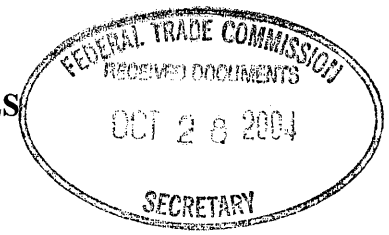
UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION
OFFICE OF ADMINISTRATIVE LAW JUDGES



In the Matter of	)	
	)	
BASIC RESEARCH, L.L.C,	)	
A.G. WATERHOUSE, L.L.C.,	)	
KLEIN-BECKER USA, L.L.C.,	)	
NUTRASPORT, L.L.C.,	)	
SOVAGE DERMALOGIC LABORATORIES, L.L.C.,	)	
d/b/a BASIC RESEARCH, L.L.C.,	)	
OLD BASIC RESEARCH, L.L.C.,	)	
BASIC RESEARCH, A.G. WATERHOUSE,	)	
BAN, L.L.C.,	)	**DOCKET NO. 9318**
d/b/a KLEIN-BECKER USA, NUTRA SPORT, and	)	
SOVAGE DERMALOGIC LABORATORIES,	)	
DENNIS GAY,	)	
DANIEL B. MOWREY,	)	
d/b/a AMERICAN PHYTOTHERAPY RESEARCH	)	
LABORATORY, and	)	
MITCHELL K. FRIEDLANDER	)	
	)	
Respondents.	)	

RESPONDENTS' SUPPLEMENTAL BRIEF OPPOSING COMPLAINT COUNSEL'S MOTION TO STRIKE RESPONDENTS' ADDITIONAL DEFENSES

Respondents Basic Research, LLC, A.G. Waterhouse, LLC, Klein-Becker USA, LLC, Nutrasport, LLC, Sövage Dermalogic Laboratories, LLC, Ban, LLC, Dennis Gay, Daniel B. Mowrey, Ph.D and Mitchell K. Friedlander (collectively "Respondents"), pursuant to the Administrative Law Judge's August 18, 2004 Order on the Motion to Strike Respondents' Additional Defenses ("Order") filed on behalf of the Federal Trade Commission ("Commission" or "FTC"), hereby file their Supplemental Brief in support of their Opposition to Complaint Counsel's Motion to Strike, and in support thereof state as follows.

I. INTRODUCTION

This brief is filed in response to the Court's October 18, 2004 Order, which provided that the parties "shall provide concurrent supplemental briefs which provide a summary of the controlling case law regarding: (1) whether the Administrative Law Judge has the authority to decide the issues presented and, if not, the consequences thereof, (2) whether a Fifth Amendment challenge to a regulatory approach by a federal agency is a valid defense to an administrative proceeding, (3) whether Respondents are entitled to amend any stricken defenses, and (4) whether discovery should be limited if Respondent's defenses are not stricken." Order at 1.

II. ARGUMENT

A. The Administrative Law Judge Does Not Have The Authority To Decide Constitutional Defenses Or Issues Touching On Commission Discretion.

The October 18, 2004 Order requires Respondents to address whether the Administrative Law Judge ("ALJ") has the authority to decide the "issues presented" and if not, the consequence thereof. *See* Order at 1. This question requires Respondents to discuss the issues presented and address the proper scope of an ALJ's power, in general, and when ruling on a motion to strike where, as here, the additional defenses raise both constitutional and non-constitutional issues.

1. The Issues Presented.

The FTC has interpreted Sections 5 and 12 of the Federal Trade Commission Act (the "FTC Act") as imposing on advertisers "two basic obligations: 1) advertising must be truthful and not misleading; and 2) before disseminating an ad, advertisers must have adequate substantiation for objective product claims."[1] Congress has provided direction on the first issue,[2]

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[1] *See* FTC's November 30, 2000 denial of the December 20, 1999 Petition for Rulemaking filed on behalf of Dr. Julian Whitaker *et al.* ("Whitaker Rulemaking Petition"), Exhibit 1 to Compendium of Exhibits Filed in Support of Motion for Summary Decision ("Ex."); FTC's (continued...)

and the FTC has defined a claim for deceptive advertising as having three elements.[3] As to the FTC's substantiation requirement, the FTC has interpreted Sections 5 and 12 of the FTC Act as requiring advertisers to have a "reasonable basis" for making objective product claims.[4]

Under the FTC's substantiation program, to determine whether an advertiser has satisfied its obligation to have a "reasonable basis" for an alleged product claim, the FTC undertakes two inquires: First, the FTC must determines whether the advertiser has any evidence to support the alleged product claims (a "falsity theory"); second, if the advertiser has some evidence supporting the alleged product claims, the FTC weighs and balances the advertiser's evidence against some standard to determine whether the advertiser's evidence "adequately substantiates" the alleged product claims (a "reasonable basis" theory).[5]

Respondents' Additional Defenses that are the subject of Complaint Counsel's Motion to Strike challenge, *inter alia,* the substantiation standard the FTC has adopted for dietary supplement and weigh-loss claims. They also challenge how the FTC has implemented that

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April 1, 2004 denial of the April 16, 2003 Petition for Rulemaking filed on behalf of The First Amendment Health Freedom Association ("FAHFA Rulemaking Petition"), Ex. 2 ("Advertisers are prohibited from making false or misleading claims for [products] and also must have adequate substantiation for objective product claims before the claims are disseminated.").

[2] *See* 15 U.S.C. § 55(a)(1) (defining "false advertisement" as misleading representation of material fact or omission of material fact necessary to make advertisement non-misleading).

[3] The three elements of an action for deceptive advertising under Sections 5 and 12 of the FTC Act are (1) a representation, omission or practice that is (2) likely to mislead consumers acting reasonably under the circumstances; and (3) the representation, omission or practice must be material to the consumers' purchasing decisions. *See* FTC's *Policy Statement on Deception* appended to *In the Matter of Cliffdale Associates,* 103 F.T.C. 110 (1984).

[4] *See In re Pfizer, Inc.*, 81 F.T.C. 23 (1972); FTC's *Policy Statement on Advertising Substantiation* appended to *In the Matter of Thompson Medical Co.*, 104 F.T.C. 648 (1984).

[5] *See FTC v. Pantron I Corp.*, 33 F.3d 1088, 1095-96 (9th Cir. 1994) (citing *Cliffdale Associates*, 103 F.T.C. at 1645-65 and *Thompson Medical,* 104 F.T.C. at 818-19, and stating that under FTC Act, FTC can proceed under two different theories of liability—"falsity theory" and "reasonable basis" theory—and that FTC had elected to proceed under falsity theory).

standard to regulate Respondents' advertisements. Respondents contend that (1) the FTC's interpretation of Sections 5 and 12 of the FTC, that "competent and reliable scientific evidence" is required for all health and safety claims, including each dietary supplement and weight-loss claim in this case, is contrary to the law; and (2) that the FTC's implementation of that standard of liability against Respondents is contrary to the law. The FTC's policy decisions and the facts of this case show that the FTC's interpretation and implementation of Sections 5 and 12 of the FTC Act in regulating dietary supplement and weight-loss claims (a) is contrary to the intent of Congress, (b) is unconstitutionally vague, (c) constitutes an unlawful delegation of authority, (d) violates the Administrative Procedures Act ("APA"), (e) violates the First Amendment of the U.S. Constitution, and (f) cannot form the basis of the Commission's Complaint.

2. The Commission Has The Obligation, But Neither The Commission Nor The ALJ Has The Authority, To Decide Whether The Commission's Interpretation And Implementation Of Sections 5 And 12 Of The FTC Act Are Constitutional.

