IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND
(SOUTHERN DIVISION)

UNITED STATES OF AMERICA	:	
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Petitioner	:	
	:	
v.	:	**Misc. No. _____**
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RANBAXY, INC.,	:	
	:	
and	:	
	:	
PAREXEL CONSULTING	:	
	:	
Respondents.	:	

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MOTION TO ENFORCE SUBPOENAS AND POINTS AND AUTHORITIES

The United States of America, by its undersigned counsel, hereby moves to enforce administrative subpoenas, pursuant to 18 U.S.C. § 3486(c), directed at Ranbaxy, Inc., for itself and related corporate entities, and PAREXEL Consulting. The subpoenas seek records that are relevant to an investigation currently being conducted by the United States Department of Justice, through the United States Attorney's Office for the District of Maryland and the Civil Division, Office of Consumer Litigation, into the practices of Ranbaxy, Inc. Ranbaxy has asserted that the materials that are the subject of this Motion are protected from production by attorney-client and work-product privileges. The government disagrees that any privilege attaches to these documents.

I. SUMMARY

Ranbaxy Laboratories Limited ("RLL") is a public pharmaceutical company based in Gurgaon, India. Established in 1961, Ranbaxy is India's largest domestic pharmaceutical company and ranks

within the top ten largest generic drug manufacturers in the world. PAREXEL Consulting is an independent division of PAREXEL International Corp., a publicly-traded company that provides various services worldwide to biotechnology, pharmaceutical, and medical device industries.

In February 2006, the FDA inspected Ranbaxy's plant in Paonta Sahib, India and issued a Warning Letter as a result of significant violations from FDA regulations. At about the same time, Ranbaxy, ostensibly through counsel, retained PAREXEL Consulting to review its operations and to recommend means to bring Ranbaxy into compliance. In the process, PAREXEL created various audits involving Ranbaxy's manufacturing processes and business practices. The government served Ranbaxy and PAREXEL with administrative subpoenas under the Health Insurance Portability and Accountability Act ("HIPAA"), 18 U.S.C. § 3486, for these audits, and backup documentation, which are the subject of the instant motion.

The government is investigating Ranbaxy and certain of its employees concerning possible violations of federal laws pertaining to failure to comply with federal statutes, including the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 *et seq*., and provisions of Title 18 of the United States Code, as well as federal regulations. The government has reason to believe that these violations have resulted and continue to result in the introduction of adulterated and misbranded products into interstate commerce with the intent to defraud or mislead, in violation of 21 U.S.C. §§ 331(a) and 333(a)(2). The investigation also involves allegations of conspiracy, 18 U.S.C. § 371, false statements, 18 U.S.C. §§ 1001 and 1035, health care fraud, 18 U.S.C. § 1037, all relating to health care benefit programs, and other possible violations. The government is also investigating whether Ranbaxy committed contract fraud and caused the submission of false claims to Federal health benefit programs

under the False Claims Act. 31 U.S.C. § 3729 *et seq*.

Allegations from reliable sources and supporting documents indicate a pattern of systemic fraudulent conduct, including submissions by Ranbaxy to the FDA that contain false and fabricated information about stability and bioequivalence, failure to timely report the distribution of drugs that were out-of-specification ("OOS"), and attempts to conceal violations of current Good Manufacturing Practices ("cGMP") regulations from the FDA. Specific allegations under investigation include fabricating bioequivalence and stability data to support Abbreviated New Drug Applications ("ANDAs") filed with the FDA for generic drugs to be distributed in the United States, and also for anti-retroviral drugs ("ARVs") paid for by the President's Emergency Plan for Aids Relief ("PEPFAR") program and distributed to foreign countries. The government is investigating whether Ranbaxy failed to maintain and/or destroyed data that it was required to preserve, falsified data, and failed to follow cGMP with respect to quality control in the manufacture of active pharmaceutical ingredients ("API")[1] and finished products.

