

Complaint Counsel contends that ECM's "biodegradable" claim is misleading because, essentially, it lacks adequate qualifications that would inform the consumer what "biodegradable" means. That argument is an *admission* that the claim is not "inherently" but is only "potentially" misleading because, if the claim were inherently misleading, there would be no room for qualification to serve as a remedy. *In the Matter of Pom Wonderful LLC, et al.*, 9344, 2012 WL 7831828, at *611 (F.T.C. Jan. 13, 2012) (explaining that the government "may not place an absolute prohibition on certain types of *potentially* misleading information … if the information also may be presented in a way that is not deceptive") (emphasis original). FTC Orders look prospectively, and they must satisfy the First Amendment. *Warner-Lambert Co. v. FTC*, 562 F.2d 749, 760 (D.C. Cir. 1977) (the First Amendment "triggers a special responsibility on the Commission" to issue orders that are no greater than necessary to serve the interest involved). Where speech is only "potentially" misleading, this Court must assess whether the

restrictions on prospective speech are the least restrictive means to further the government's substantial interest.

This case is distinct from conventional FTC cases in many respects. As relevant under the First Amendment, in this case Complaint Counsel has failed to show that use of the claim "biodegradable" is inherently misleading and, so, the analysis must turn on what *type* of qualification, if any, is appropriate, rather than whether the claim "biodegradable" is permitted at all. Complaint Counsel has also suggested claim qualifications that are specific and restrictive, demanding rate information that is by its very nature unattainable and, if asserted, necessarily misleading (given the fact that no rate for any specific plastic can be predicted with certain given variability inherent in the environment and the plastics themselves). Those qualifications are unreasonable under the law and the facts of this case.

ECM's statement that its additive renders plastics "biodegradable" is literally true. The scientific experts in this case testified that many scientifically accurate definitions exist for terms like "biodegradable," "biodegrade," and "biodegradation." (RPFF ¶¶ 782–95, 797–805). The definitions for those terms are necessarily broad to accommodate a range of potential mechanisms. The Merriam-Webster dictionary defines "biodegradable" as something "capable of being slowly destroyed and broken down into very small parts by natural processes, bacteria, etc." or "capable of being broken down especially into innocuous products by the action of living things (as microorganisms)." (RPFF ¶ 780).[341] Other sources have defined "biodegradable" to mean "capable of being decomposed by bacteria or other biological means." (RPFF ¶ 781).[342]

[341] *See* "Biodegradable." *Merriam-Webster.com*. Merriam-Webster, n.d. Web. 22 July 2014, *available at* http://www.merriam-webster.com/dictionary/biodegradable.

[342] *See* "Biodegradable." *Collins English Dictionary*, 10th Ed. 2009 (July 22, 2014), *available at* http://dictionary.reference.com/browse/biodegradation.

The definitions universally describe a biological process of breakdown and equally universally do not include either a time limit on the process or a specified degree of disintegration or elimination of the degrading product. (RPFF ¶¶ 774–81).

ECM's experts have testified that "biodegradation" is properly described as an *ongoing process*, and the word "biodegradable" refers, simply, to a material capable of undergoing that process. (RPFF ¶¶ 791, 793, 794, 798–800). As understood in science, the term "biodegradation" refers to the process by which microorganisms, bacteria, fungi, etc., combined with their natural mechanisms of action, effect the breakage of plastic bonds through acids and enzymatic action. (RPFF ¶¶ 774–82, 790, 794).

The tests prove that ECM plastics are "biodegradable." Even if the accelerated lab tests show only partial biodegradation, or biodegradation that occurs over time, the tests nonetheless show intrinsic "biodegradation," which means that the plastics are by generally accepted scientific standards in this field "biodegradable." Because plastics manufactured with ECM's additive satisfy the generally accepted scientific definitions of "biodegradable," ECM's biodegradable claim is literally true. Complaint Counsel suggests, however, that a small subset of consumers might interpret the claim "biodegradable" to mean that a product should completely disappear within one year (an assumption contradicted by the only competent survey evidence of record, Dr. Stewart's). Even were the consumer survey evidence relied upon by Complaint Counsel valid, the scientifically unreasonable opinions of a minority of consumers cannot render a truthful statement inherently misleading, because more education of the consumer would correct that misunderstanding of the science and render the claim non-misleading. Thus, a claim that can be corrected by more education is, by definition, a "potentially" misleading claim fit for reasonable claim qualification.