Although Complaint Counsel has essentially argued that Respondents' challenges to the Commission's substantiation program are futile, the Commission cannot ignore is obligation to protect constitutional freedoms. *See, e.g., In the Matter of Trans Union Corp.*, 2000 WL 257766 (Feb. 10, 2000) (Commission, in action under Fair Credit Reporting Act, ordered by D.C. Circuit to hear Respondent's defense that "the FCRA's definition of consumer report is unconstitutionally vague under the Fifth Amendment."). In fact, the Commission has in no uncertain terms recognized its obligation to zealously guard protected freedoms in discharging its duties to protect consumers under Sections 5 and 12 of the FTC Act:

> We bow to no one in our concern and responsibility to protect the public from any invasion of its Constitutional rights, particularly those associated with the rights of freedom of speech and expression. In today's increasingly computerized society with the ever-increasing involvement of Government in the lives of its citizens, we would be derelict in our duties as public officials and citizens if we were not

> especially zealous to protect the individual from any encroachment by Government on his fundamental freedoms.

In re Rodale Press, Inc., 71 F.T.C. 1184 (1967).

The Commission's obligation to protect Constitutional freedoms derives from Congress' delegation of authority. Sections 5 and 12 of the FTC cannot lawfully be interpreted and applied by the Commission to infringe upon the Constitutional rights of U.S. Citizens, including advertisers. It must be construed and applied consistently with the U.S. Constitution.

Although the Commission has the obligation to protect the Constitutional rights of advertisers, it is the sole province of the U.S. Supreme Court, and the U.S. Supreme Court has the entire authority, to decide whether the Commission's interpretation and implementation of Sections 5 and 12 of the FTC Act comport with the U.S. Constitution. *See Weinberger v. Salfi*, 422 U.S. 748, 764-67 (1975); *Ticor Title Ins. Co. v. F.T.C.,* 814 F.2d 731, 739 n. 11 (D.C. Cir. 1986) ("agency is without jurisdiction or competence to decide the constitutional question"). All questions, both fact and law, will be reviewed *de novo*. *Crowell v. Benson*, 285 U.S. 22, 60 (1932) ("the judicial power of the United States necessarily extends to the independent determination of all questions, both of fact and law, necessary to the performance of [its] supreme function."); *Peel v. Attorney Registration and Disciplinary Commission of Ill.*, 496 U.S. 91, 108, 111-117 (1990) (in determining constitutionality of Illinois State Bar's regulation of potentially misleading speech, federal courts must make their "own determinations of 'constitutional facts.'"); *Bose Corp. v. Consumers Union of U.S., Inc.*, 466 U.S. 485, 510-11 (1984) (federal courts determine characterization of speech); *National Federation of Blind v. FTC,* 303 F. Supp. 2d 707, 714 (D.Md. 2004) ("the opinion of the FTC as to the constitutionality

of its regulations is not entitled to any deference").[6] As plainly stated by the district court in *Puerto Rico Tele-Com, Inc. v. Rodriguez*, 747 F. Supp. 836, 843 (D. Puerto Rico 1990):

> If commercial speech is to be afforded *any* meaningful constitutional protection, the government cannot simply justify its regulations with a hollow or talismanic determination that an advertisement is "misleading." Wooden deference to [an agency's] determination as to the misleading nature of an advertisement would obviously place in jeopardy some commercial speech that is in fact not misleading and thus deserving of at least limited first amendment protection.

3. The FTC's Adoption And Enforcement Of Its Competent And Reliable Scientific Evidence Standard Constitute Final Agency Action Subject To Immediate Review.

There is, and can be, no dispute that Respondents are challenging final agency action. Agency action is final where the action marks "the 'consummation' of the agency's decisionmaking process" and is "one by which 'rights or obligations have been determined,' or from which 'legal consequences will flow.'" *Bennett v. Spears*, 520 U.S. 154, 177 (1997). Interpretative opinions and regulatory standards constitute final agency action subject to review where the agency treats them as controlling and binding on its personnel in the field, bases enforcement decisions on them, and expects compliance. *Appalachian Power Co. v. EPA,* 208

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[6] *Accord Kraft, Inc. v. FTC,* 970 F.2d 311, 318-20 (7th Cir. 1992). Although the *Kraft* court narrowly applied the plurality and concurring opinions in *Peel,* it recognized the broader application and importance of *Peel*, and distinguished *Peel* only on the facts. It held that *Peel* involved review of an Illinois State Bar "regulation applicable to all lawyers," whereas *Kraft* involved the review of "an individualized FTC cease and desist order." *Id.* at 320. In other words, the *Kraft* court did not consider whether the FTC's interpretation and implementation of Sections 5 and 12 of the FTC, as those statutory directives apply to "all" advertisers, complied with the First and Fifth Amendments of the U.S. Constitution. It only considered the deference that should be afforded the FTC in connection with a particular, fact specific, cease and desist order, as that particular order applied to an adjudicated wrongdoer. *Id.* Whether *Kraft* is correct is immaterial. It would not alter that (1) the *Kraft* court did not reach the issue presented in *Peel*, (2) had no authority to reverse, but remains bound by *Peel*, and (3) as the Supreme Court has made clear long before *Peel,* the constitutionally of the FTC's interpretation and implementation of Sections 5 and 12 of the FTC Act as applied to "all" advertisers is reviewed *de novo*.

F.3d 1015, 1021 (D.C. Cir. 2000); *Ciba-Geigy v. EPA,* 801 F.2d 430, 438 (D.C. Cir. 1986) (agency interpretation of guiding statute "with the expectation that regulated parties will conform to and rely on this interpretation, is final agency action fit for judicial review.") (citation omitted); *McClouth Steel Products Corp v. Thomas*, 838 F.2d 1317,1321 (D.C. Cir. 1988) (EPA model used to determine contamination constituted final action, because "despite its claim that it is open to 'new approaches' to delisting decisions . . . , EPA has evidenced almost no readiness to reexamine the basic propositions that make up the VHS model.") (citation omitted).

The FTC's adoption of and reliance upon its substantiation standard of "competent and reliable scientific evidence" constitute final agency action. By its own admission, the FTC basis law enforcement actions on this standard; treats it as controlling all health and safety related claims, including dietary supplement and weight-loss claims; expects compliance with, and determines the rights and obligations of advertisers based on, this standard; and imposes legal consequences for violations of this standard. *See, e.g., FTC Targets Products Claiming to Affect the Stress Hormone Cortisol* (Oct. 5, 2004) ("In its warning letters, the FTC states that is not aware of any competent and reliable scientific evidence to support [the subject] claims and warns that unsupported claims are unlawful under the FTC Act. Accordingly, the FTC's warning letters instruct [advertisers] to discontinue any false or deceptive claims immediately."); *FTC Notice of Potential Illegal Marketing of Products that Claim to Cause Weight-Loss, Reduce the Risk of Disease, or Produce Other Health Benefits by Affecting the Stress-Related Hormone Cortisol* (Oct. 1, 2004) ("This letter places you on notice that any claim that a product affects cortisol and thereby causes weight loss . . . or produces other health benefits . . . **must be supported by competent and reliable scientific evidence**. . . . Without such evidence, the claims are illegal under the Federal Trade Commission Act and **should be discontinued**

immediately. Violations of the FTC Act may result in legal action, which may in turn require you to pay money back to consumers.") (emphasis original).

The Commission has also made it clear that, notwithstanding *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999), wherein the D.C. Circuit held that the Food and Drug Administration's ("FDA") substantiation program violated the First Amendment and the APA, it is not going to voluntarily change its substantiation program, or its law enforcement practices and procedures implementing its competent and reliable scientific evidence standard, to regulate dietary supplement and weight-loss claims. *See* FTC's November 30, 2000 denial of the Whitaker Rulemaking Petition; FTC's April 1, 2004 denial of the FAHFA Rulemaking Petition (arguing that *Pearson* was distinguishable). Complaint Counsel's argument in its Reply that Respondents are not challenging final agency action discredits the rights and obligations of everyone involved in this proceeding, including the Commission, the ALJ, and Respondents.