The government is investigating whether Ranbaxy's actual practices have been consistent with representations made to the FDA by the company. Drug manufacturers are required to make certain representations in ANDAs and in annual reports to the FDA. Ranbaxy is required to identify the source of API (whether Ranbaxy or a third party vendor) and the site of manufacture.[2] Evidence suggests that

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[1]Active Pharmaceutical Ingredient, or API, is any substance or mixture of substances used to manufacture a drug that supplies pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of diseases.

[2]Ranbaxy purchases approximately 20% of API used in its generic drugs from other sources. Ranbaxy obtains all API for ARVs from third parties.

Ranbaxy uses API from unapproved sources, blends unapproved API with approved API, and uses less API in its drug than had been approved by the FDA. Any of these conditions would cause a drug to be subpotent, superpotent, or adulterated. Ranbaxy is also required to identify a particular plant as the only site of manufacture for finished drug products. Manufacturers are required to use approved manufacturing sites and approved API sources, which have been subjected to FDA inspections, to ensure that drugs meet established standards. Evidence suggests that Ranbaxy manufactures products at other plants and obtains API from unapproved sources to accommodate corporate convenience, resources, and priorities.

As a result of an FDA inspection of the Paonta Sahib plant, 2006, the FDA imposed a compliance hold on agency approval of Ranbaxy's ANDAs originating from that plant. Over the course of several months, Ranbaxy released substantial information about the PAREXEL audits and, on some occasions, actual portions of the audits, attempting to persuade the FDA to lift the hold. In the process, Ranbaxy waived any privilege that arguably might have attached to the audits. Still, the company continues to assert privilege as to some of the audit documents, and these baseless privilege assertions have significantly impeded the government's investigation. Compliance with the subpoenas follows this path: PAREXEL first produces audit documents responsive to the subpoena to Ranbaxy. Ranbaxy's counsel then perform interminable privilege reviews to attempt to separate those documents that the company maintains are still privileged from those which it must concede are not because the audits have already been produced to the government in some form. This process is not only unjustified as a matter of law, but it has caused lengthy delays in document production and, accordingly, in the government's investigation.

The PAREXEL audits, including drafts and workpapers, will provide evidence about the conditions and activities in Ranbaxy's plants in India that is directly relevant to the government's investigation. These documents should be produced because the audits are not privileged. First, PAREXEL did not translate complicated, technical regulatory concepts so that counsel could provide legal advice to Ranbaxy. Moreover, Ranbaxy always intended to disclose to the FDA its communications with PAREXEL, at least those communications that advanced the company's business interests. Finally, even assuming the PAREXEL audits were privileged, Ranbaxy waived any privilege by selectively disclosing to the government those parts of the audits that Ranbaxy considered helpful in its efforts before the FDA.

Therefore, the government moves for an Order directing Ranbaxy and PAREXEL to comply fully and promptly with the subpoenas and to produce all responsive audit documents. This memorandum sets forth the facts and law supporting judicial enforcement of the subpoenas duces tecum.

II. FACTUAL BACKGROUND

A. The Subpoenas to Ranbaxy and PAREXEL for the Audit Documents

On December 4, 2007, the government served Ranbaxy, through counsel, with the administrative subpoena that is attached hereto as Exhibit 1.[3] The subpoena directs Ranbaxy to produce, among other things:

> 10. All internal or external audits of the complaint and adverse event investigation and reporting procedures, manufacturing processes and testing of drug products, including annual product reviews.

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[3] Exhibit 1 expanded some language, including reference to specific drugs, contained in a first subpoena served on Ranbaxy on March 8, 2007, but left this request unchanged.

On September 21, 2007, the government served PAREXEL Consulting with the administrative subpoena that is attached hereto as Exhibit 2.[4] The subpoena directs PAREXEL to produce:

> 1. All documents relating to any audit, study, review, or other assessment of Ranbaxy, including but not limited to:
>
> a. Documents relating to Ranbaxy's laboratory program and practices, quality control/quality assurance program, manufacturing processes, standard operating procedures, drug product testing, cGMP practices, and inventories.
>
> b. Interviews, reports, summaries, workpapers, notes, memoranda, correspondence, spreadsheets, electronic mails, and minutes of meetings, including all drafts.