Second, even assuming that Complaint Counsel's interpretation of the survey evidence was reasonable (it is not), the data supports ECM's First Amendment argument. Although a certain "minority" of consumers may be legally relevant under precedent governing when an implied claim exists, in the First Amendment context which is superior to and controlling over regulatory precedent (*Central Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of New York*, 447 U.S. 557, 564-65 (1980)), the fact that only a "minority" of consumers draw the so-called misleading impression only shows that the claim itself is basically truthful and non-misleading. In other words, but for a small number of consumers who would draw a misleading claim, the claim is not misleading to the majority of consumers. That fact, again, demonstrates that the claim is only potentially (as opposed to inherently) misleading, because the misleading impression conveyed by the claim is not a reasonable interpretation held by the majority, and education of the minority would suffice to eliminate any misleadingness.

In short, because Complaint Counsel has conceded that the "biodegradable" claim is "potentially" misleading (by calling for disclaimers or qualifiers as the remedy in this case), Complaint Counsel must satisfy its constitutional burden to show that their suggested qualifications are the least restrictive means to remedy misleadingness. They must show that there are no obvious, less speech restrictive alternatives to the limits they propose. They have not met that burden and, so, the requested Order cannot constitutionally be imposed.

### 2. The Government's Interest in Censoring Potentially Misleading Biodegradable Claims Is Not Substantial Because Those Claims Present No Risk of Harm to Consumers or The Environment

In *Central Hudson*, the Court explained that it must "evaluate a government scheme to regulate potentially misleading speech" by first asking "whether the asserted government interest is substantial." *Pearson v. Shalala*, 164 F.3d at 655 (quoting *Central Hudson*, 447 U.S. 557, 566

(1980)). Although the Court observed that the government has a substantial interest in ensuring the accuracy of commercial information in the marketplace, here that interest is mitigated by application of the public interest facts. *See supra* at Part VI(B) at 185 (explaining that this action is not in the public interest). The government can identify no risk of consumer injury or risk to the health, safety, or welfare of its citizens. Consumers do not make purchasing decisions based on ECM's representations (there is no record evidence of that); consumers merely receive ECM plastics as packaging or ancillary materials related to other consumer goods irrelevant to this case, quite often completely oblivious to biodegradability claims and ECM. ECM's expert testified that, even if ECM plastics last much longer in the environment, there is no material difference for the landfill environment, which benefits from slower degrading materials and is designed to handle infinite storage of waste. (Barlaz, Tr. 2246-90).

Complaint Counsel argues, however, that a heightened risk of injury exists because ECM's claims could lead customers away from other environmentally friendly products or practices. *See* CC Amend. Post-Trial Br. at 63. That is precisely the same argument the *Pearson* Court rejected in assessing the government's interest in that case:

> It is important to recognize that the government does not assert that appellants' dietary supplements in any fashion *threaten* consumer's health and safety. The government simply asserts its "common sense judgment" that the health of consumers is advanced *directly* by barring any health claims not approved by the FDA. Because it is not claimed that the product is harmful, the government's underlying-if unarticulated-premise must be that consumers have a limited amount of either attention or dollars that could be devoted to pursuing health through nutrition, and **therefore products that are not indisputably health enhancing should be discouraged as threatening to crowd out more worthy expenditures. We are rather dubious that this simplistic view of human nature or market behavior is sound, but, in any event, it surely cannot be said that this notion-which the government does not even dare openly to set forth-is a *direct* pursuit of consumer health; it would seem a rather indirect route, to say the least.**

*Pearson v. Shalala*, 164 F.3d 650, 656 (D.C. Cir. 1999) (emphasis added; internal citations omitted); *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 503 (1996) (opinion of Stevens, J., joined by Kennedy, J., and Ginsburg, J.) ("The First Amendment directs us to be especially skeptical of regulations [of indisputably non-misleading information] that seek to keep people in the dark for what the government perceives to be their own good").