4. The ALJ Should Provide Its Recommendation On The Constitutional Issues And Matters Touching Upon Administrative Discretion; It Has No Authority To Decide These Issues.

Under the Rules of Practice, an ALJ is endowed with certain enumerated powers to conduct administrative proceedings. 16 C.F.R. §3.42. These enumerated powers include the general power to regulate the course of a hearing, and to consider and rule upon, as justice may require, all procedural and other motions appropriate in an adjudicative proceeding. 16 C.F.R. §3.42(6), (8). However, because these powers are limited, the ALJ is endowed with the power and the obligation to certify questions to the Commission for the Commission's determination in those situations where the ALJ "has no authority to rule." 16 C.F.R. §§3.22(a), 3.42(10). In these situations, the ALJ is to provide its recommendation to the Commission. *Id.*

The ALJ has no authority to rule upon or decide the *merits* of Respondents' Constitutional and Non-Constitutional defenses challenging the Commission's interpretation and

implementation of Sections 5 and 12 of the FTC Act as requiring "competent and reliable scientific evidence" before advertisers can make a health and safety claim, including a dietary supplement or weigh-loss claim. Respondents are challenging final agency action that touches upon the Commission's administrative discretion, undertaken *before* they spoke, but which is *now* being "felt in a concrete way by the challenging parties." *Abbott Laboratories v. Gardner,* 387 U.S. 136, 148 (1967); *Ohio Forestry Ass'n v. Sierra Club,* 523 U.S. 726, 735 (1998). Congress delegated to the Commission the power to interpret and implement Sections 5 and 12 of the FTC Act, and the Commission has interpreted and implemented these statutory directives as it has seen fit. Whether the FTC's regulatory scheme and substantiation standard comply with the law is something far beyond the authority of the ALJ to resolve, one way or the other.

With respect to Complaint Counsel's Motion to Strike, the ALJ's powers, as discussed further below, are very limited, although Commission precedent has varied on the appropriate standard for granting a motion to strike.[7] The general rule is that an ALJ may strike an additional defense that will have absolutely no bearing on the outcome, if maintaining the defense will unduly prejudice Complaint Counsel. *In the Matter of Dura Lube Corporation, et al.*, 1999 WL 33577395, *1 (F.T.C. Aug. 31, 1999). However, once the ALJ determines that a

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[7] For example, some cases have held that issues of law or fact that are irrelevant or immaterial can be resolved on a motion to strike, and other cases have held that it is inappropriate to resolve issues of law or fact on a motion to strike. *Compare, In re Warner-Lambert Co.*, 82 F.T.C. 749 (upholding ALJ decision to strike defenses as irrelevant and frivolous); *In re Kroger Co.*, 1977 FTC LEXIS 70 (striking defenses as insufficient as a matter of law); and *In re Volkswagen of America, Inc.*, No. 9154, slip op. (striking defenses as injecting invalid and extraneous issues and as insufficient as a matter of law) with *Home Shopping Network*, 1995 FTC LEXIS 259 (refusing to strike defenses asserting legally sufficient issues and factual issues that should be determined on the merits); *General Motors Corp., et al.*, 1976 FTC LEXIS 237 (July 9, 1976) (refusing to strike defenses unless they are unquestionably insufficient as a matter of law); and *In re Volkswagen of America, Inc.*, No. 9154, slip op. (refusing to strike defenses raising substantial questions of fact and law and defenses raising questions of law which cannot be deemed wholly frivolous, irrelevant, or immaterial).

defense raises a relevant question of fact or law, the ALJ's power to rule upon the *substance* of the defense is limited in two significant ways. First, the ALJ cannot decide the question if it touches on a matter of administrative discretion. 16 C.F.R. §§3.22, 3.42(10); *In the Matter of Herbert R. Gibson, Sr., et al.*, 90 F.T.C. 275, 275, 1977 WL 189044, at *1 (Oct. 12, 1977) (It is well established that an administrative law judge lacks authority to "rule on and must certify motions to dismiss . . . *and other motions containing questions pertaining to the Commission's exercise of administrative discretion.*") (citations omitted, emphasis added). Second, if it does not touch on a matter of administrative discretion, the ALJ should decide the issue only to determine whether it is relevant and material, and whether if left unresolved, it will prejudice Complaint Counsel. *Dura Lube*, 1999 WL 33577395 at *1 (citations omitted).

Because all of Respondents' defenses will have a bearing on the outcome of this case, and will not unduly prejudice Complaint Counsel, none of Respondents' defenses should be stricken. The consequences are twofold. First, as to matters touching upon administrative discretion, the ALJ must either deny Complaint Counsel's motion or certify the questions to the Commission. These defenses include without limitation those predicated on Fifth Amendment—Due Process; First Amendment—Freedom of Speech; Administrative Procedures Act (5 U.S.C. §706)—Improper Agency Action; Administrative Procedures Act (5 U.S.C. §§706(1) and/or 555(b))—Unreasonable Delay; Federal Trade Commission Act (15 U.S.C. §45(b)—No Reason to Believe; and Federal Trade Commission Act (15 U.S.C. §45(b)—Interest of the Public. Second, as to matters not touching upon administrative discretion, the ALJ should defer their resolution for the appropriate procedural device—a motion for summary decision.

5. None Of Respondents' Affirmative Defenses Should Be Stricken.

Although the Rules of Practice do not provide for motions to strike, the Commission has held that under certain circumstances such motions may be granted by an ALJ. *Dura Lube*, 1999 WL 33577395 at *1. Motions to strike defenses, however, are viewed with disfavor. *FTC v. Commonwealth Marketing Group, Inc.*, 72 F. Supp. 2d 530, 545 (W.D. Pa. 1999); *Dura Lube*, 1999 WL 33577395 at *1. Consequently, the appropriate circumstances are few and limited.

In order for the striking of a defense by an ALJ to be appropriate, the defense must be "so unrelated to the [Respondents'] claims as to be unworthy of any consideration as a defense and that [Complaint Counsel] is prejudiced by the presence of the allegations in the pleading." *Commonwealth Marketing Group*, 72 F. Supp. 2d at 545 (citing *Great West Life Assur. Co. v. Levithan,* 834 F. Supp. 858, 864 (E.D.Pa 1993)). *Accord Dura Lube*, 1999 WL 33577395 at *1 (Defenses may be stricken where they (1) are unmistakably unrelated or so immaterial as to have no bearing on the issues; and (2) prejudices Complaint Counsel by threatening an undue broadening of the issues or by imposing an undue burden on Complaint Counsel). In other words, the power to strike additional defenses is limited, and so too the ALJ's power in this regard, to procedural circumstances in which "the insufficiency of the defense is 'clearly apparent.'" *Commonwealth Marketing Group*, 72 F. Supp. 2d at 545 (citing *Cipollone v. Liggett Group, Inc.*, 789 F.2d 181, 188 (3rd Cir. 1986)).

Here, as mentioned, Respondents have raised defenses based on the following:

> Fifth Amendment—Due Process; First Amendment—Freedom of Speech; Administrative Procedures Act (5 U.S.C. §706)—Improper Agency Action; Administrative Procedures Act (5 U.S.C. §§706(1) and/or 555(b))—Unreasonable Delay; Federal Trade Commission Act (15 U.S.C. §45(b)—No Reason to Believe; Federal Trade Commission Act (15 U.S.C. §45(b)—Interest of the Public; Puffery; Laches; Estoppel; Lack of Causation; Lack of Interstate Commerce; Lack of Dissemination; Inherently Unfair Complaint Allegations; and Bias and Impropriety by Commission Chairman.

