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

ORIGINAL

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

RESPONDENT ECM BIOFILM'S PRETRIAL BRIEF

Jonathan W. Emord, Esq.
Emord & Associates, P.C.
11808 Wolf Rune 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.
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

Regulations

I. STATEMENT OF THE CASE

The totality of the scientific evidence establishes more than a reasonable basis, and at least competent and reliable scientific evidence, that plastics infused with the ECM additive (in accordance with ECM manufacturing instructions and at a 1% load rate) will biodegrade within a reasonably short period of time under conditions of customary disposal, particularly when compared with conventional, untreated plastics. The totality of the scientific evidence, including generally accepted science on microbiological mechanisms that degrade plastics and on biodegradation in landfills as well as at least 33 separate biodegradation tests and assessments of the ECM additive by the plastics industry, establish more than a reasonable basis, and at least competent and reliable scientific evidence, that ECM's additive causes biodegradation of the most widely used plastic resins in the external environment, including in landfills.

The term "biodegradable" defines *an on-going process*: "the chemical dissolution of materials by bacteria or by other biological means."[1] "Biodegradation takes place by the action of enzymes, chemical degradation with living organisms."[2] It has been described as a "two step" process.[3] "The first step is the fragmentation of the polymers into lower molecular mass species by means of abiotic reactions, like oxidation, photodegradation or hydrolysis, or biotic reactions, like degradations by microorganisms."[4] The second step is "the bioassimilation of polymer fragments by the microorganisms and their mineralization."[5] Degradation results "from the action of naturally occurring microorganisms such as bacteria, fungi, and algae."[6] Scientific

[1] G. Gnanavel, V.P. Mohana Jeya Vali, and M. Thirumarimurugan, 1:3 International Journal of Pharmaceutical and Chemical Sciences 670, 671 (July–Sept. 2012).
[2] *Id.*
[3] *Id.*
[4] *Id.*
[5] *Id.*
[6] *Id.*

definitions in the peer-reviewed literature vary, but all echo that fundamental concept, and none attach a specific timeline, extent, or rate of biodegradation before a substance is considered "biodegradable." The evidence amassed in this proceeding complemented by the testimony of four experts in the respective fields of environmental science, microbiology, biodegradation, and landfill science prove that the ECM plastic additive when mixed into plastic resin during plastic manufacture (in accordance with ECM's precise instructions for so doing) results in a finished plastic product that is biodegradable, establishing ECM's qualified claims of biodegradation to be well substantiated and non-deceptive.

The complaint in this case presumes as valid anachronistic, decades-old concepts of landfill science. Those concepts have been debunked and are no longer generally accepted in the scientific community. Complaint Counsel seek to enforce a standard concerning "biodegradability" claims that is in fact unscientific and misleading. To get there, Complaint Counsel beg this Court to raise the evidentiary standard above that prescribed in *In re Pfizer, Inc.* and its progeny to require a higher degree of proof than is accepted in the scientific community that studies plastics biodegradation. In particular, Complaint Counsel seize upon a select subset of studies that fail to show biodegradation within the parameters set and the time period specified, presuming the absence of evidence of biodegradation in this subset to be the same as affirmative evidence that the ECM additive does not cause biodegradation and to be the only science creditable as competent and reliable. Those select studies, however, fail to account for the affirmative evidence of biodegradation present in over 33 other studies of comparable design and the same or longer duration. Complaint Counsel ignores a salient and recurrent fact in this artificial test environment which accounts for test failings: that these tests, to be valid, must ensure the presence of one or more strains of living bacteria, a perennial confounding factor that

contributes to test failures (among other variables that might influence test outcomes). Despite that confounding factor, more than 33 independent tests involving bacteria strains from landfills do show that the ECM additive causes plastic biodegradation under testing conditions in which the biota survive. Those redundant, independent positive tests are dispositive.

Complaint Counsel are engaged in an enforcement campaign exclusively against one industry sector, the biodegradable additive plastics sector, and in furtherance of the market interests and advantage of that sector's chief competitor, the compostable plastics sector. Compostable plastics are ones infused with highly biodegradable ingredients, causing them to break down rapidly, within the span of a year. It was that sectors lobbying campaign that led the FTC to adopt the arbitrary one year limit. The rapid destruction of compostable plastics in the environment makes them of limited utility because they cannot be used in plastics for which there is a need for endurance and strength, and they evoke production of a far greater volume of pollutants in the form of toxic gasses and by-products at a single time (due to their rapid degradation) than occurs with biodegradable additive plastics.

By vigorously routing out of the market the biodegradable additive plastics sector through consent orders and this prosecution, Complaint Counsel are effectively establishing a national environmental policy. That is an ultra vires action which invades the province of the Environmental Protection Agency (EPA). It also conflicts with the duties and responsibilities of that agency and supplants EPA policy on waste disposal with that of the FTC. Indeed, if successful, Complaint Counsel will not only effect a fundamental change in environmental policy but also change the actual environment, fundamentally. By forcing plastics manufacturers and waste disposal companies and landfills that prefer biodegradable additives to be without that choice, FTC's enforcement brings about far reaching and adverse environmental consequences.

Many plastics now made with biodegradable additives that cannot be made compostable because to do so would destroy their market utility will be made without those additives and without compostable plastics. Those conventional plastics will accumulate in the environment and in landfills and will remain largely intact for thousands of years. The result will be a substantial increase in the ambient level, degree, and extent of plastics pollution. Moreover, depriving plastics manufacturers of additives like ECM's and effectively compelling them to rely, if at all, exclusively on compostable plastics will increase the number of entities using those rapidly degrading polymers which produce a greater adverse environmental impact in the volume of toxic gasses and by-products at a single time than plastics made with biodegradable additives.

Complaint Counsel depend principally on one witness with plastics experience, Dr. Steven McCarthy. Complaint Counsel's two other experts lack requisite background and experience to opine on the science of plastics biodegradation: Dr. Shane Frederick who is a purported survey expert and Dr. Thabet Tolaymat who is a purported landfill expert.

Dr. McCarthy (upon whom Complaint Counsel exclusively depend to meet its burden of proof that ECM's biodegradation claim lacks a reasonable basis) testifies in contradiction to the scientific literature and without that degree of independence and integrity necessary to be credited. *Ab initio*, Dr. McCarthy adopts a definition of "biodegradation" admittedly given him not by peers but by Complaint Counsel. The definition given him is not from the scientific literature (indeed is nowhere found there), but is instead legally contrived and conflicts with the definition in the literature (including McCarthy's own published scientific writings). The given definition arbitrarily excludes from consideration any degradation of plastic due to biological mechanisms unless the biodegradation results in 100% elimination of the plastic, breaking it down into oxygen, hydrogen, and carbon (and biomass or humus), within 365 days after

customary disposal in a landfill. By this definition, if a plastic on day 365 has degraded by 95% and then on day 366 it degrades by 100%, it is not biodegradable. By this definition a banana peels is not biodegradable, and neither are tree trunks. The precise definition reads as follows:

> Complaint Counsel asked me to assume that the unqualified marketing claim "biodegradable" means that the entire treated plastic will completely break down and return to nature (*i.e.*, decompose into elements found in nature) within one year after customary disposal (*i.e.*, incinerator, landfill, or recycling).[7]

That definition is nowhere present in the scientific literature; is not even found in any article on biodegradation by Dr. McCarthy in the scientific literature; and conflicts with the definition accepted by Dr. McCarthy in his articles and in his own patent for a biodegradable plastic resin (wherein he deemed a scientific study of 45 days duration using a test he created, not ASTM 5511 and not ^{14}C radiological testing, that resulted in only 14% biodegradation of the plastic resin to be proof of "biodegradation").

While contending in his scientific report that biodegradation may only be said to exist if a plastic resin is tested under, and is completely eliminated during, an ASTM (formerly the American Society for Testing and Materials) D5511 test or is proven completely eliminated during what he calls "definitive" ^{14}C radiological testing, Dr. McCarthy can cite to no article in the peer reviewed scientific literature endorsing that position. Moreover, he contradicts that position when, in his own original research on biodegradation of plastics, he has never relied on either form of testing, including in his submissions to the United States Patent and Trademark Office in support of a "biodegradable" resin he invented, U.S. Patent No. 5883199 (Mar. 1999).

[7] CCX-891, at 5 n. 1 (McCarthy Rep.). All citations to Complaint Counsel's exhibits correspond to the numbers assigned by Complaint Counsel to those specific exhibits in their Revised Final Proposed Exhibit List, submitted to ECM on July 18, 2014. Complaint Counsel subsequently submitted their "Final Proposed Exhibit List" on July 28, 2014. This more recent version identified specific exhibits by numbers different from those in their July 18 Exhibit List.

In short, at deposition Dr. McCarthy revealed himself to be an expert who testifies precisely as his Complaint Counsel handlers would have him and, critically, in opposition to the generally accepted science. Moreover, that willingness to be devoid of scientific dependence and to abandon the generally accepted science is entirely consistent with his own financial interests. Complaint Counsel have selected as their primary witness on the subject of biodegradation an individual who has a direct financial stake in the outcome of this litigation.

Dr. McCarthy is the inventor of a biodegradable plastic resin, the patent holder of which is the University of Massachusetts at Lowell (where he works as a professor), the party assigned the patent from Dr. McCarthy. Dr. McCarthy receives royalties from the University under that patent. The patent is exclusively licensed to Metabolix. Metabolix uses the patented formulation to make resin for the creation of biodegradable plastic bags. Metabolix (which also supplies grants to Dr. McCarthy's center at the University of Massachusetts at Lowell) lobbied FTC to commence the present action against ECM and sells Dr. McCarthy's biodegradable plastic resin to companies for which Metabolix and ECM compete in the market. To the extent plastics companies turn to Metabolix for its plastic resin when making biodegradable plastic bags, they turn away from ECM for its additive and vice versa. Moreover, Metabolix's plastic resin is more costly than ECM's additive. Consequently, absent a legal force effectively prohibiting ECM from being in the market, ECM has the preferable market position. Dr. McCarthy's financial interest in the outcome of this litigation, combined with his assumption of a position that contradicts the generally accepted science in furtherance of a contrived definition of biodegradation given him by Complaint Counsel, is proof beyond per adventure of doubt that his testimony is not credible. It should be rejected due to its lack of scientific integrity and due to its furtherance of McCarthy's economic bias. If there was any doubt about the prudence of that

course, it should be allayed by the fact that two experts in this proceeding, Drs. Sahu and Burnette, as well as a professor who is a colleague of Dr. McCarthy in his own department at UMass Lowell, Dr. Steven Grossman, all conclude that Dr. McCarthy's scientific report contradicts the totality of the scientific evidence in its assumptions, analyses, and conclusions. They note at length that not only is Dr. McCarthy's report largely bereft of citations for the broad propositions he makes, but it also runs counter to the scientific literature and generally accepted science in the field of plastics biodegradation.

Thus, at root, Complaint Counsel errs when they presume the ECM additive inherently incapable of causing plastics to biodegrade. The evidence substantiates that plastics infused with the additive in accordance with ECM's specific manufacturing instructions do biodegrade faster than plastics without the additive. The foundation of Complaint Counsel's argument that all biodegradation claims made by ECM are literally false thus fails.

Contradicting McCarthy, who by his own patent and research, adheres to the view that plastics can be made biodegradable in landfills, is Complaint Counsel's other expert, from the EPA, Dr. Thabet Tolyamat. Dr. Tolyamat takes the view that landfills are dry tombs wherein microbiological activity is in all material respects non-existent. On this theory, he finds that landfills are too inhospitable for plastics biodegradation to occur (effectively robbing Dr. McCarthy's patent of its validity). Dr. Tolyamat is, however, not the expert he is purported to be. Indeed, he is not the EPA's expert on biodegradation in landfills, and he admits a lack of basic knowledge of microbiology and plastics biodegradation. He takes the position that because he is unaware of the science governing biodegradation in landfills, it must not exist. That position is refuted by a man who Dr. Tolyamat has turned to edit papers he has given critiquing landfill science and is one of the world's leading experts in biodegradation in landfills, Dr.

Morton Barlaz, an expert for ECM. Dr. Barlaz explains, based on generally accepted scientific research, that landfills are in fact not dead but alive with aerobic and anaerobic bacteria and fungi, and that landfills present hospitable conditions for aerobic and anaerobic biodegradation.

Next, Complaint Counsel argues that ECM's claims concerning the rate of biodegradation are false and misleading. As to this aspect of Complaint Counsel's case, it adopts an erroneous premise. It presumes that ECM's discontinued claim of biodegradation within 9 months to 5 years was unqualified. It presumes further that ECM customers purchased the additive in reliance on that allegedly unqualified claim. Both presumptions are contradicted by the evidence.

At the outset, we should recognize that ECM permanently discontinued making this claim, even in its qualified state, almost three years ago. Despite that fact, Complaint Counsel spend considerable effort endeavoring to prove the abandoned claim false. The factual evidence reveals five fundamental flaws in the foundation for Complaint Counsel's argument.

First, when ECM made a 9 month to 5 year claim, the claim was qualified in ways ignored by Complaint Counsel. In particular, ECM explained that while its additive may cause biodegradation within 5 years, it is impossible to predict beforehand precisely how much time biodegradation will in fact take in any specific location, which rate is inherently variable, not only dependent on the kind of plastic involved but also on the precise ambient circumstances present at the spot where the plastic comes to rest.

Second, to the extent that there is any common understanding of the term biodegradable among the industry, it refers to a process of microbes producing enzymes that break down carbon bonds in plastic resins, which process (dependent upon microbial life cycles) invariably begins for the ECM additive within 9 months to 5 years after customary disposal of plastics but does not

always end within that period (but, rather, at such time as the environment becomes unsuitable for microbial life to remain present, or the substrate is consumed).

Third, sales of the additive take place over several phone calls wherein ECM explains in detail the nature of the additive, its utility, and precisely how it is to be mixed into plastics during manufacture. Moreover, ECM remains in contact with its customers, repeatedly explaining the technical and scientific aspects of product use and effect. During that interaction variously with sales, scientific, and technical representatives of each company, ECM explains that precise predictions of how much time it will take for elimination of plastics to occur in the environment are impossible because they depend on numerous variables, including, *inter alia*, the kind of plastic involved and the peculiar environment present which varies from location to location and, within landfills, from locus of deposit to locus of deposit. The most common example given by Robert Sinclair to customers is that the rate of biodegradation will not be the same if a plastic ends up in a landfill in Antarctica than if it ends up in a landfill in the tropics.

Fourth, ECM does not sell its additive to end-use consumers. It sells to sophisticated plastics manufacturers. Indeed, no end use consumer has ever purchased ECM's additive. None of the plastics manufacturers who purchase ECM's additive is naïve enough to believe that an additive dependent upon a biological process in nature (wherein the additive serves as an attractant for living hosts to colonize and initiate enzymatic activity that breaks carbon chains) will result in elimination of all plastics by an invariable set date or time. Plastics manufacturers comprehend differences in the strength of the plastics they sell and appreciate the variable longevity of those plastics in the environment based on the composition of the resins that make them. Many, if not most, plastics manufacturers rely on their own tests to determine

biodegradability, including the numerous independent tests of the ECM additive by plastics companies that are evidence in this proceeding.

To the extent there is a common understanding of the term biodegradation, scientists and industry understand the term to refer to a biological process rather than a completed event, wherein there are multiple phases, (1) initiation where microbes and fungi attach to the plastic at different opportunistic points, colonize, and produce enzymes that break carbon chains; (2) continuation accentuated by generation after generation of microbes and fungi, each furthering the enzymatic destruction of carbon bonds; and (3) the point at which all enzymatic destruction of carbon bonds ends (indicative of the complete death of all microbes and fungi that produce biodegrading enzymes), which usually means the plastic has been eliminated to all but residue.

Fifth, a well-designed telephone survey by Dr. David Stewart reveals that not even a significant minority of end-use consumers agrees to a single definition of biodegradation, including rates of biodegradation. Instead, the evidence reveals that most consumers are bereft of knowledge concerning even the basics of biodegradation. Put simply, they lack fundamental knowledge to understand the science involved, including, for instance, the expected rate or extent of biodegradation in various environments. Arbitrary limitations on the time period for degradation before the term "biodegradation" can be employed are unscientific and unsupportable. Moreover, rapidly degrading substances are not preferable from an environmental standpoint, not possible from a materials perspective, and not supported by consumer impression. Consequently, there is no materiality to claims involving those terms among end-use consumers. It should be noted that ECM has never sold to end-use consumers and, to the extent that companies chose to make end-use consumer claims, they did so without ECM's involvement except to the extent they used ECM's biodegradation certificate on their

products, but that certificate merely affirms that the product containing the ECM additive is biodegradable (without mention of rate), which is backed by competent and reliable scientific evidence.

Complaint Counsel substantially hangs its argument on claims of biodegradation rate, excerpting them from qualified context. ECM's experts will explain that, from an environmental perspective, whether ECM plastics degrade within a few years or decades is scientifically irrelevant, so long as they biodegrade, because, in part, plastics disposed in landfills are intended for indefinite storage. Neither plastics manufacturers nor end-use consumers nor landfill owners derive a tangible benefit if ECM's plastics degrade by a precise time in landfills, and that helps explain why so many companies prefer ECM's additive over compostable plastic resins. Complaint Counsel's campaign against ECM's additive technology is therefore misleading, owing to the demonstrably false supposition that the rate of biodegradation in this context is material to plastics manufacturers and end-use consumers, when it is not.

Sixth, a well-designed pilot study by Dr. Stewart of companies that purchased the ECM additive likewise reveals that not even a significant minority of ECM's actual customers agrees to a set meaning for the term biodegradation or harbors any notion as to the rate at which ECM's additive will effect complete elimination of ECM plastics in the environment. That data, although limited in scope, confirms that there is no consensus at all among purchasers of ECM's technology with respect to core terms here at issue. Put simply, Complaint Counsel cannot demonstrate that consumers are misled by "biodegradable" claims where the definitional elements differ dramatically from one individual to the next and from one company to the next. Consequently, there is no materiality to claims involving those terms among ECM's actual customers or the general public.

Against Dr. Stewart's telephone survey evidence confirming a complete lack of agreement among end-use consumers as to the meaning of biodegradation and as to the rate of biodegradation of plastics, Complaint Counsel defends the two surveys the Commission deemed flawed in its Green Guides (the Synovate and APCO studies), based on an even more profoundly flawed Google Consumer Survey—all of which lack required elements for validity and reliability.

In its Complaint, and in its opening brief, the FTC explained what it intended to prove in these proceedings, which it must do by a preponderance of the evidence. *See, e.g.*, *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"). That proof would consist of competent and reliable scientific evidence (1) that the ECM additive did not cause plastics to biodegrade and (2) that ECM claimed unqualifiedly that biodegradation occurred within 9 months to 5 years or some period greater than a year, and that both claims were false and misleading. Complaint Counsel has failed to meet its burden of proof. The evidence demonstrates that, indeed, the ECM additive causes plastics to biodegrade more rapidly in the environment than untreated plastics, creating a truly beneficial product demanded by many large plastics manufacturers. Moreover, the evidence reveals that ECM permanently discontinued its 9 months to 5 years claim almost three years ago; that the claim when made was not material to ECM's customers purchasing decisions; that ECM's customers are sophisticated and frequently tested the ECM product to assess its biodegradability; and that all were apprised by ECM truthfully that biodegradation was a natural process and that the rate of biodegradation necessarily varies unpredictably in each individual case. Moreover, not even a substantial minority of plastics manufacturers or end-use consumers

have an agreed upon definition of biodegradation or subscribe to the view that biodegradation means complete breakdown of plastics into elements found in nature within one year of customary disposal in a landfill, the legally contrived definition adopted by Complaint Counsel in this case.

Accordingly, void of requisite proof of competent and reliable scientific evidence for its case, and surrounded by an abundance of proof contrary to its assumptions and conclusions, Complaint Counsel has failed to satisfy its burden and the charges against ECM should be denied and dismissed.

II. FACTUAL AND PROCEDURAL BACKGROUND

A. Factual Background

1. ECM BioFilms, Inc.

ECM BioFilms, Inc. is a small Ohio-based corporation started by Patrick Riley of Micro-Tech Research, Inc. in 1998.[8] Micro-Tech was found in 1995, and years later began marketing a biodegradable masterbatch pellet that renders plastics resins (e.g., polystyrene, polyethylene, and polypropylene) biodegradable. As the oldest such products in the market today, the ECM product has had success as a cost-effective solution for companies looking to have less of a long-term environmental impact.[9]

In 2000, Robert Sinclair assumed leadership of ECM Biofilms.[10] Mr. Sinclair had served as a lawyer (general practitioner) in the local community prior to that time and before that had taught science in northeast Ohio public schools. When he became the President of ECM, he

[8] *See* CCX-818, at 19–20 (R. Sinclair deposition).
[9] *Id.* at 120 ("cost is a huge thing"); CCX-820, at 56–57; CCX-445.
[10] CCX-818, at 7–8.

inherited the proprietary formula for ECM's technology from Mr. Riley, the formula's inventor.[11] ECM's proprietary formula is a trade secret.[12] Only two individuals have had knowledge of the formula, Messrs. Sinclair and Riley. Mr. Riley is now deceased. Although ECM had once considered applying for patent protection, it eventually decided that trade secret afforded the best long-term protection for ECM's intellectual property.[13] The ECM proprietary formula is a closely held secret. Although analytical laboratories have attempted to assay the specific ingredients, none have identified the correct formula.[14]

Mr. Sinclair also received test data from Micro-Tech, including studies demonstrating the efficacy of the product, and claim language that had been used with the product in commerce.[15] Although Mr. Sinclair is not a scientist, he considered himself competent to review the scientific material.[16] As discussed below, ECM's customers are sophisticated plastics manufacturers who ordinarily perform extensive testing on ECM's product themselves or rely on such testing obtained from others before incorporating the technology in their plastics.[17]

ECM has employed on average six employees.[18] Those employees include Robert Sinclair (President and CEO), Kenneth Sullivan (CFO), and one or two administrative employees and one or two sales people. Although other employees have initiated or maintained business relationships, Mr. Sinclair is primarily responsible for communicating with clients concerning

[11] *Id.* at 19–20.
[12] *Id.* at 27.
[13] *Id.* at 73–74.
[14] *See*, *e.g.*, RX-563, at 1.
[15] *See* RX-551; RX-260; RX-263; RX-264; RX-265; RX-269; CCX-241; CCX-799, at 135, 138–141, 266.
[16] *See* CCX-818, at 23–24
[17] *See* CCX-818, at 121–123.
[18] CCX-819, at 327–28.

ECM's technology.[19] As a provider of a plastic additive, ECM sells almost exclusively to plastics manufacturers and, on occasion, to distributors who sell to plastics manufacturers. ECM's product is not purchased by end-consumers and, in fact, it would be useless to an end-use consumer because it is in pellet form and is sold in bulk quantities of no use unless infused into plastic during manufacture. Anyone not capable of manufacturing plastics through inclusion during the extrusion or molding process has no use for this product.

ECM markets its technology through sales meetings, published material (e.g., brochures), and networking functions. As with most technologies sold between corporate entities at the manufacturing level, ECM sales are subject to negotiation. Sales and confidentiality agreements are customary. A prospective customer often performs product testing (including performance testing) before deciding whether the ECM product is a fit. ECM invites independent testing of its product and sells quantities to individual corporate entities to facilitate that testing. In that manner, ECM's sales are best characterized as complex business transactions, in contrast with retail sales to end-consumers.

2. ECM Additive and Plastics Manufacturing

ECM sells a "MasterBatch Pellet" that includes a biodegradable component along with an otherwise non-biodegradable (or conventional) plastic carrier resin.[20] The formula for the "active" component is a trade secret.[21] ECM offers a "load rate" of 70% in its pellets, meaning that every pellet will contain approximately 70% of the "active" biodegradable formula, along with 30% conventional polymer resin. ECM prescribes that plastics manufacturers blend the pellet into their plastics at a 1% rate, resulting in a uniform distribution of the pellet throughout

[19] *See* CCX-813, at 15 (T. Nealis deposition);
[20] *See* RX-371; RX-656; RX-681.
[21] RX-371.

the plastic and at a level that ensures maximum utility without compromising the plastic's integrity.[22]

Like many other plastic additives (e.g., coloring agents), manufacturers introduce the ECM additive into the plastic during the initial blending process.[23] Plastics are commonly manufactured using one of several techniques, including extrusion molding, injection molding, or blow molding.[24] For instance, extrusion molding involves a heated plastic compound continuously injected through a long die cast in the desired shape.[25] The plastic is cooled under blown air and hardens into items such as thin films which are eventually coiled or cut.[26]

There are many different types of plastic polymers, but where ECM additives are used, the additive is intended to be mixed uniformly throughout the plastic polymer through a heated blending process, just like a coloring additive.[27] Through testing and history of use, ECM has established that a 1% load rating in finished plastics is required to maintain the additive's efficacy vis-à-vis biodegradation.[28] Thus, for all plastics properly manufactured with ECM's additive, at least 1% of the final plastic will include the ECM additive based on weight.[29]

ECM's customers manufacture many plastic polymers, but the bulk of the plastics incorporating ECM's technology consist of polypropylene (PP), polystyrene (PS), and polyethylenes (PE).[30] Over seventy (70) percent of ECM plastics are PE plastics. Companies frequently use ECM's technology in plastics such as films (e.g., grocery "t-shirt" bags,

[22] CCX-20.
[23] RX-135.
[24] RX-656.
[25] RX-783.
[26] *Id.*
[27] RX-520.
[28] RX-683; CCX-2.
[29] RX-678.
[30] RX-458; RX-522.

packaging cushions, etc.).[31] ECM's additive is included within so-called "conventional" plastics to form a blend of ECMs' copolymer additive within the larger plastic polymer.[32] In North America, conventional plastics like PE or PP primarily come from domestic natural gas and are substances that contain varying formations of hydrocarbon bonds or polymers.[33] In the rest of the world they are primarily manufactured from the naptha from crude oil distillation. A polymer is simply a molecular structure consisting of a string of similar units bonded together.[34] In other words, in certain plastics, a repeating chain of hydrocarbon bonds. For instance, the following is a diagram of a simple polyethylene polymer:

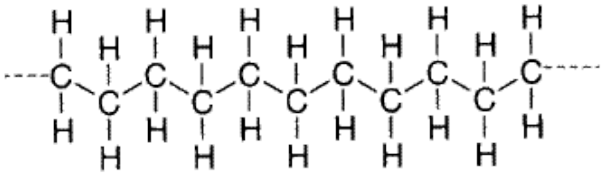


Figure 1. Polyethylene polymer

ECM offers a cost-effective means to achieve biodegradable plastics.[35] There are competing technologies available, such as "bioplastics" which are biodegradable plastic polymers or resins derived from biological substances instead of petroleum.[36] Bioplastic can be non-biodegradable such as bio-based polyethylene or they can be biodegradable such as PHA. Many of those technologies will produce an end-product that biodegrades more rapidly or readily

[31] RX-520; RX-471; RX-849.
[32] RX-458.
[33] *Id.*
[34] RX-458.
[35] RX-335.
[36] RX-748; RX-678.

than plastics made with the ECM additive in an industrial composting operation.[37] However, those competing technologies come at a substantial cost.[38] Companies choosing to invest in most bioplastics must change their entire manufacturing process to accommodate the use of the new natural resins.[39] The bio-based polymers are almost always significantly more expensive.[40] Additional additives are needed to stabilize the bioplastics for the intended use of the end product.[41] After all, the primary purpose of a plastic product is to serve a function in the market, not to biodegrade in landfills. The bioplastics are often suitable only for certain limited uses in the market.[42] There are thus many reasons why a plastics manufacturer might not be able (or not want) to use competing technologies that come at substantial cost and may compromise plastic strength or utility.