The *Pearson* Court observed that the FDA could have an interest that "take[s] on added importance in the context of a product … that can affect the public's health." *Pearson*, 164 F.3d at 565. Logically, so too can the interest take on *lesser* importance in the context of a product that presents no risk at all. That axiom is embedded within the FTC's analysis of the "public interest" and the *Pfizer* factors which consider the potential consequences of a negative claim. Here, too, in the First Amendment context the lack of consumer injury should require a heightened burden on Complaint Counsel to justify its restrictive qualifiers in the Proposed Order. It is already indisputably the case that regardless of what regulatory burden shifting exists within the FTC's regulatory jurisprudence, the First Amendment burden of proof remains squarely on the government proponent of speech restriction. *Central Hudson*, 447 U.S. at 565; *44 Liquormart, Inc. v. Rhode Island*, 116 S. Ct. 1495, 1509 (1996) (holding that the government bears the burden of showing that a speech restriction will advance its interest "to a material degree"); *In the Matter of Pom Wonderful LLC, et al.*, Dkt. No. 9344, 2012 WL 7831828 (F.T.C. Jan. 13, 2012). If the proposed censorship must fit within the government's interest, a lessening of that interest must also increase the commensurate obligation to limit interference with speech.

The First Amendment mandates that speech restrictions be narrowly drawn to fit the government's interest (*In re Primus*, 436 U.S. 412, 412, 438 (1978)), and *Central Hudson*

dictated that those restrictions cannot extend any further than the government interest necessitates:

> The regulatory technique may extend only as far as the interest it serves. The state cannot regulate speech that poses no danger to the asserted state interest…

*Central Hudson*, 447 U.S. at 565. Here, as explained *supra* Part III(D)(2) at 152, ECM's biodegradability claims present no danger to the government's interest in protecting against deception, because there is no evidence that end-consumers have relied or considered ECM's claims in making *purchasing* decisions; there is no evidence that consumers have suffered an economic loss; no evidence that consumers have suffered a diminution in the value of their products with the ECM claims; and no evidence that the ECM products have harmed the environment in any way.

### 3. Complaint Counsel's Draconian Order is Far From the Least Restrictive Means of Achieving the Government's Goal Because There are Substantially Less Speech-Restrictive Alternatives That Would Cure any Potential Misleadingness

In *Whitaker I* the United States District Court for the District of Columbia explained the high First Amendment standard applicable:

> Specifically, *Pearson I* identified two situations in which a complete ban would be reasonable. First, when the '[agency] has determined that *no* evidence supports [a health] claim,' it may ban the claim completely. *Id*., 164 F.3d at 659-660 (emphasis in original). Second, when the [agency] determines that 'evidence in support of the claim is qualitatively weaker than evidence against the claim--for example, where the claim rests on *only one or two old studies*,' it may impose an outright ban. *Id.*, 164 F.3d at 659 n.10 (emphasis added). Even in these two situations, a complete ban would only be appropriate when the government could demonstrate with empirical evidence that disclaimers similar to the ones [the Court] suggested above ["The evidence in support of this claim is inconclusive" or "The [agency] does not approve this claim"] would bewilder consumers and fail to correct for deceptiveness.

*Whitaker v. Thompson*, 248 F.Supp. 2d 1, 10 (D.D.C. 2002) ("*Whitaker I*") (quoting *Pearson I*, 164 F.3d at 659-660) (emphasis in original). The burden is the FTC's alone:

> The First Amendment places the burden on the government to prove that its method of regulating speech is the least restrictive means of achieving its goals. The First Amendment does not allow the [agency] to simply assert that Plaintiff's Claim is misleading in order to supplant [its] burden to demonstrate that the harms it recites are real and that its restriction will in fact alleviate them to a material degree.

*Id*. at 9 (internal citations omitted).