Consistent with the foregoing authority, the ALJ may rule on the *threshold issue* of whether each defense is unmistakably unrelated or so immaterial as to have no bearing on the issues, and whether they prejudice Complaint Counsel by threatening an undue broadening of the issues or by imposing an undue burden. *Dura Lube.*, 1999 WL 33577395 at *1. As set forth above and in Respondents' Opposition to Complaint Counsel's Motion to Strike, these defenses cannot be stricken as none can be deemed "unrelated" or "immaterial" to the Commission's charges, so as to warrant being stricken from consideration by the ALJ and the Commission. Moreover, it is anything but "clearly apparent" from Complaint Counsel's papers that any defense should be stricken. Complaint Counsel continues to avoid addressing the substantive issues raised by Respondents' defenses. As Respondents have shown, their defenses are directly related and material to these proceedings. They have been properly pled or provide sufficient notice. And none of them unduly prejudice Complaint Counsel's prosecution of Respondents.[8]

6. Complaint Counsel's Arguments Lack Merit.

Having concluded that Respondents' defenses should not be stricken, the question becomes to what extent, if any, may the ALJ consider the issues presented by such defenses. Respondents have raised both constitutional and non-constitutional defenses to the FTC's regulatory scheme and law enforcement action against Respondents. Of the aforementioned defenses, certain defenses do not concern or touch upon administrative discretion (*e.g.*, puffery,

[8] None of Complaint Counsel's arguments, including its references to "efficiency" and "judicial economy," effect these conclusions. At most, Complaint Counsel is simply proffering its opinion that, on the merits, it is *futile* to assert the challenged defenses, and that Respondents should be *denied* the opportunity to develop a record to support their defenses in this proceeding. Indeed, Complaint Counsel's own arguments acknowledge that it is not truly trying to strike Respondents' defenses. Rather, once the rhetoric is set aside, it is clear that Complaint Counsel is trying to summarily adjudicate the issue presented, so as to avoid having to defend their regulatory scheme and charges before the Commission, through an improper procedural device.

lack of causation, lack of interstate commerce, lack of dissemination), and as such, may be considered by the ALJ when appropriate. The remaining defenses, however, which are predicated on the FTC's repeated violations of Respondents' fundamental rights that underlie these enforcement proceedings, must be certified to the Commission for resolution.

For example, Respondents have asserted that the FTC's past and present actions under its regulatory scheme governing dietary supplement and weight-loss claims have violated their rights under the First and Fifth Amendments to the U.S. Constitution. Similarly, Respondents have asserted that the FTC's procedures and law enforcement practices governing dietary supplement and weight-loss claims constitute arbitrary and capricious action under the Fifth Amendment and APA.[9] Respondents have also raised claims predicated on the Commission's decision, in this case, to bring this action, which violated the FTC Act and APA.

As discussed above, these issues touch upon administrative discretion and should be certified to the Commission and reviewed by appropriate Circuit Court of Appeals. For example, the standard as to which Respondents' conduct will be judged is a matter of administration discretion resting solely with the Commission. Neither the ALJ nor Complaint Counsel has any authority to set the standard, or the ability to communicate with the Commission during the adversarial process, so as to find out what the standard of conduct the Commission has charged Respondents of violating. Similarly, the Commission's decisions to bring and maintain this action are discretionary. The constitutional questions for the Commission include:

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[9] Respondents have rights, and the Commission has violated those rights, because the Commission has implemented and threatens to enforce a vague and extremely high "substantiation doctrine" pursuant to a subjective, *post hoc* regulatory scheme, with no procedural requirements protecting the rights of advertisers, to regulate commercial speech.

(1) Whether the Federal Trade Commission's substantiation program, as applied to dietary supplement and weigh-loss claims, violates the Due Process Clause of the Fifth Amendment, because the Federal Trade Commission has not adopted a meaningful, concrete, content-neutral advertising standard, and/or procedural safeguards protecting the First Amendment rights of advertisers from improper law enforcement action, and whether Respondents have been deprived of their constitutional rights (a) to judge their commercial speech against the precise standard of liability the Federal Trade Commission is applying against them before they spoke, and/or (b) to correct any perceived potentially misleading message before the Federal Trade Commission initiated coercive law enforcement action against them;

(2) Whether the Federal Trade Commission's prosecution of Respondents violates the Due Process Clause of the Fifth Amendment and/or the Administrative Procedures Act (5 U.S.C. §§ 701, 706), because the Federal Trade Commission has failed to disclose in its charging document the legal standard against which Respondents' advertisements are being judged; what that standard requires of advertisers; the definitions for terms used by the Commission to form the operative allegations in the charging document; and the factual basis of the Commission's charges that Respondents' advertisements violated the undisclosed legal standard. The issues that should be certified to the Commission include whether the Federal Trade Commission has (a) failed to provide "fair notice" of its charges, (b) provided Complaint Counsel with excessive latitude to interpret Respondents' advertisements and change the nature of the Commission's charges, (c) permitted the Commission and Complaint Counsel to prosecute this action pursuant personal or subjective predilections and beliefs, and/or to advance paternalistic governmental policies, (d) disregarded reasonable expectations of consumers and evaluated Respondents' advertising in favor of subjective, *post-hoc* third-party opinions, and (e) deprived Respondents of the protections afforded by 15 U.S.C. §45(a), including the requirements that the Commission have a legitimate "reason to believe" that Respondents had violated the FTC Act, and that prosecution an action against Respondents was and is in "the interest of the public"; and

(3) Whether the Federal Trade Commission's regulatory scheme and substantiation standard violate the First Amendment of the U.S. Constitution, because (a) they operate as a prior restraint on protected speech, (b) they unduly burden the exercise of commercial speech, (c) the Commission is engaged in a policy of suppressing, not correcting, potentially misleading speech, (d) the Commission has no evidence that its regulatory scheme and substantiation standard is directly protecting consumers in a material way, and (e) there is a far less restrictive way of protecting consumers from the perceived risks of confusion arising from allegedly unsubstantiated speech, including an optional, non-binding, fee-based prescreening system, or simply a warning letter system notifying advertisers of the particular risk of confusion and how to correct the perceived potentially misleading message with qualifying language or disclaimers, and affording advertisers engaged in protected speech the opportunity to correct any perceived potentially misleading message, as directed by the D.C. Circuit in *Pearson.*

With respect to Respondents' defenses under the APA (5 U.S.C. §§ 701, 706))—Improper Agency Action, the Administrative Procedures Act (5 U.S.C. §§706(1) and/or 555(b))—Unreasonable Delay, the Federal Trade Commission Act (15 U.S.C. §45(b)—No

Reason to Believe, and the Federal Trade Commission Act (15 U.S.C. §45(b)—Interest of the Public, these issues also must be certified to the Commission. Because these defenses rely upon facts similar to those underlying Respondents' constitutional defenses, the issues presented by these non-constitutional defenses touch on matters of administrative discretion. Just as the ALJ has no authority to resolve whether the Commission's policy decision to regulate commercial speech with vague and high standards with no procedural safeguards is constitutional, the ALJ has no authority to resolve whether the Commission's chosen regulatory scheme governing dietary supplement and weight-loss claims violates the FTC Act and APA. Similarly, the ALJ has no authority to rule on whether the Commission's decisions to bring an enforcement action against Respondents, including at the time it was brought, were proper under the FTC Act and APA. Thus, the ALJ must certify the defense of improper agency action, unreasonable delay, no reason to believe, and no public interest to the Commission.

