ORIGINAL

TRADE COMMISSION

FEB 1 0 2011

SECRETARY

HEARING REQUESTED

UNITED STATES OF AMERICA FEDERAL TRADE COMMISSION

In the Matter of)	
)	
POM WONDERFUL LLC and)	
ROLL INTERNATIONAL CORP.,)	
companies, and) .	Docket No. 9344
)	PUBLIC
)	
STEWART A. RESNICK,)	
LYNDA RAE RESNICK, and)	
MATTHEW TUPPER, individually and)	
as officers of the companies.)	,

RESPONDENTS' RENEWED MOTION TO EXCEED THE FIVE (5) EXPERT LIMIT AND MEMORANDUM IN SUPPORT

Pursuant to Rule 3.31A(b) of the Commission's Rules of Practice, Respondents respectfully renew their request that the Court enlarge the number of expert witnesses that Respondents may designate from five to a maximum of eight. Rule 3.31A(b) empowers the Court to grant this relief. Indeed, when it recently adopted the five-per-side default for "the vast majority of cases," the Commission specifically adopted a "safety valve" allowing for more than five experts when "extraordinary circumstances" exist. *See* FTC Interim Final Rules With Request for Comment, 74 F.R. 1804, 1814 (Jan. 13, 2009); Rule 3.31A(b) ("A party may file a

¹ As noted at the Initial Scheduling Conference, since the outset of this matter Respondents have indicated that the myriad of issues in this case require more than five experts. Complainant's counsel declined to consent to Respondents' request to designate more than five experts and, therefore, on January 28, 2011, Respondents filed a Motion to Exceed the Five Expert Limit. Thereafter, Respondents filed their Expert Witness List with the Court and requested that the Court hold its motion in abeyance so that they could provide additional support for the specific expert testimony reflected in the Expert Witness List. In response to the suggestions in the Court's correspondence on February 4, 2011, Respondents withdrew their initial motion on February 9, 2011, indicating their intent to renew the motion in order to provide additional information regarding the expert testimony required.

motion seeking leave to call additional expert witnesses due to extraordinary circumstances.").

The circumstances of this case are, if anything, extraordinary.

Unlike many advertising substantiation cases where there is a single core claim,

Complainant challenges here a variety of alleged health claims that touch upon multiple, wholly
distinct and independent areas of science. In order to respond meaningfully to the Complainant's
varied allegations, Respondents require expert witnesses from each of the fields of science
implicated by the Complaint. In addition to scientific testimony, and as is common in
advertising substantiation cases, Respondents also will need to designate experts to opine on
consumer responses to the advertisements at issue in this case, the meaning of such
advertisements, and to opine on any interpretation of the ads proffered by Complainant.

In light of the breadth of the issues framed by the Complaint, extraordinary circumstances warrant Respondents' designation of eight expert witnesses. Permitting Respondents to designate these experts will not result in duplicative expert testimony at the administrative hearing, but, rather, will allow Respondents to address the various and diverse allegations in this case. Accordingly, this motion should be granted.

Background

This advertising substantiation case involves an unusual variety of allegations and a truly unprecedented amount of relevant scientific research regarding a botanical food product.

Scope of Issues Framed by the Complaint

Complainant alleges, among other things, that Respondents made unsubstantiated claims in their advertising and promotional materials regarding the health benefits of their pomegranate products ("Challenged Products"). In particular, the Complaint alleges that Respondents made claims, either expressly or impliedly, regarding the benefits that the Challenged Products have on

cardiovascular health and disease, prostate cancer, and erectile dysfunction. With respect to cardiovascular claims, Complainant alleges that Respondents claimed that the Challenged Products would help prevent, treat, or cure heart disease, including blood pressure, blood flow, and could lead to a decrease in arterial plaque. Compl. ¶ 12. Each of these cardiovascular issues involve distinct and areas of specialization and expertise. The Complaint further alleges that, with regard to prostate cancer, Respondents made claims that the Challenged Products would help prevent, treat, or cure prostate cancer, including by prolonging prostate-specific antigen doubling time ("PSADT"). Compl. ¶¶ 14-15, 19(E)-(F). The Complaint also alleges that Respondents made unsubstantiated claims regarding the Challenged Product's ability to prevent, treat, or cure erectile dysfunction. *Id.* ¶¶ 16-17, 19(E)-(F).

The Complaint also identifies more than twenty (20) advertising or promotional pieces, see generally Compl. at Exhibits A-N, and more than eight alleged unsubstantiated claims.