Complaint Counsel cannot show that the limited qualification language meets the First Amendment standard because the qualification suggested in the Proposed Order would restrict truthful and non-misleading speech, and impose a prior restraint on substantially more speech than is necessary to meet the government's objectives. Thus, the Court in *Pearson* observed that the government had difficulty with its "consumer fraud justification" for censorship, because there was no "reasonable fit between the government's goals and the means chosen to advance those goals." *Pearson*, 164 F.3d at 567. So too, here, Complaint Counsel cannot mesh its impossibly high qualification standards with its interests in controlling consumer deception that has no risk of injury (economic or physical) to the consumer.

As explained *supra* at Part VI(A) at 181, because the proposed qualifiers in the Order are impossible to satisfy (and cannot be satisfied with competent and reliable science), the Proposed Order effectively prohibits any biodegradable claims by ECM. The inability to meet those disclaimers with competent and reliable evidence effects a blanket ban on speech, an absolute prior restraint. Under the First Amendment, the agency may only ban a scientifically-backed claim if it can prove that the evidence in support of the claim is qualitatively weaker than the evidence "against" it. The Court has explained exactly what is meant by evidence "against": The "mere absence of significant affirmative evidence in support of a particular claim … does

not translate into negative evidence 'against' it." *Pearson v. Thompson*, 141 F.Supp. 2d 105, 105 (D.D.C. 2001) ("*Pearson III*") (citing *Pearson I*, 164 at 660); *Pearson v. Shalala*, 130 F.Supp. 2d 105, 115 (D.D.C. 2001) ("*Pearson II*"). In this case, Complaint Counsel's inconclusive tests plainly do not equal negative test results that would qualify as evidence "against" ECM's affirmative proof of biodegradation of ECM additive containing plastics.

Complaint Counsel defends its approach as follows: "For example, if ECM had valid testing that demonstrates 10% biodegradation in a landfill in a year, it could represent that result in their marketing but must clearly and conspicuously disclose that there is no evidence that biodegradation continues beyond 10%." CC Amend. Post-Trial Br. at 93-94. That qualification statement is grossly misleading, however, because the evidence shows that ECM's plastics are intrinsically biodegradable and will thus continue to biodegrade when environmental conditions permit. (Barlaz, Tr. 2217-21, 2246-70; RX 968; Barber, Tr. 2057; Burnette, Tr. 2437-40; Sahu, Tr. 1848-49, 1864-65).

More importantly, in the First Amendment context, the Government bears the burden to show that its disclaimers are a reasonable fit, meaning that they do not overreach and bar protected speech. *See Pearson*, 164 F.3d at 659-660; *Whitaker I*, 248 F.Supp. 2d at 9; *Warner-Lambert Co*., 562 F.2d at 760. The government must meet that goal with empirical evidence showing that the required disclaimers would obviate or eliminate consumer confusion, and no other reasonable disclaimers would suffice. *See, e.g., Whitaker I*, 248 F.Supp. 2d at 5. Here there is no evidence to support the Proposed Order but ample evidence to prove that it imposes an impossible standard that necessarily results in a ban on protected speech. The qualification statements suggested by Complaint Counsel would serve to increase consumer confusion not alleviate it, because Complaint Counsel is requiring transmission of a misleading message (a set

rate of biodegradation or a ban on biodegradation claims altogether in the absence of a set rate and in those instances when biodegradation is achieved over a period greater than a year). The statement that "no evidence that biodegradation continues" beyond the test period is an inherently misleading statement. That statement suggests to the uniformed and uneducated consumer that the biodegradation terminated because the *plastic* is no longer biodegradable, when the evidence proves that biodegradation plateaus because of the test environment. (Burnette, Tr. 2401-02, 2412-13, 2442-43; Barlaz, Tr. 2272-73).

Finally, there is no evidence that consumers can properly understand the qualifications that Complaint Counsel offers, including the limitations of percentage language vis-à-vis the science of biodegradation. In fact, because Complaint Counsel's proposed qualifications are scientifically unreasonable, it is equally unreasonable to expect consumers to understand a concept of "rate" or "extent" when scientists view biodegradation as a process of microbial destruction of plastic not understood to be limited by an arbitrary year figure or amount of break down into elements in nature within that year. Complaint Counsel has introduced no evidence showing that consumers can comprehend the test limitations that might result in a plateau effect. Moreover, Dr. Stewart testified that there is no evidentiary basis that suggests consumers care about, or have sufficient scientific knowledge to evaluate, "rate" claims with respect to biodegradability. (RX 856 at 15-16).