ECM's customers are primarily concerned with the balance between product performance (i.e., tensile strength, shelf-life, etc.) after the ECM additive is included and ECM additive's effectiveness.[43] In fact, most ECM customers first perform product performance testing on their finished ECM-infused plastic before ordering product.[44] Because the ECM additive can accomplish a biodegradable plastic with load rates of just over 1% by weight, plastics manufacturers are not required to make substantial changes to their manufacturing process to

[37] RX-725; RX-178.
[38] RX-335.
[39] RX-520.
[40] *Id.*
[41] *Id.*
[42] RX-335.
[43] *See, e.g.*, CCX-811, at 44 (Island Plastic Bags ("IPB") deposition transcript, noting that the company experimented for one year with ECM's additive to determine if it could be incorporated into their process). As explained by the manufacturer, "ECM at that time said it's biodegradable, but it doesn't do us any good if we can't use it through our machines. So what we were doing was putting the additive inside of our plastics to see if it could actually run through our extruders and then be cut and sealed as plastic bags." *Id.* at 44:10–15.
[44] RX-413; RX-412.

accommodate the additive, which is included in the plastic in much the same way a colorant or plasticizer would be, thus ensuring uniform distribution throughout the plastic.[45] As a corollary, ECM's additive technology has a much smaller impact on manufacturers' cost basis.[46] The ECM additive thus offers manufacturers the flexibility to add a biodegradable plastic to their line, without having to substantially alter business operations.

ECM customers are often plastics manufacturers who sell to multiple other, second-layer manufacturers.[47] Those downstream manufacturers place orders for different kinds of plastics, and ECM's customers fill orders accordingly. The ECM technology permits those first-layer manufacturers to add the biodegradable component on a project-specific basis, again, without overhauling manufacturing practices, or investing in expensive alternative resins and components. ECM-infused plastics often pass through at least two levels in the supply chain before ever reaching a so-called "end-user."[48]

For those manufacturers, and their customers, the first goal is to manufacture a quality plastic product that will serve its function in the market. For instance, the shopping bag must hold a certain weight load. With ECM's technology, the biodegradable component is an option they can implement, thus helping the environment, where they would otherwise not have the resources or financial incentive to invest in the more expensive competing technologies.[49]

[45] RX-326; RX-520.
[46] RX-520.
[47] RX-471.
[48] In the IPB example, ECM would sell to Island Plastic Bags in Hawaii, who then manufactured plastic bags in bulk (without printing) through various manufacturing plants, some in China. *See* CCX-811, at 10, 112. IPB then provides manufactured plastics to distributors in Guam or Honolulu. *Id.* at 11. IPB's distributor then provides bulk product a sub-manufacturer, or printer, who produces finished bags. *See id.* at 45:11–14.
[49] RX-520.

In its pursuit of ECM in this case, Complaint Counsel has entirely ignored the fundamental fact that, for plastics manufacturers like ECM's customers, issues of biodegradation rate are, at best, collateral to the primary question concerning the balance between product performance and additive effectiveness in achieving biodegradation. Those customers seek only to market a "biodegradable" product and frequently do not want or generally do not care if the additive achieves biodegradation in the environment by a specific date, within a specific time frame, or at a specific rate. The rates of biodegradation matter only to the extent the FTC has told industry that rates are required before a claim can be made. Thus it is that FTC in this instance that is shaping market realities in ways that detract from actual customer demand and in ways that bring about greater harm to the environment. .

3. FTC Biodegradability Enforcement

a. Complaint Counsel's Allegations

The Complaint presented four essential arguments, supported by anachronistic scientific assumptions. In some cases, Complaint Counsel's theories are supported by scientific assumptions over twenty years old. Complaint Counsel alleged that:

- ECM Plastics will not completely break down and decompose into elements found in nature within a reasonably short period of time after customary disposal.

- ECM Plastics will not completely break down and decompose into elements found in nature within a reasonably short period of time after disposal in a landfill.

- ECM Plastics will not completely break down and decompose into elements found in nature within respondent's stated qualified timeframes after customary disposal.

- ECM Plastics have not been shown to completely break down and decompose into elements found in nature within a reasonably short period of time after customary disposal, after disposal in a landfill, or within respondent's stated

> qualified timeframe, under various scientific tests, including, but not limited to, ASTM D5511.[50]

In support, Complaint Counsel argued that "[a]pproximately 92 percent of total municipal solid waste in the United States is disposed of either in landfills, incinerators, or recycling facilities. These disposal methods do not present conditions that would allow ECM Plastics to completely break down and decompose into elements found in nature within a reasonably short period of time."[51] Complaint Counsel also challenges so-called "unqualified" claims made by ECM directly or by trade consumers.[52] Finally, Complaint Counsel rejects the use of the ASTM D5511 standard and test data because, according to Complaint Counsel, the test will not simulate or replicate the physical conditions of landfills or other disposal facilities.[53] Complaint Counsel has not, however, described or presented any evidence concerning the type of testing that it concludes *would* simulate or replicate the landfill environment precisely.

b. The Green Guides

FTC's interest in regulating degradable claims increased in 1990. "Green marketing" claims were investigated by parallel forces including a ten-state task force of Attorneys General and the FTC. The AG task force, the FTC, and the EPA held a national Public Forum in March 1990 for businesses and regulators to discuss environmental claims, including plastic

[50] RX-902.
[51] *Id.*
[52] *Id.* ("Consumers likely interpret unqualified degradable claims to mean that the entire product or package will completely decompose into elements found in nature within a reasonably short period of time after customary disposal.")
[53] *Id.*

"degradable" claims.[54] After hearing from industry, the AG Task Force published its first report in November 1990, finding that:

> Products that are currently disposed of primarily in landfills or through incineration—whether paper or plastic—should not be promoted as "degradable," "biodegradable," or "photodegradable."[55]

The FTC held separate hearings in July 1991, which culminated in the FTC's first issue of the Green Guides.[56]

In July 1989, the Senate Committee on Governmental Affairs held a hearing on the Degradable Commodity Plastics Procurement and Standards Act of 1989.[57] The ASTM appeared before Congress and introduced testimony concerning biodegradable plastics.[58] Dr. Ramani Narayan appeared as a researcher with the Laboratory of Renewable Resources Engineering at Purdue University.[59] It is during his speech that Dr. Narayan "introduce[d] the concept of composting."[60] Dr. Narayan also stated that "[b]iodegradaable plastic does not imply that that the entire material just completely disappears overnight . . . [t]his is a myth."[61] Dr. Narayan discussed prior landfill "digs" and opined that, given the biological inactivity in existing

---

[54] *See* Environmental Task Force, The Green Report: Findings and Preliminary Recommendations for Responsible Environmental Advertising (1990) (hereinafter "Green Report I"), *available at*, http://infohouse.p2ric.org/ref/24/23677.pdf.

[55] *Id.* at 39–40.

[56] *See, e.g.*, Guides for the Use of Environmental Marketing Claims, 16 CFR § 260 (1994); John M. Church, *A Market Solution to Green Marketing: Some Lessons From the Economics of Information*, 79 Minn. L. Rev. 245, 322 (1994).

[57] *See* Environmental Labeling of Consumer Products: Hearing Before the Subcomm. On the Consumer of the Senate Comm. On Commerce, Science, and Transportation, 101st Cong., 2d Sess. (1990), *available at* http://babel.hathitrust.org/cgi/pt?id=pst.000015610690;view=1up;seq=3.

[58] *Id.* at 28.

[59] *Id.*

[60] *Id.* at 31.

[61] *Id.* at 33.

MSW landfills, disposal therein was just "preserving garbage for posterity."[62] Dr. Narayan explained that:

> The degradable plastics, in terms of landfills, which is where you bury them and then you come back and you find out whether anything has happened or not happened, is dictated by the environment in which it is buried in. If you bury it in Arizona maybe it will take you forever for it to degrade under the conditions. If it is in Florida, it may happen overnight.[63]

Dr. Narayan testified that traditional, so-called "sterile," municipal landfills are inadequate to produce appreciable biodegradation, but "active" landfills (e.g., bio-digesters) were preferable.[64]

Complaint Counsel have relied on advice of Dr. Narayan during this case, and even considered adding him as an expert.[65] Dr. Narayan has close affiliations with "compostable" groups that support rapidly degrading substances.[66] Dr. Narayan has published opinions wherein he stated that a plastic product would need to biodegrade within two growing seasons before it could be called "biodegradable."[67]

The FTC has a history of enforcement against biodegradable claims. *See, e.g., In re Ex-Cell-O Corp.*, 82 F.T.C. 36 (1973). In 1973, the FTC entered a consent order against the makers of Pure-Pak plastic-coated cardboard cartons for milk, juice, and other products. *See id.* at 38–39. Ex-Cell-O had advertised its products as "completely biodegradable" and claimed that its products would degrade in a "fairly short time." *Id.* FTC prohibited Ex-Cell-O from making any "biodegradable" claims without disclosing that the rate of biodegradation depends on various environmental factors. *See id.* at 44. Based on the above information generated in the early

[62] *Id.* at 34.
[63] *Id.* at 42.
[64] *Id.* at 26–42.
[65] *See, e.g.*, RX-743; RX-735; RX-452.
[66] RX-452. Dr. Narayan also claims a close connection with compostable technologies in competition with ECM, including many patents to technologies that so compete. *See* http://report.president.msu.edu/360/soybeans/ramani-narayan/ (last visited July 30, 2014).
[67] *See, e.g.*, RX-743

1990s, FTC enforcement activity increased substantially following enactment of the Green Guides. *See, e.g., Mobile Oil Corp; Proposed Consent Agreement*, 57 Fed. Reg. 35589-01 (Aug. 10, 1992) (challenging degradability claims concerning "ADM Master Batch" and "Polyclean" additive products); *In re N. Am. Plastics Corp.*, No. 902-3184, 1993 WL 766976 (Jan. 14, 1993) (challenging degradability claims concerning "EnviroGard" plastic trash bags); *In re Matter of N. Am. Plastics Corp., et al.*, 118 F.T.C. 632, 1994 WL 16011102 (Sep. 7, 1994) (consent order); *In re Matter of BPI Envtl, Inc.*, No. 902-3225, 1992 WL 696753 (May 5, 1992) (challenging degradability claims concerning plastic grocery bags); *In re Matter of RMED Int'l, Inc., et al.*, 115 F.T.C. 572, 1992 WL 12011051 (May 14, 1992) (challenging degradability claims concerning "TenderCare" brand disposable diapers); *Ame. Enviro Products, Inc., et al.*, 56 Fed. Reg. 46184 (Sep. 10, 1991) (challenging degradability claims concerning disposable diapers).

The complaint in the ECM matter mirrors those same allegations, and is based on similar, antiquated apprehensions of the science. For instance, literature supporting the FTC's position was published in 1993.[68] The FTC's core allegations also mirror those in prior degradation cases, with one critical addition. In ECM's case, the FTC also explains that "[c]onsumers likely interpret unqualified degradable claims to mean that the entire product or package will completely decompose into elements found in nature within a reasonably short period of time after customary disposal."[69] That the "reasonably short period of time" must be a year or less derives from FTC's 2012 revisions to the Green Guides.[70]

[68] *See* RX-593 (e-mail from Complaint Counsel to ECM's former counsel citing a 1993 article for the antiquated proposition that an additive cannot alter a plastic's chemical structure or its susceptibility to biodegradation); RX-590 (the 1993 article).

[69] RX-902.

[70] RX-173.

Complaint Counsel has partnered with experts they intend to call in this case for more than four years, including consultants like Dr. Ramani Narayan, who has offered the same scientific theories on landfill science since 1990. They have thus relied on the same scientific rationale, often untested in litigation, for years to achieve consent judgments against entities, including two of ECM's customers.[71]

The regulatory activity culminated in the "Green Guides" in 1992, which were eventually revised several times, including the most relevant revision here in 2012. For more than twenty years, the FTC has required in 16 C.F.R. §§ 260.7–260.8 that companies possess evidence that a product or package "will completely break down and return to nature, *i.e.*, decompose into elements found in nature within reasonable short period of time after customary disposal." However the concept of a "reasonably short period of time" was never defined, until 2012 when the FTC expressly stated:

> It is deceptive to make an unqualified degradable claim for items entering the solid waste stream if the items do not completely decompose within one year after customary disposal. *Unqualified degradable claims for items that are customarily disposed in landfills, incinerators, and recycling facilities are deceptive because these locations do not present conditions in which complete decomposition will occur within one year.*

See 16 C.F.R. § 260.8(c). Because the overwhelming majority of products are destined for Municipal Solid Waste (MSW) landfills (73.89%),[72] that so-called "One Year Rule" effectively defined the term "biodegradable" for nearly all disposable consumer goods. As explained below, the One Year Rule is scientifically invalid. Equally impossible is the collection of data that could prove with any confidence the expected timeframe or rate of degradation in an MSW

[71] *See* FTC Cracks Down on Misleading and Unsubstantiated Environmental Marketing Claims (October 29, 2013), *available at* http://www.ftc.gov/news-events/press-releases/2013/10/ftc-cracks-down-misleading-unsubstantiated-environmental.

[72] RX-511, at 13.

landfill. The landfill environment is highly variable and heterogeneous, from one landfill to the next, but also within each landfill itself.[73] Predicting precise rates of degradation sufficient to satisfy the Commission is in fact scientifically impossible, whether the product is an additive, like ECM's, or a compostable product, like those favored by the FTC's choice not to enforce against them.

Perhaps more troubling, the One Year Rule is scientifically baseless. Experts agree that even the most biodegradable substances (including food waste, etc.) will not biodegrade in an MSW landfill within one year.[74] Indeed, not even tree trunks, orange peels, or banana peels, all generally accepted to be biodegradable in the environment, can reliably break down into elements found in nature within one year of customary disposal.[75] That means the FTC's "One Year Rule," which defines the "reasonably short period of time" for degradation, is unattainable for every single product on the market. In fact, under the FTC's One Year Rule, a banana peel is not biodegradable and could not be marketed to consumers as such.[76] The rule was based not on sound science, but on what the FTC claimed was consumer perception of degradable claims.[77] When national environmental policy is effectively struck based on that perception (which, as we shall see is a misperception in any event), it replaces rational science with arbitrary and capricious decision-making and it succeeds in aggravating rather than militating the environmental goal of lessening pollution.

---

[73] *See* CCX-893, at 8 (noting that composting accounts for just 11% of disposal waste when recycling is excluded).

[74] *See* RX-853, at 11; CCX-893, at 16.

[75] RX-841, at 187:2–7 (McCarthy deposition explaining that a tree is biodegradable even if it does not completely return to elements found in nature within one year).

[76] *Id.* at 186:1–8.

[77] *See* Green Guide Policies, at 3.2

The FTC explained that its One Year Rule was supported by "[t]he available consumer perception evidence." [78] FTC explained that:

> In a survey by APCO Insight, 60 percent of respondents expected that an item marketed as degradable without qualification will fully decompose in less than one year. The Commission concludes that this survey is a more reliable indicator of consumer perception than the Synovate study in which only 25 percent of respondents had the same expectation.[79]

In doing so, the Commission rejected another survey that had, incidentally, a higher sample size (the Synovate study).[80] In the Synovate study, ninety-three percent (93%) of all respondents thought it was acceptable to label a product "biodegradable" provided the product would decompose in a landfill.[81] The FTC rejected the Synovate study and based its Green Guide recommendations on the APCO study instead.[82] FTC explained that "[b]oth studies may be faulted for lacking control groups and presenting the timeframe questions with close-ended, rather than open-ended, answers, but they nevertheless are *the only studies in the record*."[83] Based on a well-designed telephone survey from Dr. David Stewart, ECM here presents current and reliable survey evidence that establishes the One Year Rule to be devoid of a basis and, thus, wholly arbitrary and capricious.[84]

The FTC chose the APCO study because, "[u]nlike the APCO study, the Synovate study results suggest that respondents' answers may have been not only biased, but also influenced by a tendency to avoid extreme answers."[85] FTC also explained that "respondents were informed that 'non-biodegradable plastic products take hundreds of years to decompose,'" but "[s]uch

[78] RX-195, at 121.
[79] *Id.*
[80] *Id.* at 118–122.
[81] RX-673.
[82] RX-195, at 118–122.
[83] *Id.* at 121 n. 409 (emphasis added).
[84] RX-856.
[85] RX-195, at 121.

statements are absent from most marketing contexts, and did not appear in the APCO questionnaire."[86] Moreover, according to FTC, the design of the Synovate study revealed a "pattern of responses, together with the absence of choices in the range of less than one year," which "suggests that some respondents were avoiding an extreme response."[87] Accordingly, the "Commission conclude[d] that the proportion of consumers expecting full decomposition in under one year would be closer to 60 percent rather than 25 percent."[88]

ECM's expert in consumer psychology, Dr. David Stewart, will testify that the One Year Rule was based on flawed evidence and remains uncured by the patently unreliable Google Consumer Survey evidence from Complaint Counsel's expert, Dr. Shane Frederick.[89] Dr. Stewart will explain that consumers actually lack the necessary background to opine on biodegradable claims, a complex scientific issue that not even most scientists agree on in full.[90] Furthermore, his consumer survey data reveals that no consensus exists (not even a significant minority) among consumers with respect to biodegradable claims.[91]

The so-called "reasonably short period of time" for degradation after customary disposal must be examined through the scientific evidence, which reveals that void of biodegradable additives conventional plastics will last, at least, for thousands of years in the environment. Thus, plastics which biodegrade in decades, or even hundreds of years, are environmentally beneficial as they degrade in reasonably short periods of time when compared with non-biodegradable plastics. The evidence will show that ECM plastics should be compared not with

[86] *Id.* at 122.
[87] *Id.*
[88] *Id.*
[89] RX-856.
[90] *See, e.g., id.* at 26–27.
[91] *Id.* at 25–26.

an arbitrary and capricious "One Year Rule," but with untreated plastics that have an almost indefinite environmental fate.

4. The Scientific Definition of Biodegradation Versus Complaint Counsel's Definition

The scientific experts in this case will testify that many scientifically accurate definitions exist for terms like "biodegradable," "biodegrade," and "biodegradation." The definitions for those terms are necessarily broad to accommodate a range of potential mechanisms. For example, 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)."[92] Other sources have defined "biodegradable" to mean "capable of being decomposed by bacteria or other biological means."[93]

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. Noticeably absent from scientific definitions of "biodegradation" or "biodegradable" is any reference to a specified rate, extent, or time period for degradation. Outside of this case, Complaint Counsel's experts have never used time or rate limitations on definitions of "biodegradation" in their own scientific publications. As relevant here, 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.

---

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

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

By contrast, Complaint Counsel's experts were asked by Complaint Counsel to adopt a peculiar, artificial construct alien to the scientific literature for the definition of "biodegradable," to wit: "that the entire plastic will completely break down and return to nature (*i.e.*, decompose into elements found in nature) within one year after customary disposal (*i.e.*, incinerator, landfill, or recycling)."[94] Dr. McCarthy, Complaint Counsel's expert, testified that he prepared his expert report as a "collaborative effort between [himself] and complaint counsel."[95] He testified that the definition of "biodegradable" which included the one-year limitation "was the definition that [he] used with respect for this case" throughout his report and in his expert opinion.[96] His scientifically baffling testimony evidenced the extreme position Complaint Counsel's interpretation of "biodegradation" places upon their witnesses.

Asked whether a product could be considered "biodegradable" if it degraded 95 percent in 364 days, Dr. McCarthy testified that it "would not satisfy the definition."[97] He maintained that position even though all other qualified experts in this case have accepted that a product will almost never biodegrade to one hundred percent, as most substances will leave behind some residue or humus. Dr. McCarthy's strained attempt to defend Complaint Counsel's erroneous definition of "biodegradable" continued:

> Q: Assuming that on day 365 [a product] was only 95 percent [biodegraded] still, but on day 366 it becomes 100 percent, would that satisfy the definition of biodegradable in [McCarthy's report]?
>
> A: That wouldn't satisfy the definition.[98]

[94] *See* RX-841, at 20:11–21:22 (McCarthy's deposition transcript); CCX-891 at P. 5, n.1 (McCarthy's expert rep.).
[95] RX-841, at 20:15–17.
[96] *Id.* at 21:21–22.
[97] *Id.* at 28:21–24.
[98] *Id.* at 29:5–10.

Consider the implications, from a scientific perspective, of an FTC policy that limits the definition of "biodegradability" in that manner, excluding products that are obviously—and scientifically proven to be --"biodegradable" simply because the achievement cannot be documented within one year.

Perhaps most troubling is that no article can satisfy Dr. McCarthy's definition of biodegradable. Complaint Counsel's purported expert in landfills explained in his report that even "rapidly degrading wastes" such as food waste and sewage sludge might take between 7 to 14 years to fully biodegrade. Moreover, Dr. McCarthy himself has marketed "biodegradable" plastic polymers, and even achieved patent protection for same, based on technologies that would not degrade completely within one year.[99]

Complaint Counsel's definition of "biodegradable" is designed to trap businesses. It cannot be satisfied and, so, any company charged will necessarily fail the arbitrary One Year Rule. Complaint Counsel's approach therefore becomes one where *no unqualified* claim concerning "biodegradation" can ever exist in the market, even if the products are, in fact, "biodegradable." Because plastics manufactured with ECM's additive ostensibly satisfy the generally accepted scientific definitions of "biodegradable," Complaint Counsel cannot show that ECM's claims are false or misleading absent reference to its scientifically defunct and implausible definition. The use of the claim "biodegradable" in marketing is, at worst, potentially misleading commercial speech for which the constitutional resort remains imposition of a reasonable and succinct claim qualification, not excessive prosecution and prospective speech limiting orders on the right to communicate in whole categories, such as in use of the term biodegradation.

[99] RX-362; RX-755, at 13.

5. The Anti-Competitive Effect of Enforcement of Complaint Counsel's Biodegradation Definition

Complaint Counsel's narrow and invalid definition of "biodegradable" substantially limits innovation by erecting unpassable obstacles to market, and favors companies that offer rapidly-degrading (but economically infeasible) alternatives like compostable bioplastics. Private interest groups heavily lobbied the FTC to enact more rigorous regulations in the 2012 amendments to the Green Guides. Among those groups were organizations like the Biodegradable Products Institute (BPI), which is a member-based organization representing compostable technologies.[100]

"Biodegradable" plastics are not the same as "compostable" products. While a "compostable" product might also be considered part of the "biodegradable" universe, the process of composting involves different environmental elements than those present in landfill environments.[101] Composting involves aerobic processes (with oxygen) as opposed anaerobic processes common in landfills.[102] Because composters, including commercial systems, are actively managed to promote optimal conditions, composting is expected to yield higher rates of degradation over time.

The ASTM has established testing protocols that assess the compostability of products including plastic polymers.[103] Partly because compostable systems benefit from rapidly degrading waste, the standards concerning "compostability" are generally pass/fail, whereby a product must degrade past a certain extent within a specified period of time before the product

[100] *See, e.g.*, RX-172.
[101] RX-875, at 85:3–15.
[102] *Id.*
[103] *See, e.g.*, RX-367.

can be called "compostable." For instance, the ASTM D6400 protocol is the "Standard Specification for Labeling of Plastics Designed to be Aerobically Composted in Municipal or Industrial Facilities."[104] That standard requires 60% biodegradation by biological processes during composting within 180 days.[105] Other similar standards (e.g., EN 13432) require 90% biodegradation in that time period.[106] Under the D6400 standard, a product that degrades only 59% in 180 days is not considered "compostable," but a product that degrades 61% would be "compostable."[107]

Witnesses (fact and expert) will testify in this case that the ASTM body is largely a political arena, where methods/standards are largely driven by members financially interested in the outcome. There are no membership requirements in the ASTM working groups that promulgate standards. Any company or individual with a vested interest, and financial support, can participate in the voting process that results in industry standards.[108] Those standards have no legal precedence, and language in the standards that relates to legal issues such as claim language or substantiation can logically be ignored. The ASTM standards are relevant to the extent they embody methodologically sound methods to gather scientific data, which must then be interpreted.

Members of the compostable industry have heavily influenced the publication and revision of certain ASTM standards related to plastics biodegradability testing.[109] Tests like the D6400 are tailored to rapidly degrading products that can perform well enough within the narrow

[104] CCX-91.
[105] *Id.*
[106] *See* RX-772.
[107] CCX-91.
[108] RX-875, at 285:4–20.
[109] *Id.* at 172:1–10.

180 day testing period.[110] Those tests, however, are inadequate to measure the long-term biodegradability of more slowly degrading products, like plastics manufactured with ECM's technology.[111] While it is not the case that ECM plastics are non-biodegradable, those products are not expected to degrade rapidly and, so, manufacturers of compostable technologies can use the unscientific claim language in the ASTM protocols to limit marketing claims by competitors.

The same outcome occurs with Complaint Counsel's definition of "biodegradable" which includes the narrow one-year window. Products that cannot achieve rapid degradation in short periods of time are essentially outlawed because under the One Year Rule they cannot lawfully communicate to the market that they are biodegradable when they degrade in a period of time greater than a year. Makers of compostable products, like some bioplastics or oxodegradable polymers, stand to gain a substantial market advantage as a direct and predictable result of the One Year Rule and Complaint Counsel's campaign of enforcement. After all, compostable products cost substantially more than the biodegradable additives (of which ECM is just one of many companies selling similar technologies) and without agencies of the government doing their bidding, the market favors ECM's technology from a cost-benefit standpoint. Plastics manufacturers are less inclined to use the expensive technology if a cheaper alternative exists that will produce an environmentally friendly, biodegradable plastic in the general sense. One solution is to restrict the market for "biodegradable" plastics such that only those expensive technologies qualify. Because the marketing interest lies primarily with "biodegradable" products, as opposed to biodegradable products that disappear within certain time periods, manufacturers are willing to pay for the most cost-effective product that satisfies the FTC's

[110] *Id.* at 263:23–264:15, 56:21–25.
[111] *Id.* at 89:2–18.

definition of "biodegradable." By eliminating alternatives through administrative regulation, ECM's competitors gain market share.

That process was evident here, where for years ECM's competitors directly lobbied FTC attorneys to pursue enforcement action against additive companies, including ECM. [112] Representatives from BPI had open channels to FTC attorneys and frequently reported marketing claims by additive companies.[113] ECM competitors, like Metabolix, Inc., also lobbied for enforcement against additive companies and, in particular, against ECM.[114] Groups like the BPI, and scientists affiliated with same, zealously lobbied the ASTM to incorporate limited language in biodegradability test standards that would (unscientifically) limit *claim language* based on test results.[115] Finally, organizations like the BPI commissioned biased and methodologically unsound consumer perception studies in an attempt to persuade the FTC that end-consumers preferred rapidly degrading plastic products. Whether wittingly or unwittingly, the FTC has rewarded those efforts by directly incorporating sections of BPI's comments (almost verbatim) into the 2012 Green Guide revisions, and through enforcement actions such as that against ECM memorializing the arbitrary concept that a product must fully degrade within one year before it can be considered "biodegradable."[116]

Perhaps in an effort to limit exposure to an apparent constitutional infirmity, the FTC explained in 16 C.F.R. § 260.8(c) that "unqualified" biodegradability claims were deceptive unless evidence showed complete degradation within one year, perhaps leaving room for qualified claims. In Section 260.8(d), the FTC explained that:

---

[112] *See, e.g.*, RX-211.
[113] *See, e.g.*, RX-718–RX-733.
[114] RX-211.
[115] *See, e.g.*, RX-741.
[116] RX-857, at 16–21.

> Degradable claims should be qualified clearly and prominently to the extent necessary to avoid deception about:
>
> (1) The product's or package's ability to degrade in the environment where it is customarily disposed; and
>
> (2) The rate and extent of degradation.[117]

See 16 C.F.R. § 260.8(d). That language is illusory, however, because there are no test methods sufficient to satisfy Complaint Counsel's heavy standards to prove the precise rate and extent of degradation occurring in a landfill environment (whether in landfills generally, specific landfills, or specific locations within individual landfills).