The case of *In the Matter of Boise Cascade Corp.*, 97 F.T.C. 246 (1981) is illustrative of why these issues should be certified to the Commission. There, "[t]he administrative law judge . . . certif[ied] to the Commission . . . four issues which he believed outside of his authority to decide . . . ." *Id.* Each issue concerned a matter of the Commission's administrative discretion: "(1) whether the Commission determined that it had 'reason to believe' a violation of the law had occurred and that issuance of the complaint was in the public interest; (2) whether the complaint issued as the result of industry pressure and congressional interference; (3) whether Boise' suppliers who allegedly violated Section 2(a) of the Clayton Act, as amended by the Robinson-Patman Act, should have been joined as parties; and (4) whether instead of issuing the complaint the Commission should have instituted a rulemaking proceeding." *Id.*

In its Reply to Respondents' Opposition to Motion to Strike Respondents' Additional Defenses ("Reply"), Complaint Counsel concedes that in both *Boise Cascade Corp* and *Gibson*, the issues were properly delegated to, and ruled upon by the Commission. *See* Reply at 3, Complaint Counsel concedes that in both *Boise Cascade* and *Gibson*, the issues were properly certified to the Commission. *See* Reply at 4. While Complaint Counsel also cites to several cases that stand for the proposition that the ALJ, under the circumstances discussed above, has the authority to strike certain defenses (*see* Reply at 3), these cases do not stand for the overbroad proposition that constitutional or APA defenses, which are relevant and material or do not unduly prejudice the prosecution, may be stricken whenever Complaint Counsel invokes the talismans of economy or efficiency. To the contrary, the cases are in accord with Respondents' discussion of the law, and Respondents' defenses should not be stricken.[10]

Complaint Counsel's Reply also does not refute Respondents' position that certain defenses, if not stricken, present issues solely for the *Commission* to decide. Indeed, the case law *supports* Respondents' position that the Commission—not the ALJ—may consider constitutional questions and issues arising under the APA, which touch on these questions. For example, Complaint Counsel relies on *In re Trans Union Corp.*, Docket No. 9255, 2000 WL 257766 (2000) to support the contention that both the Court and Commission may rule on constitutional and APA issues. However, in *Trans Union*, the D.C. Circuit ordered the Commission, not the

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[10] For example, in certain cases on which Complaint Counsel relies, the ALJ refused to strike Respondents' defenses predicated on constitutional grounds. *See, e.g., In re Volkswagen of America, Inc.*, No. 9154, slip op. (where ALJ refused to strike defense "that proceeding violated the due process clause because the complaint itself allegedly was vague, indefinite and failed to apprise [Respondent] of the conduct deemed unlawful").

ALJ, to hear the Respondent's defense that "the FCRA's definition of consumer report is unconstitutionally vague under the Fifth Amendment."

In sum, the FTC's regulatory scheme and the standards the FTC uses to regulate commercial speech are matters of administrative discretion. Accordingly, whether the FTC's regulatory scheme and commercial speech standards are constitutional and properly implemented are issues that cannot be stricken but must be certified to the Commission.

B. Fifth Amendment Challenges To The FTC's Regulatory Approach Is A Valid Defense To The FTC's Administrative Proceeding.

The October 18, 2004 Order requires Respondents to address whether a Fifth Amendment challenge to a regulatory approach by a federal agency is a valid defense to an administrative proceeding. *See* Order at 1. This question requires an understanding of Respondents' position as to the Commission's obligations under the FTC Act, and why the Fifth Amendment is a valid defense to the FTC's administrative proceeding against Respondents.

1. The FTC's Obligations Under The FTC Act.

The FTC's obligation under the FTC Act is to properly define, up front, its substantiation standard, and provide advertisers with an adequate outlet for protected speech that does not meet that standard. In defending against the Commission's charges, Respondents intend to prove the following: The FTC Act does not authorize or permit the FTC to interpret its "reasonable basis" limitation on commercial speech to create a new benchmark for protected speech without specifying up front what constitutes unprotected speech under that standard. The APA and the Fifth Amendment bar the FTC from regulating a fundamental liberty with a vague "competent and reliable scientific evidence" standard, without adopting adequate procedures protecting the First Amendment rights of advertisers. The Fifth Amendment also prohibits the FTC from relying on third parties to set the substantiation standard on a case-by-case basis after the

Commission files its charges, but rather requires the Commission to specify the applicable standard and the factual basis of its charges in its Complaints. Finally, the First Amendment bars the FTC from enforcing a vague and extremely high benchmark to suppress dietary supplement and weight-loss claims. It requires the FTC to use a quantifiable and measurable standard to regulate health and safety claims, and the least restrictive (or, at least, a far less restrictive) means to protect consumers from what the Commission perceives as a risk of confusion.

2. The Fifth Amendment Is A Valid Defense.

The Fifth Amendment is a recognized defense in administrative proceedings. *See, e.g., In the Matter of Trans Union Corp.*, 2000 WL 257766 (Feb. 10, 2000) (Commission addresses Respondent's defense that "the FCRA's definition of consumer report is unconstitutionally vague under the Fifth Amendment."); *In re Volkswagen of America, Inc.*, No. 9154, slip op. (1981) (due process defense not stricken because it raised substantial questions pertaining unlawful agency action); *In re Pfizer,* 81 F.T.C. 23 (1972) (Commission addressed Fifth Amendment based defense); *In re Hearst Corp.*, 79 F.T.C. 1007 (1971) (Commission considered effect of Fifth Amendment defenses in ruling procedural motion).

Here, the Fifth Amendment provides three valid defenses to the Commission's attempt to require Respondents to have "competent and reliable scientific evidence" before making dietary supplement and weight-loss claims under Sections 5 and 12 of the FTC Act. First, the FTC's substantiation standard, on its face, is void for vagueness, because it contains all the infirmities of a vague statute: It fails to provide a reasonable opportunity to know what is prohibited; it permits arbitrary and discriminatory enforcement on a subjective, *ad* and *post hoc* basis; and it operates to inhibit the exercise of First Amendment freedoms. *Grayned v. City of Rockford,* 408 U.S. 104, 108 (1972). In *Grayned*, the U.S. Supreme Court set forth the reasons why vague laws offend the Fifth Amendment—each one of which applies to the FTC's interpretation and

implementation of Sections 5 and 12 of the FTC Act as requiring advertisers to have "competent and reliable scientific evidence":

> First, because we assume that man is free to steer between lawful and unlawful conduct, we insist that laws give the person of ordinary intelligence a reasonable opportunity to know what is prohibited, so that he may act accordingly. Vague laws may trap the innocent by not providing fair warning. Second, if arbitrary and discriminatory enforcement is to be prevented, laws must provide explicit standards for those who apply them. A vague law impermissibly delegates basic policy matters to policemen, judges, and juries for resolution on an *ad hoc* and subjective basis, with the attendant dangers of arbitrary and discriminatory application. Third, but related, where a vague statute abuts upon sensitive areas of basic First Amendment freedoms, it operates to inhibit the exercise of those freedoms. Uncertain meanings inevitably lead citizens to steer far wider of the unlawful zone than if the boundaries of the forbidden areas were clearly marked.

Id. at 108 (internal quotes and citations omitted, emphasis added).

The FTC's "competent and reliable scientific evidence" standard is virtually the same standard that the D.C. Circuit rejected in *Pearson*, where the D.C. Circuit held the FDA's substantiation program unconstitutional and in violation of the APA. The *Pearson* court expressly noted that the FDA had "rejected arguments asserted by commenters [] that the 'significant scientific agreement among experts' standard violates the Constitution because it is impermissibly vague." *Id.* at 653. The D.C. Circuit further noted that "a standard may be sufficiently well-defined to satisfy the APA but not the First *or Fifth Amendment*. And, the APA may allow the agency to provide guidance in implementation, whereas the First *or Fifth Amendment may require the agency to define its standard up front*." *Id.* at 660 n.12 (emphasis added). Despite its constitutional concerns, the D.C. Circuit was able to avoid such issues and strike the FDA's standard under the APA. It held that the APA required the FDA to give "some definitional content to the phrase 'significant scientific agreement.' . . . It simply will not do for a government agency to declare—without explanation—that a proposed course of private action is not approved. *See Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto Ins. Co.*, 463 U.S. 29, 43

(1983) ('[T]he agency must . . . articulate a satisfactory explanation for its action.')." *Id.*

The validity of Respondents' void for vagueness challenge is also demonstrated by *American Home Products Corp. v. Federal Trade Commission*, 695 F.2d 681 (3rd Cir. 1983). There, the Circuit court struck down for excessive vagueness a broad "fencing-in" provision of an FTC cease and desist order that required an adjudicated wrongdoer to have "competent and reliable scientific evidence" for future product claims. 695 F.2d at 710-11. The court found that the order essentially required a former wrongdoer to pass a "reasonable basis" test, and that "any order which relies upon 'reasonable basis' language will be imprecise. . . . " *Id.* Of particular significant to the court was the fact that the Commission did not explain "why the circumstances require such imprecision." *Id.* at 711. While the FTC in subsequent cases have issued, and circuit courts have approved, more narrowly drawn "fencing-in" provisions against an adjudicated wrongdoer in cases where the FDA has provided a factual basis justifying the use of such a vague standard, the FTC has never explained why it needs such imprecision to regulate *all* commercial speech of *all* advertisers not subject to cease and desist orders.

Indeed, the very predicate of Complaint Counsel's Fifth Amendment argument is missing. At issue in *Pearson* was a pre-market approval scheme. In that situation, the D.C. Circuit was willing to accept, under the APA, informal "guidance" by the FDA as sufficient content to the FDA's otherwise overly vague "significant scientific agreement" standard. *Id.* at 660 n.12. The rationale is simple: The entire scheme was already "up front." The FDA was going to inform advertisers whether or not they could speak, without any fear of law enforcement action. The D.C. Circuit simply demanded that the FDA provide a better "up-front" explanation.

In stark contrast, the FTC has refused to adopt a pre-approval system, when it denied the Whitaker Rulemaking Petition. It has also refused to adopt practices and procedures that would

differentiate unprotected from protected speech, and protect the rights of advertisers engaged in protected speech from coercive law enforcement action, when it denied the FAHFA Rulemaking Petition. Thus, the very foundation for the apparent deference the *Pearson* court was inclined to give under the APA (but not under the Fifth Amendment) to the FDA's otherwise overly vague regulatory scheme is missing. As Justice Brennan recognized *Zauderer v. Office of Disciplinary Counsel of the Supreme Court of Ohio*, 471 U.S. 626 (1985), the inability of businesses to require the FTC to pre-prescreen their advertisements with a similarly detailed explanation, "wholly undermines one of the basic justifications for allowing punishment for violations of imprecise commercial regulations—that a businessperson can clarify the meaning of an arguably vague regulation by consulting with government administrators." *Id.* at 668 (BRENNAN, J., concurring and dissenting in part). In *FTC v. Colgate-Palmolive Co.,* 380 U.S. 373 (1965), and in every other case where the FTC has prevailed against a due process challenge, the Supreme Court and the lower federal courts expressly relied upon the fact that the adjudicated wrongdoer had an immediate remedy for the vagueness problem of the particular FTC cease and desist order's "fencing in" provision: It could require the FTC to prescreen ads. *See id.* at 394 ("[If] situation arises in which respondents are sincerely unable to determine whether a proposed course of action would violate the present [cease and desist] order, they can, by complying with Commission's rules, oblige the Commission to given them definitive advice as to whether their proposed action, if pursued, would constitute compliance with the order").

Second, the FTC's standard unlawfully delegates legislative authority to third parties in the trade or profession. To constitute lawful agency action, a FTC requirement must (a) specify the unfair or deceptive acts or practices made unlawful by the requirement, (b) survive the rigors of the FTC Act's notice-and-comment procedures or an equally rigorous review by an

administrative law judge, and (c) be subject to meaningful judicial review. *See A.L.A. Schechter Poultry Corp. v. U.S.*, 295 U.S. 495, 532-33 (1935) (holding unconstitutional the Code of Fair Competition, former 15 U.S.C. §§ 700 *et seq.*, which delegated to the President the power to approve "codes of fair competition" recommended by trade associations and industry leaders; and distinguishing the FTC Act, as there, Congress prescribed specific requirements, administrative procedures, and judicial oversight).

The Fifth Amendment bars the FTC from trying to avoid its statutory obligations by relying upon third parties to set a legal standard and opine on whether it has been violated after an advertiser has undertaken conduct that concerns the government. *See, e.g., Women's Medical Center of Northwest Houston v. Bell*, 248 F.3d 411, 421-22 (5th Cir. 2001) (regulation invalid because it subjected physicians to sanctions based not on any violation of objective standard of behavior, but on the subjective viewpoints of others—specifically, regulation required licensed abortion providers to provide "quality care," defined as "[t]he degree to which care meets or exceeds the expectations set by the patient."); *Bella Lewitzky Dance Foundation v. National Endowment for the Arts*, 754 F. Supp. 774, 781-83 (C.D. Cal. 1991) (government National Educational Association ("NEA") grant, which required recipients to certify that funds would not be used to promote "obscene" material, unconstitutionally vague because term "obscene" was not defined, but instead determination of obscenity was left in hands of NEA).

Finally, assuming *arguendo* that the FTC's substantiation program is not unconstitutional and complies with the APA, the Fifth Amendment provides a valid "fair notice" defense. *See In re Schering-Plough Corp.*, 2001 FTC LEXIS 198, *11 (Oct. 31, 2001) (quoting *Conley v. Gibson*, 355 U.S. 41, 47 (1957) (federal complaints must give "'fair notice' of what . . . the claim is and the grounds upon which it rests."). As this Court recognized at the pleading stage of this

case, the Commission's Complaint must "inform the defendants of the crimes and violations which they were accused . . . ." Order Denying Motions for More Definite Statement at 4 (quoting *McHenry v. Renne*, 84 F.3d 1172 (9th Cir. 1996)). Federal law is clear that a charging document that does not sufficiently identify the offense charged, but allows the government to "shift its theory" at any stage of the case, fails to give fair notice of the offense charged and violates the Fifth Amendment, despite the fact that the charging document requires only a plain, concise and definite written statement of facts. *See Russell v. U.S.*, 369 U.S. 749, 767-768 (1962); *U.S. v. Hernandez*, 980 F.2d 868, 871 (1992); *U.S. v. McClulloch*, 6 F.R.D. 559, 560 (D.C. Ind. 1947) (indictment held invalid for lack of definiteness).