The narrow and ill-defined approach articulated in the Proposed Order is not the "least restrictive means" to further the FTC's goal because other more accurate qualifiers plainly exist. ECM could make a "biodegradable" claim, but explain, as it has historically to its customers, that the rate and extent of biodegradation is impossible to predict and varies based environmental factors of disposal.

As it has historically, ECM could explain that plastics made with the additive are intrinsically biodegradable, but the precise "rate" of biodegradation cannot be predicted in advance of disposal and varies based on environmental factors, the presence of biodegrading biota, and characteristics of the plastic product.

As stated *supra* at Part V(B)(3) at 177, the focus of any discussion concerning qualifiers should remain on the information ECM can convey to its target "customers," who are plastics manufacturers not end use consumers, and not the information that might be provided to end-use consumers.

The First Amendment permits ECM to make truthful claims about the efficacy of its additive technology, to its actual customers, without regard to what ECM's customers may on their own accord choose to convey in the marketplace. That information includes a truthful and non-misleading statement concerning the intrinsic biodegradability of conventional plastics made with ECM's additive, without need to specify a single (and necessarily false and misleading) "rate" or "extent" of biodegradation, which cannot accurately be conveyed. The record includes no evidence that a truthful and non-misleading "rate" or "extent" claim can ever be made for land-fillable products and, accordingly, Complaint Counsel's Proposed Order is unconstitutional under the First Amendment (it thereby constituting an absolute prior restraint due to an impossible to satisfy standard).

## VII. CONCLUSION

For the foregoing reasons, ECM requests that this Court deny Complaint Counsel's complaint and their requests for relief, and enter judgment in ECM's favor.

Respectfully submitted,

*/s/ Jonathan W. Emord*
Jonathan W. Emord
Peter A. Arhangelsky
Bethany R. Kennedy
Eric J. Awerbuch
EMORD & ASSOCIATES, P.C.
Telephone: 202-466-6937
Fax: 202-466-6938
Email: jemord@emord.com

DATED: October 16, 2014

**CERTIFICATE OF SERVICE**

I hereby certify that on October 16, 2014, I caused a true and correct copy of the foregoing to be served as follows:

One electronic copy to the **Office of the Secretary** through the e-filing system:

Donald S. Clark, Secretary
Federal Trade Commission
600 Pennsylvania Ave., NW, Room H-113
Washington, DC 20580
Email: secretary@ftc.gov

One electronic courtesy copy and three (3) hardcopies to the **Office of the Administrative Law Judge**:

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

One electronic copy to **Counsel for Complainant**:

Katherine Johnson
Division of Enforcement
Bureau of Consumer Protection
Federal Trade Commission
600 Pennsylvania Avenue, NW
Mail stop M-8102B
Washington, D.C. 20580
Email: kjohnson3@ftc.gov

Arturo Decastro
Division of Enfoncement
Bureau of Consumer Protection
Federal Trade Commission
600 Pennsylvania Avenue, NW
Mail stop M-8102B
Washington, D.C. 20580
Email: adecastro@ftc.gov

Jonathan Cohen
Division of Enforcement
Bureau of Consumer Protection
Federal Trade Commission
600 Pennsylvania Avenue, NW
Mail stop M-8102B
Washington, D.C. 20580
Email: jcohen2@ftc.gov

I certify that I retain a paper copy of the signed original of the foregoing document that is available for review by the parties and adjudicator consistent with the Commission's Rules.

Respectfully submitted,

*/s/ Jonathan W. Emord*

Jonathan W. Emord (jemord@emord.com)
EMORD & ASSOCIATES, P.C.
11808 Wolf Run Lane
Clifton, VA 20124
Telephone: 202-466-6937
Facsimile: 202-466-6938

DATED: October 16, 2014