Evidence Substantiation Burden May Soon Shift To FTC

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Law360, New York (January 17, 2017, 10:36 AM EST) -- The Federal Trade Commission is headed by five commissioners, who are nominated by the president and confirmed by the Senate, with the president choosing one commissioner to serve as chairperson. Of the five commissioners, only three can be of the same political party. Commissioners serve a seven-year term. Currently, only three of the commissioner spots are filled, by Chairwoman Edith Ramirez (D), Maureen K. Ohlhausen (R) and Terrell McSweeny (D). Ramirez's term expired on Sept. 25, 2015, and she has continued to serve under an expired term. Chairman Ramirez announced on Jan. 13, 2017, that she intends to step down in the near future, but no later than Feb, 10, 2017. Accordingly, when President-elect Donald Trump assumes office, he will be positioned to immediately nominate three new commissioners — two to fill the two open seats and one to fill the expired seat currently being held by Ramirez. In this regard, he also has the power to designate either a new or existing commissioner as chairperson. Current speculation is that Trump will select Ohlhausen as the next chairwoman, at least in an interim capacity. Additionally, McSweeney's term expires Sept. 25, 2017, positioning Trump to nominate a fourth person as a commissioner as early as the second half of this year.

To date, questions about how the Trump administration will impact the FTC have focused primarily on antitrust issues, without the same focus on consumer protection issues. Clues to how the new administration will affect consumer protection issues might be found by examining the record of former Commissioner Joshua D. Wright, whom Trump has named to lead the FTC transition efforts. Wright was at the FTC from Jan. 11, 2013, until he resigned on Aug. 24, 2015. During this time he pushed for the FTC to provide more transparency and guidance on what constituted unfair and deceptive practices under Section 5 of the Federal Trade Commission Act (Section 5). He also emphasized the importance of economic, data-driven evidence to show consumer harm caused by unfair and deceptive practices.

The sole Republican commissioner currently serving has expressed a similar view in terms of the need for greater clarity as to what constitutes unfair and deceptive practices as well as the need for data and/or scientific evidence substantiation.

An examination of dissents issued by Ohlhausen and Wright from 2015 to the present relating to consumer protection issues emphasizes their view that the FTC needs to substantiate its assertions of Section 5 violations with competent evidence. This is in contrast to the majority in such matters, which placed the burden of evidence substantiation on the respondents that the FTC alleged to have violated Section 5. These dissents are discussed below.

ECM Biofilms Inc.

ECM Biofilms Inc., an Ohio-based company that produces, advertises and sells additive technology for biodegrading plastic,[1] found itself the subject of an FTC administrative action filed in 2013. In the action, the FTC alleged that ECM's advertising regarding the biodegradability of plastics containing ECM additives was false, misleading or not substantiated, in violation of Section 5 of the FTC Act.[2] Although so advertised, the FTC alleged that ECM had no reasonable basis to conclude that the additives would cause plastics to decompose, decompose within nine months to five years or decompose within a reasonably short period of time after customary disposal.

After an administrative trial, the administrative law judge found that some of ECM's representations were false and unsubstantiated, as scientific testing did not prove ECM's claimed biodegradation rate. However, the ALJ also found that ECM's unqualified representation that the additives cause plastics to biodegrade was not deceptive, as there was no implied claim that the plastics would biodegrade in one year. Additionally, reliable, competent scientific evidence showed that the plastics would biodegrade.[3] Both parties filed appeals with the commission. In October 2015, the FTC issued a statement and a final order in the case, partially reversing the ALJ's findings.[4] The commission focused on the implied rate claim, examined the four consumer surveys in the record and found that reasonable consumers would expect "biodegradable" to mean decomposition within five years or less.[5] ECM was ordered to not represent, directly or indirectly, that their products caused biodegradation unless the claims were substantiated by competent and reliable scientific evidence.[6] Enforcement of the final order has been stayed pending review by the Sixth Circuit.[7]

Commissioner Ohlhausen partially dissented from the commission's final order, questioning whether "ECM's unqualified [biodegradability] claim caused reasonable consumers to believe that plastics treated with ECM plastics product would

biodegrade either in a year (the time period in the Green Guides and Complaint Counsel's original position) or between one and five years (the commission majority's interpretation of a reasonably short period)."[8] Her dissent rested on two grounds: first, that the majority improperly relied on flawed evidence by using data from consumer surveys that the ALJ, who had the opportunity to observe the credibility of the experts, had discredited; and second, Ohlhausen argued that the majority "inappropriately interpret[ed] the significant minority exception."[9]

In finding that a significant minority of consumers would understand "biodegradable" to mean decomposition within five years, Ohlhausen argued that the majority cherry-picked data and the applicable number of "reasonable" consumers. Ohlhausen explained that this reduced the reasonableness test "to a mere game of stacking percentages." Rather, Ohlhausen would have required higher levels of substantiated extrinsic evidence "to prove that ECM's unqualified claim [was deceptive and] caused consumers to believe that treated products would biodegrade in either a year or in a period between one and five years."

Health Discovery Corporation and Avrom Boris Lasarow

Health Discovery Corporation (respondent), the developer of MelApp, a consumer-directed software system that purportedly assessed melanoma risk through mathematical algorithms and image-based pattern recognition technology,[10] became the subject of an administrative action filed by the FTC in 2015. The action alleged that, in connection with the advertising, promotion and sale of MelApp, the respondent made false, misleading or unsubstantiated claims in violation of Section 5. For example, the FTC alleged that the respondent represented that MelApp "accurately analyzes moles and other skin lesions" for melanoma and "increases consumers' chances of detecting melanoma in early stages." The FTC also alleged the respondent falsely represented that scientific testing proved these claims.

The commission issued a decision and order prohibiting the respondent from representing that MelApp detects or diagnoses melanoma or associated risk factors or that MelApp increases users' chances of early detection unless substantiated by competent and reliable scientific evidence.[11] The respondent also was enjoined from making representations regarding the efficacy or benefits of the product without relying on competent and reliable scientific evidence, sufficient in quality and quantity based on standards generally accepted in the relevant scientific fields to substantiate that the representation is true. The respondent also was ordered to pay the FTC $17,693.

The FTC also filed suit in the Northern District of Illinois in 2015 against Avrom Boris Lasarow, L Health Ltd., Kristi Zuhlke Kimball and New Consumer Solutions LLC (defendants) for their production, advertisement and sale of "mole detective" apps.[12] As per the defendants, the mole detective apps are "consumer-directed computer software applications that use camera-enabled mobile communication devices" to assess melanoma risk via mathematical algorithms. The FTC alleged that the defendants' representations of accurate symptom analysis and an increase in the chances of early detection were false, misleading or not substantiated in violation of Section 5.

Between April and August 2015, stipulated final judgments were issued against the defendants, permanently enjoining each from making representations regarding the detection of melanoma risks unless substantiated by competent and reliable scientific evidence.[13] In addition, the defendants were prohibited from making representations about the health benefits or efficacy of the product unless relying upon competent and reliable scientific evidence.[14] A monetary judgment was entered against each defendant in favor of the FTC: Kristi Zuhlke Kimball and New Consumer Solutions LLC were ordered to pay $3,930 jointly and severally, while L Health Ltd. and Avrom Boris Lasarow were each ordered to pay $58,623.42.[15]

The commission issued a joint statement for Health Discovery Corp. and Avrom Boris Lasarow, noting its concern with the powerful language of MelApp and mole detective apps advertising.[16] For both products, the majority noted that scientific testing must demonstrate accuracy "at a level appropriate to the claims being made."

Ohlhausen submitted a responding dissent.[17] These matters, she argued, were "another example of the commission using an unduly expansive interpretation of advertising claims to justify imposing an inappropriately high substantiation requirement on a relatively safe product." The final orders and judgments would require undue levels of substantiation for companies, inhibit the development of products and chill the dissemination of useful health information to customers. Instead, Ohlhausen contended, substantiation should be based on the claims made. She further argued that the FTC must determine what claims consumers likely derived from the ads before determining the level of substantiation required. In this case, by implying that reasonable consumers expected the apps to substitute for professional medical care, she argued that the commission had overstepped. She further argued that "[t]he commission should not subject such apps to overly stringent substantiation requirements, so long as developers adequately convey the limitations of their products."

In August 2013, after the commission entered the last stipulated final judgment and order for permanent injunction and other equitable relief in Avrom Boris Lasarow, Ohlhausen entered a second dissent for the same reasons.[18

Genesis Today, Inc.

Genesis Today Inc., Pure Health LLC and Lindsey Duncan (defendants) worked together to market and promote various dietary supplements. In 2015, the FTC filed suit in the Western District of Texas for the advertisement, marketing, promotion and sale of green coffee bean extract (GCBE) in violation of Section 5.[19] The defendants had previously promoted GCBE on "The Dr. Oz Show," relying on the "Oz effect" to sell a substantial amount of the product. In their advertisements, the defendants repeatedly touted the purported results of a study on GCBE, claiming that GCBE would cause consumers to lose substantial weight or cause substantial fat loss without diet or exercise. Among other allegations, the FTC alleged that the defendants' representations were not substantiated and relied upon a clinical study

that did not show GCBE caused the purported weight loss effects.

The defendants stipulated to a final judgment and order for a permanent injunction and other equitable relief. The order prohibited the defendants from representing that GCBE causes, or helps cause, weight loss or fat loss unless substantiated by competent and reliable scientific evidence.[20] Additionally, the defendants were enjoined from making any other representations regarding the health benefits or efficacy of GCBE without relying upon "competent and reliable scientific evidence that is sufficient in quality and quantity based on standards generally accepted in the relevant scientific fields." The commission noted that the speech in question was "squarely commercial," despite the fact that the defendants discussed public concerns.[21] Further, the defendants relied on studies that failed "to substantiate even a claim of modest weight loss." Judgment was entered in the amount of $9 million against the defendants jointly and severally.[22]

Ohlhausen and then-Commissioner Wright, while supporting the complaint against the defendants, dissented from the proposed stipulated order.[23] The dissenting commissioners argued that the majority did not adequately consider two critical considerations in calculating redress. First, the order penalized some protected noncommercial speech. Exacting such a high amount of redress is this case, where not all of the speech was commercial, could "chill the speech of future speakers ... who would otherwise discuss health or nutrition topics ... [as they] may fear being held liable for failing to meet the FTC's rigorous advertising substantiation requirements." The dissent argued that, in protecting consumers, the commission should not suppress all speech about a public concern simply because the speech is unreliable or unproven. Second, the redress failed to take into consideration that GCBE has some mild efficacy in terms of weight loss. Given that even mild weight loss effects can be valuable, failure to account for potentially valuable weight loss effects was improper.

Nomi Technologies Inc.

Nomi Technologies Inc. (respondent) developed and sold technology that allowed retailers to track consumers' movements through retail stores.[24] The technology "hashed" consumers' media access control addresses into a unique identifier for the mobile device. In its privacy policy, Nomi provided two opt-out mechanisms: consumers could opt out on the Nomi website or opt out at participating retail locations. In a 2015 complaint, the FTC alleged that Nomi failed to provide the opt-out mechanism at participating retail locations. Thus, any statements to the contrary were false and misleading in violation of Section 5. The claims were settled in a consent agreement prohibiting the respondent from misrepresenting the extent of consumers' control over their data and the extent to which consumers would be provided notice about how data is collected, used, disclosed or shared.[25]

Both Republican commissioners, Ohlhausen and then-Commissioner Wright, dissented as to the complaint entered against the respondent.[26] Wright also dissented as to the acceptance of a consent decree for public comment.[27] He emphasized that the commission did not have a reason to believe a violation of Section 5 occurred, as there was no evidence to support the allegation that the in-store opt-out mechanism was material to consumers. A deceptive statement under Section 5 requires a representation to be material. Further, there was no injury to consumers. Given that the respondent chose to offer an opt-out policy — which it was not legally required to do — the FTC should have used prosecutorial discretion. "[A]ggressive prosecution," Wright warned, "will inevitably deter industry participants like Nomi from engaging in voluntary practices that promote consumer choice and transparency — the very principles that lie at the heart of the commission's consumer protection mission."

Ohlhausen agreed.[28] The respondent, she noted, "attempted to go above and beyond its legal obligation to protect consumers" in offering an opt-out policy. Although the privacy policy was partly inaccurate, consumers were not harmed by the failure to offer the in-store opt-out option. Ohlhausen also asserted that the FTC should have used prosecutorial discretion, as the final order will only encourage companies to provide the bare minimum on privacy policies. Ohlhausen reiterated these views in a second dissent following the decision and order.[29] De facto strict liability absent consumer harm, she argued, inappropriately punishes companies that act consistently with the FTC's privacy goals. The commission's final decision would work to diminish incentives for transparent privacy policies.

Conclusion

Given Wright's prominent role in leading the FTC transition efforts, it is likely that individuals nominated by Trump to fill open commissioner slots will, like Wright, advocate for placing the burden on the FTC to substantiate Section 5 violation claims with data and/or scientific evidence. Indeed, as the above-discussed dissents illustrate, this view is shared by the current Commissioner Ohlhausen. This would appear to be in contrast to the Democratic majority under the Obama administration, which has generally placed the burden on a company to substantiate why its product and/or advertising is not unfair or deceptive. Accordingly, FTC attorneys likely will be expected to put forward data-driven evidence to substantiate Section 5 violation assertions in any administrative actions they bring.

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[1] About, ECM Biofilms, http://www.ecmbiofilms.com/sustainable-solutions/ (last visited Dec. 7, 2016).

[2] ECM Biofilms Inc., FTC Docket No. 9358 (Oct. 18, 2013), https://www.ftc.gov/sites/default/files/documents/cases/131028ecmbiofilmscmpt.pdf.

[3] Initial Decision, ECM Biofilms Inc., FTC Docket No. 9358 (Jan. 28, 2015), https://www.ftc.gov/system/files/documents/cases/150206ecmdecision-1.pdf.

[4] Final Order, ECM Biofilms Inc., FTC Docket No. 9358 (Oct. 11, 2015) (ECM Final Order), https://www.ftc.gov/system/files/documents/cases/151019ecmorder.pdf.

[5] Opinion of the Commission, ECM Biofilms Inc., FTC Docket No. 9358 (Oct. 19, 2015), https://www.ftc.gov/system/files/documents/public_statements/819651/151019ecmbiofilmsopinioncomm.pdf.

[6] The commission clearly defined "competent and reliable scientific evidence," requiring that degradability claims (i) be substantiated by scientific technical protocol showing complete decomposition within the specified time frame or within one year and (ii) replicate physical conditions found in the type of disposal facility or method stated in the representation. See ECM Final Order.

[7] Order Granting Respondent's Application to Stay Final Order Pending Judicial Review, ECM Biofilms Inc., FTC Docket No. 9358 (Dec. 8, 2015), https://www.ftc.gov/system/files/documents/cases/151208ecmorder.pdf.

[8] Partial Dissent of Commissioner Maureen K. Ohlhausen, ECM Biofilms Inc., FTC Docket No. 9358 (Feb. 23, 2015), https://www.ftc.gov/system/files/documents/public_statements/819661/151019ecmbiofilmsmkopartialdissent.pdf.

[9] Ohlhausen defined the "significant exception" standard, noting that: "To be deceptive, an alleged interpretation of an advertisement must be reasonable ... [A]n interpretation may be reasonable even though fewer than 50 percent of reasonable consumers hold that interpretation." Id. (internal citations omitted).

[10] Health Discovery Corp., FTC File No. 132-3211 (March 30, 2015), https://www.ftc.gov/system/files/documents/cases/150413hdcmelappcmpt.pdf.

[11] The commission required such tests to be "blinded, conform to actual use conditions, and include a representative range of skin lesions; be conducted by researchers qualified by training and experience to conduct such testing; and all underlying data and documents generally accepted by experts in the relevant field as relevant to an assessment of such testing ... must be available for inspection and production to the commission." Decision and Order, Health Discovery Corp., FTC Docket No. C-4516 (Mar. 30. 2015), https://www.ftc.gov/system/files/documents/cases/150413hdcmelappdo.pdf.

[12] See FTC v. Avrom Boris Lasarow, et al., No. 15 C 1614 (N.D. Ill. Feb. 23, 2015), https://www.ftc.gov/system/files/documents/cases/150223avromcmpt.pdf.

[13] For this section, competent and reliable scientific evidence should be sufficient in quality and quantity, based on standards generally accepted by experts in the relevant field, and done by blind testing, conforming to actual use conditions, including a range of skin lesions, and conducted by researchers qualified by training and experience to conduct such testing. See Stipulated Final Judgment and Order for Permanent Injunction and Other Equitable Relief Against Defendant Kristi Zuhlke Kimball and New Consumer Solutions LLC, FTC v. Avrom Boris Lasarow, et al., No. 15 C 1614 (N.D. Ill. April 30, 2015), https://www.ftc.gov/system/files/documents/cases/new_consumer_solutions_5-1-15.pdf; Default Judgment and Order for Permanent Injunction and Other Equitable Relief Against Defendant L Health Ltd., FTC v. Avrom Boris Lasarow, et al., No. 15 C 1614 (N.D. Ill. May 29, 2015), https://www.ftc.gov/system/files/documents/cases/150813moledetectivedefjdgmt.pdf; Stipulated Final Judgment and Order for Permanent Injunction and Other Equitable Relief Against Defendant Avrom Boris Lasarow, FTC v. Avrom Boris Lasarow, et al., No. 15 C 1614 (N.D. Ill. Aug. 13, 2015), https://www.ftc.gov/system/files/documents/cases/150813lasarowstip.pdf.

[14] For this section, competent and reliable scientific evidence is defined as "tests, analyses, research or studies (A) that have been conducted and evaluated in an objective manner by qualified persons; (B) that are generally accepted in the profession to yield accurate and reliable results; and (C) when they are human clinical tests or studies, all underlying or supporting data and documents generally accepted by experts in the field as relevant to an assessment of such testing [as set forth in this order]." See sources cited in Footnote 13.

[15] See sources cited in Footnote 13.

[16] Statement of Chairwoman Ramirez, Commissioner Brill, and Commissioner McSweeny in the Matter of Health Discovery Corporation, File No. 132 3211, and FTC v. Avrom Boris Lasarow, et al., File No. 132 3210 (Feb. 23, 2015), https://www.ftc.gov/system/files/documents/public_statements/626041/150223moledetectiveerjbtmstmt.pdf.

[17] Dissenting Statement of Commissioner Maureen K. Ohlhausen in the Matter of Health Discovery Corporation, File No. 132-3211 and FTC v. Avrom Boris Lasarow, et al., File No. 132-3210 (Feb. 23, 2015), https://www.ftc.gov/system/files/documents/public_statements/626051/150223moledetectivemkodiss-stmt.pdf.

[18]Dissenting Statement of Commissioner Maureen K. Ohlhausen in the Matter of FTC v. Lasarow, et al. (Mole Detective) Matter No. X150035 (Aug. 13, 2015),

https://www.ftc.gov/system/files/documents/public_statements/735351/150813moledetectiveohlhausenstatement.pdf.

[19] FTC v. Genesis Today Inc., et al., No. 1:15-cv-62 (W.D. Tex. Jan. 26, 2015), https://www.ftc.gov/system/files/documents/cases/150126linddunc mpt.pdf.

[20] Stipulated Final Judgment and Order for Permanent Injunction and Other Equitable Relief, FTC v. Genesis Today Inc., et al., No. 1:15-cv-62 (W.D. Tex. Jan. 27, 2015) (Genesis Final Judgment), https://www.ftc.gov/system/files/documents/cases/150126linddunorder.pdf.

[21] Statement of Chairwoman Edith Ramirez, Commissioner Julie Brill, and Commissioner Terrell McSweeny, Federal Trade Commission v. Genesis Today Inc., Pure Health LLC, and Lindsey Duncan (Jan. 26, 2015), https://www.ftc.gov/system/files/documents/public_statements/620651/150126linddunstmter-jb-tm.pdf.

[22] Genesis Final Judgment.

[23] Dissenting Statement of Commissioners Maureen K. Ohlhausen and Joshua D. Wright, Federal Trade Commission v. Genesis Today Inc., Pure Health LLC, and Lindsey Duncan (Jan. 26, 2015), https://www.ftc.gov/system/files/documents/public_statements/620661/150126linddunstmtmko-jdw.pdf.

[24] Nomi Technologies Inc., FTC Docket No. C-4538 (April 23, 2015), https://www.ftc.gov/system/files/documents/cases/150902nomitechcmpt.pdf.

[25] Decision and Order, Nomi Technologies Inc., FTC Docket No. C-4538 (Aug. 28, 2015), https://www.ftc.gov/system/files/documents/cases/150902nomitechdo.pdf.

[26] Although, unlike the other noted dissents, Nomi Technologies Inc. does not relate to data substantiation, it does highlight the broader trend of Republican commissioners placing a high burden of proof on the FTC for complaints and consent agreements. Thus, despite the fact that this case involves a company's privacy policy, it is relevant to this article.

[27] Dissenting Statement of Commissioner Joshua D. Wright in the Matter of Nomi Technologies, Inc. (April 23, 2015), https://www.ftc.gov/system/files/documents/public_statements/638371/150423nomiwrightstatement.pdf.

[28] See Dissenting Statement of Commissioner Maureen K. Ohlhausen in the Matter of Nomi Technologies, Inc. Matter No. 1323251 (April 23, 2015), https://www.ftc.gov/system/files/documents/public_statements/638361/150423nomiohlhausenstatement.pdf.

[29] Dissenting Statement of Commissioner Maureen K. Ohlhausen in the Matter of Nomi Technologies, Inc. Matter No. 1323251 (Aug. 28, 2015), https://www.ftc.gov/system/files/documents/public_statements/799571/150828nomitechmkostatement.pdf.