Here, the Commission's Complaint does not provide "fair notice" of the FTC's charges in this case. The operative language that controls what the Commission contends Respondents were supposed to substantiate is vague, subjective, and not defined. The Commission has not alleged objective product claims that would support a substantiation inquiry. In addition, the Complaint does not allege that Respondents had to have "competent and reliable scientific evidence" before making the alleged claims, nor does it allege what any substantiation standard required of Respondents. The Commission's Complaint also fails to allege why the Commission had "reason to believe" the evidence obtained from Respondents during the FTC's near four (4) year investigation did not meet its standard. These omissions have deprived Respondents of "fair notice" of the Commission's charges, which cannot be cured by references to discovery, because the Commission's own Rules of Practice prohibit Respondents from propounding discovery on the Commission to (a) define the operative words in the Complaint, (b) define the legal standard that forms the foundation of the charges being brought against Respondents, and

(c) disclose why, after investigating Respondents for nearly four (4) years, the Commission had "reason to believe" Respondents' evidence did not meet the undisclosed legal standard.[11]

C. The ALJ Should Allow Respondents To Amend Affirmative Defenses.

Because Respondents have pled legally sufficient defenses, this Court must allow Respondents to amend them in the event that they have been defectively pled.[12] *See Miller v. Beneficial Management Corp.*, 844 F.Supp. 990 (D.N.J. 1993) (improper not to allow amendment to affirmative defenses where amendment is not futile); *Freedom Intern. Trucks, Inc. v. Eagle Enterprises, Inc.*, 182 F.R.D. 172 (E.D. Penn. 1998) (in discussing denials of amendment generally, the court noted, "a court may justify the denial of a motion to amend on the grounds that the amendment would be futile. 'Futility' challenges an amendment's legal sufficiency. In assessing futility, the Court 'applies the same standard of legal sufficiency as applies under Rule 12(b)(6)," citation omitted). Amendment of Respondents' Additional Defenses should be allowed because any defect would, at most, be merely technical and no prejudice would inure to the Commission. Any other result would be inconsistent with the language and intent behind the Commission's Rules of Practice.

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[11] Consequently, the Commission has deprived Respondents of a full and fair opportunity to evaluate and understand the nature and scope of the charges brought against them; to determine whether to litigate those charges, and if so, how to defend against them; and if not, whether to take a judgment and appeal the Commission's order, or simply accept the terms of a proposed consent order. The Commission's charges, as drafted, unlawfully permit Complaint Counsel to alter the charges brought by the Commission, midstream, through (a) manipulating the Commission's vague and subjective interpretation of the advertisements, (b) manipulating the standard that formed the grounds of the Commission's charges, and (c) altering the factual basis of the Commission's charges as necessary to prosecute Respondents, which subjects Respondents to unlawful agency action without detection or meaningful judicial review.

[12] Respondents have argued the legal sufficiency of each Additional Defense challenged by Complaint Counsel in their Opposition to the Motion to Strike. As requested, here, Respondents answer the ALJ's question of whether Respondents are entitled to amend any stricken defense.

Commission Rule of Practice 3.15 governs the amendment of pleadings in FTC cases. It provides in pertinent part:

> (a) *Amendments*—(1) *By leave.* If and whenever determination of a controversy on the merits will be facilitated thereby, the Administrative Law Judge may, upon such conditions as are necessary to avoid prejudicing the public interest and the rights of the parties, allow appropriate amendments to pleadings or notice of hearing: *Provided, however,* that a motion for amendment of a complaint or notice may be allowed by the Administrative Law Judge only if the amendment is reasonably within the scope of the original complaint or notice.

Respondents have uncovered no Federal Trade Commission case law discussing in detail the role of the ALJ in deciding whether amendment to affirmative defenses is allowed. The language of the Rule and Commission case law on amending complaints, however, is instructive and provides guidance, as does federal jurisprudence.

Commission Rule of Practice 3.15 limits an ALJ's authority to permit amendment when it would infringe upon the Commission's role. *See In the Matter of Champion Home Builders Co.,* 99 F.T.C. 397 (1982) (ALJ may enter an order allowing amendment only if the amendment is reasonably within the scope of the original complaint); *Capital Records Distributing Corp.,* 58 F.T.C. 1170 (1961) (where new theories to complaint are added, the amendments go beyond scope of ALJ power to allow). The ALJ, for example, cannot allow amendment to a complaint when amendment would introduce new charges. *Standard Camera Corp.* 63 F.T.C. 1238 (1963) (Commission, not ALJ must pass on amendments beyond the scope of original complaint because commission is charged with determining whether proceeding is in public interest and whether there exists a reason to believe the law has been violated). Only the Commission is authorized to determine when a proceeding is in the public interest. *Id.* The ALJ's power is thus limited to amendments that fall with the scope of the Commission's complaint. *Orkin Exterminating Co.,* 1984 WL 251774 (F.T.C.) (because amendments to add claims relating to contract fell with scope of original complaint, amendment by ALJ was proper); *Zale Corp.* 77

F.T.C. 1635 (1970) (amendment was allowed, if unnecessary, because evidence on issue was sufficiently related to complaint because it went to the scope of relief).

When Complaint Counsel seeks to amend a complaint within the scope of the ALJ's discretion, the ALJ may still refuse to permit the amendment if the Respondent can demonstrate that it will suffer prejudice because of the amendment. The most common factor leading to a determination that prejudice to the Respondent should preclude amendment appears to be whether the Respondent has had the opportunity to conduct discovery on the issues raised by the amendment. *Champion Home Builders,* 99 F.T.C. 397 (1982) ("At the outset, it is clear that amending the complaint at this relatively early stage of the proceeding, where discovery is still ongoing and trial some months distant, would not prejudice respondent. Respondent would have adequate time to respond fully to the charges in the amended complaint"); *Exquisite Form Brassiere, Inc. v. F.T.C.*, 301 F.2d 499 (D.C. Cir. 1961) *cert. denied*, 369 U.S. 888 (1962); *Swanson v. van Otterloo,* 177 F.R.D. 645, 650 (N.D. Iowa 1998) and cases cited therein; *James Carpets, Inc.*, 81 F.T.C. 1043, 1046 (1972). But because of the limitations on what amendments may be allowed, typically, a Respondent's basis for objecting is similarly limited. *Zales*, *supra.* (noting that the amendment while allowable was unnecessary as the issues raised by amendment were already at issue in the litigation). To avoid prejudice, Complaint Counsel often argues that discovery is ongoing and prejudice may be cured through available discovery mechanisms.

A Respondent's amendment of affirmative defenses, however, does not implicate the same concerns as a Complaint Counsel trying to amend a complaint, because there is no issue of intruding on the Commission's power. Accordingly, the ALJ's proper concern in deciding whether to allow an amendment of an affirmative defense centers on whether the amendment would prejudice the rights of the Commission as a party. *Champion Home Builders, supra.* By

analogy to the situation where the proposed amendment does not infringe on Commission power, if a Respondent's affirmative defense is at least potentially sufficient, the amendment would not be futile as a matter of law. *Miller, supra.* As such, the only ground to refuse amendment would be that of prejudice to the Commission. But because the amendment would essentially consist of refinement to the defense already pled, any argument of prejudice would or should fail. Because the Commission would have had notice of the defense at issue, Complaint Counsel would have prepared, or can take, discovery on the issues. Where time remains for additional discovery, any prejudice could be cured in the course of conducting discovery.

Turning to the analysis this Court should employ to determine whether to allow amendment to Respondents' Additional Defenses, if any are stricken, it is clear that the balance weighs in Respondents' favor. Discovery is ongoing and depositions are scheduled to continue through January. Thus Complaint Counsel will have adequate opportunity to conduct discovery on any amendment to Respondents' defenses. Even though it unlikely that any amendment of Respondents' Additional Defenses is needed, given the notice pleading employed in these actions, leave to amend should be granted if any are stricken. Indeed, Respondents raised the Additional Defenses to place the Commission on notice as early as possible as to what it was going to have to prove, and defend, to prevail in this case. Because Complaint Counsel has had, and will have, adequate time to conduct any necessary discovery, should the ALJ require re-pleading of any Additional Defense, there would be no prejudice to the Commission.

D. Discovery Should Not Be Limited For Defenses Not Stricken.

The final issue the ALJ requested Respondents to discuss is whether discovery should be limited if Respondent's defenses are not stricken. It should not. Discovery should only be limited if defenses are stricken without leave to amend. *See Lewis v. ACB Bus. Serv., Inc.*, 135 F.3d 389, 402 (6th Cir. 1998); *Oppenheimer Fund, Inc. v. Sanders*, 437 U.S. 340, 351-352

(1978). Defenses not stricken constitute subject matter for which discovery may be sought. *National Credit Union Administration v. First Union Capital Markers Corp.*, 189 F.R.D. 158, 161 (D. Md. 1999). As stated in the Code of Federal Regulations, "[p]arties may obtain discovery to the extent that it may be reasonably expected to yield information relevant to the allegations of the complaint, to the proposed relief, *or to the defenses of any respondent.*"[13] 16 C.F.R. § 3.31(c)(1) (emphasis added). Thus, according to the plain language of 16 C.F.R. § 3.31(c)(1), discovery is permitted for defenses.

For example, in *National Credit Union*, the plaintiff National Credit Union ("Credit Union") filed a motion for protective order regarding two depositions noticed by defendant First Union Capital Marketer's ("First Union"). 189 F.R.D. at 159. Before addressing the applicable motions, the court addressed the general principles of law dealing with the scope of discovery. In so doing, the court first looked to the language of Federal Rule 26(b)(1), which lays out the general scope and limits of discovery. It provides that:

> Parties may obtain discovery regarding any matter, not privileged, which is relevant to the subject matter involved in the pending action, whether it *relates to the claim or defense of the party seeking discovery or to the claim or defense of any other party.*[14]

Id. at 160-161 (emphasis added). The key issue in limiting the scope of discovery therefore is relevance. *Id.* Relevance is construed broadly and may encompass "any matter that bears on, or that reasonably could lead to other matters that could bear on, any issue that is or may be in the case." *Id.* at 161. The standard for determining relevance is so low that discovery requests are

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[13] This language is almost identical to that of Federal Rule 26(b)(1).

[14] Though the language of Federal Rule 26(b)(1) has been modified since *National Credit Union* ("[p]arties may obtain discovery regarding any matter, not privileged, that is relevant to the claim or defense of any party..."), there is no meaningful change of note here.

not even required to be limited to issues raised in the pleadings, the merits of the case or the admissibility of the discovered information. *Id.* Simply put, "discovery requests may be deemed relevant if there is *any* possibility that the information may be relevant as to the general subject matter of the action." *Id.* (emphasis added). The party challenging a discovery request bears the heavy burden of showing that the requested discovery is not relevant. *Id.* In *National Credit Union*, the court found that the two depositions at issue were in fact relevant. *Id.*

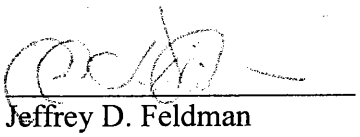
Notwithstanding the court's finding, the Credit Union stated that it intended to file a motion to strike First Union's affirmative defenses. *Id.* Though the Credit Union's motion to strike was not timely filed, the court unambiguously stated that "the affirmative defenses are still in [the] case and constitute part of the subject matter for which discovery is sought. Accordingly, the present posture of the case, with defendant's affirmative defenses unchallenged, informs the scope of permissible discovery." *Id.* Thus, discovery was permitted relating to defenses still at issue in the matter. *See also Lewis*, 135 F.3d at 402 (stating that "'it is proper to deny discovery of matter that is relevant *only to claims or defenses that have been stricken,*'" *quoting Oppenheimer Fund*, 437 U.S. at 351-352 (emphasis added); *Resolution Trust Corp. v. Sands*, 863 F.Supp. 365 (N.D. Tex. 1994) (holding that a motion to limit discovery would be granted *insofar* as it addressed stricken defenses). Permitting discovery on defenses is not limited to federal courts. The FTC has held that defenses entitle a party to engage in extensive discovery. *See In the Matter of The Hearst Corp.*, 79 F.T.C. 1007 (1971) (discussing relevance and stating that, "[a]s expressed in the Commission's Rules, Section 3.34(b)(2), the test is stated to be whether the materials sought are likely to 'constitute or contain' relevant evidence."); *In the Matter of Metagenics, Inc.*, 1996 WL 17003144 (F.T.C. 1995) (stating that defenses that are legally sufficient authorize the discovering party to engage in extensive discovery).

As Respondents' affirmative defenses are still "in [the] case," they constitute part of the subject matter for which discovery may be sought. *National Credit Union*, 189 F.R.D. at 161. Further, any discovery relating to defenses should not be limited because it will be relevant, as it "bears on,... or reasonably could lead to other matters that could bear on, any issue that is or may be in the case." *Id.* Thus, discovery sought by Respondents should not be limited.

III. CONCLUSION

For the foregoing reasons, Complaint Counsel's Motion to Strike should be denied and/or certified to the Commission for resolution of the issues presented.

Respectfully submitted,



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DATED this 27TH day of October, 2004.

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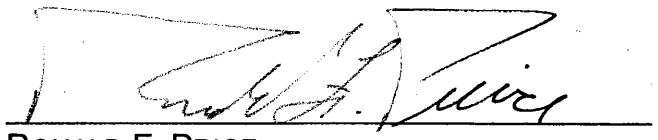

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Pro Se Respondent

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing was provided to the following parties this 27th day of October, 2004 as follows:

(1) One (1) original and two (2) copies by Federal Express to Donald S. Clark, Secretary, Federal Trade Commission, Room H-159, 600 Pennsylvania Avenue, N.W., Washington, D.C., 20580;

(2) One (1) electronic copy via e-mail attachment in Adobe® ".pdf" format to the Secretary of the FTC at Secretary@ftc.gov;

(3) Two (2) copies by Federal Express to Administrative Law Judge Stephen J. McGuire, Federal Trade Commission, Room H-104, 600 Pennsylvania Avenue N.W., Washington, D.C. 20580;

(4) One (1) copy via e-mail attachment in Adobe® ".pdf" format to Commission Complaint Counsel, Laureen Kapin, Joshua S. Millard, and Laura Schneider, all care of lkapin@ftc.gov, jmillard@ftc.gov; rrichardson@ftc.gov; lschneider@ftc.gov with one (1) paper courtesy copy via U. S. Postal Service to Laureen Kapin, Bureau of Consumer Protection, Federal Trade Commission, Suite NJ-2122, 600 Pennsylvania Avenue, N.W., Washington, D.C., 20580;

(5) One (1) copy via U. S. Postal Service to Elaine Kolish, Associate Director in the Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580

(6) One (1) copy via United States Postal Service to Stephen Nagin, Esq., Nagin Gallop & Figueredo, 3225 Aviation Avenue, Suite 301, Miami, Florida 33131.

(7) One (1) copy via United States Postal Service to Richard Burbidge, Esq., Jefferson W. Gross, Esq. and Andrew J. Dymek, Esq., Burbidge & Mitchell, 215 South State Street, Suite 920, Salt Lake City, Utah 84111, Counsel for Dennis Gay.

(8) One (1) copy via United States Postal Service to Ronald F. Price, Esq., Peters Scofield Price, A Professional Corporation, 340 Broadway Centre, 111 East Broadway, Salt Lake City, Utah 84111, Counsel for Daniel B. Mowrey.

(9) One (1) copy via United States Postal Service to Mitchell K. Friedlander, 5742 West Harold Gatty Drive, Salt Lake City, Utah 84111, *Pro Se*.

CERTIFICATION FOR ELECTRONIC FILING

I HEREBY CERTIFY that the electronic version of the foregoing is a true and correct copy of the original document being filed this same day of October 27, 2004 via Federal Express with the Office of the Secretary, Room H-159, Federal Trade Commission, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580.