In this case, Complaint Counsel has criticized ECM's reliance on ASTM standards because they do not "simulate or replicate" the landfill environment[118] (in contradiction, Dr. McCarthy cleaves to ASTM standard D5511 as a demonstrative test of biodegradation[119]). Moreover, Complaint Counsel's own experts have used those same methodologies outside of this case to prove that products biodegrade.[120] More significantly, Complaint Counsel and its experts have never explained precisely what type of scientific testing would be sufficient to show that a product biodegrades at a certain rate or to a certain extent within the variable landfill environments. When asked directly to explain what type of testing would be sufficient, an element to which Complaint Counsel has the burden, Complaint Counsel's experts were evasive:

> Q: You've said to me that it's a multitude of studies that would be necessary, in your opinion, to support a claim that a product is biodegradable, but you have not said specifically any threshold or standard that has to be met in order to establish that the product is biodegradable. Do I have that correct?

---

[118] *See, e.g.*, RX-851, at 126:20–127:11 (Dr. Tolaymat's deposition transcript).
[119] CCX-891.
[120] *See* RX-362.

A: Yeah, that is.

Q: So I can understand this, is your opinion an I'll-know-it-when-I-see-it type of thing for biodegradability or is there some type of quantifiable threshold that we can cross and now we can say our product is biodegradable?

A: There is no one test that'll give you that answer; however, it's a collection of data points, collection of tests, a body of evidence that supports the conclusion.[121]

…

Q: What specific type of scientific evidence do you require … to show that a product is biodegradable in landfills?

A: There isn't one test. It is a body of evidence. It is the collectiveness of the data. It is not just one silver bullet, one test you would run and be able to say with a hundred percent accuracy whether something is biodegradable or not.[122]

As will be discussed below, that lack of clarity shows that Complaint Counsel cannot demonstrate under its demanded definition of "biodegradation" the type, and accessibility, of evidence adequate to form a reasonable basis for making ECM's claims. *See In re Pfizer Inc.*, 81 F.T.C. 23 (1972). Its construct is a straw man, bereft of a scientific or survey evidentiary foundation, that *cannot ever* be satisfied. Indeed, even were it to be applied to compostables, which Complaint Counsel enforcement to date has assiduously avoided, it would not be capable of satisfaction. That is because the variable conditions in landfills worldwide make presupposition of a precise rate and extent of biodegradation impossible.

The narrow FTC definition of biodegradation, and the absence of defined standards to support it, effects a change in national environmental policy due to its suppression of the entire non-compostable biodegradable plastics industry. If FTC insists on compliance with this

[121] RX-851, at 149:16–150:9.
[122] *Id.* at 151:23–152:6

arbitrary and capricious definition of biodegradation in this case, what company would invest in beneficial technologies that could not meet the rigors of the One Year Rule?[123]

What Complaint Counsel seeks—a judicial decree that only businesses selling compostable products can employ the term "biodegradable"—"is nothing less than an order establishing property rights in the language. Words are not born with meanings. They acquire meaning with use, and as use changes so does meaning." *First Health Grp. Corp. v. BCE Emergis Corp.*, 269 F.3d 800, 804 (7th Cir. 2001). If compostables are "better" than biodegradables, then BPI and the FTC "should be able to explain this to potential customers." *Id.* at 805. "No business is entitled to a trial after which judge and jury will determine how language *ought* to be used, as if usage were a question of law or logic. It is enough to guard against misleading expressions that play on how language *is* used." *Id.*

6. The Financial Interest of Complaint Counsel's Lead Scientific Expert in the Outcome of the Litigation

Complaint Counsel retained Dr. Steven McCarthy approximately two years ago as a consultant, and eventually as a testifying witness against ECM in this case.[124] Dr. McCarthy's scientific positions were apparent in Complaint Counsel's pre-complaint decisions. Email correspondence from Complaint Counsel to ECM in July 2013 mirrored the content in Dr. McCarthy's expert report.[125] Dr. McCarthy is a professor at UMass Lowell in Massachusetts

[123] The FTC's nearly flawless record in administrative enforcement actions only adds to any apprehension. *See* David Balto, "FTC's winning streak is over," TheHill.com (Feb. 11, 2014) (quoting Chairman of the House Judiciary antitrust subcommittee Spencer Bachus (R-Ala.): "With this kind of record and an unbeaten streak that Perry Mason would envy, a company might wonder whether it is worth putting up a defense at all in a system in which the FTC brings a complaint, the case is tried before an administrative law judge at the FTC, and the FTC holds the authority to overturn a decision adverse to the agency").

[124] CCX-891.

[125] *Compare e.g.*, RX-593 *with* CCX-891.

("UMass").[126] He is not a reliable expert witness.[127] He has accepted on behalf of UMass millions of dollars in funding from ECM competitors that offer bioplastics and compostable products.[128] Dr. McCarthy has directly profited from research he performed for ECM competitors.[129] UMass-Lowell has boasted of Dr. McCarthy's income earning potential, noting in 2012 that Dr. McCarthy "has obtained nearly $9 million in externally sponsored research grant and contracts, plus nearly $33 million in intellectual property donations to UMass Lowell."[130] Dr. McCarthy's success at UMass appears directly linked with his ability to generate income through IP "donations" and grant money.

For instance, Dr. McCarthy directly profits from compostable plastic resin patent royalties paid to UMass. Under an agreement with the University and in accordance with UMass policy, Dr. McCarthy assigned his patent rights in a compostable plastic resin he invented to UMass.[131] In exchange, he receives a profit share of the royalty stream.[132] One of Dr. McCarthy's patents was purchased, and has been used, by an ECM competitor, Metabolix Inc.[133] To the extent Metabolix's sales increase based on incursions into ECM's market, royalties from the patent will increase and Dr. McCarthy's income from those royalties will increase as well.[134]

---

[126] RX-841, at 15:21–25.

[127] *See, e.g.*, RX-857, at 29–33 (Volokh Expert Rep. detailing McCarthy's conflicts of interest).

[128] CCX-891, at 42–44 (McCarthy's CV listing contract and grant support from ECM competitors such as Solutia, Metabolix, and Warner Lambert).

[129] RX-841, at 60:10–21 (McCarthy's deposition explaining that he receives $4,000–$5,000 per year in royalties from a patent he invented and that is licensed to Metabolix).

[130] *See* Aguirre, "Plastics Engineering Educator Praised for Research, Service" (Sep. 21, 2012), *available at* http://www.uml.edu/News/stories/2011-12/University-Professor-reception.aspx.

[131] RX-841, at 57:14–17.

[132] *Id.* at 59:10–12.

[133] *See* RX-362 (U.S. Patent No. 5,883,199 (issued Mar. 16, 1999)).

[134] *See* RX-841, at 51:23–52:5, 55:23–61:15.

Once again, UMass is the patent's assignee.[135] Metabolix is the exclusive licensee of the technology.[136] Metabolix's potential royalties from licensing UMass patents surpass $100,000 per year.[137] Dr. McCarthy testified that he receives money directly from the '199 patent, which is licensed by Metabolix.[138] He acknowledged that Metabolix's products compete directly with ECM's technology for market share.[139] If the Commission is successful against ECM in this matter (and by extension against similar additive products), Metabolix's market share increases along with the return to Dr. McCarthy from his royalty payments. Although this patent reveals a direct financial interest by Dr. McCarthy in the outcome of the litigation, it is not the only evidence revealing such an interest.

Dr. McCarthy also collects a share of research grant money that he secures for UMass Lowell from compostable product competitors of ECM, such as Metabolix and other compostable product manufacturers.[140]

Metabolix supplied grants to UMass of approximately $2.5 million, sponsored more than 50 students for their master's and doctorate degrees, and has made substantial equipment donations (over $500,000).[141] Since 2008, Metabolix has also been lobbying the FTC to act

[135] *See* RX-761; RX-757 (Metabolix Website Article).
[136] *See*. RX-209.
[137] *Id.*
[138] *See* RX-841, at 59:10–60:21 (explaining that, as an inventor, Dr. McCarthy gets ten percent (10%) of the royalties of the '199 patent if there is a profit).
[139] *Id*. at 64:22–66:14 (acknowledging that it is a competitive marketplace and that products based on the '199 patent are in competition with other products marketed as biodegradable, compostable, and recyclable).
[140] *Id*. at 52:6–55:22 (explaining that a project account receives forty-six percent (46%) of the research grants Dr. McCarthy secures, and that he is in control of that account when he is the principal investigator).
[141] RX-210.

against ECM.[142] Dr. McCarthy has worked with BPI, and collected substantial revenue (approximately $40,000), performing BPI "certifications" for trade customers in the compostable industry which compete with ECM.[143] Metabolix is also a member of the Biodegradable Products Institute ("BPI"), a primary ECM competitor, and sells approximately a dozen products that are "BPI certified" in direct competition with ECM.[144] BPI is a vocal opponent of ECM, and has lobbied the FTC repeatedly since at least 2005 to act against ECM and ECM's customers.[145]

Dr. McCarthy's personal affiliations and financial interest in ECM's competitors makes his scientific opinions unreliable because he has well established financial interests in opposition to those of ECM. He is an agent of ECM's competitors, profiting directly from their success either by the receipt of royalties, payment for services (such as his service for years as a certifier for BPI, or grants to UMass-Lowell in support of his research). A successful prosecution of ECM and the additive market would bestow a substantial windfall on Metabolix, BPI and related compostable product manufacturers, who would immediately stand to gain market advantage. Dr. McCarthy is compensated $100/hour for his work in this matter (except deposition and trial testimony).[146] The idea that he would enter an opinion in a high profile FTC case that cut against the businesses that support him financially defies credulity. Indeed, the evidence suggests that he tailored his opinion to meet Complaint Counsel's needs, even accepting the

[142] RX-211 (requesting FTC to investigate Good Earth and ECM for alleged deceptive environmental claims).
[143] *See* RX-841, at 92:11–24.
[144] *See* RX-171; RX-172.
[145] *See, e.g.*, RX-744 (BPI Correspondence to FTC of April 25, 2005).
[146] CCX-891.

fundamental definition of what "biodegradation" means from Complaint Counsel, despite contrary representations in his own scientific articles and in his own patent.[147]

Dr. McCarthy has adopted positions that contradict prior work he performed for ECM's competitors. For example, his expert report stated that radiological marker ^{14}C testing is the only test that can dispositively prove that ECM's additive causes biodegradation of plastics, but he himself has relied on extrapolation and other tests (that neither adhere to an ASTM standard nor involve radiological markers), such as one he created himself, UML-7645, and measures of weight loss, to prove biodegradability of polymer products.[148] Plus, in other materials Dr. McCarthy was silent on the need for a product to biodegrade within a year to be biodegradable, and yet, for ECM's additive, Dr. McCarthy is adhering to the one year rule contained in FTC's Revised Green Guides in collaboration with Complaint Counsel.[149]

Moreover, Dr. McCarthy's report stated that "evidence that a substance is biodegradable is not 'competent and reliable' unless the tested sample reaches 'at least 60% biodegradation,' and there is both a 'negative control' and a 'positive control,'" but Dr. McCarthy's '199 patent made biodegradable claims even though the rate of biodegradation was lower than 60%.[150]

Dr. McCarthy himself has used the very same test methods ECM has used to demonstrate a "biodegradable" product before the U.S. Patent and Trademark Office. Dr. McCarthy's prior research on biodegradable plastics did not meet the same 60% threshold that he now requires of

[147] *See Supra* Part II.A.4.

[148] *See* RX-841 at 74:9–75:8, 148:18–149:9, 165:13–172:5.

[149] *See id.* at 19:7–15, 20:21–42:12. *See also id*. at 69:8-76:17 (explaining that the '199 patent used the term "biodegradability" without requiring complete biodegradation within a year); *Id*. at 185:10–187:16 (explaining that a banana peel, tree trunk, and orange peel are biodegradable even if they do not biodegrade within a year of customary disposal).

[150] RX-756, at Figure 11.

ECM's additive.[151] Dr. McCarthy's insistence that ECM obtain ^{14}C testing is not the consensus in the relevant scientific community.

Perhaps caught on the science, Dr. McCarthy's June 30, 2014 rebuttal report eventually presented new theories in response to ECM's expert testimony that had not before been presented by Complaint Counsel. For instance, Dr. McCarthy had previously contended that the "priming effect" would have accounted for the positive results in ECM's testing. When the priming effect was eventually debunked (as we discuss below), Dr. McCarthy shifted to a new theory concerning the split between amorphous and recalcitrant properties of plastic polymers.[152] He also posited that polyethylene polymer chains could only be reduced through the use of pro-oxidants, which ECM's technology did not involve.[153] Truth be told, ECM's additive falls within the types of alternative technologies that have been shown to facilitate polyethylene degradation.

Consequently, the evidence reveals that Dr. McCarthy has fashioned his scientific opinion to suit Complaint Counsel's purposes and further Dr. McCarthy's financial interests. Dr. McCarthy is not an objective expert in this case, and his purported scientific opinion should be rejected.

7. The Scientific Evidence that the ECM Additive Biodegrades Plastics

Over 30 individual tests from multiple laboratories show plastics made with ECM's additive will biodegrade in various environments, including MSW landfills.[154] ECM's test data (including the inconclusive test results) reveal that Complaint Counsel's criticisms are

[151] *Id.*
[152] CCX-892, at ¶ 22.
[153] *Id.* at ¶ 11.
[154] *See infra*, Part II.A.7.e.

unfounded or unsupported. Here we address the various levels of proof ECM will supply in support of the conclusion that its additive technology renders non-degradable plastics "biodegradable" in landfill conditions. We will then address each of the scientific criticisms upon which Complaint Counsel erroneously rely to condemn ECM's product.

When compared with conventional plastics, plastics manufactured with ECM's additive degrade over varying lengths of time in MSW landfills. ECM has consistently explained to its customers that the ECM additive is "not a poof and it's gone" technology.[155] The test data and peer-reviewed literature demonstrate that ECM plastics will, in fact, biodegrade where untreated plastics will not. Complaint Counsel posits a number of criticisms of that theory, but ultimately their position distills to the following points not supported by the scientific evidence: that ECM's accelerated testing has not shown that ECM's technology causes the conventional plastic to become biodegradable in a landfill environment because the tests do not precisely mirror those conditions in a landfill, and no test has been run long enough to show complete degradation.[156] Given the many tests favoring ECM, and the overwhelming weight of the scientific evidence on both the mechanism of action in biodegradation and the fact of it occurring in a wide range of plastics, that position is scientifically invalid.

While the scientific disputes are complex and numerous, the crux of Complaint Counsel's position is that test data revealing relatively small amounts of biodegradation (when compared to cellulose, a very rapidly degrading substance) is irrelevant because ECM cannot extrapolate test results beyond the four corners of each test report. However, ECM will show through peer-

[155] *See, e.g.*, RX-680 ("It's not a 'poof it's gone' system but simply makes the plastic product biodegradable as if it were a stick or a branch off a tree rather than 'sticking around' for hundreds of years."); RX-371, at 4 (same).

[156] *See, e.g.*, RX-865 (Complaint Counsel stating to another regulated entity that "we have serious concerns about these additives and whether they work at all," and later explaining that the additive companies "would have to shut down and close [their] doors").

reviewed literature and test data that the relative amounts of biodegradation observed in ECM tests is quite substantial when compared to non-degrading conventional plastics and is accepted by experts as predictive of landfill environments (even consistent with Dr. McCarthy's own extrapolation methodology undergirding his '199 patent).[157] ECM will prove through test data and other scientific evidence that products manufactured with ECM's additive will continue biodegrading to completion in the landfill environment.

a. Biodegradation Testing Methods

Industry has relied on several test models to prove biodegradability, but most experts agree that "gas evolution" data is the most practical and widely used measure of biodegradation (both aerobic and anaerobic).[158] There are no tests that precisely simulate or replicate landfill conditions, and Complaint Counsel has offered no such method through its experts, but tests showing that one or more common bacteria do in a closed test environment biodegrade plastic are generally accepted as predictive of biodegradation in landfills where many multiple kinds of biodegrading bacteria and fungi are present.[159] Supporting biodegradability claims therefore requires extrapolation of data from the laboratory environment based on known consistencies in the natural environment.[160] The process of extrapolation is scientifically valid, and is used in almost every scientific field that handles laboratory data.[161] Nonetheless, the laboratory closed-system model has limitations that are relevant to this case. Biodegradability testing is often accelerated in the laboratory because the testing environment often will not remain viable, e.g., the bacteria have difficulty surviving for long enough periods to record complete biodegradation

[157] *See* RX-362.
[158] *See* RX-853, at 7–8.
[159] *See, e.g.*, RX-756, at 6–12; RX-853, at 7–9; RX-865, at 41–47.
[160] *See* RX-855, at 44–45, 54.
[161] *Id.*

data.[162] Furthermore, because products will take many years (or decades) to fully biodegrade in landfill settings, accelerated test conditions are necessary to avoid the many costs and problems associated with years of long-term term gas evolution testing.[163]

Gas Evolution Tests (e.g., ASTM D5511):

A gas evolution reaction is a chemical reaction that produces gas, in this case, methane and carbon dioxide.[164] The process of biodegradation involves the cleavage of carbon bonds from the substrate, which are then combined with available hydrogen and oxygen to produce methane and carbon dioxide.[165] In a gas evolution test, the laboratory exposes test articles to conditions that theoretically favor biodegradation, and then gas emissions are monitored. By comparing the levels of gas emitted from the test vessel, the laboratory can measure the amount of gas produced from the test articles themselves.[166] Figures of methane and carbon dioxide gas are shown below:

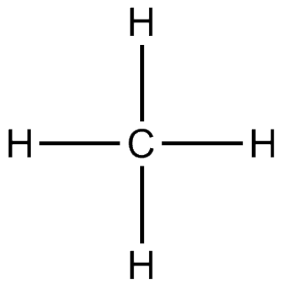


Figure 2. Methane diagram

Gas evolution tests generally have several common characteristics. Within a closed, watertight vessel, test articles are exposed to "inoculum" that is comprised, in part, of leachate

[162] *See, e.g.,* RX-854, at 25–27; CCX-799, at 106, 125–26.
[163] *See,* RX-855, at 41–45; RX-842, at 35, 350–52 (Sahu Deposition).
[164] *See* RX-853, at 8.
[165] *Id.* at 8–9.
[166] *Id.* at 8–9.

from local municipal waste stations.[167] The leachate therefore contains microbes that would also be present in the environment.[168] Some tests bolster the inoculum by adding minerals and food to grow the bacterial colonies before the test period.[169] Laboratories usually incubate the inoculum for a period beforehand to stabilize the material for testing.[170] The test articles are mixed with the inoculum in the test vessel and, for anaerobic testing, the vessels are flushed with gases like Nitrogen to eliminate most oxygen content that might remain.[171] Gas collection tubes are connected to the test vessel, and gas produced by the vessel is gathered and later measured.[172] The laboratory records the total amount of gas produced, and the ratios of methane gas to carbon dioxide.[173] A diagram of the typical ASTM D5511 gas evolution test is presented below:

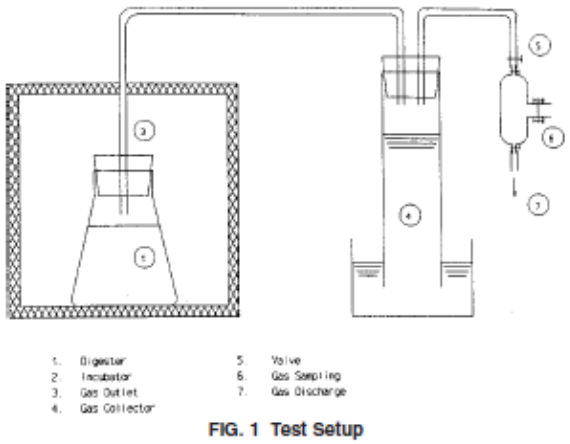


Figure 4. ASTM D5511 Setup

See RX-356, at 2 (ASTM D5511-12).

[167] *See* RX-385, at 3.
[168] *See, e.g.*, RX-854, at 5–6.
[169] *See* CCX-84, at 3 (§ 9) (ASTM D5511 Standard).
[170] *Id.*
[171] *See, e.g.*, RX-873, at 46 (NE Labs Deposition).
[172] *See* RX-356, at 2 (D5511 test method, summary and apparatus).
[173] *See* CCX-84.

Results of the tests are based, in part, on the theoretical carbon yield for a test sample.[174] A sample can contain only so much carbon, and the amount of carbon in a sample can be calculated based on the molecular formulas for the substrate plastic.[175] The gas evolution tests, like ASTM D5511, also test against negative controls, positive controls, and inoculum blanks. As is relevant here, the negative control is often a copy of the test plastic without the additive technology.[176] The inoculum blank is a test vessel that simply records gas production from the inoculum by itself. The positive control is always cellulose, which is a rapidly biodegrading substance like filter paper.[177] The positive control serves only to indicate whether the test environment had sufficient life (e.g., fungi, microbes, bacteria, etc.) to adequately measure biodegradation.[178] The positive control is important because closed-system laboratory vessels are inhospitable to long-term testing.[179] However, the positive control is not an indication of how the test article should perform comparatively.[180] Biodegradation should be assessed relative to the negative control instead.

The laboratory can determine the level of gas attributable to the samples by subtracting the gas known to have been produced by the inoculum blank.[181] The inoculum contains living organisms that will emit gases while digesting other parts of the solid waste within the inoculum mixture. The laboratory can determine the proper gas level attributable to the test vessel by

[174] *See* RX-864, at 119–20 (Barlaz Deposition);
[175] *See* RX-356, at 4 (§ 12).
[176] *See, e.g.*, RX-860; RX-839; RX-836; RX-838.
[177] *See* RX-864, at 17:1–12; RX-356, at 4 (§ 13).
[178] *See* RX-356, at 4 (§ 13.2);
[179] *See* RX-870, at 125–127 (Barber Deposition); RX-854, at 23 ¶ 64.
[180] *See* RX-854, at 24, 25 ¶ 74.
[181] *See* RX-356, at 4 (§ 12).

comparing the overall gas levels of the inoculum blank to those of the test article and negative control.[182]

The laboratory calculates the percentage of biodegradation by comparing the level of gas attributable to test sample with the theoretical maximum yield of gas from that same sample.[183] In sum, because the gas emissions contain carbon, the test sample can only contain so much carbon, and the inoculum will produce only a certain amount of carbon, researchers can conclude that excess carbon recorded in the gas emissions represent a certain fraction of the carbon that had once been locked within the test article.[184]

ECM has been able to show through gas evolution tests that the ECM additive causes the plastic polymer to biodegrade.[185] That is evidenced by the amount of biodegradation observed through gas evolution data. ECM customers include the ECM additive in varying amounts, usually around 1% by weight of the final plastic, but sometimes up to 1.75%.[186] The "load rate" of ECM's actual pellet is around 70%, meaning that the ECM additive contains 70% active components and 30% carrying resin (which is ordinarily not biodegradable).[187] Thus, in a final plastic subject to gas evolution testing, the plastic polymer blend with a 1% ECM load rating is expected to contain approximately 0.7% of the active proprietary ECM component by mass.[188]

ECM's gas evolution tests report amounts of biodegradation considerably in excess of that 0.7% figure. In other words, the gas volumes recorded from the tests exceed what can be

---

[182] *Id.*
[183] *Id.*
[184] *See, e.g.*, RX-864, at 134–41 (Barlaz Deposition).
[185] *See id.*; RX-855, at 41–49.
[186] *See, e.g.*, RX-875, at 60, 62–63; RX-871, at 11–12, 57–58.
[187] This value has changed in recent years. ECM offered a 50% load rating in years past. *See* CCX-818, at 118–120.
[188] *See* RX-875, at 119.

produced by the additive alone when adjusted for the inoculum.[189] Thus, to the extent the additional biodegradation is attributable to the test article (and it is), that extra carbon content must have come from the plastic polymer and not the ECM additive. Importantly, in ECM's positive tests, the negative control (i.e., the plastic without the ECM additive) did not demonstrate any appreciable biodegradation, which demonstrates that the biodegradation was triggered and maintained by the ECM additive.

ASTM D5511:

Gas evolution tests for biodegradation come in many iterations, but industry has consistently relied on the ASTM D5511 standard because it is efficient and cost-effective.[190] In 1994, the ASTM first published the standard titled "Determining Anaerobic Biodegradation of Plastic Materials Under High-Solids Anaerobic-Digestion Conditions, ASTM D5511." The purpose of the ASTM D5511 standard was to test for intrinsic anaerobic biodegradability of samples. The D5511 test is designed to record data under accelerated conditions. Thus, the test calls for environmental conditions that promote biodegradation. The temperature of the test is increased to around 52 degrees centigrade. The solids content is lowered to 20%, meaning the test is performed under rather wet conditions (80% moisture).[191]

Although the conditions of D5511 testing do not represent those in all landfills, many bioreactors landfills would be expected to exhibit similar conditions, at least in parts.[192] Landfill

[189] *See infra* Part II.A.7.e (table).

[190] In fact, when measuring the anaerobic biodegradability of various plastics, one of Complaint Counsel's proposed experts, Dr. Frederick Michel, also used an ASTM D5511 protocol. Similarly, Complaint Counsel's other expert, Dr. McCarthy, has used gas evolution tests similar to the ASTM D5511 test to support claims of biodegradability for his bioplastic polymers.

[191] *See* RX-356; RX-855, at 41-49.

[192] *See* RX-855, at 42-43; RX-870, at 178-80; RX-864, at 39-40.

conditions are highly variable, and differ greatly from one landfill to the next, and even within each individual landfill.[193] In any landfill, there are pockets that likely exhibit conditions similar to the D5511, but also pockets that may be considered less conducive to microbial or fungal life. The variable and unpredictable nature of landfills substantially limits the ability to predict with certainty how the D5511 test data would transfer into the natural environment. However, scientists can and do determine that the mechanisms of action observed in the D5511 test also occur in the natural environment, including in landfills.[194]

Industry has relied on the D5511 test, in part, because the protocol is cost-effective.[195] Many D5511 tests of short duration will cost several thousand dollars.[196] Plastics manufacturers seeking to have product-specific data thus prefer the D5511 because it gives scientifically valid gas evolution data within a reasonable period of time. The accelerated test conditions allow companies to evaluate product samples in months as opposed to years, thus allowing the companies to make timely marketing and purchasing decisions.[197]

ASTM has published other gas evolution test protocols, for instance the ASTM D5526. The environmental conditions in the D5526 differ slightly from D5511 test. For instance, the D5526 calls for testing at solid levels "more than 30%" rather than 20%, and temperatures at about 35 degrees centigrade rather than 52. However, the D5526 also requires large pressure-resistant glass vessels capable of withstanding an overpressure of two atmospheres.[198] Moreover

[193] *See* RX-864, at 38–40.
[194] *See* RX-854, at 26–27.
[195] *See, e.g.*, RX-876, at 96.
[196] *See* RX-873, at 72–73.
[197] *See* RX-855, at 44–45.
[198] *See, e.g.*, RX-358 (ASTM D5526-12).

the D5526 will return test results at a much slower pace. Thus, the D5526 increases laboratory costs associated with the equipment and labor.[199]

BMP Testing:

Biomechanical Methane Potential (or "BMP") testing is a gas evolution test that is designed to measure potential biodegradability of a test sample. The BMP test is performed in a liquid environment, with very high moisture content.[200] BMP testing varies significantly from one laboratory to another.[201] In many instances, BMP testing calls for grinding the test product and screening it through a 1 mm screen.[202] That process, if used with ECM's products, would likely dissociate much of the ECM additive from the host plastic, thus nullifying the product's efficacy.

The ASTM D5511 test is comparable to the BMP test and the D5511 test presents conditions more like the natural environment.[203] Dr. Barlaz, ECM's expert witness, performed several tests of ECM plastics purportedly including the ECM additive. He performed those tests prior to, and independent of, his role as an expert witness in this case. Several of the test articles appeared to involve recycled ECM plastic, which would likely have contained less additive than the 1% necessary to foster biodegradation.[204] Drs. Sahu, Burnette, and Barlaz will also testify that the presence of inconclusive tests does not nullify favorable tests, which clearly indicate that

[199] *See* RX-873, at 70–72.
[200] *See* RX-864, at 73–75.
[201] *See* RX-851, at 146:19–25.
[202] *See* RX-851, at 134.
[203] *See, e.g.,* RX-851, at 138; RX-870, at 101–02; RX-864, at 74–75.
[204] *See,* RX-477 ("[a] varying percentage of the reclaimed material in the bags is reprocessed film containing the biodegradable additive. The purpose of this test is to see what effect (if any) the amended film will have as it enters the recycle stream and is mixed with other recycled plastic.").

the ECM plastic has degraded.[205] A test may produce inconclusive results for many reasons that have nothing to do with the plastic substrate, not least of which is the death of the bacteria in the inoculum, a persistent problem.[206] In particular, variables in the manufacturing process could result in a product that lacks the ECM additive in substantial parts, or the test environment may not be conducive to the longer duration testing required.

Qualitative Testing:

ECM has produced qualitative testing that demonstrates the presence of biodegradation through qualities such as mass loss or gravimetric calculations. Dr. Timothy Barber is a renowned environmental scientist at Environ Corp.[207] Environ is a global leader in environmental and human health testing. Dr. Timothy Barber is a principal working out of Environ's Ohio group.[208] He designed a test based on the conditions of an ASTM D5526 test that would measure biodegradation of test samples based on weight loss over time.[209] Dr. Barber testified credibly that the gas evolution tests had limitations when testing slowly degrading substances over long duration studies.[210] His test results demonstrated that ECM's additive

[205] *See, e.g.,* RX-864, at 140–41.
[206] *See* RX-854, at 27 ¶ 82.
[207] *See* RX-870, at 246–61.
[208] *See* RX-870, at 256–57.
[209] *See, e.g.,* RX-573; CCX-791.
[210] *See* CCX-799, at 106 (Barber deposition transcript) ("The measurement of carbon dioxide and methane are required under those test protocols are designed for relatively short periods of time. Because we needed to run these test out to 17, 23 months, we needed to use a protocol that did not require the capture and analysis of metabolic gases…"); *Id.* at 125–26 ("One of the challenges … of trying to maintain an active microbial community in a static enclosure is how long you can maintain a functioning microbial community, and this was something in part of why we made modifications to some of the pre-existing ASTM protocols, because we knew we would have to run these tests 12 to 18 months").

would render plastics such as PVC fully degradable with a 1.9 year half–life.[211] He confirmed his gravimetric endpoints by looking at free chloride content in the test solution, noting that the chloride ions would have come from the degraded sections of the PVC plastic.[212] Dr. Barber also reviewed test data from other laboratories concerning ECM's additive technology.[213] He was convinced based on the test results that ECM's technology produced a biodegradable plastic.[214]

Other qualitative tests included electron microscopy performed of degraded ECM samples. Those tests revealed visual evidence of microbiological formation and attack on the ECM-treated plastics.[215] Several other laboratories have demonstrated ECM's effects through qualitative evidence as well. ECM employees, including Mr. Sinclair, performed tests of the ECM additive in gardens, backyard soils, and in 50-gallon drums to assess biodegradation in real-time.[216]

Radiolabeling Tests:

Complaint Counsel's experts have suggested that ECM should have performed ^{14}C radiolabeling tests to demonstrate that the plastic itself degrades during the gas evolution tests.[217] Complaint Counsel's reliance on ^{14}C radiolabeling tests is confounding for several reasons. First, the test is entirely impractical, and no one runs it. Not even Complaint Counsel's expert,

---

[211] *See* RX-254, at 1 ("[t]he environmental half-life of bioPVC under aerobic conditions is estimated at 1.9 years").

[212] *See* RX-370, at 6; RX-259 ("Certification of Results," noting that "an increase in soil leachate chloride content and reduction in tensile strength was observed, indicated the PVC molecules were being effectively degraded").

[213] *See* RX-269 ("ChemRisk" report).

[214] *See, e.g.,* RX-870, at 90 ("the polyethylene film provided to me … purportedly containing the ECM additive was determined to be biodegradable in our study").

[215] *See infra* Part II.A.7.e (table).

[216] *See* CCX-818, at 63-69; CCX-820, at 8-9.

[217] *See, e.g.,* CCX-891, at ¶ 891.

Dr. McCarthy, who competes against ECM in the market, has performed ^{14}C testing on his technology (yet he falsely submits in his report that it is accepted as the definitive test for plastic biodegradation).[218] Radiolabeling is very expensive and difficult to perform.[219] ECM would need to find a plastics manufacturer capable of manufacturing a radiolabeled polymer with the ECM additive included in such a way that the ^{14}C content does not mix with the additive.[220] Many laboratories can perform ^{14}C testing if given a suitable sample, but few if any companies are willing to prepare the radioactive plastic sample for eventual testing.[221] Because ^{14}C is a radioactive isotope, the manufacture would need to operate under strict containment conditions, and undertake massive burdens to decontaminate their facility following production.[222] The costs associated with that form of testing are so extreme, Complaint Counsel has not been able to produce a single example of a competitor using ^{14}C testing to support biodegradation claims, although there are many competing companies selling biodegradable technologies.

Furthermore, even assuming that ^{14}C was feasible, the ultimate test of the plastic must still be performed for biodegradation. That test would still be a *gas evolution* test similar to (or perhaps exactly the same as) the D5511 test.[223] So the ^{14}C testing does not address Complaint Counsel's central theory of this case, which is that gas evolution studies do not simulate or replicate the landfill environment. Radiolabeled testing is just one *kind* of gas evolution study, run under similar conditions as the tests now in the record. If Complaint Counsel's concern is

[218] *See* RX-841, at 90; RX-362.
[219] *See* RX-853, at 9; RX-855, at 47–48; RX-755, at 15.
[220] *See* RX-842, at 113–16.
[221] *See Id.* (explaining that ECM had attempted to obtain prices for radiolabeling testing but was unable to find manufacturers capable or willing to manufacture the radioactive components for testing).
[222] *See* RX-842, at 116–23.
[223] *See* RX-842, at 321–22 (expressing concerns that Complaint Counsel had not seemed to appreciate that radiolabeled products must still undergo gas evolution testing, like ASTM D5511 testing, to test for biodegradability).

that ASTM D5511 tests do not simulate landfills, then the radiolabeling test does not appease those concerns. Put simply, the kind of testing needed to provide Complaint Counsel what it considers competent and reliable scientific evidence of plastics biodegradation in landfills does not exist.

b. The Kinds, Nature and Functions of Microbes That Biodegrade Plastics

Complaint Counsel argues that extrapolation of data from the D5511 test environment into the landfill is scientifically inappropriate because (1) the test environment does not simulate or replicate the landfills; and (2) several studies involving ECM plastic appear to "plateau." ECM expert Dr. Ryan Burnette, a microbiologist with expertise in anaerobic microbiology, explains that landfills (and most environments) have been shown to contain an assortment of microbiological life, and that biodegrading microorganisms present in the D5511 laboratory environments are a subset of those present in landfills.[224] He will explain that microorganisms have been shown to degrade polymers through processes such as enzymatic digestion, and that microorganisms responsible for biodegradation in laboratory environments can thrive and metabolize matter under in landfill settings.[225]

Moreover, Dr. Burnette explains that the so-called "plateau" effect is likely the result of environmental conditions, or limitations of the close-system lab test.[226] The lab environment is a closed, finite system that prevents microbial growth and succession, like a fish tank that is never cleaned or emptied. Thus, it is not accurate to describe the conditions of a D5511 test as

[224] *See, e.g.*, RX-854, at 6–14.
[225] *See id.*
[226] *See id.* at 14–15.

"optimal" in long term tests. [227] For instance, feedback inhibition occurs much more rapidly (and is permanent) in a laboratory environment, whereas in the natural environment the flow of liquid and the settlement of materials would be expected to disperse or diffuse levels of enzymes and byproducts that limit cellular metabolism.[228]

Finally, in some instances, the evidence suggests that the testing conditions were never adequate to support biodegradability testing. For instance, in at least several of the tests that did not show biodegradation of ECM products (but likewise did not prove ECM products fail to cause biodegradation), the positive control (cellulose) plateaued prematurely along with the test article.[229] That is what happened with Complaint Counsel rebuttal expert Dr. Frederick Michel's test, albeit other methodological problems also plague his testing. [230] Because cellulose is well-established to completely mineralize and biodegrade, the plateau is a sure sign of the test environment.[231]

Complaint Counsel, by contrast, lack a microbiologist with sufficient credentials to address the specific microbiological issues presented in this case. Complaint Counsel's expert in landfills, Dr. Tolaymat, authored a report wherein he specifically claimed that the microbiological communities differed in the landfill.[232] However, when asked about that point in his deposition, he confessed that he had absolutely no knowledge of the bacterial

[227] *See* RX-854, at 25–27.
[228] *Id.* at ¶¶ 35, 77.
[229] *See id.* at ¶ 33; RX-755, at 4.
[230] *Id.*
[231] *See* RX-870, at 153–54.
[232] *Compare* CCX-893, at ¶ 79 ("ASTM D5511 also calls for use of an inoculum that is not available from a U.S. laboratory—and likely not comparable to the bacterial community found in the typical U.S. landfill."); *with* RX-851, at 76–77, 225–26.

communities. Likewise, Dr. McCarthy professes ignorance as to what microbial life forms exist in landfills and declines the invitation to describe himself as a microbiologist.[233]

c. Microbes that Adhere to Plastic in Landfills, Opportunities for Colonization, Enzymatic Destruction of Carbon Bonds, Multi-Generational Development, ECM Additive Acceleration of Microbial Degradation

ECM's additive permits the biodegradability of otherwise non-biodegradable plastics by (1) facilitating the breakdown of plastic polymers into smaller chains suitable for enzymatic digestion; and (2) fostering the formation of biofilms at or around the plastic, which, in turn, weaken and break the carbon bonds in polymers through enzymatic and acidic digestive processes.[234] ECM's expert, Dr. Ranajit Sahu, is an expert in environmental and applied sciences.[235] He has over twenty years of experience in environmental, mechanical, and chemical engineering, much of which includes work related to landfills and materials used in landfill construction (e.g., plastic polymers).[236] He explains that the peer-reviewed literature and testing data shows plastics to be biodegradable in time, and that the ECM additive acts to exponentially increase the rate of biodegradation. [237] Complaint Counsel's own experts (e.g., Dr. McCarthy), have relied on polymer "blends" of conventional plastics with other biodegradable components to achieve a "biodegradable" end product.[238]

---

[233] *See* RX-841, at 17–19.
[234] *See* RX-855, at 27–29.
[235] *See* RX-855, at 5–6.
[236] *See id.*; *see also* RX-842, at 26–32.
[237] *See generally*, RX-855.
[238] *See* RX-362 (claiming a "biodegradable blend" of biodegradable components with conventional plastics like polyesters).

Bacteria can achieve initial and minimal adherence to plastics via weak interactions, such as hydrophobic, van der Waals, temperature, and other variable interactions.[239] Biofilms have been shown to grow and accumulate on substrates, including plastics, for purposes of degradation.[240] Studies in the peer-reviewed literature have documented that bacteria and fungi are able to use natural and synthetic plastics as food sources.[241] Much research has been dedicated to the ability of microbes to degrade plastics such as Polyethylene (PE).[242] The ECM additive has been shown through testing to result in the formation of biofilms.[243] Anaerobic bacteria in landfills (and present in the laboratory tests) release enzymes that have the ability to weaken and eventually discharge carbon bonds.[244]

d. The Living Nature of Landfills

Dr. Morton Barlaz is Professor and Head of the Department of Civil, Construction, and Environmental Engineering at North Carolina State University.[245] He has a B.S. in chemical engineering and an M.S. and Ph.D. in Civil and Environmental Engineering.[246] His M.S. and Ph.d. research focused on biodegradation in landfills. Complaint Counsel's witness, Dr. Tolaymat, recognizes Dr. Barlaz as an authority in the area of biodegradation.[247] Dr. Barlaz will explain that Complaint Counsel's view of landfill science is wholly flawed and anachronistic.

---

[239] *See* RX-854, at 14.
[240] *Id.* at 15.
[241] *Id.* at 17.
[242] *Id.* at 18 (citing, e.g., *Phanerochaete chrysosoporium*, *Rhodococcus rubber*, *A. oryzae*, *Brevibacillus borstelensis*, *Penicillum simplicissim YK*).
[243] *Id.* at 25–27.
[244] *Id.* at 18–20.
[245] *See* RX-853, at 2 (summarizing experience).
[246] *See* RX-853, at Exh. 3 (Barlaz, M., Curriculum Vitae).
[247] *See* RX-851, at 22–23. Dr. Barlaz has reviewed and edited Dr. Tolaymat's work. *Id.* Dr. Tolaymat supported his opinions throughout his deposition by reference to Dr. Barlaz's work.

Landfills are characterized by their biological activity and, in fact, most U.S. landfills produce a substantial amount of methane and carbon dioxide gas—directly resulting from biological activity in the form of biodegradation.[248]

Thus, Complaint Counsel is incorrect and misleads by characterizing modern landfills as "dry tombs" wherein little or no biodegradation can occur. Landfills, while not as biologically productive as bioreactor landfills, do indeed permit biodegradation in substantial quantities.

Landfills are also characterized, however, by their variability in environmental conditions.[249] The moisture content, temperature, density, and composition of MSW landfills change constantly, will differ substantially from one landfill to another, and often within each landfill from one cell to another.[250] There is also variability in the actual time required before the microbiological system becomes established for anaerobic biodegradation following waste disposal.[251]

That high degree of variability makes difficult any exact prediction of the time for biodegradation in the environment.[252] Nonetheless, Dr. Barlaz explains that gas evolution tests (such as the ASTM D5511) are useful and accepted as indicative of a substance's ability to biodegrade anaerobically.[253] Moreover, if a product is shown to degrade anaerobically in a test environment, then it is also likely to biodegrade in a landfill, but perhaps at a slower rate. Thus, the dichotomy between the landfill and the test environment should relate more to the *rate* of biodegradation but not the extent.[254]

---

[248] *See* RX-853, at 5–6.
[249] *See* RX-853, at 8–9; RX-864, at 39–40.
[250] *See* RX-864, at 39–40.
[251] *See* RX-853, at 6.
[252] *See* RX-853, at 9–11.
[253] *See* RX-853, at 8.
[254] *See* RX-853, at 7–8.

Landfills are responsible for mostly anaerobic degradation, but also a limited amount of aerobic degradation. For instance, the emission of carbon dioxide gases from landfills around the country indicates the presence of oxygen, which can be trapped within the landfill or released during the degradation of other MSW components.[255]

Dr. Barlaz has also assessed many of the scientific studies for which the parties possessed raw data.[256] Moreover, Dr. Barlaz has visited Eden Laboratories to review its test methods and facilities.[257] Dr. Barlaz will explain that the positive tests in the record before this Court are indicative of biodegradation in excess of the ECM additive (contrary to Dr. McCarthy's "priming effect" theory).[258] He has explained that "reactor tests" of the kind ECM presents provide "results on what is possible in a landfill given appropriate environmental conditions."[259]

Complaint Counsel's purported expert in landfills, Dr. Thabet Tolaymat, lacks the education, experience, or training sufficient to opine on the issues central to this case. Dr. Tolaymat lacks an understanding of the microbiology and bacterial communities at work in the landfills or test environments.[260] Although he testified as an "employee of the federal government," his antiquated opinions concerning "dry tomb" landfills are inconsistent with the EPA's regulation of those landfills and the EPA's statutory goals. Dr. Tolaymat prepared his expert report, which may have far-reaching consequences for environmental policy, without consulting with any expert in the areas he is not at the U.S. EPA.[261] Not a single EPA employee or representative reviewed Dr. Tolaymat's work product to determine if his views were

[255] *See id.* at 5–6.
[256] *See* RX-853, at 14.
[257] *See id.*
[258] *See* RX-864, at 175–76.
[259] *See* RX-853, at 8.
[260] *See, e.g.*, RX-851, at 225–26.
[261] *See* RX-851, at 29–30.

consistent with those of that agency.[262] Dr. Barlaz will testify that Dr. Tolaymat's report is erroneous on certain fundamental points concerning landfills, landfill management, and biodegradation testing.

e. Proof that ECM's Additive Biodegrades Plastics

The following representative tests have shown that plastics manufactured with ECM's technology biodegrade significantly:

Test	Year	Method	Duration	Plastic/ECM	% Biodeg.
McLaren/Hart (RX-269)[263]	1999	Scientific Evaluation and Review of existing study data (anaerobic/aerobic report)	15 days 22 months	ECM Pellet 5% ECM Film	24% (pellet) Qualitative evidence of biodegradation (film)
Univ. of NM Electron Microscopy	2006	Scanning Electron Microscope (SEM) images of treated test samples	n/a	Treated bubblewrap	Qualitative evidence of biodegradation
Univ. of NM Electron Microscopy	2007	Scanning Electron Microscope (SEM) images of treated test samples	n/a	Treated PS foam	Qualitative evidence of biodegradation
SSCCP (RX-465)	2009	UNI EN 14043/2003,[264] aerobic[265] degradation test of Italcom product	91 days	PET PVC Film	4.95% (PET)[266] 50.09% (PVC) 4.80 (Film)
SSCCP (RX-467)	2013	ISO 14855, UNI EN 14046, aerobic degradation ,Colplast	91 days	Unknown	11.9%

[262] *Id.*

[263] Respondent/Complaint Counsel Exhibit Nos. RX-269, CCX-266E, CCX-268A.

[264] Some of the SSCCP tests involved the grinding of test samples in liquid nitrogen to obtain particles with sizes of <1 mm. The grinding process, which could separate the additive components from the plastic, is likely to significantly reduce, if not nullify, any expected biodegradable effect achieved through biofilm formation and quorum effects.

[265] Aerobic tests are relevant to prove the mechanism of action and intrinsic biodegradability of ECM plastics.

[266] Averages of three datasets recorded.

Test	Year	Method	Duration	Plastic/ECM	% Biodeg.
SSCCP (RX-468)	2013	ISO 14855, UNI EN 14046, aerobic degradation, Colplast	91 days	Unknown	6.96%
Ecologia Applicata s.r.l. (RX-273)	2010	UNI EN ISO 14855, aerobic degradation, for Co.ind. s.c.	180 days	PP/1%	19.3%
Sondor (RX-274)	2011	Sondor Biofoam degradation test	775 days	Various/2%	Qualitative evidence of biodegradation (mass loss, etc.)
Environ (RX-275)	2012	Environ PS & PE testing for FP International (modeled after ASTM D5338 & D5511)	120 days	PS & PE/1%	>5%
Ecologia Applicata s.r.l. (RX-276)	2011	UNI EN ISO 14855, aerobic degradation, for Colplast S.r.l.	180 days	Polyammide & Nylon/% unknown	46.67%
Intertek India (RX-277)	2012	D5511, ISOE Printpack Industries, PVT, LTD, sample sheet	45 days	Sample sheet unknown	Qualitative evidence of biodegradation; gas data; no negative control
Clemson Univ. Study (RX-388-91)	2009	*In situ* testing of various treated samples for Dispozo Products Inc.	477 days	EcoPure	Qualitative evidence of biodegradation
Case Western (RX-278)	n/a	Prof. Morton Litt SEM Examination of ECM plastic in	n/a/	n/a/	Qualitative evidence of biodegradation
Eden 092511B (RX-248)	2011	ASTM D5511, for FP International	120 days	Airbag film/1%	11.5% 15.2%
Eden 070312C (RX-839)	2012	ASTM D5511, for Shields Bag & Printing	22 weeks	Film/1%	7.9%
Eden Fellows (RX-403)	2012	ASTM D5511 for Fellows	197 days	Amended film/1%[267]	71.8% 16.1%
Eden FPI (RX-402)	2014	Updated ASTM D5511 standard for FP International	290 days	1% ECM film 1.75% ECM film	5.5% 11.5%

[267] The Fellows product was treated with additional biodegradable elements.

Test	Year	Method	Duration	Plastic/ECM	% Biodeg.
Eden FPI (CCX-548)	2013	Modified ASTM D5511 for FPI EPS Samples	291 days	Expanded PS/1%	30.4%
Eden Smithers (RX-401)	2013	ASTM D5511 for Smithers Oasis	148 days	Foam/1.1% Foam/3%	2.4% 5.8%
Eden FPI (CCX-546)	2011	ASTM D5511 for FP International	977 days	Air bag (TKN)/1% Air bag (HOP)/1%	36.7% 39.8%
Environ (RX-254)	2008	Anaerobic study based on ASTM D5526	180 days	Amended PVC	2.7% (based on gravimetric data)
NE Labs N0843980 (RX-399)	2008	ASTM D5511 study for Bio-Tec Environmental LLLC	14 days	PP Sheet	8.4% (based on gravimetric data)
NE Labs N0946510-01 (RX-398)	2009	ASTM D5511 study for Masternet Ltd.	15 days	PE/1%	4.91%
NE Labs 1048742-01 (RX-405)	2010	ASTM D5511 study for Eco SmartPlastics	45 days	LDPE/1.5%	7.37%
NE Labs 1048819 (RX-396)	2010	ASTM D5511 study for Eco SmartPlastics	43 days	PET	7.01%
NE Labs 1150851 (RX-395)	2011	ASTM D5511 study for Sweet Tape Enterprise (M) Sdn. Bhd.	45 days	PP	4.54%
NE Labs 1150851 (RX-394)	2011	ASTM D5511 study for Tycoplas Sdn Bhd	15 days	PS foam	5.89%
NE Labs 1253020 (RX-393)	2012	ASTM D5511 study for National Tree Co.	15 days	PVC PE	9.89% 5.75%
NE Labs 1048036 (RX-392)	2011	ASTM D5511 study for Transilwrap Co.	233 days	Film Laminate	7.85% 8.53%
NE Labs N1048340 (RX-836)	2013	ASTM D5511 study for Pregis (PPC)	900 days	PE Poly Bags/1%	49.28%

Test	Year	Method	Duration	Plastic/ECM	% Biodeg.
OWS PFR-1 (RX-263)	1998	Aerobic Biodegradation under controlled composting conditions (ISO 14855)	45 days	5% film 5% natural film	4.5% 2.6%
OWS PFR-4 (RX-265)	1999	High Solids Anaerobic Digestion (HSAD) concept test	15 days	ECM pellet	24.0%
OWS PFR-5 (RX-266)	2000	Aerobic Biodegradation Under Controlled Composting Conditions (40 Gal Trash Bag)	45 days	Treated bag	5.2%
OWS BFI-1 (RX-268)	2010	High Solids Anaerobic Digestion (HSAD) Test for Covidien	15 days	PP	3.9%
Eden MicroTek (CCX-534)	2011	ASTM D5511 test for MicroTek	811 days	PE	17.9%
Eden EcoLab (CCX-547)	2013	ASTM D5511 test for EcoLab	452 days	Film	19.6% 46.5%
NE Labs 1149980 (RX-838)	2011	ASTM D5511 & D6579 tests for Minigrip	365 days	LDPE/LLDPE/ 1.5%	17.07%
NE Labs 1048215	2010	ASTM D5511 test for Dansko	15 days	Rubber/2.5%	1.5%[268]

8. Testing of the ECM Additive Confirms that It Accelerates the Biodegradation Process

Despite the overwhelming evidence of ECM's additive causing plastics to biodegrade, Complaint Counsel presents a variety of inconsistent theories in an effort to discredit the entire body of scientific evidence. None of those theories, taken alone or in combination, overcome the totality of the evidence showing that ECM's additive, when properly blended within major plastic resins (e.g., PP, PS, and particularly PE), will produce a biodegradable plastic that biodegrades in landfills. In short, Complaint Counsel would have this Court rule that every

[268] The unconventional use of the ECM additive in rubber produced a degradation rate of 1.5% (which was less than the percentage of the additive), which tends to validate the Northeast Labs results.

single one of the dozens of positive ECM tests are each uniquely flawed to the point of irrelevance, but that the Court should accept the very same or similar tests that support Complaint Counsel's theory of the case. Consider the following theories crucial to Complaint Counsel's case:

ECM's testing conditions adequately simulate or replicate landfill settings:

According to Complaint Counsel, no test can actually simulate or replicate the landfill environment and, so, every test must be rejected. That position is contrary to the generally accepted scientific evidence which routinely extrapolates from closed system tests to the landfill environment. The flawed nature of that argument is most apparent when considering that Complaint Counsel's own experts relied on the *same* testing methodologies as ECM to prove that products were biodegradable in the landfill environment. For instance, Dr. Frederick Michel performed an ASTM D5511 to assess whether seven plastics would be considered anaerobically biodegradable in the environment.[269] Dr. McCarthy, Complaint Counsel's lead scientific witness, performed similar gas evolution studies to determine that his own technology was aerobically and anaerobically degradable.[270] Dr. Tolaymat, Complaint Counsel's landfill expert, testified that a BMP test should be used to measure biodegradability, which is a gas evolution test arguably less representative of a landfill than the D5511 standard.[271]

In short, Complaint Counsel has failed to identity a single test or analysis that it concludes *would* be representative of the landfill environment. Therefore, their theory appears to be that no such claim could ever be substantiated, which is a false premise built on a constitutionally infirm prior censorship.

[269] *See* CCX-905.
[270] *See* RX-756.
[271] *See* CCX-893, at 21.

ECM's Positive Test Results do not Have Fatal Methodological Flaws:

Complaint Counsel has identified a series of so-called methodological "flaws" to justify its categorical rejection of the over 33 tests showing the ECM additive causes biodegradation. Significantly, almost all of those "flawed" tests employed suitable negative controls. The use of negative controls in those instances mitigates any perceived issues in the methodology, as explained below.[272]

For example, Complaint Counsel contends that tests did not maintain anaerobic conditions throughout the test. That is incorrect. In certain situations, laboratories (e.g., Northeast Labs) would "re-innoculate" the test vessel with fresh inoculum. The labs re-inoculated specifically to test the theory that a plateau effect indicated that the test article had finished degrading. NE Labs would flush the vessels with Nitrogen after adding inoculum, which effectively purges the system of oxygen and restores immediately the anaerobic environment. However, even assuming that some oxygen was introduced in limited quantities, the presence of a potentially aerobic condition is irrelevant because the point of the re-inoculation was to assess whether the plastic was still biodegradable. In other words, Complaint Counsel contends that microorganisms degrade the ECM additive and then stop when the additive is finished, leaving nothing but non-degradable, recalcitrant plastic. But Complaint Counsel also says that such recalcitrant plastic is non-biodegradable in both aerobic and anaerobic environments. Moreover, the tests relied on negative controls involving untreated

[272] Complaint Counsel also refers to their own "well-documented studies" conducted by laboratories like O.W.S. and North Carolina State University. *See* CC Pretrial Br. at 37. However Complaint Counsel is unclear what they mean by "well-documented." Unlike many of ECM's studies, those studies to which Complaint Counsel referenced were not accompanied by raw data. Most of them included just final reports or results. Complaint Counsel apparently thinks that the data is of more quality simply because the final report can be construed as support for its position.

plastics. So even if the re-inoculation introduced oxygen, if Complaint Counsel was correct, then no further degradation would occur—but there was further degradation, which defeats Complaint Counsel's position. If the uptick in activity seen in the inoculum was caused by the oxygen, then you would see that as well in the negative control too (which did not occur).