Compl. ¶ 13-16; see also Complaint Counsel's Response to Respondent POM Wonderful LLC's First Set of Interrogatories at 3-12, attached hereto as Exhibit A. Despite Respondents' attempts to get Complaint Counsel to commit to a specific set of ads and claims, Complaint Counsel continues to introduce additional advertisements during depositions and to expand the potential scope of this case.

Respondents have attempted to try to resolve this issue with Complainant Counsel; however, Complainant has declined to consent to any enlargement in the number of experts. Thus, Respondents bring the instant motion.

Argument

The Court should allow Respondents to designate up to eight expert witnesses because the array of allegations in this case -- which touch on distinct areas of science -- coupled with

the number of advertisements referenced in the Complaint involve more than five areas of expertise and, therefore, more than five experts are required for Respondents to cover the waterfront of issues raised by this case. Unlike traditional substantiation cases where there is a central core claim at issue, here, the Complaint alleges that Respondents' made a variety of distinct claims -- each of which require expert testimony.

Scientific Experts

Expert testimony regarding health claims is typical in advertising substantiation cases.

See, e.g., In re Daniel Chapter One, et. al., 2009 WL 5160000 (Dec. 21, 2009) (considering scientific expert testimony (oncology) in evaluating substantiation of cancer treatment claim); In re Kraft, Inc., 114 F.T.C. 40 (1991) (considering scientific expert testimony in evaluating substantiation of ingredient claim); In re Bristol-Myers Co., 102 F.T.C. 21 (1983) (considering clinical and scientific testimony in evaluating substantiation claim for aspirin); In re Sterling Drug. Inc., 102 F.T.C. 395 (1983) (considering scientific expert testimony in ad substantiation case). For example, in Daniel Chapter One, a case that concerned whether the respondents' product was an effective therapy for cancer treatment, this Court considered the expert opinion of Dr. Denis Miller, a medical doctor with specialization in oncology to evaluate the substation for the alleged cancer treatment claims. Unlike Daniel Chapter One, here, Complainant has not only alleged that Respondents' made cancer treatment claims, but they also contend that Respondents' made unsubstantiated claims regarding cardiovascular issues (including blood pressure, blood flow, and arterial thickness) and regarding the benefits of the Challenged

² Dr. Miller was designated in that case by the complainant. This Court criticized the expert testimony offered by respondents in *Daniel Chapter One*, as the respondents failed to designate a scientist appropriately qualified to opine on the support for the alleged cancer claims. Unlike the respondents in *Daniel Chapter One*, here Respondents will introduce testimony from leading experts in the various fields of science referenced in the Complaint.

Products in treating erectile dysfunction. Other Commission advertising substantiation cases have also typically involved only a single core claim. *E.g., In re Daniel Chapter One, et al.* 2009 WL 5160000 (alleging unsubstantiated cancer and tumor treatment claims); *In re Novartis Corp., et. al.*, 1998 WL 34060101 (1998) (alleging unsubstantiated efficacy claim relating to back pain); *In re Telebrands Corp., et al.*, 140 F.T.C. 278 (2005) (alleging claim of weight loss and abdominal benefits); *In re Kraft, Inc.*, 114 F.T.C. 40 (1991) (alleging unsubstantiated claims regarding product ingredient). As noted above, however, the Complaint here contains allegations touching on many distinct and independent areas of science.

Human Nutrition and Health Properties of the Challenged Products

As set forth in Respondents' Answer and as Respondents further noted at the initial Scheduling Conference before the Court, there is a vast array of scientific research demonstrating the healthy properties of the Challenged Products. To demonstrate the healthy properties of the Challenged Products and, specifically, that there was more than adequate scientific substantiation to support Respondents' health claims, Respondents are entitled to offer expert testimony regarding the general nutritional and healthy properties of the Challenged Products, including the benefits of antioxidants present in the Challenged Products. Specifically, such expert testimony will discuss, among other things, the mechanisms of action, bioavailability and metabolism of pomegranate polyphenols in the human body, and the way that such polyphenols relate to antioxidation and inflammation.

³ Indeed, the parties' ability to elicit testimony from the many scientists and researchers who performed research on the Challenged Products about that work will be crucial here: otherwise Respondents would need even more experts to review and opine on this material. As counsel noted at the initial scheduling conference, counsel for Respondents is working with Complaint Counsel to clarify the ground rules for that testimony to avoid issues under Federal Rule of Evidence 701.

It is particularly noteworthy that in their initial designation of experts, Complaint Counsel not only designated experts to address specific issues relating to prostate cancer, erectile dysfunction and cardiovascular disease, but also a Professor of Epidemiology and Nutrition. *See* Complaint Counsel's Expert Witness List, attached as Exhibit B. Respondents agree (without knowing the substance or details of the testimony to be offered by this witness) that such a broad perspective is appropriate when evaluating the health benefits of a natural product such as pomegranate juice. Respondents therefore will require a scientific expert to provide an explanation of the nutritional benefit and role of the Challenged Products and to rebut the testimony of Dr. Stampfer, who has been designated as an expert by Complainant.

Expert Testimony on the Role of the Challenged Products with Regard to Cardiovascular Claims

Complainant has put at issue a myriad of cardiovascular issues in this case, including allegations that Respondents claimed the Challenged Products treat, cure, and prevent cardiovascular disease, including high blood pressure and arterial thickness. In order to meaningfully respond to these allegations, Respondents will need to introduce expert testimony as to the role of the Challenged Products in the separate areas of cardiovascular health implicated by the Complaint. Expert testimony is also required to interpret the vast array of literature involving the cardiovascular benefits of pomegranate on cardiovascular health.

Expert Testimony on the Role of the Challenged Products and Erectile Dysfunction

In addition to the variety of cardiovascular issues that Complainant has put at issue in this case, the Complaint also alleges that Respondents made claims that the Challenged Products treat, cure, or prevent erectile dysfunction. In order to respond to such allegations, Respondents will need to introduce expert testimony regarding the effect of the Challenged Products in these areas.

Expert Testimony on the Complex Chemistry of Nitric Oxide

Expert testimony is also needed in order to explain the role that chemical compounds, specifically nitric oxide (NO), play in erectile dysfunction and with regard to blood flow. The complex science regarding nitric oxide is relevant to both erectile dysfunction issues and cardiovascular issues, including because a lack of nitric oxide affects the level of oxygen that is delivered to blood tissues and can restrict blood flow. Thus, Respondents will also need to introduce expert testimony to elaborate the role that the Challenged Products play in protecting nitric oxide against oxidative destruction and to interpret the scientific literature regarding the effect that pomegranate products have on the availability of nitric oxide in the human body.

Expert Testimony on The Role of The Challenged Products in Prostate Health

Complainant has also alleged that Respondents made claims that the Challenged Products treat, prevent, and cure prostate cancer. Respondents therefore require expert testimony regarding the nutritional and chemical properties of the Challenged Products and their role with regard to prostate health.

Expert Testimony Regarding the Level of Substantiation Required for Health Claims

In addition to introducing expert testimony regarding the properties of the Challenged

Products, Respondents will also need to introduce testimony regarding the level of substantiation
required for the alleged claims. The Complainant has put at issue how "competent and reliable
scientific evidence," the Commission's traditional standard for advertising substation, should be
applied to food marketing -- both as to liability and remedy. As only one example, Complainant
alleges that Respondents have represented that the Challenged Products treat, prevent, or cure
prostate cancer by prolonging prostate-specific antigen doubling time ("PSADT"), but dispute
the validity of such claims and critique the criteria by reference to FDA's drug approval

standard. Expert testimony regarding the level of substantiation required for these claims, including the appropriateness of PSADT as an endpoint, is required for a meaningful evaluation of these allegations.

As demonstrated in the sections above, the array of allegations in this case coupled with the vast body of scientific literature regarding the healthy properties of the Challenged Products presents the requisite extraordinary circumstances under Rule 3.31A(b), which empowers the Court to extend the number of expert witnesses. The scientific expert testimony proffered by Respondents will not be duplicative; rather, it will address the myriad complex scientific matters at issue in this case. Complainant implicitly acknowledges the need for at least four of these experts, as they, too, have designated experts to opine on the nutritional properties, cardiovascular properties, erectile dysfunction properties, and prostate properties of the Challenged Products. *See, e.g.,* Ex. B. Respondents are entitled to present their own expert testimony on these areas, and also on the complex nature of nitric oxide and on the general substantiation for health claims, as these issues also involve distinct areas of expertise.