The subpoenas to Ranbaxy and PAREXEL were issued under the authority of the Health Insurance Portability and Accountability Act ("HIPAA"), 18 U.S.C. § 3486, to facilitate a federal criminal investigation relating to allegations of health care fraud. Section 3486 authorizes the Attorney General or his designee to issue subpoenas "in any investigation relating to any act or activity involving a Federal health care offense." Judicial enforcement of such a subpoena is proper when "the inquiry is within the authority of the agency, the demand is not too indefinite and the information sought is reasonably relevant." *United States v. Morton Salt Co.*, 338 U.S. 632, 652 (1950). Courts, including the Fourth Circuit, have routinely enforced administrative health care subpoenas. *See In re Subpoena Duces Tecum*, 228 F.3d 341 (4th Cir. 2000); *Fresenius Medical Care v. United States*, 526 F.2d 372 (8th Cir. 2008); *Doe v. United States*, 253 F.3d 256 (6th Cir. 2001).

Ranbaxy has not complied fully with the subpoena for the PAREXEL audits and has asserted

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[4] Exhibit 2 is identical to a first subpoena served on PAREXEL on May 8, 2007, except that it omits the limitation regarding the FDA's Warning Letter dated June 15, 2006.

attorney-client and work product privileges without legal justification. Moreover, Ranbaxy has dictated PAREXEL's response to its subpoenas and has directed PAREXEL to withhold certain audits and workpapers on the basis of privilege. As discussed more fully below, Ranbaxy has no legitimate basis to assert any privilege, with the possible exception of limited opinion work product immunity, which may extend to a few documents.

B. The Ranbaxy Corporate Entities

Through its various entities[5], Ranbaxy manufactures, markets, and distributes generic and brand drugs, in the forms of finished products and API, to treat high cholesterol, hypertension, diabetes, seizures, infections, and other conditions. Ranbaxy's products are sold in more than one hundred countries and manufactured in eleven countries, including the United States, which is Ranbaxy's largest market. Global sales in 2007 exceeded $1.51 billion, with U.S. sales alone contributing approximately $390 million.[6]

As a generic pharmaceutical company doing business in the United States, Ranbaxy and its subsidiaries supply drugs paid in whole or part by Medicare, Medicaid, and other Federal health benefits programs in addition to private insurers. Ranbaxy also manufactures generic ARVs used to treat HIV/AIDS. The President's Emergency Plan for Aids Relief , or PEPFAR, funds the manufacture and

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[5]Ranbaxy Pharmaceuticals, Inc. ("RPI") is a wholly owned subsidiary of RLL with operations in New Jersey, Florida, and New York. Ohm Laboratories, Inc. ("Ohm") is a subsidiary of RPI located in New Jersey. Ranbaxy Laboratories, Inc. ("RLI") is another subsidiary located in New Jersey and is the branded prescription division of the RLL in the United States. Another subsidiary, Ranbaxy USA, Inc., is located in Florida.

[6]Ranbaxy Laboratories Ltd., 2007 Annual Report 12 (2008), *available at* http://www.ranbaxy.com/investorinformation/annual_pr2007.aspx

distribution of some of Ranbaxy'S ARVs in certain foreign countries, as do international organizations such as The World Health Organization, The World Bank, and UNICEF, to which the United States contributes funding, and non-profit foundations such as the William J. Clinton and Bill and Melinda Gates Foundations.

Ranbaxy operates several manufacturing sites within India, all in locations remote from urban centers. Finished drug products and API, some shipped to the United States, are manufactured at Paonta Sahib and Dewas. Finished drug products and API are also produced at the Toansa and Mohali plants.

C. The FDA's Requirements for Generic Drugs

The FDA is responsible for assuring that drugs are safe and effective for their intended uses. To legally market a drug intended for interstate commerce, a manufacturer is required to comply with all applicable provisions of the FDCA and its implementing regulations. A generic manufacturer submits Abbreviated New Drug Applications, or ANDAs, for approval of generic versions of approved "innovator" drug products. 21 U.S.C. § 355(j). ANDA applicants need not submit clinical data to demonstrate the safety and efficacy of the generic product[7] but can rely on the FDA's previous findings that the innovator product is safe and effective. The generic manufacturer must demonstrate that the generic drug is bioequivalent to the innovator drug, meaning that it can be expected to have the same pharmacological effect when substituted for the brand name product. The generic drug also must be

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[7] Generic drugs account for approximately 60% of prescriptions filled in the United States. As much as 20% of finished generic prescription and over-the-counter drugs, and more than 40% of active pharmaceutical ingredient ("API") in pills manufactured in the United States, come from India and China. Within 15 years, it is projected that as much as 80% of the API used in the United States will be derived from sources in India and China. http://www.washingtonpost.com/wp-dyn/content/article/2007/06/16/AR2007061601295.html

stable, meaning that it will remain potent and unchanged until the expiration date.

Generic drug manufacturers, whether located in the United States or abroad, must comply with the FDA's Current Good Manufacturing Practices ("cGMP") set forth at 21 C.F.R. § 211 *et seq.*, in order to market and sell products in the United States. These provisions regulate the control, management, and documentation of manufacturing and quality testing of generic drugs. Deviations from cGMP mean that the generic drug is deemed adulterated within the meaning of section 501(a)(2)(B) of the FDCA. 21 U.S.C. § 351(a)(2)(B).

The FDCA authorizes civil and criminal penalties for violations of the statute or the FDA's implementing regulations. 21 U.S.C. §§ 331, 333. Moreover, the FDA is authorized to withdraw an ANDA if "approval was obtained, expedited, or otherwise facilitated through bribery, payment of an illegal gratuity, or fraud or [a] material false statement." 21 U.S.C. § 335c(a)(1). The FDA ensures that drug manufacturers comply with the FDCA and FDA regulations through inspections and audits of drug manufacturing facilities, including international sites.

D. Chronology of the FDA Inspections of Paonta Sahib, the PAREXEL Contracts, and Ranbaxy's Responses

1. Events in 2006

After notifying Ranbaxy management,[8] the FDA conducted an inspection of Ranbaxy's finished drug product manufacturing facility in Paonta Sahib from February 20 through 25, 2006. The inspection revealed significant deviations from cGMP regulations. At the close of the inspection, the FDA

[8] As a practical matter, foreign drug manufacturers have four to six weeks notice of, and accordingly the opportunity to prepare for, the FDA inspections.

presented Ranbaxy management officials with an Inspectional Observations Form (called an FDA 483), a standard form that is issued by inspectors upon observation of significant objectionable conditions and regulatory violations. Exhibit 3.

Ranbaxy responded to the FDA several times in writing about the violations noted in the 483. The FDA determined that those responses were inadequate and issued a Warning Letter[9] to Ranbaxy on June 15, 2006. Exhibit 4. The Warning Letter identified relevant cGMP violations including the failure to include complete drug testing data, insufficient documentation to demonstrate that stability tests were valid, and the lack of sufficient laboratory personnel and instrumentation in the Quality Control Unit to conduct drug stability testing. The Warning Letter also reflected that until the FDA confirmed the correction of deficiencies and compliance with cGMPs, the inspection office would recommend withholding approval of ANDAs for drugs and API manufactured at Paonta Sahib. Exhibit 4 at p. 6.

After the inspection, but before the Warning Letter was issued, PAREXEL commenced consulting work for Ranbaxy under the terms of a letter agreement from Kate Beardsley, an attorney with the law firm of Buc & Beardsley, to Ronald F. Tetzlaff, PhD, Corporate Vice President for PAREXEL, dated May 11, 2006. The agreement states that the law firm

> would like to retain PAREXEL International LLC ("Consultant") to assist us in providing legal advice to our client, Ranbaxy . . . in connection with Client's compliance with FDA's Good Manufacturing Practices regulations. [Ranbaxy] is facing the possibility of enforcement action, its pending ANDAs have been placed on hold, and the Firm is advising Client with respect to these issues.

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[9]A Warning Letter is a public document and the principal means by which the FDA provides notice of violations to the drug industry.

See Exhibit 5.[10] PAREXEL internally identified this work for time accounting and billing purposes as Project 81937. Ranbaxy paid all fees associated with this work.

After the Warning Letter was issued, Ranbaxy and the FDA communicated regularly by letter and during face-to-face meetings. In his August 29, 2006, letter to the FDA, Alok Ghosh, Vice President of Global Quality for Ranbaxy wrote:

> We have retained Ron Tetzlaff and his colleagues at PAREXEL Consulting (PAREXEL) to verify that our stability laboratory program improvements are effective and systemic, and to verify the effectiveness of our commitments made in response to the Warning Letter. PAREXEL's assessment began during the week of July 10, and is continuing. In addition, PAREXEL will provide expert input to help evaluate our quality systems more generally.

Exhibit 6 at p. 1. In response to specific concerns raised in the Warning Letter, Ghosh further wrote that PAREXEL had verified documented training records for all responsible laboratory personnel and would review and evaluate in-depth laboratory practices and SOPs (Standard Operating Procedures):

> On July 10, 2006, a team of PAREXEL consultants (Dr. Ronald Tetzlaff, Jack Goodson, and Jim Evans, all of whom are former FDA investigators with more than 25 years FDA experience each) initiated an audit at the Paonta Sahib facility including a review of the documentation systems used to record sample storage conditions. Since then, two more PAREXEL consultants have joined the team. The PAREXEL audit of the Stability and QC [Quality Control] Laboratories is currently in progress. When completed, Ranbaxy will carefully consider the audit findings and will take appropriate actions.

Exhibit 6 at pp. 5-6.

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[10]The agreement was amended to outline the scope of work, which Ranbaxy counsel redacted from the version provided to the government, and to assign a $1,050,000 cost ceiling. The agreement was again amended effective December 7, 2006, apparently to revise the scope of work, also redacted in the copy provided to the government, and to increase the cost ceiling to $1.8 million. A third amendment effective February 27, 2007, increased the ceiling to $2.8 million. *See* Exhibit 5, Amendments 1, 2, and 3.

Ghosh assured the FDA that, with a few exceptions, PAREXEL independently verified the accuracy of the drug sample inventories that had been the subject of findings in the Warning Letter. Exhibit 6 at p. 15. Moreover, according to Ghosh, PAREXEL reviewed and confirmed training records for all employees in the stability department. Exhibit 6 at p. 18. Clearly, Ranbaxy intended to, and did, communicate to the FDA PAREXEL's integral involvement in the review process and any corrective actions.

On September 27, 2006, the FDA responded in writing to Ranbaxy and requested additional information, including PAREXEL's report of findings and recommendations, and a meeting. In response, on October 13, 2006, Ghosh again wrote to the FDA, emphasizing PAREXEL's involvement:

> We have retained PAREXEL Consulting as part of our Quality Assurance program to conduct an audit and provide critical review of all the processes and procedures in the Stability and Quality Control laboratories. Nevertheless, Ranbaxy would much prefer not to provide the audit report. We do, however, want to work with you to provide you the information necessary to respond to any concerns you may have regarding the operations of our stability laboratory at Paonta Sahib.

Exhibit 7 at p. 2.

On November 29, 2006, Ranbaxy executives and Ronald Tetzlaff met with FDA representatives to present a status update and describe the quality improvement program. Ranbaxy presented an agenda and summary of actions that the company had undertaken in response to the Warning Letter. Exhibit 8. Using a PowerPoint presentation, Ranbaxy represented that it had "[r]etained PAREXEL to do a comprehensive audit of Laboratory Practices." Exhibit 9 at p. 19. The company noted that it had evaluated 28 quality systems and formed a steering committee and project teams to review each system

and that PAREXEL was integrally involved in the work of each team. Exhibit 9 at p. 22. Dr. Tetzlaff summarized the audit and improvement measures undertaken by the PAREXEL team on Ranbaxy's behalf, including audit activities by PAREXEL's highly experienced consultants, most of whom were former FDA experts. Exhibit 9 at p. 26. The work included comprehensive reviews of the stability and QC laboratories, a comprehensive systems audit, including review of SOPs, analytical records and reports, documentation practices, equipment qualification, validation, management controls, method transfers, stability protocol preparation, logbooks, sample inventory and accountability, OOS investigations, complaint samples and other areas. Exhibit 9 at p. 27. According to Dr. Tetzlaff, PAREXEL's work with Ranbaxy was ongoing. Exhibit 9 at p. 28. The FDA again requested to review the actual audits rather than Ranbaxy's summary of its findings. Ranbaxy agreed to consider the request. Exhibit 10 at p. 5.

On December 7, 2006, Ranbaxy and PAREXEL entered into another agreement, this time directly. Exhibit 11. PAREXEL's Project Orientation Memo outlines a scope of work that included development of a Quality Manual, a GAP Assessment (audit) of quality systems, development of flow diagrams, SOPs and forms, drafting forms, training, implementation, and management. The work was referred to as Quality Systems Improvement Program ("QSIP") and designated by PAREXEL as Project 85636. Exhibit 12. The Project Orientation Memorandum indicates that 4 of the 5 services are not privileged, yet inexplicably attempts to carve out the GAP Assessment for privileged treatment: "PAREXEL will conduct GAP Assessments (Audit) of existing quality system procedures. The Gap Assessments (Audits) are performed under Attorney-client Privilege." Exhibit 12 at p. 1. *See also* Exhibit 11 at p. 6.

2. Events in 2007

From January 26 through 29, 2007, the FDA inspected Ranbaxy's API facility at Paonta Sahib and issued Inspectional Observations in a Form FDA-483, to which Ranbaxy responded on February 28, 2007.

On February 14, 2007, federal agents executed search warrants at Ranbaxy facilities in New Jersey and seized documents and imaged computers. On February 18, 2007, counsel for Ranbaxy sent government counsel a letter, identifying individuals whose seized documents would be "presumptively privileged." These individuals included 5 in-house counsel and their paralegal, numerous outside counsel, and "Ronald Tetzlaff and his firm, PAREXEL Consulting." Exhibit 13. On March 8, 2007, the government served Ranbaxy with the administrative subpoena that was the precursor to the December 4, 2007, subpoena that is Exhibit 1.

On April 5, 2007, counsel for Ranbaxy, Kate Beardsley, on her own initiative, conferred by telephone with FDA representatives. According to the FDA's notes of the telephone call, "Ms. Beardsley acknowledged that Ranbaxy had not yet addressed all of [the FDA's] concerns from the June 2006 Warning Letter. She reported that Ranbaxy was auditing their stability raw laboratory data and comparing this against data submitted in applications for the U.S. market." Exhibit 14 at p. 2. The FDA again emphasized that the agency could not complete its assessment without the PAREXEL audit reports. Exhibit 14. Ms. Beardsley "did not specify a specific date or time period" when the FDA could expect to receive PAREXEL's audit, but "said that she clearly understood [the FDA's] position." Exhibit 14.

On June 18, 2007, Dr. T.G. Chandrashekhar, Ranbaxy Vice President for Analytical Research

and Stability Studies, wrote to the FDA to confirm the completion of retrospective stability verification and the update of ANDA submissions. Exhibit 15. Again, