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

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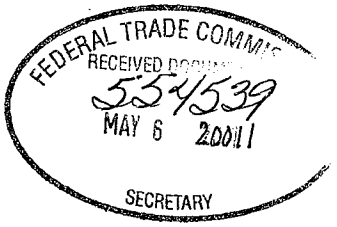

In the Matter of	)	
POM WONDERFUL LLC and ROLL GLOBAL LLC, as successor in interest to Roll International Corporation, companies, and	)	DOCKET NO. 9344
STEWART A. RESNICK, LYNDA RAE RESNICK, and MATTHEW TUPPER, individually and as officers of the companies.	)	

ORDER ON COMPLAINT COUNSEL'S MOTION FOR *IN CAMERA* TREATMENT FOR CERTAIN DOCUMENTS PRODUCED BY THE FOOD AND DRUG ADMINISTRATION

I.

Pursuant to Rule 3.45(b) of the Commission's Rules of Practice and the October 26, 2010 Scheduling Order entered in this matter, on April 20, 2011, Complaint Counsel filed a motion seeking *in camera* treatment of certain documents produced by the Food and Drug Administration ("Motion"). Complaint Counsel represents that Respondents' counsel stated that while Respondents have no objection to Complaint Counsel's filing of this Motion, Respondents' counsel take no position on the substantive statements contained therein. As set forth below, the Motion is GRANTED.

II.

Under Rule 3.45(b) of the Federal Trade Commission ("FTC")'s Rules of Practice, the Administrative Law Judge may order that material "be placed *in camera* only after finding that its public disclosure will likely result in a clearly defined, serious injury to the person, partnership or corporation requesting *in camera* treatment." 16 C.F.R. § 3.45(b). Accordingly, in proceedings at the Federal Trade Commission, "requests for *in camera* treatment must show 'that the public disclosure of the documentary evidence will result in a clearly defined, serious injury to the person or corporation whose records are involved.'" *In re Kaiser Aluminum & Chem. Corp.*, 103 F.T.C. 500, 500 (1984), quoting *In re H. P. Hood & Sons, Inc.*, 58 F.T.C. 1184, 1188

(1961). Under Commission Rule 3.45(b)(3), indefinite *in camera* treatment is warranted only "in unusual circumstances," including circumstances in which "the need for confidentiality of the material . . . is not likely to decrease over time." 16 C.F.R. § 3.45(b)(3). In order to sustain the burden for withholding documents from the public record, an affidavit or declaration is required. *In re North Texas Specialty Physicians*, 2004 FTC LEXIS 109, at *2-3 (Apr. 23, 2004).

III.

Complaint Counsel states that the documents for which it seeks *in camera* treatment were provided to the FTC by the Food and Drug Administration ("FDA") pursuant to a letter of understanding between the agencies and subject to a federal regulation, 21 C.F.R. § 20.85, that prohibits public disclosure of such material without the FDA's written permission. Complaint Counsel further asserts that the documents at issue are materials submitted as part of Investigational New Drug ("IND") applications filed with the FDA by Respondent POM Wonderful, LLC ("POM"). As described by Complaint Counsel, the documents include correspondence between the FDA and POM, as well as other competitively sensitive information from the IND applications. Complaint Counsel further states that these materials reveal the existence of non-public INDs and include competitively sensitive information provided by POM to the FDA.

Complaint Counsel includes, in support of the Motion, the Declaration of Nancy B. Sager, Director of the Division of Information Disclosure Policy, Center for Drug Evaluation and Research, United States FDA ("Sanger Declaration"). Sanger avers that the materials that the FDA provided to the FTC are, or relate to, documents from, about, or relating to two INDs sponsored by POM. Sanger further avers that IND and IND-related submissions typically include proprietary information, including clinical trial protocols, plans and data, as well as proposed labeling, manufacturing, formulation information, and/or other trade secret or confidential commercial information.

According to the Sanger Declaration, FDA's regulation 21 C.F.R. § 20.85 provides that, with limited exception, FDA records that are otherwise exempt from public disclosure may be disclosed to other Federal Government departments and agencies and that such record(s) will not be further disclosed without the FDA's written permission. Sanger further avers that, pursuant to 21 C.F.R. § 312.130(a), the FDA is prohibited, without temporal limit, from publicly disclosing the existence of an IND "unless it has previously been publicly disclosed or acknowledged."[1] Sanger further states that even when the existence of an IND has been publicly disclosed, generally "no data or information in the application . . . is available for public disclosure before the agency sends an approval letter." Sanger affirms that the FDA cannot consent to public disclosure of these materials in this proceeding. In addition, Sanger avers, the FDA is legally prohibited from producing to the public POM's IND documents under the Trade

[1] In the public version of their own motion for *in camera* treatment, filed April 20, 2011, Respondents have disclosed that they submitted materials to the FDA in support of INDs. Thus, the fact that Respondents have filed INDs has already been publicly disclosed.

Secrets Act, 18 U.S.C. § 1905 and FDA regulations, 21 C.F.R. § 20.61.

In its proposed order, Complaint Counsel seeks *in camera* treatment be extended "until such time as the [FDA] provides written permission for further release of any nonpublic information contained therein." The Sanger affirmation states that the prohibition on the release of this information is "without temporal limit . . . ."

Under the circumstances presented here, where federal regulations prohibit a federal agency from disclosing information, prevention of a clearly defined, serious injury has been codified, and *in camera* treatment, for an indefinite period, is appropriate. Accordingly, the request for *in camera* treatment is granted for the documents provided to the FTC by the FDA, designated as: FTC-0007436-7797; FTC-0013759-13802; and FTC-0013804-15288.

IV.

The materials submitted do not make clear the trial exhibit numbers assigned to the above referenced documents. Therefore, Complaint Counsel is instructed to develop a list of these documents that indicates by CX or RX the proposed exhibit numbers for which *in camera* treatment has been granted by this Order. In addition, because *in camera* treatment is appropriate only for information that is offered into evidence, after the conclusion of the final prehearing conference, the parties shall prepare a joint proposed order, with a signature line for the Administrative Law Judge, listing by exhibit number the documents that, by this Order, have been granted *in camera* treatment and setting forth the expiration date of *in camera* treatment for each exhibit.

ORDERED:

D M Chappell

D. Michael Chappell
Chief Administrative Law Judge

Date: May 9, 2011