Consumer Science and Marketing Expert Testimony

This Court routinely considers the testimony of consumer science and marketing experts to help determine the meaning of advertisements and claims at issue in advertising substantiation cases. Where, as here, the Complaint alleges that certain claims were made implicitly by the advertisements at issue, the Court looks to extrinsic evidence regarding the advertisements' meaning, including "expert opinion as to how an advertisement might reasonably be interpreted, copy tests, generally accepted principles of consumer behavior, surveys, or 'any other reliable evidence of consumer interpretation." *In re Telebrands Corp.*, et. al., 140 F.T.C. 278, 290-291 (2005) (citing *Cliffdale Associates*, 103 F.T.C. 110, 166 (1984); *In re Thompson Medical Co.*,

104 F.T.C. 648, 789-90 (1984) (expert testimony; consumer survey), aff'd, 791 F.2d 189 (D.C. Cir. 1986), cert. denied, 479 U.S. 1086 (1987); In re Novartis, 127 F.T.C. 580, 611-12, 617-33, 682-84 (expert testimony; copy tests); In re Kraft, 114 F.T.C. 40, 121-22 (expert testimony; copy tests); In re Figgie Internat'l, Inc., 107 F.T.C. 313, 337-39, 377 n.10 (1986) (expert testimony), aff'd, 994 F.2d 595 (9th Cir. 1993), cert. denied, 510 U.S. 1110 (1994)).

In many cases, parties have put forth numerous experts to, among other things, opine on the reasonable consumer interpretation of advertisements, interpret consumer surveys that have conducted to evaluate the message presented by such advertisements, and to evaluate whether the claims at issue were material to customers' purchasing decisions. For example, in *In re Novartis Corp.*, et. al., 1998 WL 34060101 (1998), this Court considered the opinion of seven experts in determining the meaning of the advertisements at issue -- five of which were designated by respondents.

In this case, which involves more claims and distinct scientific areas of inquiry than in *Novartis*, Respondents will need to introduce expert testimony regarding (1) the advertisements themselves (including linguistic and semiotics analysis) and also (2) regarding the way in which consumers interpret such advertisements, including whether the alleged claims are material to their decisions to purchase the Challenged Products. Respondents believe that they will need at least two experts to present this testimony, as it involves at least two distinct fields of expertise. This is reasonable in light of the fact that in many less complex advertising cases numerous consumer experts have been designated. *E.g.*, *In re Novartis Corp.*, *et. al.*, 1998 WL 34060101 (1998) (designation of five consumer research experts by respondent), *In re Kraft, Inc.*, 114 F.T.C. 40 (1991) (designation of three consumer research experts by complainant).

Equitable Considerations

Granting this motion will not prejudice Complainant, who will have the opportunity through rebuttal to respond to expert testimony offered by Respondents. Moreover, Respondents are willing to consent to the Complainant designating more than five experts if it can demonstrate the need for such witnesses. In contrast to the Complainant, who will not be prejudiced if this motion is granted, Respondents will be highly prejudiced if they are not able to present expert testimony regarding the array of advertisements and claims at issue and the scientific substantiation supporting their claims.

Conclusion

For the foregoing reasons, Respondents' motion should be granted. Respondents respectfully request a hearing on this motion.

Respectfully Submitted,

/s John Graubert

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Counsel for Respondents

EXHIBIT A

REDACTED

EXHIBIT B

REDACTED

UNITED STATES OF AMERICA FEDERAL TRADE COMMISSION

COMMISSIONERS:	Jon Leibowitz, Chairman William E. Kovacic J. Thomas Rosch Edith Ramirez Julie Brill		
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POM WONDERFUL LLC	and)	
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STEWART A. RESNICK,)	
LYNDA RAE RESNICK, a	and)	
MATTHEW TUPPER, ind	ividually and)	
as officers of the companies	•)	

CERTIFICATE OF SERVICE

I hereby certify that this is a true and correct copy of the PUBLIC version of Respondents' RENEWED MOTION TO EXCEED THE FIVE (5) EXPERT LIMIT AND MEMORANDUM IN SUPPORT, and that on this 10th day of February, 2011, I caused the foregoing to be served by FTC E-File and hand delivery on the following:

Donald S. Clark
The Office of the Secretary
Federal Trade Commission
600 Pennsylvania Avenue, NW
Rm. H-135
Washington, DC 20580

The Honorable D. Michael Chappell Administrative Law Judge Federal Trade Commission 600 Pennsylvania Avenue, NW Washington, DC 20580

I hereby certify that this is a true and correct copy of the PUBLIC version of Respondents' **RENEWED MOTION TO EXCEED THE FIVE (5) EXPERT LIMIT AND MEMORANDUM IN SUPPORT**, and that on this 10th day of February, 2011, I caused the foregoing to be served by e-mail on the following:

Mary Engle Associate Director for Advertising Practices Bureau of Consumer Protection Federal Trade Commission 601 New Jersey Avenue, NW Washington, DC 20580

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Dated: February 10, 2011