Complaint Counsel contends that tests were missing information required to be reported under the methodology. *See* CC Pretrial Br. at 37. The "method," however, is just a description of a scientific methodology. The failure to describe what is a generally accepted and used standard of testing does not render the study invalid. In fact, Complaint Counsel's own experts have followed methodologies that were not even subject to methods, or they created their own. The laboratories here followed sound scientific principles, collected reliable data, and produced enough information sufficient to assess the data.

For several tests where ECM received the raw datasets, Dr. Barlaz completed statistical analyses to determine standard deviations, t-tests, ratios, and other relevant calculations to test the sufficiency of the data. Based on the raw data provided, Dr. Barlaz determined that the tests revealed that methane generation from the test materials was significantly ($p<0.05$) greater than what could be attributed to the inoculum.[273] Moreover, based on calculations of the theoretical carbon yield from ECM's additive (by weight), the tests reveal that significantly more carbon would have come from the test article than what could reasonably have been supplied by the ECM additive. In other words, the plastic substrate had biodegraded.

Complaint Counsel claims that tests were not run for periods of time validated under the methodology. Again, this criticism is hard to comprehend, considering that the methodologies

[273] *See* RX-853, at 14.

are unsuited to measure slowly degrading substances. ECM's experts will explain that there is nothing inherently unscientific or problematic with an extension of the test periods.

Last, Complaint Counsel argues that tests did not report load rates, plastic types, etc. That information, however, is not necessarily required to assess the efficacy of ECM's additive, particularly where, as here, the tests employed negative controls and actually used the ECM product at a 1% load rate. The issue in this case is whether the plastic, combined with ECM's additive, creates a biodegradable plastic. Thus, many of the laboratories were only concerned with that question, not whether the biodegradability was owed specifically to the ECM additive. However, because we know that the plastics are not otherwise biodegradable (or degrade extremely slowly), and because the tests used negative controls as a comparison, the data gleaned from the tests is reliable, material, and scientific valid.

The limited Inconclusive Tests Showing Little to No Biodegradation Are not Evidence that ECM's Product Is Inefficacious:

Complaint Counsel selectively relies on a lesser number of tests said to have shown no biodegradation of plastics with ECM's additive. Those tests are in the minority, and they often support ECM's position that inconclusive tests are likely the result of the laboratory environment. Complaint Counsel's argument also reveals hypocrisy and inconsistency. First, these tests were conducted under largely the same conditions and protocols as the positive tests ECM relies on. It is disingenuous to argue that ECM's favorable tests are worthless because they are flawed or do not simulate the landfill environment, but then embrace the inconclusive tests simply because the outcome better fits Complaint Counsel's theory of the case.

Second, those tests that reported *zero* or negative biodegradation totals are highly suspect. For context, Complaint Counsel has argued that favorable results in ECM testing are owed to

something called the "priming effect." As used by Complaint Counsel, the "priming effect" allegedly occurs when the inoculum gears up to digest the ECM additive, which, as Complaint Counsel concedes, is composed of biodegradable material. We address the flaws in the priming effect theory below. The crucial point, however, is that the ECM additive is biodegradable. Any legitimate test should show a statistically higher rate of biodegradation in the test sample to account for the degradable nature of the ECM additive. If the test shows *zero* degradation, then questions immediately arise as to (1) the manufacturing quality of the test sample; (2) the inclusion of the additive in the test article uniformly (as ECM requires); or (3) the viability of the laboratory environment. For instance, on that latter point, several of the inconclusive tests Complaint Counsel rely upon showed that the positive control (cellulose) stopped degrading prematurely and plateaued. Cellulose is indisputably biodegradable, so the plateau is a true indication that the test was inadequate.[274] Such is true of the Michel test, for example. Closed systems have inherent limitations that might skew data. While those variables may not be to blame in every instance of inconclusive test data, evidence of improper testing conditions should be ascribed the proper weight.[275]

The Priming Effect is Mythical:

Complaint Counsel's experts have tried to diminish ECM's positive test data by arguing that any reported biodegradation is owed to a supposed "priming effect." They argue, also, that

[274] ECM notes the irony that, in these tests (e.g., the Michel & Gomez study, CCX-905), the cellulose would not be considered "biodegradable" under Complaint Counsel's one-year definition, because it plateaued and never reached complete degradation within one year. Cellulose is, of course, one of the most biodegradable substances on earth, which is why laboratories use it as a positive control.

[275] For example, a fish tank is also a closed ecological system. Imagine a fish tank that was never cleaned or cared for. Over a short period of time, that closed system would develop conditions that rendered certain processes or life unable to continue. Those similar limiting factors might not be expected in the ocean.

the small amounts of biodegradation reported in ECM's studies are insignificant and should be disregarded. Although unclear from Complaint Counsel's presentation, their experts appear to argue that the degradation reported in ECM's favorable tests is a result of the inoculum increasing metabolic activity when exposed to the ECM additive. Dr. Barlaz has testified that the concept of "priming effect" has not been seen in anaerobic systems and is invalid in relation to tests on the ECM product.

The major flaw in that theory is that it depends on the idea that biodegradation recorded is solely attributed to the additive, or catalyzed by the additive. ECM's test data frequently show amounts of degradation far in excess of the amount of additive present in the test plastic. Thus, if the theory is that the inoculum is triggered by the ECM additive, then Complaint Counsel cannot explain why the amounts of degradation would continue beyond the amount fairly attributed to the additive (e.g., 1% degradation). Moreover, Complaint Counsel's theory presupposes that all of the ECM additive is available to the biota at the start of the test, which is also untrue. The ECM additive is uniformly mixed throughout the plastic and, so, only a small percentage of the additive is immediately available for consumption at the outset. The biota may opportunistically find the additive or a defect in the plastic at or near the surface but must then consume the plastic substrate to reach new additive, a food source, which does occur and results in the biodegradation recorded.

Finally, Complaint Counsel's dismissal of ECM tests that reported single digit biodegradation is erroneous. Tests must be compared to negative controls, or untreated plastics without the ECM additive. For instance, a 2011 test of ECM's additive in a Low Density Polyethylene plastic bag revealed 5.94% biodegradation in 30 days. *See* RX-838. The product contained 1.5% of the ECM additive. When compared to the cellulose positive control the rates

seem low. *Id.* (the cellulose had degraded to more than 86% in the same time period). However, in that same 30-day period, and under so-called "optimal" conditions, the negative control had degraded just 0.09%. *Id.* Therefore, 5.94% biodegradation in a short term lab test is powerful validation for a product that is not otherwise biodegradable. In fact, in this test, the laboratory extended the duration to one calendar year, and recorded total degradation of about 17%. *Id.* The rate of biodegradation slowed, but continued consistently well beyond the amount that could fairly be attributable to biodegradable nature of ECM's additive.

9. The Qualified Claims Actually Made Versus the Claims Charged

Complaint Counsel bases this case on ECM's marketing claims taken out of context, or discontinued long ago. Complaint Counsel also fails to acknowledge the substantial differences between this case and many other FTC adjudications. The bulk of ECM's promotional and marketing information is exchanged through detailed business transactions between sophisticated corporations, to wit, plastics manufacturers, and ECM.[276] Those manufacturers seek only to market a "biodegradable" plastic. They have many choices in the market. ECM's advertising budget is less than $12,000 per year, which is mainly devoted to website maintenance.[277] The web site is of no utility to consumers because the additive is a pellet unusable to consumers; interest, if at all, from an individual not within a plastics company, is thus academic. Over the past decade, ECM's qualifications have changed to accommodate an evolution of scientific understanding concerning how its additive technology works in landfill environments. In the first instance, ECM offered its "9 month to 5 year" degradable claim not as a performance claim,

[276] RX-875, at 258:17–20 (the "vast majority" of ECM's customer "are very large and sophisticated companies").

[277] CCX-820, at 25:7–27:18; *Id.* at 382:12–13 ("[t]here would have been extensive conversations like with all customers").

but as a means to distinguish its technology from competing technologies claiming to satisfy the short-term compostability standards.[278] Later, the FTC revised its Green Guides to prohibit unqualified biodegradable claims without suitable qualifications.[279] ECM has *always* qualified its marketed claims[280] and explained to customers that the time frame for biodegradation is entirely dependent on environmental factors.[281] ECM updated its website to include the following explanation:

> 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. Under specific composting conditions with additional accelerants sprayed on them, some customers have reported biodegradation in as little as a couple of months. Under the more usual, commercial composting conditions using high heat processes, a time frame of around some period greater than a year is a reasonable expectation.[282]

That type of marketing is consistent with ECM's position in communications with all customers.[283]

Troubled with the concept that the FTC would require a specific rate of biodegradation (a near impossible task given the environmental variances), ECM has used disclaimer language intended to satisfy the FTC's unattainable standards. The evidence suggests that ECM customers are, in fact, only concerned with marketing a "biodegradable" claim and, so, they considered

[278] RX-875, at 274:8–15 (the 9 month to 5 year claim is intended "to distinguish [ECM] from shorter biodegradable alternatives—in other words, the composters").

[279] RX-173.

[280] RX-875, at 277:18–19 (ECM "always qualified the claims").

[281] *See, e.g.*, RX-135.

[282] RX-681, at 61.

[283] *See Id.* ("It is not a 'poof, it's gone' system but simply makes the plastic product biodegrade as if it were a stick or a branch off a tree rather than 'sticking around' for hundreds of years").

ECM's statements concerning the "rate" of biodegradation only to the extent those claims were apparently mandated by the Federal Trade Commission.[284]

Following the revisions to the Green Guides, ECM dispatched a truthful and non-misleading email to all of its customers explaining the FTC's requirements concerning biodegradable claims.[285] This e-mail, in response to the Green Guide revisions, explained:

> If you have evidence that your products with our additives will fully biodegrade in one year or less in the environment where it will be customarily disposed you may still make an unqualified claim of "biodegradable" for those products. But for most of our customers' plastic products with our additives whose customary disposal is in a landfill, they will not be able to use that unqualified claim.[286]

ECM continued by discussing the benefits of its product: "Municipal Solid Waste that biodegrades **slowly but surely over periods from a few years to tens of years** provides the (sic) [landfill gases] that is captured, processed and sold to the public renewable energy or even new chemical source. This is the end-of-life scenario that has made plastic products **with our additives** so ever-increasingly popular." [287]

Sophisticated ECM customers have understood that each product is unique, and biodegradation testing is likely required to assess how their specific product performs. For instance, in response to ECM's gratuitous 2012 customer email, one ECM customer invited ECM to "review the data that was collected by Eden on our products and make a recommendation as to what sort of qualifying statement we [they would] have to make."[288]

---

[284] *See* RX-87 at 193 (J. Blood deposition).
[285] *See, e.g.*, RX-35–RX-77.
[286] *See id.*
[287] *Id.* (emphasis added).
[288] *See* RX-72.

The evidence reveals that ECM has truthfully and accurately informed customers that the rate of degradation in the environment is highly variable and uncertain, and dependent on many factors.

10. The ECM Customer: A Sophisticated Corporation, not an End-Use Consumer

ECM customers are sophisticated manufacturers often several layers removed from end-consumers.[289] Moreover, Complaint Counsel has not identified precisely who the "end-consumer" might be here. ECM sells its additive to plastics manufacturers.[290] Most (if not all) of ECM's customers extensively test the ECM product before determining whether to incorporate ECM's technology in their plastics.[291] Those manufacturers generally sell to sub-manufacturers or distributors as bulk plastic products.[292] The mid-level distributors market and sell items like plastic bags or packaging cushions to corporations (e.g., grocery stores or common carriers).[293] For the majority of products in ECM's supply chain, therefore, a so-called "end consumer" never actually purchases an ECM plastic. They *receive* the ECM plastic either in the mail (for packaging products) or at the grocery store (for plastic grocery bags). Moreover, the ECM plastics is received by the consumer *after* a sale in commerce. Thus, there is no evidence at all in in this case that, for the bulk of the products ECM manufactures, a consumer ever makes a purchasing decision based on a single ECM claim or a single claim made by an ECM customer.

---

[289] *See, e.g.*, RX-178, at 34 (page labeled as "BPI 004025").

[290] RX-875, at 217:16–17 (ECM's "customer[s] [are] plastic product manufacturers").

[291] *See, e.g.*, CCX-802, at 92:9 (A. Leiti deposition transcript, noting that Dispoz-o conducted its own tests).

[292] *See, e.g.*, RX-178, at 34 (page labeled as "BPI 004025").

[293] *See, e.g.*, CCX-811, at 9:24–10:5 (A. Hong deposition transcript, explaining that Island Plastic Bags manufactures and sell plastic bags and plastic cutlery).

ECM's direct customers are ordinarily far larger than and equipped with more knowledge of plastics and degradation of their own plastics than ECM possesses.[294] ECM's customers, unlike ECM, are plastics manufacturing companies ordinarily with scientific officers and layers of corporate review. As plastics manufacturers, those companies are keenly aware of plastics chemistry. Moreover, the evidence suggests that most ECM competitors actively review ECM's competition, and even test competing products to determine if ECM is the best fit from a performance and biodegradation perspective.[295] Most of the test data gathered in this case comes from ECM's customers directly.

Given that ECM has fully disclosed the nature of its products, there is transparency in ECM's advertising and a distinct lack of deception in the market. First, ECM's customers purchased products hoping to achieve a "biodegradable" plastic. They did that without regard to the rates of biodegradation. Complaint Counsel argued in its Pretrial Brief that "[c]ustomers buy the ECM additive because they want biodegradable plastic—and they want to be able to advertise their plastic as biodegradable."[296] In fact, with the exception of several isolated instances, among what Complaint Counsel calls "millions" of customer contacts, claims concerning the *rate* of biodegradation have rarely appeared in the end-consumer market. Almost invariably, the end-customer is provided with a naked "biodegradable" claim, which is the only claim ECM has in its certificate of biodegradability.[297]

Second, ECM has routinely provided its scientific testing in full to corporations and customers. That information has included clearly favorable data, but also tests that Complaint

[294] RX-875, at 258:23–25 (ECM's customer "have all the resources, ten times, hundred times the resources that [ECM] may have").
[295] *See, e.g.* RX-159.
[296] *See* CC Pretrial Br. at 14
[297] *See, e.g.*, RX-17.

Counsel has used to suggest that ECM's product is inefficacious. ECM's willingness to share information in its negotiations with customers is evidence that ECM has in good faith attempted to explain the level of science supporting its product. It also reveals that ECM's customers have had the information necessary to evaluate ECM's claims and determine, just as ECM has, whether those claims are adequately supported. Unlike traditional retail sales where end-customers are often presented with little more than the product and a claim, in this case ECM's sales have been preceded (and followed) by substantial interaction with corporate customers. Those interactions commonly involve discourse concerning the type and format for product claims. However, significantly, many of the claims conveyed in the stream of commerce are not ECM's claims. Those claims are constructed by ECM's customers based on information generated and reviewed by same and based on their finished plastic products, not ECM's additive alone.[298]

ECM's customers were aware of the FTC's requirements in the Green Guides, and they tailored their advertising content according to those policies.[299] One of ECM's leading customers testified that they adapted advertising claims to fit their perception of the Green Guides:

> Q: How did FP come to the decision to transition its claims from the ones we discussed earlier to the claim that ECM plastic will biodegrade in landfills in one to five years or more?
>
> A: There were several contributing factors. One of them was the FTC's green guides. And even though we didn't agree necessarily with the one-year time frame that the FTC decided was appropriate, we decided that we

[298] *See, e.g.*, CCX-48 (EcoSmart Plastic advertising that its products will "compost" in "9 months–7 years").

[299] *See, e.g.*, RX-871, at 193:10–21 (J. Blood deposition, explaining that one of the reasons FP International changed its claim was "The FTC's green guides [] even though [FP] didn't agree necessarily with the one-year time frame that the FTC decided was appropriate").

> would incorporate that to make it clear to our customers that it was not under a year. And so that was an element where we decided to go ahead and make that component of the claim, instead of the nine months.[300]

ECM customers have thus demonstrated that they understand the nature of ECM's advertising claims, and have been guided substantially in their decision to choose certain marketing language by the FTC's positions, which have skewed the claims in the market and national environmental policy.

11. The Survey Evidence Reveals Absence of Agreement on Meaning of Biodegradation Among Industry and End-Use Consumers

a. Well-Designed Telephone Survey Confirms that Not Even a Significant Minority of End-Use Consumers or ECM Customers Has a Single Definition of Biodegradation or Expectation as to the Rate at Which ECM Plastics Will Biodegrade

i. Dr. Stewart's Telephone Survey Was Well-Designed, Incorporated Open-Ended Clear Questions, And Incorporated Established Principles Of Survey Research.

A survey expert whose work has repeatedly been credited by ALJs of the FTC and the Commission itself, Dr. David Stewart designed a telephone survey in order to determine how consumers who actually purchase products made from or packaged in plastic perceive the meaning of the term "biodegradability."[301] Phone surveys are the most common form of survey used in marketing research. The primary reason Dr. Stewart opted for a telephone interview is because he was interested in "meaning." In order to understand what people believe a term means, a competent researcher needs a real life interviewer appropriately trained to conduct research. This survey also assessed the message that consumers take away from claims made by

[300] *Id.*
[301] RX-856, at 15 (Dr. Stewart's expert report).

ECM.[302] Dr. Stewart's survey used well-designed, non-leading, and clear open-ended questions that allowed real 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 appear (or single questions are posed without human interface) in a survey.[303]

Dr. Stewart designed and conducted this survey in accordance with well-established principles of survey research offered in litigation, as articulated in the Manual for Complex Litigation.[304] 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.[305] From this sample, respondents were disqualified if they stated that they did not have a general understanding of what the term "biodegradable" means.[306] 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.[307] Both of these companies are highly respected, well-known providers of samples for use in survey research.[308]

Dr. Stewart determined that a sample size of 400 respondents was the sufficient amount 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.[309] The respondents' answers were accurately reported by well-trained interviewers who had been specifically trained in

[302] *Id.*
[303] *Id.*
[304] *Id.* at 16.
[305] *Id.* at 17.
[306] *Id.*
[307] *Id.*
[308] *Id.*
[309] *Id.* at 18.

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. Importantly, the interviewers were also randomly monitored by supervisors to assure that the interviews were conducted in the prescribed manner. These interviewers and their supervisors were blind in the sense that they did not know for whom the survey was being conducted.[310]

Once the respondents were appropriately selected from a list of telephone numbers based on an algorithm employed by the CATI system, interviewers clarified to potential respondents that the call was for research purposes and not telemarketing.[311] The interviewers and respondents then went through both parts of the survey. The first part contained a screener, and the second part was the main questionnaire.[312] The screener was used to determine whether the respondent met the screening criteria and was a member of the relevant population. These questions ensured that the respondent was over 18, asked their age and gender to ensure that appropriate diversity was represented within the sample, ensured that they or anyone in their household did not work for a manufacturer of plastic products or a waste disposal organization,[313] ensured that they had purchased a product in a plastic container or containing plastic within the past month, and ensured they had a general understanding of the term biodegradable.[314]

[310] RX-843, at 276:9–14.
[311] RX-856, at 19.
[312] *Id.*
[313] 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, at 19–20.
[314] *Id.* at 19–20.

Respondents who qualified in the survey sample based on the screen questions were asked a series of substantive questions in the main questionnaire. 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.[315]

The questions in the main questionnaire were clear and not leading.[316] The first few questions asked respondents about their perceptions of biodegradability generally.[317] For example, Q4 asked, "If something is biodegradable, how long do you it would take for it to decompose or decay?"[318] 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. *Id.*

The survey was conducted by qualified persons following proper procedures. Dr. Stewart himself personally designed the survey. *Id.* A well-known survey research agency, California Survey Research Services (CSRS), coordinated interviewing and data tabulation. *Id.* The field work for the survey was $37,500. *Id.* at 23. In addition, the survey was pre-tested by conducting a small pilot project, which confirmed that no changes to the survey design were necessary. *Id.* The coding of the responses to the open-ended questions was carried out by experienced staff members at CSRS who were blinded, and the codebook used was suggested by CSRS and approved by Dr. Stewart. The coders themselves were blind to both the sponsor and the purpose of the survey. *Id.* All verbatim responses were coded independently by two coders and any disagreements were resolved in discussion. *Id.*

---

[315] *Id.* at 20.
[316] *Id.*at 22.
[317] *Id.* at 21.
[318] *Id.*

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

Dr. Stewart's survey first concluded that while consumers do have a conceptual understanding of what biodegradability is, that understand is not material to any sizable minority of consumers.[319] The survey also concluded that 68% of the respondents recognize differences in the rate of decomposition depending on the type of material or the context.[320] 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.[321] Furthermore, 98% of respondents believe that different types of products take different amounts of time to biodegrade, decompose, or decay.[322] Such differences, according to the respondents, include the type or size of the material, the context, or the environment.[323] Therefore, Dr. Stewart concluded that consumers 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.[324]

As for the questions which incorporated ECM's claims made to industrial purchasers, 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.[325] This lack of understanding, confusion, and skepticism make it highly unlikely that these claims would be material to an end use consumer, even if these claims were directed right at the end use

[319] *Id.* at 24.
[320] *Id.* at 25.
[321] *Id.* at 25–26.
[322] *Id.* at 26.
[323] *Id.*
[324] *Id.*
[325] *Id.*

consumer.[326] 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.[327]

Dr. Stewart also conducted a limited Manufacturers Pilot Survey in an attempt to ascertain whether more knowledgeable purchasers have a more common understanding of biodegradability.[328] To this end, ECM provided Dr. Stewart a list of representatives from customer organizations who were involved in the purchase of materials for the manufacturer of plastics.[329] *See John Crane Prod. Solutions, Inc. v. R2R and D, LLC*, 861 F. Supp. 2d 792, 799 (N.D. Tex. 2012) (citations omitted)(explaining that even if "a company's engineers may be distinct from the employees who purchased the [product] . . . [s]uch business transactions are at least as complex as transactions that other courts have classified as sophisticated").

Representatives from 10 of ECM's customers participated in this survey, which was also carried out by CSRS.[330] Like the consumer survey, this survey concluded that even among these more knowledgeable and sophisticated customers there is substantial variation in opinions about how quickly a biodegradable product should take to decompose.[331] Dr. Stewart stopped conducting this survey after receiving only ten responses because Dr. Stewart believed he would run out of time before he could complete the survey and obtain any meaningful results.[332]

---

[326] *Id.*
[327] *Id.* at 27.
[328] RX-856, at 27–28.
[329] *Id.* at 27.
[330] *Id.* at 26–27.
[331] *Id.* at 27.
[332] RX-843, at 230:5–25; Dr. Stewart held this belief primarily Because it took CSRS 20 hours of calling to obtain the information reported in the study from the 10 survey respondents. RX-843, at 218:11–13.

b. Complaint Counsel's Survey Expert Relies on Incompetent Google Survey to Correct Incompetent Synovate and APCO Surveys

In support of the One Year Rule, FTC relies on a survey conducted by APCO Insight, and dismisses a survey conducted by Synovate.[333] According to FTC, this APCO survey concluded that 60% of respondents expect that an item marketed as degradable will fully decompose in one year or less. The problem with the FTC's reliance on the APCO study is that the APCO study is rife with flaws, as acknowledged by both Dr. Stewart and Complaint Counsel's own expert, Dr. Shane Frederick. For example, the APCO study uses closed ended question, which are unhelpful and misleading when there are many possible answers among respondents.[334] Importantly, when beginning consumer perception work in a new area, open-ended questions are an essential tool.[335]

One of the critical limitations of closed-ended questions is particularly important where, as here, the FTC is trying to pigeon hole a consumers' perception of the term "biodegradability" into one uniform definition. Closed-ended questions inherently suggest greater homogeneity within a sample of respondents than may actually exist because closed ended questions exist in a universe with only four or five possible response.[336] Self-evident is the fact that even where there is maximum disagreement, 20% of respondents will nevertheless appear to agree on an answer to a question in which there are only five possible answers. This fact makes the FTC's "significant minority" argument problematic when they conclude that a significant minority of consumers believe something, when that alleged uniform belief is based upon a question that, if

[333] RX-195, at 121.
[334] RX-856, at 7; RX-858, at 165:5–7 (Frederick deposition).
[335] RX-856, at 7.
[336] RX-856, at 7.

people answered wholly randomly, would be expected to yield 20% agreement on any one of the possible five answers.

Dr. Stewart explains that an example of misleading homogeneity is found in the APCO survey question regarding how long it should take for something to decompose if it is labeled biodegradable.[337] In that question, four of the six response options are a year or less, so it is not surprising that 60% of respondents chose an option of one year or less. Indeed, random responses spread among the six options would result in 66% of the responses falling in one of the four categories related to one year or less. This is what one must expect when people are asked a question about which they have little knowledge—a near perfect proportion of random responses.

Well aware of the problems in the APCO survey, Complaint Counsel engaged the services of Dr. Shane Frederick in an attempt to support the One Year Rule. Dr. Frederick, who, like Dr. Stewart, unapologetically contests that open-ended questions are superior to closed-ended questions, performed his own "survey" using largely open-ended questions. The problem for Complaint Counsel, however, is that unlike Dr. Stewart's survey, Dr. Frederick's survey does not meet generally accepted standards for survey research.[338] In fact, Dr. Frederick readily admits that he is not familiar with the standards that are used to determine the qualifications of survey experts in federal court or in proceedings before the FTC.[339] Similarly, 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.[340] In fact, Dr. Frederick does not "know what other

[337] *Id.*
[338] RX-856, at 10.
[339] RX-858, at 19:8–16.
[340] RX-858, at 186:7–12.

people have written" regarding what constitutes acceptable survey principles that define a valid survey.[341]

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 to attempt to support the One Year Rule.[342] 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, and that its use has never been approved of or validated in any peer reviewed literature.[343] The Google Consumer Survey is simply unproven at best. If Dr. Frederick wanted to do an Internet survey there are well constructed consumer panels available, that, for example, Dr. Stewart often uses. FTC seemingly presents Frederick's survey as the modern and more valid alternative to telephone surveys. That is not a validated position or one supported in the peer reviewed literature. The reasons for the lack of support for Google Consumer Surveys are obvious. For one, there is no way to ascertain the degree to which the sample of respondents used in such surveys is representative of any identifiable population. The sample itself is unknown and unknowable. That is because there is no verification of respondents with Google Survey; rather information on respondents is merely inferred by Google from information associated with or that resides on a computer.[344] Google survey uses no screener questions to assure that the respondent is of relevant age or even understands the English language.[345]

[341] *Id.* at 186:25–187:4.

[342] Cost was also another factor. RX-858, at 123:3–5. 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, at 8:11–15.

[343] *Id.* at 189:5–10.

[344] RX-856, at 10–11.

[345] *Id.* at 11.

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 are at best a distraction and barrier to respondents whose objective is to access information, not complete a survey.[346] This type of questioning creates a disinterest bias; a concept alien to Dr. Frederick at the time of his deposition.[347] That explains why so many respondents answered Dr. Frederick's survey[348] with nonsensical answers.

In addition, Dr. Frederick, and his students who acted as his coders, failed to accurately report the data received from the Google Survey. For example, Dr. Frederick coded non-sensical answers such as "1 second" as "less than one year." That may be because, unlike Dr. Stewart's survey which utilized well-trained coders, Dr. Frederick believes that coders only need to be able to read and follow directions.[349] Moreover, Dr. Frederick's survey failed to code accurate and relevant responses such as "don't know."[350] Even more bothersome, however, is the fact that Dr. Frederick's supervising coder, Andrew Meyer, was aware that their research was going to be used by Complaint Counsel against ECM.[351] In short, the coders were not blinded, so bias infected the study *ab initio*.

In addition, as Dr. Stewart makes clear, even if Dr. Frederick's survey was valid—it is not—its results, like Dr. Stewart's survey results, suggest that there is considerable diversity among respondents in terms of their claimed knowledge about biodegradable products and their

---

[346] *Id.*

[347] RX-858, at 72:10–16.

[348] It is also a stretch to even call the Google surveys "Dr. Frederick's survey" as many of the survey questions were not created by Dr. Frederick, but by his student Andrew Meyer, and even Google consumer survey itself.

[349] RX-858, at 168:18–169:6; Based on some of the initial coding disclosed to ECM by Dr. Frederick, it appears that Dr. Frederick's coders were even unable to read and follow directions correctly. RX-856, at 13.

[350] RX-856, at 12.

[351] RX-858, at 176:5–24.

views about the time it takes various materials to biodegrade.[352] Therefore, because Dr. Frederick's "survey" is plainly not valid as judged against generally accepted survey principles, and because its results do not show any uniform understanding amongst consumers about how long a biodegrade product takes to decompose, the concerns that both he and Dr. Stewart have regarding the APCO study cannot be alleviated by the existence of Dr. Frederick's "survey."[353]

B. Procedural Background and Irregularities

ECM, a small corporation with only six employees, has endured significant and atypical burdens in this case. Consistent with Complaint Counsel's desire to "close ECM's doors" (along with the remainder of the additive industry), the discovery in this case has been wrought with unfair surprises and unmanageable burdens.

1. Discovery Calculated to Impose Maximum Burdens

In November 2013, Complaint Counsel began issuing discovery request that would have had ECM disclose nearly every business record in its possession, including highly sensitive information concerning its proprietary formula. Complaint Counsel's discovery requests were without limitation, seeking all files related to the "ECM's additive," which would have included every single document in ECM's possession, custody, or control. ECM opposed those over-burdensome requests, and attempted to negotiate reasonable limits in discovery. Eventually, owing to the cost of excessive motions practice, ECM agreed to meet Complaint Counsel's remarkable request for ECM's email files containing more than 100,000 pages of email communications with customers. Complaint Counsel moved this court for relief when ECM could not keep pace with the volume of information required to be disclosed under Complaint

[352] RX-856, at 13–14.
[353] RX-858, at 151:16–152:6.

Counsel's discovery requests, arguing that an extension of the parties' discovery agreements by two weeks was unacceptable.

Complaint Counsel eventually received more than 115,000 responsive emails. Having refused to limit their discovery requests or tailor them to seek relevant information, ECM was forced to locate and review all of those files within several weeks. Because of delays inherent to Complaint Counsel's blunderbuss discovery approach, Complaint Counsel moved the Commission to extend the hearing date by 90 days. ECM opposed that motion, and explained that an extension of the hearing would result in a substantial economic hardship. The Commission extended the hearing by 45 days.

Meanwhile, on their end, Complaint Counsel had failed to produce documents responsive to ECM's requests of considerable import in this action. This Court Sanctioned Complaint Counsel for failing to disclose information to ECM that was later used against ECM's principles in depositions through a planned "gotcha" moment. That document was Dr. Michel's analysis of several competing biodegradable technologies. Although Dr. Michel has been an FTC consulting witness since 2012, Complaint Counsel feigned any knowledge of his work. But when ECM attempted to subpoena Dr. Michel for information concerning his study, Complaint Counsel intervened and instructed him not to timely respond to ECM's non-party subpoena.

Complaint Counsel has also escalated costs in an effort to limit ECM's defense. The cost of Complaint Counsel's erratic, meandering and ill-timed discovery practice has been considerable.[354] Complaint Counsel has performed nineteen (19) fact depositions of testing laboratories and ECM customers all over the country, in Hawaii, California, New York, Ohio,

[354] The transcripts alone in this case have cost over $1,000 per document. Other costs include attorney fees, costs of travel and lodging, and document costs. Perhaps the biggest cost, however, is the loss of time and resources during the final pretrial phase of this case when multiple deadlines arrive each week.

and the District of Columbia, to name a few.[355] Those depositions included the following persons and entities:

- Northeast Labs (May 9, 2014)
- BER Plastics (May 8, 2014)
- D&W Fine Pack, LLC (May 5, 2014)
- Down to Earth (Apr. 29, 2014)
- Eagle File Extruders (May 14, 2014)
- Eden Labs (May 19, 2014)
- Elsevier (May 30, 2014)
- Flexible Plastics (May 15, 2014)
- Island Plastic Bags (April 28, 2014)
- Kappus Plastic Company (May 6, 2014)
- Quest Plastics (May 7, 2014)
- 3M Corporation (May 16, 2014)
- ANS Plastic (May 5, 2014)
- FP International (May 1, 2014)
- Timothy Barber, Ph.D. (May 7, 2014)
- Thomas Nealis, ECM Employee (March 5, 2014)
- Alan Poje, former ECM Employee (March 6, 2014)
- Robert Sinclair, ECM President (February 18, 2014)
- Kenneth Sullivan, ECM Officer (February 20, 2014)

Each of the foregoing depositions were noticed and conducted by Complaint Counsel. Also, the parties have taken eight 8 additional expert depositions. The burdens and costs associated with the many fact depositions forced ECM to appear unrepresented, or have counsel appear telephonically at a distinct disadvantage. Knowing that ECM could not appear at the depositions themselves, or entered limited telephone appearances, Complaint Counsel intends to rely exclusively on the transcripts from those very depositions in lieu of live witness testimony, thus ensuring that ECM lacks an opportunity to perform any meaningful examination of witnesses Complaint Counsel will rely upon at trial.

[355] By contrast, to eliminate extraordinary burden, the Federal Rules of Civil Procedure generally prohibit a party from seeking more than ten (10) depositions. *See* Fed. R. Civ. Pro 30(a)(2)(A)(i). Parties seeking to expand that number must justify the *necessity* of each deposition. *See, e.g., Archer Daniels Midland Co. v. Aon Risk Services, Inc. of Minnesota*, 187 F.R.D. 578, 586 (D.Minn. 1999) (collecting cases).

Complaint Counsel's many fact depositions also created an *in terrorem* effect in the market as ECM's customers fear FTC enforcement. On October 29, 2013 the FTC announced six enforcement actions against companies, including ECM, for violating the revised Green Guides and the One Year Rule.[356] The FTC has already secured two consent orders from ECM former customers. Parties participating in depositions have been forced to disclose their business records to the FTC. Those customers now reasonably fear FTC action, which renders them more willing to please the FTC and offer testimony unfavorable to ECM.

Knowing that ECM was unable to provide live counsel during depositions of ECM customers, Complaint Counsel lead witnesses excessively, effectively testifying for those witnesses through counsel's questions.[357] For example, Complaint Counsel asked questions concerning ultimate legal issues in controversy:

- "[I]s [company] an entity sophisticated in the biodegradability of plastic?"[358]
- "Did [company] rely on ECM's testing as proof that its additive worked?"[359]

Complaint Counsel now seeks to present that testimony in written form only, where ECM cannot cross-examine the witnesses, and the ALJ cannot make assessments of witness credibility. Complaint Counsel essentially asks the Court to take these witnesses' statements at face value. Complaint Counsel has suggested that its decision to present the partisan transcripts is out of a desire to avoid inconveniencing non-parties. In a case that has already amassed considerable costs for both parties, that would be the first instance to date that Complaint Counsel restrained themselves in any capacity. Indeed, after having performed literally dozens of fact depositions,

[356] http://www.ftc.gov/news-events/press-releases/2013/10/ftc-cracks-down-misleading-unsubstantiated-environmental

[357] *See, e.g.*, CCX-811, at 33–38.

[358] *See* CCX-811, at 33. Similar questions, which are vague and leading, are replete throughout the customer transcripts.

[359] *See* CCX-800, at 24.

the sudden desire to avoid live testimony is transparently designed to prejudice ECM to the greatest extent possible for failing to afford the massive discovery bill imposed by Complaint Counsel during fact discovery.[360]

2. Dr. McCarthy's Moving Target

Dr. McCarthy submitted an expert report in this case on June 4, 2014. As part of his essential opinion, he maintained that "microorganisms do not produce enzymes that metabolize plastic." *See* McCarthy Rep. at 29-30. He gave short shrift to the notion that naturally produced enzymes could metabolize conventional plastics, which, he argued, "remain resistant to microbial attack." *See id.* Because Dr. McCarthy's biased expert opinion hinges on the presupposition that additive technologies are ineffective, Dr. McCarthy unequivocally explained that conventional plastics are not biodegradable. He explained that the "evidence indicates that the minimal biodegradation observed in the tests ECM relies on is the result of the 'priming effect,' *i.e.*, biodegradation of the additive (which contains organic compounds highly susceptible to biodegradation) and the organic materials of the test medium (the bacteria used for testing) rather than the plastic." *Id.* at 36. Dr. McCarthy offered those opinions without the benefit of a single supportive citation; indeed, he generally avoided citations of any kind throughout his report.

ECM's experts countered with a large body of peer-reviewed literature showing that conventional plastics can be, and are in fact, enzymatically degraded. ECM's experts explained that the phenomena observed in ECM's tests were supported by the peer reviewed literature. *See* Sahu Rep. at 29-40 (collecting references demonstrating the enzymatic biodegradability of

[360] ECM notes that many of the deponents were located in New York, Connecticut, Ohio, which are within several hours of Washington, D.C. by flight. Two such depositions (CCX-801 & CCX-801) were actually conducted at the FTC's offices at **600 Pennsylvania Avenue**.

certain plastics); Burnette Rep. at 17-22. In response, Dr. McCarthy presented a rebuttal report on June 30, 2014, wherein he first presented a new opinion concerning what he terms amorphous versus crystalline structures of plastic polymers. *See* McCarthy Rebuttal at 10. Therein he does a *volte face*, shifting course and explaining that plastics may be biodegradable after all, however, only amorphous sections of the plastic biodegrade: "[t]he material to biodegrade is the amorphous region of a polymer, which biodegrades at a fast rate. If the material were 50% crystalline, then the biodegradation rate would be very rapid until it reached 50% biodegradation." *Id.* Of course, Dr. McCarthy never posits or explains the percentage he actually thinks is "amorphous" in ECM's plastic products tested; nor does he rely on scientific literature to establish a foundation for his opinion. He likewise fails to explain what percentage of crystalline polymers are present in his patented "blends" of polyesters that are manufactured using blending techniques like ECM's technology. *See* McCarthy '199 Patent. In reality, his new theory is a *post hoc* construct that permits him to testify that ECM cannot claim complete biodegradability unless they present a test showing one hundred percent elimination of the plastic. That theory is scientifically erroneous and in direct contradiction to his own peer reviewed articles and his own '199 patent, wherein he identifies biodegradation without proof of one hundred percent elimination of the plastic.

Complaint Counsel also presented the rebuttal testimony of Dr. Frederick Michel. Complaint Counsel had negotiated stipulations concerning Dr. Michel's testimony as a fact witness, and held him out as a potential fact witness. On June 30, 2014, Complaint Counsel suddenly added without prior notice Dr. Michel as a rebuttal expert witness, all within 24 hours of the expert discovery cutoff.

In response, ECM moved to add a surrebuttal witness, Dr. Steven Grossman. Dr. Grossman is a colleague of Dr. McCarthy, Complaint Counsel's scientific expert. He would have provided crucial testimony concerning false or misleading statements in Dr. McCarthy's expert report and testimony. He would have explained that Dr. McCarthy is inherently biased because of his personal connections, and that, more importantly, his scientific opinion is fatally flawed and inconsistent with Dr. McCarthy's prior work. He would have addressed the new argument first presented in Dr. McCarthy's rebuttal report. As a polymer scientist and patent attorney, Dr. Grossman would have testified that Dr. McCarthy's scientific opinion concerning plastics manufactured with ECM's plastic is erroneous. On July 23, 2014, ECM was denied an opportunity to present that critical information. As part of that decision, the Court noted that ECM had not submitted a request for leave within five (5) days of the deadline set by Rule 3.31A. The Court ignored the fact that Complaint Counsel had failed to timely complete their service and production of the actual rebuttal report by June 30th. The Court improperly calculated the return date of ECM's motion by failing to include the July 4th holiday. However, the Court held ECM strictly to the five day deadline, and compounded the substantial prejudice ECM suffers now by prohibiting ECM to call a key witness. Although the purpose of the Part III adjudication is to present a recommended decision based on "the whole record relevant to the issues decided," this record will now decidedly be truncated to omit material information in ECM's defense. *See* 16 C.F.R. § 3.51(a).

III. ARGUMENT

A. The FTC Fails to Satisfy Their Burden of Proof that the Biodegradation Claim Is Literally False

"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." 16 C.F.R. § 3.43(a); *see also* 5 U.S.C. § 556(d) (explaining that "the proponent of a rule or order has the burden of proof"). Regardless of the level of substantiation required, the FTC will bear the burden of proving advertising claims are false or misleading. *See Sterline Drug, Inc. v. F.T.C.*, 741 F.2d 1146, 1150 (9th Cir. 1984); *Porter & Dietsch, Inc. v. F.T.C.*, 605 F.2d 294, 305 (7th Cir. 1979); *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"). 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 of its case 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").

There are two ways the FTC can prove that an advertisement is likely to mislead consumers. "One [way] is to carry the burden of proving that the express or implied message conveyed by the ad is false. The other [way] is to show that the advertiser lacked a reasonable basis for asserting that the message was true." *F.T.C. v. Bronson Partners, LLC*, 564 F. Supp. 2d 119, 135 (D. Conn. 2008) (citing *In the Matter of Thompson Med. Co., Inc.*, 104 F.T.C. 648 (1984)).

The FTC must also establish materiality. "A 'material' misrepresentation is one that involves information that is important to consumers, and that is therefore likely to affect a consumer's choice of or conduct regarding a product." *F.T.C. v. Bronson Partners, LLC*, 564 F. Supp. 2d 119, 135 (D. Conn. 2008) (quoting *In Re Kraft, Inc.*, 114 F.T.C. 40 (1991)); *see also FTC Policy Statement on Deception*, Federal Trade Commission (1983)).

B. ECM's Discussions and Claims Concerning the Rate of Biodegradation Were Not Material

"To establish that an act or practice is deceptive under Section 5, the FTC must demonstrate that '(1) there was a representation; (2) the representation was likely to mislead customers acting reasonably under the circumstances; and (3) the representation was material.'" *F.T.C. v. NHS Syss., Inc.*, 936 F. Supp. 2d 520, 531 (E.D. Pa. 2013) (citations omitted). 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").

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." *Id.* The first situation applies "[w]here the seller knew, or should have known, that an ordinary consumer would need 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." *Cliffdale*, 103 F.T.C. at 49. The third situation can apply when the advertisement concerns information that "pertains to the central characteristics of the product or service." *Clifford*, 103 F.T.C. at 49.

"A representation is material if likely relied upon by a reasonable prospective purchaser." *F.T.C. v. Wash Data Ress.*, 856 F. Supp. 2d 1247, 1272 (M.D. Fla. 2010). Importantly, "[r]ather than an isolated word, phrase, or sentence, the representations net impression controls." *Id.* at 1272 (citations omitted). "What is important in determining whether a statement is misleading is the over-all impression it tends to create on the public." *Country Tweeds, Inc. v. F.T.C.*, 326 F.2d 144, 148 (2d Cir. 1964) (citing *Murray Space Shoe Corp. v. F.T.C.*, 304 F.2d 270 (2d Cir. 1956)).

A respondent can counter a 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*:

> 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. "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).

ECM's claims concerning the *rate* of biodegradation are not material because (1) ECM and its customers made those claims ostensibly for regulatory compliance purposes, and not as performance claims; (2) the claims largely were not passed along in commerce, and rarely to end users and, in any event, the survey evidence proves no materiality to the claims; (3) ECM's customers were only concerned with having the ability to market a "biodegradable" product; and (4) the specific rate of degradation is not scientifically or environmentally material.

First, ECM identified a specific rate of biodegradation not as a comparative or performance claim in the market. The testimony revealed that ECM began using its "5 year" claim as a means to differentiate its technology from *more rapidly degrading* compostable products.[361] Thus, if anything, ECM's use of the claim should have hurt its business. ECM wanted to be clear that its products would not perform like the compostable products, which were required to fully degrade in aerobic conditions in under 6 months (180 days). ECM chose a period of 9 months to 5 years at a time when the scientific understanding of landfills and biodegradation was evolving, thinking that the 5 year qualification would provide an adequate buffer. In 2012, when the FTC revised the Green Guides, ECM changed its claim language, added different qualifications, and informed customers that biodegradation claims should only be made if the specific customer had evidence sufficient to meet the Green Guide policies which, as

[361] *See* CCX-818, at 77-79, 85–88.

we have explained, were flawed.[362] The fact that ECM customers were only concerned with meeting the FTC requirements, but not with making a rapidly degrading product, proves that the only endpoint of interest to ECM's market was the "biodegradable" claim stamped on product packaging.

ECM customers therefore considered ECM's "rate" claims only with respect to regulatory compliance. The record shows that businesses would purchase the ECM product even if it degraded many years later, provided the customer could still use the term "biodegradable" in commerce. Customers provided different responses when asked why they would include rate claims on packaging (of those few that actually did). But the reason for printing the "rate" of biodegradation was only to tell consumers that the products would "biodegrade" generally, not to make a specific performance claim. The primary motivation was still to comply with the stilted Green Guides. For instance, Island Plastic Bags explained:

> Q: How many of the ECM plastic products that have the word "biodegradable" also contain language visible to the end consumers stating that the products would biodegrade in nine months to five years?
>
> A: So we've changed our printing when the new Green Guides came out. So they have something like [the image in IPB-8]. So a lot of our generic bags have a – have a thing that says it will break down anywhere from nine months to five years.
>
> …
>
> A: Yeah, yeah. So we put a description of how the biodegradable bags break down because we want them to know what they break down into and how long it takes. So our printing on a lot of the printed bags that you're talking about have this, because we want people to know, you know, how it breaks down and what it breaks down into.
>
> Q: And why do you want people to know that?

[362] *See* RX-195, at 121 n.409 (noting that studies supporting the "one year" rule "may be faulted for lacking control groups and presenting the timeframe questions with closed-ended, rather than open-ended, answers, but they nevertheless are the only studies in the record").

> A: 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 breaks 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.[363]

Thus, the central motivating factor behind use of a biodegradable "rate" on IPB packaging was to differentiate the product from recycled material, and that the product is actually "biodegradable." There is literally no evidence that the actual rate of biodegradation was ever important to ECM customers or their subsequent customers.[364] Another customer, BER Plastics, was asked about whether the ECM additive "would make plastic biodegrade in nine months to five years" and, tellingly, the witness replied: "Never really thought about the – how long it would take to biodegrade."[365] Still more customers testified that rate of biodegradation was only significant to the extent it showed the products were "biodegradable" generally or "green."[366] Similarly, another customer, Quest Plastics, was generally uninterested in the "rate" of degradation. When asked about ECM's five year claim, the witness testified:

> Q: So your assumption, when you read the claims on the website, was that if it stated it was fully biodegradable in nine months to five years, that it would fully biodegrade in nine months to five years?

[363] CCX-811, at 54–55 (IPB deposition).

[364] Island Plastic Bag's customer, Down to Earth, testified through its agent only that the rate claims was a significant part of the reason for purchasing ECM's product, but also noted that "price" was a major factor. *See* CCX-803, at 39–40. Complaint Counsel never asked "why" the rate claim was important to the customer.

[365] *See* CCX-800, at 32:24–25. Another customer, Kappus Plastics, was asked whether they considered the "nine months to five years" claim a "rigid standard," and the witness responded apathetically: "Again, we're not really saying anything. We took information that was provided and moved it from one piece of paper to the other. It says it on the piece of paper." *See* CCX-812, at 50 (Kappus deposition, noting that the rate claim was not perceived by the witness as "rigid").

[366] *See* CCX-882, at 12–13.

> A: I didn't know, and I left it up to my customer to decide whether this is what he wanted to use.[367]

According to the witness, his customer was simply "looking for an additive to make the biodegradable – the gold tee biodegradable."[368]

That lack of interest in the rate claim is reflected in the advertising before the Court. Throughout the hundreds of thousands of pages of advertising and correspondence in Complaint Counsel's possession, the so-called "rate" claim for biodegradation has appeared relatively infrequently, and rarely when compared to the more general "biodegradation" claim. If the rate claim was material and important to purchasing decisions, then ECM's customers would pass that information along in commerce routinely, but they didn't. Indeed, doing so, was the rare exception. The claim was unimportant.[369] In fact, Complaint Counsel has recorded pictures and samples of many ECM goods that actually reached the end consumer, and, with very few exceptions, every product includes only a generalized "biodegradable" claim without reference to, or reliance on, the rate of biodegradation.[370] Complaint Counsel acknowledges that, more

---

[367] *See* CCX-817, at 32 (Quest deposition).

[368] *Id.* at 33:1-4.

[369] The majority of advertisements that do not mention of focus on rates of biodegradation: Exhs. RX-00, RX-02, RX-03, RX-14, RX-15 (focus on cost), RX-16 (logo only), RX-17 (general biodegradable claim), RX-22, RX-26, RX-28, RX-29, RX-30, RX-315 (cost the focus), CCX-30 (general focus on biodegradability); CCX-31 (same), CCX-32, CCX-36 (labeling instructions to downstream customers without including rate); CCX-39, CCX-43, CCX-46, CCX-47, CCX-49, CCX-50, CCX-52, CCX-59 (focus on shelf life), CCX-60 (same), CCX-63, CCX-64, CCX-65 (focus on "green), CCX-66, CCX-79.

[370] All of the following exhibits represent photos of the actual consumer goods that are eventually labeled "biodegradable," but without reference or focus on the rate of biodegradation: CCX-97, CCX-98, CCX-99, CCX-100, CCX-10, CCX-103, CCX-104, CCX-107, CCX-109, CCX-110, CCX-111, CCX-112, CCX-113, CCX-114, CCX-115, CCX-116, CCX-117, CCX-118, CCX-119, CCX-120, CCX-121, CCX-122, CCX-123, CCX-124, CCX-125, CCX-126, CCX-127, CCX-128, CCX-129, CCX-130 (specifically says time "will vary due to local conditions"), CCX-131, CCX-132, CCX-133, CCX-135, CCX-136, CCX-138, CCX-139, CCX-140, CCX-142, CCX-143, CCX-144, CCX-145, CCX-146, CCX-147, CCX-148, CCX-149, CCX-150, CCX-151.

than selling just an additive, ECM really "sells the purported ability to make a 'biodegradable' advertising claim." *See* CC Pretrial Br. at 15. Exactly. Which is why ECM's customers are unconcerned about the rate of biodegradation, except to the extent it would influence their ability to make a "biodegradable" claim broadly. That means ECM's customers did not base their purchasing decisions on ECM's rate claims, but on the fact of biodegradation without regard to the precise rate. Customers were primarily concerned just with the "biodegradable" claims, and testified as such.[371] More importantly, however, the customers were interested in a "biodegradable" product that could work with their manufacturing systems, because the plastic had to serve a function foremost. Small companies particularly devoted substantial test resources to that inquiry, as Island Plastic Bags explained:

> Q: And in the email David Hong is stating that he was experimenting with ECM plastic for over a year.
>
> A: So what we—what I believe he was doing was—and we didn't, like, test it or anything, what we were doing is seeing if we could actually run it through our machines, because it could—you know, ECM at that time said it's biodegradable, but it doesn't do us any good if we can't use it through our machines. So what we were doing was putting the additive inside of our plastics to see if it could actually run through our extruders and then be cut and sealed as plastic bags.[372]

The lack of materiality is also confirmed through expert testimony. Dr. Stewart will testify that, based on several surveys of high methodological value, end users or consumers have no uniform understanding of "how long" it should take an item to decompose in landfills.[373] There is also an understanding among many consumers that the length of time required for an item to degrade is dependent on a variety of factors including the material from which it is made

[371] *See, e.g.*, CCX-811 (Island Plastic Bags deposition).
[372] *Id.* at 44.
[373] RX-856, at 15 (Stewart Rep.).

and the conditions under which degrading occurs.[374] Consumers also expressed considerable skepticism over rate claims that were presented to them in relation to plastic products.[375] Thus, according to Dr. Stewart, the results of his survey evidence make clear that consumers are highly unlikely to be misled by ECM's product claims because "(1) there is no shared understanding among consumers of the length of time required for an item to decompose and (2) the lack of understanding and skepticism of the claims make it highly unlikely that the claims will have a material influence on the consumer."[376] Put simply, if the consumer has no reasonable or accurate knowledge of how long a plastic *should* take to biodegrade in the environment, then they cannot adequately or reasonably interpret whether ECM's rate claim is good or bad.[377] The rate claim is very different from other familiar rate claims, for example miles-per-gallon (MPG), where consumers can correlate a rate with performance. Furthermore, there is no evidence in this case that ECM's competitors have offered rate claims that differ from ECM's, such that a consumer would be drawn to an ECM product through comparative advertising.

In deposition testimony, Dr. Barlaz described his attempts to calculate rates of degradation in landfill environments.[378] He testified that his work was experimental, and that the precision of his rates fluctuated sometime by a factor of two.[379] Complaint Counsel questioned whether the fluctuations would be considered significant, and Dr. Barlaz explained that it was not all that important:

> Q: Is a factor of two large or small? I really don't know.

---

[374] *Id.*
[375] *Id.*
[376] *Id.*
[377] Assuming, *arguendo*, that consumers really do expect a product to biodegrade within one year, then ECM's 5-year claim would have a negative influence on purchasing decisions. Those customers would think the product did not meet their expectations.
[378] *See* RX-864, at 106–108 (Barlaz deposition).
[379] *Id.* at 107:23–25.

A: Sure. My opinion would be that, for a landfill, a factor of two is fine, because the retention time is infinite. If I were in an engineered tank where I were putting stuff in, I needed it to biodegrade at a certain rate so I knew when to take it out so I could put more in, then the rate affects the size of the tank, and the size of the tank affects the cost of the tank. Then people would be interested in something better than a factor of two.

Q: So can you just give me an example—I work better with hard numbers, so just an example of how—and I understand that you don't recall the specific results were, but the difference between inocula coming from an anaerobic digester versus inocula coming from a sewage treatment plant, if those were two different types of inocula that you were looking at?

A: They were.

Q: Did you understand my question?

A: Let me—you are asking me, as I understand it, for an example of the difference in laboratory scale decay rate as calculated for a substrate, for example, copy paper, on two different inocula, for example, anaerobic sewage sludge and leachate?

Q: Yes.

…

Q: Okay. You said your testimony was a factor of two is fine for landfills because their retention time is infinite. So meaning it could take longer than whatever the average is?

A: What I mean is that, if I estimate a half-life of three years and the actual half-life is six years or one-and-a-half years, it's inconsequential for the performance of the landfill. Either way, there is biodegradation occurring because the material is in the landfill, in essence, forever. That's what I mean by infinite retention time. Whether we are off a few years in either direction, it doesn't really seem to matter.[380]

The salient point made by Dr. Barlaz is that there is no material benefit to a product that biodegrades in a landfill in, say, 15 years versus another that degrades in 30 years. The more rapidly degrading product offers no material environmental benefit. Landfill operators do not

[380] *Id.* at 109–110.

change waste management techniques based on the biodegradable plastic and, in turn, plastics manufacturers are not motivated by a need to somehow ensure any particular rate of biodegradation. What, then, is the materiality of a rate claim other than to satisfy the FTC's flawed and unscientific standards in 16 C.F.R. § 260.8?

Finally, ECM no longer uses the rate claims at the center of Complaint Counsel's case. Although ECM had once used a "9 month to 5 years" rate claim, they discontinued use of that claim in 2012 when the FTC revised its Green Guides.[381]

C. The Legal Significance Of ECM's Sophisticated Consumers

1. ECM Did Not Engage In Any Typical Advertising Or Promotion By Virtue Of The Fact That ECM Limited All Of Its Advertising To Sophisticated Customers

ECM spends less than $12,000 per year on advertising, almost all of which is devoted to website maintenance.[382] ECM's claims are shared with specific, sophisticated customers during the negotiations process leading to a corporate sales agreement between the two entities. Mr. Sinclair credibly testified that the bulk of his discussions with customers is through verbal communication, or targeted emails.[383] Brochures and flyers are not shared with the public at large, but dispatched to specific corporations who have expressed interest in ECM's technology.

"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

[381] Complaint Counsel has identified several limited instances where ECM distributed the 9 month–5 year rate claim accidentally by releasing outdated brochures or flyers to customers, but those have not been shown to have been intentional and were against the direction of Robert Sinclair, ECM's President.

[382] As is clear from the record, there is literally no evidence in this case that ECM's claims were designed to target end-consumers, that end-consumers have visited ECM's website, or that ECM receives considerable traffic to its website. To the contrary, the website is clearly designed for manufacturers of plastics.

[383] *See, e.g.*, CCX-818, at 45, 52–53, 202.

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).[384] 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*, 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).

With respect to claims made directly to, and between, ECM's customers that were *not* passed through the chain of commerce to a substantial audience, Complaint Counsel's theory of liability creates substantial policy concerns over the reach and scope of the FTC's jurisdiction. At the very least, prudential considerations should govern whether the FTC is empowered to regulate the terms of transactions or sales agreements between two sophisticated corporate entities and the weight given any such communications which were not "disseminated sufficiently."

2. To Determine Whether A Claim Is False Or Misleading, The Trier Of Fact Must View the Claim from the Perspective of the Target Audience

"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) ("When

[384] Black's law definition defines an "advertisement" as "notice given in a manner designed to attract public attention."

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." *Id.* "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); *see also DeSena v. Beekley Corp.*, 729 F. Supp. 2d 375, 393 (D. Me. 2010) ("A target audience's special knowledge of a class of products is highly relevant to any claim that it was misled by an advertisement for such a product").

Similarly, under state anti-competition laws, "[w]hen the practice [at issue] is targeted to a sophisticated purchaser, the question of whether it is misleading to the public will be viewed from the vantage point of members of the targeted group, not others to whom it is not primarily directed." *Ariz. Cartridge Remanufacturers Assoc., Inc. v. Lexmark Int'l, Inc.*, 290 F. Supp. 2d 1034, 1041 (N.D. Cal. 2003).

3. ECM's Target Audience and Actual Customers Were Sophisticated Purchasers Who Studied the Product and Engaged in Sophisticated Transactions

In business transactions, when the selling company provides the purchasing company with specifications or data, such transactions are "classified as sophisticated." *John Crane Prod.*

Solutions, Inc. v. R2R and D, LLC, 861 F. Supp. 2d 792, 799 (N.D. Tex. 2012). In addition, there is less likelihood of confusion when the parties to a business transaction "have a close working relationship." *Id.* at 801. 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.

Courts have classified transactions and purchasers as sophisticated in a number of contexts. *See, e.g., Checkpoint Sys., Inc. v. Check Point Software Tech.,* 269 F.3d 270, 285 (3d Cir.2001) (holding that purchasers of retail store security equipment and computer security software were sophisticated); *Rust Env't & Infrastructure, Inc. v. Teunissen,* 131 F.3d 1210, 1217 (7th Cir. 1997) (holding that purchasers of services from engineering consulting firms were sophisticated); *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."); *Armstrong Cork Co. v. World Carpets, Inc.,* 597 F.2d 496, 504 n. 10 (5th Cir. 1979) ("[A] person buying a 'big ticket' item such as carpeting would ordinarily be expected to be a more careful buyer than the impulse purchaser or the purchaser of a relatively inexpensive item.").

ECM's customers are those plastic manufacturers that introduce the ECM additive into the plastic polymer during the manufacturing process. ECM does not sell to end-users, or even

mid-level distributors. While ECM shares marketing information and literature with customers, it does not advertise or promote products directly to end-users. ECM's additive is of no value to end-use consumers in and of itself or to companies that cannot introduce the Masterbatch pellet into the plastic as an additive during manufacturing. Recognizing that, Complaint Counsel struggles to define ECM's purchasers misleadingly as "mom and pop"-type businesses (CC Br. at 18) that also apparently manufacture bulk plastic polymers. As an example, Complaint Counsel cites to Island Plastic Bags, a "very sophisticated" customer in the plastic bag realm. *See* CC Br. at 18. At sixteen (16) employees, Island Plastic Bags is more than twice the size of ECM, which has just six employees. That was the best example of a "mom and pop" manufacturer Complaint Counsel could marshal. In fact, Island Plastic Bags ("IPB") has a sophisticated operation whereby they manufacture high- and low-density polyethylene products through various manufacturing plants in Hawaii and China.[385] IPB learned of ECM's product not through website materials or marketing, but through conversations with ECM representatives at a trade show.[386] Although Island Plastic Bag testified (through extensive leading questions), that it did not have experience to review scientific literature concerning biodegradability, they could not deny that they were *provided* that literature over the course of detailed discussions with ECM.[387] And, certainly, they were able, should they desired it, to test the ECM product for their intended uses.

[385] *See* CCX-811, at 10–11 (IPB deposition).

[386] *Id.*, at 11–12.

[387] As in many of the customer depositions that occurred throughout the country, this one in Hawaii, ECM was unable to have counsel appear and instead offered a corporate representative. While that decision was ultimately ECM's, the lack of ECM's counsel should not excuse Complaint Counsel's objectionable examination throughout. Through leading questions, counsel essentially testified for the witness. *See, e.g.*, CCX-811, at 35–39. While "form of question" objections are now waived, the flawed examinations limit the credibility of witness testimony. Unsurprisingly, Complaint Counsel intends to move in the deposition transcripts

4. The Bases for Purchase Among Sophisticated Customers Differ from Those of End Use Consumers

In order to succeed in a fraud action, a challenger must establish that he or she reasonably relied on the alleged material representation. *Terra Sec. Asa Konkursbo v. Citigroup, Inc.*, 740 F. Supp. 441, 448 (S.D.N.Y. 2010). "In assessing the reasonableness of a plaintiff's alleged reliance, [courts] consider the entire context of the transaction, including factors such as its complexity and magnitude, the sophistication of the parties, and the content of any agreements between them." *Emergent Capital Inv. Mgmt., LLC v. Stonepath Grp., Inc.*, 343 F.3d 189, 195 (2d Cir. 2003). For example, [s]ophisticated investors must investigate the information available to them with the care and prudence expected from people with full access to information." *Terra*, 740 F. Supp. 2d at 448 (citing *Hirsch v. du Pont*, 553 F.2d 750, 763 (2d Cir. 1977)); *see also Banque Franco–Hellenique de Commerce Int'l., et Maritime, S.A. v. Christophides*, 106 F.3d 22, 27 (2d Cir. 1997) (finding that analysis of reasonable reliance in fraud cases "has taken account of the degree to which the truth was accessible to the defrauded person"). The rationale being that the informed or sophisticated entity has the wherewithal to determine whether claims are supported and, so, the need to protect those sophisticated "consumers" is lessened.

Other courts outside of the Second Circuit have similar requirements to determine whether sophisticated purchasers reasonably relied on misrepresentations. *See, e,g,, Metavante Corp. v. Emigrant Sav. Bank*, 619 F.3d 748, 767–68 (7th Cir. 2010) (finding that the plaintiff's alleged reliance was unreasonable where "two sophisticated businesses negotiated an arms-length transaction of a period of several months"); *Tom Hughes Marine, Inc. v. Am. Honda*

---

instead of now calling live witnesses subject to cross-examination. Complaint Counsel has represented that it will call **no fact witnesses** for live testimony. ECM objects to that strategy.

Motor Co., Inc., 219 F.3d 321, 324 (4th Cir. 2000) (affirming decision that reasoned that the plaintiff was "a sophisticated businessman … and he [was] unable to establish that he had a right to rely on [the defendant's] representation or that he justifiably relied upon it"); *Gilchrist Timber Co. v. ITT Rayonier, Inc.*, 95 F.3d 1033, 1035 (11th Cir. 1996) (collecting cases supporting the proposition that a fraud claim is not actionable where "the parties are equally sophisticated, and have an equal opportunity to discover a defect"); *Cheney Bros., Inc. v Batesville Casket Co., Inc.*, 47 F.3d 111, 114 (4th Cir. 1995) (citation omitted) (holding that "there is no right to rely, as required to establish fraud, where there is no confidential or fiduciary relationship, and there is an arm's length transaction between mature, educated people"); *Kline v. First Western Gov't Sec., Inc.*, 24 F.3d 480, 497–98 (3d Cir. 1994) (holding that the "investor could not justifiably rely on representations" where the transaction "was on the cutting edge of strategic planning"); *Roberts v. United N. Mex. bank at Roswell*, 14 F.3d 1076, 1080 at n. 4 (5th Cir. 1994) (internal quotations and citations omitted) ("If an investor is sufficiently sophisticated and experienced, that may be evidence that he did not rely on the seller's representations but on his own expertise."); *Davidson v. Wilson*, 973 F.2d 1391, 1399 (8th Cir. 1992) (noting that the "sophisticated investors should have been on notice not to rely upon those representations"); *Skeen v. C.I.R.*, 864 F.2d 93, 95 (9th Cir. 1989) (explaining that where the plaintiffs "are all sophisticated businessmen," the court "simply do[es] not believe that they would enter into profit-motivated transactions with an unknown party and rely solely on the representations of such part with respect to the most crucial aspect affecting the viability of the proposed venture").

5. No ECM Purchaser Was Misled

In the trademark context, courts find that there is a reduced likelihood that a sophisticated party, as opposed to an unsophisticated party, will be influenced by a similar mark in an advertisement. *See, e.g.*, *Mead Data Dent., Inc. v. Toyota Motor Sales, U.S.A., Inc.*, 875 F.2d 1026, 1031–32 (2d Cir. 1989). "The degree of consumer care and sophistication can be proven by survey evidence, expert testimony, or inference." *Marketquest Grp., Inc. v. BIC Corp.*, 2011 WL 5360899, at *12 (S.D. Cal. Nov. 7, 2011) (citation omitted) (finding that the buyers were likely to be sophisticated because they were institutional buyers placing bulk orders and because the marketing materials "appear to be aimed at institutional purchasers").

The issue in *Mead* was whether the use of the term "Lexus" used by Toyota Motors would dilute the profitability of the term "Lexis" as used by Mead. *Mead*, 875 F.2d at 1027. The Second Circuit explicitly made clear that "the recognized sophistication of attorneys, the principal users of [Lexis], has *substantial relevance*." *Id.* at 1031 (emphasis added). Given the fact that Lexis' users were principally sophisticated attorneys, the court concluded that there would not "be any significant amount of blurring between the LEXIS and LEXUS marks." *Id.* at 1032.

Numerous additional courts likewise find that purchasers are less likely to be confused when they are sophisticated, technical, experienced, retailers, or otherwise involved in the industry or have any relevant knowledge. *See, e.g.*, *In re Synthroid Mktg. Litig.*, 264 F.3d 712, 717 (7th Cir. 2001) (noting that "[u]nlike members of the consumers class, [third party payors] are sophisticated purchasers"); *Interstellar Starship Servs., Ltd. v. Epix Inc.*, 184 F.3d 1107, 1110 (9th Cir. 1999) (citation omitted) (holding that confusion is less likely where the "customers are sophisticated industry and university researchers" and where the "goods cost in the range of

several thousand to tens of thousands of dollars"); *Homeowners Grp., Inc. v. Home Mktg. Specialists, Inc.*, 931 F.2d 1100, 1111 (6th Cir. 1991) ("A sophisticated purchaser exercises a high degree of care and is less likely to be confused as to a product's origin."); *Pride Family Brands, Inc. v. Carl's Patio, Inc.*, -- F. Supp. 2d --, 2014 WL 186902, at *7 (S.D. Fla. Jan. 30, 2014) (noting that "[as] industry participants, retailers are a sophisticated customer base"); *Acxiom Corp. v. Axiom, Inc.*, 27 F. Supp. 2d 478, 497 (D. Del. 1998) (citations omitted) (explaining that "courts recognize that generally" when a seller "sell[s] relatively expensive products and services to sophisticated and knowledgeable purchasers that typically involve relatively long sales cycles . . . these factors indicate that great care, effort, and attention go into the purchase decision making which lessens likelihood of confusion."); *Giorgio Beverly Hills, Inc. v. Revlon Consumer Prods. Corp.*, 869 F. Supp. 176, 185 (S.D.N.Y. 1994) (citation omitted) (explaining that "[t]he more sophisticated the ordinary purchaser of a product is, the less likely it is that the use of similar marks or trade dress will lead to confusion" and holding that "women tend to be sophisticated purchasers of perfume"); *Marketquest*, 2011 WL5360899, at *11 (noting that "experienced industry distributors or agents [] are likely to be sophisticated consumers and investigate any potential confusion"); *In re Trans Union Corp. Privacy Litig.*, 2009 WL 4799954, at *11 (N.D. Ill. Dec. 9, 2009) (noting that insurance companies are sophisticated purchasers of legal services).

Like in the trademark context, parties are held to different levels of duty of disclosure when conducting business with sophisticated purchasers as opposed to the general public. For example, a purchaser is under no duty to disclose the financial conditions of its business when "the parties are represented by sophisticated businessmen, who are active and experienced in the area, and are dealing at arm's length without any fiduciary or confidential relationships or

expectations." *Nationwide Book Indus., LLC v. A & S Booksellers, Inc.*, 950 F. Supp. 2d 264, 267 (D. Mass. 2013) (citations and quotations omitted). Similarly, in the securities context, securities issuers must disclose significantly more information when making public offering as opposed to selling the securities only to sophisticated qualified institutional buyers. *Gustafson v. Alloyd Co.*, 513 U.S. 561, 569 (1995) (citing 15 U.S.C. §§ 77b(11), 77d, 77e) ("By and large, only public offerings by an issuer of a security, or by controlling shareholders of an issuer, require the preparation and filing of registration statements."). This is because the sophisticated purchaser, capable of fending for itself and determining the benefits and costs of entering a business transaction, are held liable for their own decisions. *See, e.g.*, *Miller v. Berman*, 289 F. Supp. 2d 1327, 1334 (M.D. Fla. 2003) ("Surely, as a sophisticated boat and sail maker, Mr. Miller relied on his own expertise in deciding to enter into a contract for the purchase of a highly customized catamaran boat with Cougar Marine.").

6. The Sophisticated Purchaser Defense Is Applicable In This Context

A manufacturer's duty to warn of dangers in the products liability context is "precluded in situations where the purchaser has particular knowledge of or experience with the inherent dangers in the use of a product or in instances when the purchaser has designed and requested a product for a particular application." *Byrd v. Hunt Tool Shipyards*, 650 F.2d 44, 47 at n. 1 (5th Cir. 1981); *see also O'Neal v. Celanese Corp.*, 10 F.3d 249, 252 (4th Cir. 1993) ("The [sophisticated purchaser] defense is available not only when the supplier actually warned the intermediary, but also when the supplier shows that it was reasonable to believe that a warning was unnecessary because the intermediary was already well aware of the danger."); *Goodbar v. Whitehead Bros.*, 591 F. Supp. 552, 561 (W.D. Va. 1984) ("Stated another way, when the supplier has reason to believe that the purchaser of the product will recognize the dangers

associated with the product, no warnings are mandated."). This rule of law is known as the "sophisticated purchaser defense" which is "based upon the principles set forth in the Restatement (Second) of Torts." *Akin v. Ashland Chem. Co.*, 156 F.3d 1030, 1037 (10th Cir. 1998). "This exception absolves suppliers of the duty to warn purchasers who are already aware or should be aware of the potential dangers." *Id.* (citing *O'Neal*, 10 F.3d 249, 251–52 (4th Cir. 1993); *Davis v. Avondale Indus.*, 975 F.2d 169, 171 (5th Cir. 1992)).

Indeed, in certain situations, a "manufacturer [may] reasonably [] rely on an intermediary purchaser to warn ultimate users of dangers associated with the use of a product." *Baker v. Monsanto Co.*, 962 F.Supp. 1143, 1151 (S.D. Ind. 1997). Such a situation arises where "it would be impossible for a manufacturer to access all ultimate users of a product because it had no control over the site of usage." *Id.*

In this context, the sophisticated purchase defense precludes a finding that ECM's representations to its own customers were misleading. Assuming *arguendo* that harm results from making misleading advertisements to consumers regarding a biodegradable claim, that harm is the harm of being misled by the advertisement. ECM's marketing audience—wholly sophisticated distributors and manufacturers of plastics well aware of the Green Guides—were aware of this harm when they made what the FTC considers, based on the Green Guides, misleading biodegradable claims to end use consumers. Therefore, because ECM's customers were aware of the dangers associated with selling a "biodegradable" product, ECM had no duty to the end use consumer. *Akin* 156 F.3d at 1037; *O'Neal*, 10 F.3d at 251–52; *Davis* 975 F.2d at 171. This is particularly true where, as here, ECM's customer audience was free and able to test the products themselves, consult with legal counsel, and where ECM does not have access to all

ultimate users of a product and has no control over the usage of its product. *Baker*, 962 F. Supp. at 1151.

D. ECM Has Not Made an Implied "One-Year" Claim through Its "Biodegradable" Claims

"[I]n determining what claims are conveyed by a challenged advertisement, the Commission relies on two sources of information: its own viewing of the ad and extrinsic evidence. Its practice is to view the ad first and, if it is unable on its own to determine with confidence what claims are conveyed in a challenged ad, to turn to extrinsic evidence." *Kraft, Inc. v. F.T.C.*, 970 F.2d 311, 318 (7th Cir. 1992). Therefore, the FTC does not need to point to extrinsic evidence to determine whether an advertisement makes an objectionable claim. Generally the FTC's own view of the advertisement is sufficient. *Id*. at 319.

For the vast majority of products that eventually reach end-consumers, consumers only receive a "biodegradable" claim, often in the form of a logo or a small stamp on the packaging. Using the unscientific positions expressed in the Green Guides, Complaint Counsel has inferred that *every* unqualified "biodegradable" claim is actually a claim that a product will fully degrade within one year in the environment.

1. The Legal Significance of Survey Evidence in this Case

The FTC must use extrinsic evidence to determine what the claim implies when the claim is not "reasonably clear from the face of the advertisement." *F.T.C. v. Bronson Partners, LLC*, 564 F. Supp. 2d 119, 126 (D. Conn. 2008). Similarly, *Thompson* held that the FTC must have extrinsic evidence when "the advertisement itself does not allow [the FTC] to conclude with confidence" that the advertisement at issue contains a particular implied claim. 104 F.T.C. 648, at ¶ 7. And as another case clarified, "if the language or graphic is susceptible to more than one reasonable interpretation . . . the district court must look to consumer data to determine what the

person to whom the advertisement is addressed finds to be the message." *Time Warner Cable, Inc. v. DIRECTV, Inc.*, 497 F.3d 144, 158 (2d Cir. 2007).

When an implied claim is at issue, "[t]he Commission will carefully consider any extrinsic evidence that is introduced, taking into account the quality and reliability of the evidence." *In re Stouffer Foods Corp.*, 118 F.T.C. 746, 799 (Sept. 26, 1994). Such extrinsic evidence includes "reliable results from methodologically sound consumer surveys." *Id.* In weighing survey evidence, the Commission "looks to whether such evidence is reasonably reliable and probative. Flaws in the methodology may affect the weight that is given to the results of the copy test or other consumer survey." *Id.* (citation omitted).

2. Extrinsic Evidence of High Methodological Quality Reveals that ECM Did Not Make Implied Claims Concerning the Rate or Extent of Biodegradation

In order to determine what consumers believe "biodegradable" means, ECM retained the services of expert Dr. David Stewart, an expert whose surveys have often been credited by the ALJs at the agency and by the Commission itself. Dr. Stewart conducted a well-designed telephone interview based on established principles of survey research that are consistent with the guidelines for survey research offered in litigation as articulated in the Manual for Complex Litigation. *See* RX-856, at 16. In sum, Dr. Stewart concluded that consumers have no uniform understanding of the term "biodegradable." In fact, consumers were asked "if something is degradable, how long do you think it would take for it to decompose or decay?" In response, 39% of survey respondents stated that it depends on the material or type of product. *Id.* at 25. No other single response was offered by more than **6%** of the respondents. *Id.* As proven by Dr. Stewart's survey, no significant percentage of consumers think that products labeled "biodegradable" will degrade within one year or any specific time frame. No significant

percentage of consumers have enough understanding or knowledge of the concept of biodegradation to properly assess those claims. Therefore, when ECM claims that their plastic products are "biodegradable," ECM is not implying to consumers that the products will biodegrade within one year or any other specific time frame.

3. Complaint Counsel's Straw Man: An Arbitrary and Capricious Definition of Biodegradation

A court should "hold unlawful and set aside agency action, findings, and conclusions found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706. An agency's decision is arbitrary and capricious when the agency "entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Motor Vehicle Manufacturers Association v. State Farm Mutual Automobile Insurance Co.*, 463 U.S. 29 (1983).

Review of agency action is "not merely perfunctory," the review should be a 'searching and careful' inquiry.'" *Int'l Ladies' Garment Workers' Union v. Donovan*, 722 F.2d 795 (D.C. Cir. 1983); *Specialty Equip. Mkt. Ass'n v. Ruckelshaus*, 720 F.2d 124, 132 (D.C. Cir. 1983) ("when reviewing agency's determinations under "arbitrary and capricious" standard, "we must make a substantial and searching inquiry to ensure that the agency's decisions are the product of reasoned thought and based upon a consideration of relevant factors"); *Dickinson v. Zurko*, 527 U.S. 150, 155 (1999) ("[t]he APA requires meaningful review; and its enactment meant stricter judicial review of agency fact finding than Congress believed some courts had previously conducted").

The One-Year Rule is arbitrary and capricious, lacking in any reasonable factual basis. In applying the rule to the facts of this case, Complaint Counsel attempts to hold industry responsible for a "rule" that has literally no support in reality. The rule is a construct from faulty survey evidence. Complaint Counsel therefore establishes a so-called "definition" of biodegradability for purposes of unqualified claims, but fails to acknowledge that there is literally *no product or substance* of any kind that can meet the definition. A banana peel, for example, cannot be called "biodegradable" under Complaint Counsel's definition.

E. ECM Possesses a Reasonable Basis, and at Least Competent and Reliable Scientific Evidence, that the ECM Additive Causes Plastics to Biodegrade in Landfills

ECM Biofilms has proven that plastics made with its additive technology will biodegrade within a reasonably short period of time under conditions of customary disposal, particularly when compared with conventional, untreated plastic products.

1. The *Pfizer* Factors Demonstrate that Biodegradable Claims Need Not Meet a High Standard of Competent and Reliable Evidence.

The FTC has the burden of showing that a particular claim was made without a reasonable basis. *See FTC v. Braswell*, 2005 WL 4227194 (C.D. Cal. Sept. 27, 2005); *F.T.C. v. Medlab, Inc.*, 615 F. Supp. 2d 1068, 1079 (N.D. Cal. 2009); *FTC v. Pantron I Corp.*, 33 F.3d 1088, 1096 (9th Cir.1994). In order to have a reasonable basis to make the claim at issue, an advertiser must possess "competent and reliable scientific evidence" to substantiate that claim. *Sterling Drug, Inc. v. FTC*, 741 F.2d 1146, 1156–57 (9th Cir.1984). To help determine what constitutes "competent and reliable scientific evidence," the FTC has recognized two types of claims: establishment and non-establishment claims. *See Thompson Med. Co., Inc. v. F.T.C.*, 791 F.2d 189, 194 (D.C. Cir. 1986). Establishment claims contain express or implied

representations about the level of support for a particular claim (i.e., the claim states that a product has been found to be superior by scientific tests). *Id.* For such claims, the advertiser must possess the level of proof claimed in the ad. *Id.*

In contrast, a non-establishment claim is a simple claim of efficacy. *Id.* For such non-establishment claims, "the reasonable basis inquiry has been defined more flexibly." *Id.* This standard is a "flexible standard" that calls for an evaluation of a variety of factors suited to the particular case at hand. *Direct Mktg. Concepts, Inc. v. F.T.C.*, 581 F. Supp. 2d 115, 118 (D. Mass. 2008). Therefore, the Commission's "reasonable basis cases have identified several factors that [the Commission] will weigh in determining the appropriate level of substantiation for objective advertising claims." *In the Matter of Thompson Med. Co., Inc.*, 104 F.T.C. 648, at ¶ 70 (Nov. 23, 1984). The relevant factors are: "(1) the product involved; (2) the type of claim; (3) the benefits of a truthful claim; (4) the ease of developing substantiation for the claim; (5) the consequences of a false claim; and 6) the amount of substantiation experts in the field would agree is reasonable." *Id.* These factors are used to weigh the benefits and costs of developing substantiation for the claim. *In the Matter of POM Wonderful LLC*, 2013 WL 268926, at *30 (F.T.C. Jan. 16, 2013).[388]

The level of proof required to meet the *Pfizer* test in this case is significantly reduced because all of the *Pfizer* factors favor a more relaxed standard.

2. The Nature of the Product Involved

[388] ECM has not made any "establishment" claims to end-consumers. To ECM's sophisticated manufacturing customers, it has disclosed the types of tests shown to have resulted in biodegradation. To the extent ECM's disclosure of its test data and names of test standards is an establishment claim, the claim is truthful and non-misleading. ECM does possess the tests its claims to have, and those tests do show that ECM's technology creates a biodegradable plastic.

Regarding the first factor, the product involved, the Commission has made clear that products like drugs—which improve physical welfare—as opposed to products that do not purport to improve physical welfare, "require[] a relatively high level of substantiation." *Thompson*, 104 F.T.C. 648, at ¶¶ 71–72; *see also POM*, 2013 WL 268926, at *48 (noting that the respondents "made claims regarding serious diseases"); *In the Matter of Removatron Int'l Corp.*, 111 F.T.C. 206, at *14 at n. 20 (Nov. 4, 1988) (noting that a drug or product that directly affects human safety requires more substantiation).

ECM does not market products like drugs, foods, medical devices, or dietary supplements that improve physical welfare. ECM has not made claims concerning serious diseases or health conditions. Moreover, significantly, ECM has never sold product to end-consumers. ECM sells a plastic additive to plastics manufacturers that, when manufactured correctly, will help render the finished plastic biodegradable in a landfill over time.

The intended use of ECM's product is for customers to dispossess themselves of it. Whatever benefit is achievable through ECM's product comes long after the customer or user has discarded the product, and long after the customer can likely remember that they ever once possessed same. ECM's product has no performance benefit or utility to consumers at the time of purchase or use of the product. For this reason, Dr. Mort Barlaz credibly testified that the actual product performance in a landfill environment was almost irrelevant. When discussing rates of degradation, he explained:

> I estimate a half-life of three years and the actual half-life is six years or one-and-a-half years, it's inconsequential for the performance of the landfill. Either way there is biodegradation occurring because the material is in the landfill, in essence, forever. That's what I mean by infinite retention time. Whether we are off a few years in either direction, it doesn't really seem to matter.

See Barlaz Tr. at 109-110. So, too, here, where the question involves the nature of the product, an item advertised only for its benefit after customers trash it should be subject to much less scrutiny than other products that have a chance to hurt or harm consumers during use.

3. The Type Of Claims Made

The second factor is the type of claim being made. One type of claim that requires a high a level of substantiation "is a claim that refers to specific facts or figures, rather than making generalized descriptions of the product's capabilities." *Thompson*, 104 F.T.C. 648, at ¶ 72. Therefore, a generalized claim, such as "biodegradable," would require a lower level of substantiation than a more specific claim.

Largely the only claim that reached the individual or end-consumer level is that ECM plastics are biodegradable. Even those claims presented to sophisticated manufacturing corporations conveyed the simple point that ECM plastics were "biodegradable" within a reasonably short period of time. Those claims are tantamount to general efficacy claims, and be regarded as such under the *Pfizer* analysis.

4. The Benefits Of A Truthful Claim and Ease of Developing Substantiation for the Claims

The third and fourth factors are often considered "in conjunction with each other." *Id.* at ¶ 74. The Commission's "concern in analyzing these factors is to ensure that the level of substantiation [the Commission] require[s] is not likely to prevent consumers from being told potentially valuable information about product characteristics." *Id.*; *see also Removatron*, 111 F.T.C. 206 at n. 20 ("These two factors together seek to ensure that the level of substantiation we require is not likely to deter product development or prevent consumers from being told potentially valuable information about product characteristics."). Consumers can be prevented

from being told potentially valuable information about product characteristics when the cost of developing substantiation for these claims would be high in comparison to the amount of sales the product can earn. *Id.* at ¶¶ 74–75. So, the Commission will not require substantiation that, because of its probative costs, will become non-feasible. *POM*, 2013 WL 268926, at *49.

ECM's product provides an environmentally-friendly alternative to conventional plastics. Unlike companies selling compostable technologies, or more expensive bioplastics, ECM's technology lives within the reality that the bulk of waste is deposited in landfills. While waste reduction and alternative processing techniques are laudable, they are in the minority today. Moreover, because financial considerations are always paramount to ongoing businesses, most companies are unable to undertake the extreme costs associated with emergency technologies like bioplastics. ECM offers a middle ground alternative, permitting companies to improve the environment in the long-term without incurring substantial increases to their cost bases. The ECM additive works, and it reduces the environment lifespan of many conventional plastics by a very substantial margin.

If the technology works, many manufacturers would gain access to a commercially viable solution that might encourage more plastics manufacturers to choose environmentally-friendly upgrades over conventional plastics used today.

Imposition of strict, and unobtainable standards here will chill innovation and prevent consumer access to valuable information concerning products that biodegrade in a progressive manner, over time. A product that biodegrades over a period of decades is not irrelevant in the consumer market simply because it will not degrade within one year. ECM and its customer base have taken steps to evaluate biodegradability through laboratory testing and a fully informed industry has chosen to buy the ECM products cognizant of the test results showing that

it causes biodegradation of plastics and not dependent upon proof of any particular rate of that biodegradation.

Complaint Counsel's experts have failed to even state what type of testing might be sufficient to prove biodegradation to FTC's satisfaction. Dr. McCarthy's statements, however, are revealing. Dr. McCarthy wrote that a "study must last long enough for the sample to reach at least 60% biodegradation" in a D5511 context.[389] According to Dr. McCarthy, companies can also perform ^{14}C radiolabeling tests.[390] Both of those requirements are excessive and impractical, and not even McCarthy uses them in his own original scientific research or patent.

First, because ECM's product slowly degrades when compared to more rapidly degrading items like cellulose, the ECM product would need to perform very long-term testing to reach the 60% value. For instance, in one ECM test of a polyethylene polymer, the test revealed about 50% biodegradation over 900 days of testing.[391] Extensive testing is expensive and, obviously, time consuming and, given the inherent vulnerabilities of inocula of a subset of landfill species, very difficult to maintain. Moreover, each manufacturer might elect to test their specific formulation before marketing an environmentally friendly product. Adopting Dr. McCarhty's position would therefore impose a mandatory delay of many years before environmental claims for products of this type could appear in the market. Note, also, that Dr. McCarthy would require test conditions that mirror the landfill sites (e.g., temperature, moisture content, etc.). McCarthy is actually proposing that a company come as close to an *in situ* landfill study as possible. What if a product results in biodegradation in a landfill in 25 years? When compared with a conventional plastic that takes thousands of years to biodegrade, that 25 year span is a

[389] *See* CCX-891,. at 15–16 (McCarthy Rep.).
[390] *Id.*
[391] RX-836.

substantial benefit but it would not be within the arbitrary and capricious one year limit advocated by Complaint Counsel and ensconced as an effective rule in the Green Guides. However, under McCarthy's strict criteria, he would need testing of at least 15 years duration before those products could hit the market. Most pharmaceutical cancer drugs are tested and approved in half that time.[392]

In the meantime, consumers would be purchasing and using conventional plastics without the additive, having been deprived of essential information about innovative technologies. Some degree of accelerated testing is necessary, therefore, to avoid this obvious issue. That accelerated testing includes protocols like the D5511 test, which ECM customers ran repeated with positive results. The D5511 testing, and similar gas evolution data, provides a reasonable basis for biodegradability claims as the scientific literature in this field reflects, and ECM possesses that requisite level of proof.

Dr. McCarthy also posits that ^{14}C radiolabeling should be required. That level of testing is impractical, excessively costly, and largely unavailable. Dr. McCarthy himself has labeled products "biodegradable" without resort to radiolabeling testing. ECM's experts each agree (and apparently also one of Complaint Counsel's experts, Dr. Tolaymat, based on his testimony in deposition)[393] that radiolabeling tests are not required to prove the type of claims at issue here.

5. The Consequences of a False Claim

[392] *See* 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.

[393] Dr. Tolaymat testified that radiolabeling was not used frequently because it "could be as expensive as doing [testing] in a landfill." *See* Tolaymat Tr. at 246-47.

Under the fifth factor, the consequences of a false claim can be divided into either health or economic consequences. *See Thompson*, 104 F.T.C. 648, at ¶¶75–76 (noting that false claims can be "injurious to health and economically harmful"). In order to be economically harmful, the economic harm suffered by consumers must be "material" and "substantial." *See POM*, 2013 WL 268926, at *50, n. 31 (noting that a one year supply of the POM Juice costs at least $780); *Removatron*, 111 F.T.C. 206 at n. 20 (noting that the device at issue cost approximately $4,000, and required treatments that cost $35 per hour over a period of years).

Here the consequences of a false claim are economic. Assuming, for this factor only, that ECM's product was ineffective, the economic consequences of a false claim would not be material or significant. Complaint Counsel has not offered evidence of an environmental detriment. Landfill operators are not designing landfills, or making waste management decisions, on the basis of ECM's claims. Plastic products treated with ECM additive are disposed in the normal course, along with other non-degradable plastics. As Dr. Barlaz testified, because the intended use is for infinite retention in the landfill, a false or misleading claim has no material consequence. Whether the product performs precisely as advertised in the landfill is impossible to verify *post hoc* because of the disposal conditions.

Thus, if the product does not biodegrade as advertised, the end consumer never discovers that fact. That is in contradistinction with other commercial products, like weight loss supplements, or devices, whereby the consumer suffers direct loss or injury from use of the product. The purchasers or consumers here are the corporate entities who acquire and use ECM's product in commerce. There is no evidence that those companies sell ECM plastics to end-consumers for the biodegradable nature of the plastic; indeed, most products containing the ECM additive are invisible in that respect to the end-use consumer or if identified as

biodegradable, as Dr. Stewart's survey confirms, are not understood to mean anything in particular by consumers. Even if we assume ECM's product does not perform as well as advertised, none of ECM's customers have been denied the economic benefit of that bargained for transaction.

That point notwithstanding, ECM has always indicated to its direct customers that the period for biodegradation is highly variable and depends on environmental factors. ECM's customers reasonably understood, therefore, that biodegradation could occur over significant periods of time. Those customers have even tested ECM's product and reviewed ECM's scientific literature. Customers purchasing the ECM additive for altruistic environmental reasons had the information necessary to assess ECM's claims, and suffered no economic injury as they made claims based on that information.

6. The Amount of Substantiation Experts in the Field Agree is Reasonable

The final factor is the amount of substantiation experts in the field would agree is reasonable. This factor "must be examined in relation to each field being evaluated." *POM*, 2012 WL 2340406, at *206. Currently, there is no such agreement among experts in the field of biodegradable plastics.

The FTC has not defined what constitutes "competent and reliable scientific evidence" in the context of biodegradable advertising. However, based on the *Pfizer* factors outlined above, the standard to be applied in this case must be lower than standards applied in other FTC proceedings considering advertisements related to medical or health claims. For example, in the medical context, advertising claims must be substantiated by double-blind, randomized, placebo-controlled clinical trials. *Thompson Med. Co., Inc. v. Fed. Trade Comm'n*, 791 F.2d 189 (D.C.Cir.1986); *Bristol-Myers Co. v. Fed. Trade Comm'n*, 738 F.2d 554 (2d Cir.1984).

Similarly, the standard to apply in this case must necessarily be lower than the standard for advertising claims related to food products which purport to have health benefits—"one well designed, randomized, and double-blind, placebo-controlled clinical trial involving an appropriate sample population and endpoint." *POM*, 2013 WL 268926, at *43. While these standards obviously cannot apply to biodegradability, they are important benchmarks to demonstrate that ECM's "competent and reliable scientific evidence" need not be as high as that mandated in *Thompson*, *Bristol-Myers*, and *POM*. *See Statement of Commissioner Ohlhausen*, 2014 WL 587857, at *1 (F.T.C. Jan. 7, 2014) ("[T]he burden for substantiation for health- or disease-related claims about a safe product . . . should be lower than the burdens imposed on drugs and biologics because consumers face lower risks when consuming the safe product.").

Drs. Sahu, Burnette, and Barlaz will explain that gas evolution tests (like the ASTM D5511) are sufficient, and generally accepted in the scientific community, to substantiate claims of anaerobic biodegradation. To the extent that a gas evolution test produced evidence that the test article biodegraded in excess of the additive, the evidence has shown the underlying polymer degraded, and that the ECM additive was efficacious. In tests where the ECM additive was measured against a negative control, the evidence shows that the ECM additive resulted in biodegradation of an otherwise non-biodegradable polymer. Dr. Sahu will testify that the amount of positive ECM tests lead inexorably to the conclusion that ECM plastics are biodegradable.

Concerning the rate and extent of biodegradation in a landfill, ECM experts will explain that both elements are almost impossible to predict with any certainty (for any product) given the uncertainties inherent to the landfill environment. However, Dr. Sahu will testify that the substantial evidence of biodegradation is highly probative that the product will continue to

degrade completely if within an environment that permits biodegradation. The small margin of negative studies does not represent evidence that ECM's products are ineffective. A test that does not produce affirmative evidence of biodegradation is not the same as a test that proves that the active under evaluation does not biodegrade; but the over 33 tests showing biodegradation do, in fact, prove it to be extant. The evidence must be examined as a whole, considering all relevant data points. Many variables can result in outcomes that are inconclusive, but positive evidence of a repeated nature such as this is dispositive.

7. ECM's Scientific Support

ECM has produced competent and reliable scientific evidence proving that plastics manufactured with its additive biodegrade anaerobically and aerobically. ECM's laboratory testing, when assessed with the science as a whole, prove that ECM's product is biodegradable in biologically active landfills.[394]

First, ECM has produced gas evolution studies that tested ECM-infused plastics against negative controls (i.e., untreated, conventional plastics that are known to degrade very slowly). Those tests included anaerobic lab work (e.g., ASTM D5511), and aerobic lab work related to composting (e.g., ISO 14855, UNI EN 14046). Many of the results revealed significant biodegradation of the ECM plastic. The biodegradation was measured by the amount of gas produced. Researchers can determine the amount of biodegradation in the test article by comparing the carbon in the gas emitted from treated vessels with the carbon emitted in the blank inoculum and the control vessels. The amounts of biodegradation observed in ECM's many positive tests was sufficient to conclude that the plastic polymer, and not just the ECM additive, had biodegraded substantially.

[394] *See supra* Part II.7.3 (table).

Second, ECM supported its gas evolution data with qualitative analyses performed by leading environmental scientists. Tests of ECM plastics in landfill simulated conditions demonstrated that ECM plastic was biodegradable by gravimetric endpoints. Dr. Timothy Barber (Environ Labs) further concluded that the ECM additive cause PVC polymers to degrade under simulated landfill conditions based, in part, on gravimetric endpoints, but also through an evaluation of free chloride atoms present in the test vessels.

Third, ECM confirmed that anaerobic biodegradation witnessed in the laboratory environment would translate into the real word conditions of a landfill. ECM has proven that Municipal Solid Waste (MSW) landfills are biologically active enough to support significant biodegradation in most instances. The anaerobic processes that result in landfill biodegradation are similarly present in the laboratory tests. Moreover, the laboratory tests demonstrate that ECM plastics are intrinsically biodegradable when compared with untreated plastics. As a biodegradable material, the plastics will biodegrade when environmentally favorable conditions exist for biodegradation.

Fourth, ECM determined through various studies, including those extended gas evolution studies and those where labs re-inoculated, that biodegradation of plastics would continue beyond the short testing periods.

Fifth, ECM determined based on peer-reviewed literature and expert opinion that conventional plastics of the type most ECM customers use can be enzymatically biodegraded by enzymes naturally produced by bacteria and microorganisms.

Sixth, as explained, *supra*, ECM has debunked the scientific theories posited by Complaint Counsel's experts in their efforts to prove that additive technologies (not just ECM's) are inefficacious. Those theories were primarily advanced by Complaint Counsel's scientific

expert, Dr. Stephen McCarthy. Dr. McCarthy essentially works for ECM's competitors. He has received substantial research funding (millions of dollars) from those competitors. He has licensed his intellectual property to those competitors, and received a revenue stream for that technology. He is, therefore, personally and financially interested in the success of ECM's competitors, who, in turn, stand to profit if the FTC forecloses the biodegradable additive industry. The same competitors who hire Dr. McCarthy have directly lobbied the FTC to act against additive manufacturers, including ECM by name. Dr. McCarthy's expert opinions are unreliable, and as he strains to prove ECM's technology does not work, his personal objectives and biases should be considered. ECM's experts, included the proffered expert Dr. Grossman (Dr. McCarthy's colleague), have indicated that Dr. McCarthy's scientific analysis is in error.

Finally, ECM has addressed the limited number of inconclusive test results, several of which were prepared by ECM competitors outside ECM's supply chain. Moreover, ECM's experts are of the opinion that testing should be considered as a whole, and ignoring positive test results by focusing exclusively on inconclusive results is not sound science. The data in those tests contradict Complaint Counsel's experts, revealing either that the experts had reached in their analyses, or that the inconclusive tests suffered fatal limitations.

F. The Constitution Defines Limits to the Reasonable Basis Standard

First Amendment protections directly apply to FTC orders and limit the expansion of FTC advertising regulation. *See, e.g., Standard Oil C. of California v. F.T.C.*, 577 F.2d 653, 662 (9th Cir. 1978) ("First Amendment considerations dictate that the Commission exercise restraint in formulating remedial orders which may amount to a prior restraint on protected commercial speech"); *Sears, Roebuck and Co. v. F.T.C.*, 76 F2d 385, 399 n.31 (9th Cir. 1982); *Beneficial Corp*, 542 F.2d at 611; *F.T.C. v. Simeon Management Corp.*, 532 F.2d 708, 713 (1976)

("[a]lthough commercial advertising may be subject to regulation serving an important public interest, it is not beyond the protection of the First Amendment").

ECM's claims are, at worst, truthful but potentially misleading. ECM plastics are "biodegradable" under *scientific* definitions of the phrase in the peer-reviewed literature.[395] The addition of ECM's product to conventional plastic polymers results in an end-product that will "biodegrade." The extent and rate to which that product biodegrades is not at issue for the constitutional analysis here, except that the ECM plastics are, in the literal sense, "biodegradable."

Complaint Counsel contends that ECM's truthful description of its product is misleading because a small group of consumers allegedly think the word "biodegradable" should mean that a product disappears within one year, albeit no competent evidence of that small group exists. Never mind that those consumers have no reasonable understanding of the term biodegradable. Never mind that the concept of a biodegradable product within one year is nearly impossible for most materials known to be rapidly biodegradable. Complaint Counsel maintains that industry should aspire to that unscientific and implausible standard, simply because some unreasonable consumers think it so.

Even assuming Complaint Counsel were correct, ECM's biodegradable claim would only then be potentially misleading, because the claim is literally true even if it could potentially be misunderstood by unreasonable consumers expecting a scientifically impossible result. The Constitution prohibits restriction of potentially misleading speech when there are obvious, less

[395] The dictionary also defines "biodegradable" as that which is "capable of being decomposed by bacteria or other living organisms." ECM plastics have been shown capable of being decomposed and, so, the "biodegradable" claim is literally true.

speech restrictive alternatives to imposing prospective speech burdens. *See*, *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999).

In *Pearson I*, the Court of Appeals for the D.C. Circuit held that perceived deficiencies in the scientific record must be proven incapable of being rendered non-misleading by resort to reasonable claim qualifications before the government may resort to a prospective speech ban. *See Pearson I*, 164 F.3d at 658 (holding that "[i]t is clear … that when government chooses a policy of suppression over disclosure—at least where there is no showing that disclosure would not suffice to cure misleadingness—government disregards a 'far less restrictive' means"); *see also Whitaker v. Thompson*, 248 F.Supp. 2d 1 (D.D.C. 2002); *Alliance for Natural Health U.S. v. Sebelius*, 714 F.Supp. 2d 48, 53 (D.D.C. 2010) ("*ANH I*"); *Alliance for Natural Health U.S. v. Sebelius*, 786 F.Supp. 2d 1, 8 (D.D.C. 2011) ("*ANH II*"). The same law and logic applies to FTC orders that restrain future speech through fencing in orders or other burdens.

Although the government may have an interest in protecting consumers from misleading claims, that interest cannot overcome the First Amendment's preference for disclosure (compelled or voluntary) over censorship when claim qualification is a suitable, less speech-restrictive alternative. *See Whitaker*, 248 F.Supp. 2d at 10. As in this case, when "credible evidence supports a claim, that claim may not be absolutely prohibited." *See id.* (citing *Pearson I*, 164 F.3d at 659). Moreover, significantly, "[t]he mere absence of significant affirmative evidence in support of a particular claim … does not translate into negative evidence against it." *Pearson v. Shalala*, 130 F.Supp. 2d 105, 115 (D.D.C. 2001) ("*Pearson II*"); *Edenfield v. Fane*, 507 U.S. 761, 770 (1993) ("[I]t is well established that the party seeking to uphold a restriction on commercial speech carries the burden of justifying it").

Here, the obvious less speech-restrictive alternatives are abundant. The Commission could invest in consumer education. Given the apparent lack of understanding in the marketplace, education is likely the most logical choice. The Commission has invested millions of tax dollars in an effort to support misguided consumer survey evidence, and through the initiation of deceptive advertising actions built on unscientific standards. Instead of forcing manufacturers and advertisers to satisfy scientifically invalid standards, the Commission could inform customers that their expectations with respect to biodegradable plastics are unreasonable.

In the alternative, the Commission could require succinct and reasonable qualifying language that can be truthful and non-misleading, which ECM would accept. In the Green Guides, the FTC states that the only reasonable disclaimer involves a provision of the rate and extent of biodegradation in the environment. However those qualifications are impossible to craft with any scientific validity, because the actual rate and extent of biodegradation depends on countless environmental factors that are beyond the advertiser's control, and are unpredictable. There is no "conservative" calculation of a rate for biodegradation. The rate could be zero, because even the most biodegradable product will not biodegrade in a sterile environment (i.e., a sterile pocket within a landfill cell that contains antimicrobial chemicals, or a landfill in Alaska with conditions very unsuitable for degradation, etc.). The reasonable qualification informs the consumer that the rate is variable and dependent an environmental conditions. However, even assuming that claim was inadequate, still a more reasonable qualification would involve a comparison between the efficacy of the biodegradable plastic to conventional un-treated plastic (e.g., "this product biodegrades 10x faster than conventional plastic"). Finally, a qualification could simply alert the consumer to the fact that "individual rates of biodegradation vary greatly,

depending on numerous factors, which can cause plastics to dissemble over hundreds, if not thousands, of years."

In short, a qualifier that requires an affirmative statement of the specific time or rate for degradation is scientifically infeasible and imprudent, but if one is expected, the only constitutional resort in this case is for the Commission to allow the claim of biodegradation and to require a reasonable claim qualification to be associated with it such as those represented above. To the extent the Commission refuses to rely on such a restriction in favor of more draconian and speech restrictive prospective limits on speech, it would unconstitutionally disregard an obvious less speech-restrictive burden.

Finally, shorn of the bogus and unscientific "One Year Rule," nothing in the record suggests that consumers have been misled by the general "biodegradation" claim at issue in this case. Accordingly, and unlike other FTC proceedings where the inherently misleading nature of speech overcomes the First Amendment analysis, the use of the "biodegradable" claim here is literally true and, at worst, only potentially misleading; thus the First Amendment trumps the attempt to prosecute the speaker and limit prospective speech. A limitation on the use of a broad, but scientifically accepted, definition of "biodegradable" must comply with the First Amendment commercial speech doctrine as articulated in *Pearson I.*

G. The Ultra Vires Nature of FTC Assumption of Regulatory Power Vested in the EPA

Government action is *ultra vires* if the agency or other government entity "is not doing the business which the sovereign has empowered him to do or he is doing it in a way which the sovereign has forbidden." *Ancient Coin Collectors Guild v. U.S. Customs & Border Prot., Dep't of Homeland Sec.*, 698 F.3d 171, 179 (4th Cir. 2012) (quoting *Larson v. Domestic & Foreign Commerce Corp.*, 337 U.S. 682, 689 (1949)). Courts review *ultra vires* agency action when an

agency "patently misconstrues a statute, disregards a specific and unambiguous statutory directive, or violates a specific command of a statute." *Hunter v. F.E.R.C.*, 569 F. Supp. 12, 16–17 (D.D.C. 2008). Put differently, "[a]n *ultra vires* act is one performed without any authority to act…" *Sahaviriya Steel Industries Public Co. Ltd. v. U.S.*, 601 F. Supp. 2d 1355, 1366 (C.I.T. 2009). The Administrative Procedures Act (APA) further contemplates that agency action is void if found to be "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right." *See* 5 U.S.C. § 706 (2)(C).

Complaints Counsel's definition of "biodegradable," which limits the naked term to products that degrade within one year, is patently arbitrary and capricious and in conflict with environmental policies set by the federal Environmental Protection Agency. Because the FTC has effectively regulated environmental *policy*, beyond simple adjudication of false or misleading advertising, the FTC has acted *ultra vires* and in excess of its statutory authority. By restricting the sale and marketing of slowly degrading landfillable products, the FTC has set national policy that encourages promotion of rapidly degrading plastics, resulting in greater adverse environmental consequences, as explained above.

The U.S. EPA has primary responsibility for enforcing the environmental statutes and regulations of the United States. Under the federal Resource Conservation and Recovery Act (RCRA), Congress delegated to the EPA the task of managing solid waste disposal. *See, e.g.*, 42 U.S.C. § 6901. Congress passed the RCRA, in part, to address the "ever-mounting increase … of the mass material discarded by the purchaser of … products." 42 U.S.C. § 6901(a)(1). Moreover, with respect to energy, Congress explained that "solid waste represents a potential source of solid fuel, oil, or gas that can be converted into energy." 42 U.S.C. § 6901(d)(1).

ECM experts testify that U.S. landfills have become a major source of harvestable natural gas in the form of methane emissions. The major biproduct of biodegradation in landfills is methane and carbon dioxide gas. Methane is released as a result of the biodegradation process as microorganisms in the landfill disassemble carbon bonds from the solid waste, often through enzymatic digestion. Methane is formed with one carbon atom and four hydrogen atoms. Experts in this case will explain that many modern landfills, operated under the auspices of the EPA and local regulations, are now designed to harvest gases emitted from landfills. For instance, 1 million tons of waste within a landfill generally creates 550,000 cubic feet per day of landfill gas, or one megawatt of electricity, which is enough to power 700 homes for one year. Moreover, by collecting and using those methane emissions for beneficial use, the landfill operators remove methane gas from the atmosphere equal to taking about 8,800 cars off the road for a year.

Rapidly degrading waste is inconsistent with the ideals for the operation and maintenance of landfills, however. Landfills pass through several phases in their life cycle. In the first phase, the landfill is open and accepting waste into "cells." During that period there is both anaerobic and aerobic activity. However, the systems designed for landfill gas collection are not active or functional during the open phase of landfill cells. Traditional landfill gas collection models are usually not equipped to collect gas emissions for two years.[396] Thus, products that rapidly degraded within one year would cause methane gas to be released directly into the atmosphere, contributing to atmospheric greenhouse gases where they would otherwise be collected or flared.

Dr. Morton Barlaz is one of the nation's leading experts in environmental sciences with respect to MSW landfills and biodegradation. Complaint Counsel's purported landfill expert,

[396] *See* RX-853, at 12.

Dr. Tolaymat, recognized Dr. Barlaz as an authority in the field and would defer to Dr. Barlaz. Dr. Barlaz will testify that increasing the rates of biodegradation for landfilled products is antithetical to the goals of gas collection and are detrimental to the environment. He will testify that more rapidly degrading substances in landfills provide no appreciable environmental benefit, in part, because landfilled products are intended for nearly infinite storage, and landfill sites expect to provide same. He will explain that, from an environmental perspective, plastic products that degrade in an MSW landfill within a matter of decades are preferable, and that decades would be a reasonably short period of time for degradation based on scientific principles.

H. The "One-Year" Rule Is An Industry-Wide Trade Regulation Rule

The "One-Year" Rule promulgated in the 2012 revision of the Green Guides is not an interpretative, non-binding statement of policy, but an industry-wide rule that redefines scope of products that can be marketed. The rule favors short-term degradable products to the prejudice of those products that would biodegrade slowly in a landfill, but still within a reasonably short period of time compared to conventional plastics. Furthermore, because Complaint Counsel has explained through this proceeding that no test can accurately substantiate the time for disposal in an MSW landfill, and the rule expressly states that it is "deceptive to make an unqualified degradable claim for items entering the solid waste stream if the items do not completely decompose within one year after customary disposal," the Green Guides prohibit technologies that do not, in fact, disappear in landfills within one year. *See* 16 C.F.R. § 260.8(c). In other words, the Commission has condemned the use of *landfill-able* technologies *in toto*. That is an environmental policy that says landfill-able products are not desirable—not a position with respect to consumer deception. The FTC has thus enacted a new industry-wide rule equivalent to

the FDA's prior restraint this Court condemned as unconstitutional in *Pearson I*. *See Pearson I*, 164 F.3d at 655-60.

15 U.S.C. § 57 requires that FTC proceed through Magnuson-Moss rulemaking when promulgating rules defining practices which are unfair or deceptive. *See* 15 U.S.C. § 57a (requiring heightened procedural safeguards in FTC rulemaking proceedings); *see also* 5 U.S.C. § 553 (requiring federal agencies, with limited exceptions, to follow notice-and-comment rulemaking procedures when promulgating a new rule, regulation, or interpretation of a regulation). Because the Commission has not complied with all of the requirements of Section 57a, the trade regulation rule implemented and now enforced against ECM is invalid and should be given no weight in this proceeding.[397]

IV. CONCLUSION

For the foregoing reasons, as will be proven and elicited at the hearing in this matter, ECM requests that this Court deny each of Complaint Counsel's 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.

[397] For example, because the FTC did not properly characterize the industry rule as a Trade Regulation Rule under Section 57a, the Commission did not apparently notify and seek input from the Committee on Commerce, Science, and Transportation of the Senate and the Committee on Energy and Commerce of the House of Representatives. *See* 15 U.S.C. § 57a(2).

Telephone: 202-466-6937
Fax: 202-466-6938
Email: jemord@emord.com

DATED: July 30, 2014.

CERTIFICATE OF SERVICE

I hereby certify that on July 30, 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 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**:

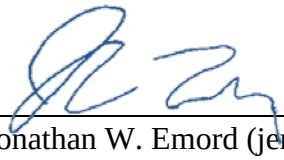
Katherine Johnson
Division of Enforcement
Bureau of Consumer Protection
Federal Trade Commission
600 Pennsylvania Avenue, NW
Mail stop M-8102B
Washington, D.C. 20580
Email: kjohnson3@ftc.gov

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,



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: July 30, 2014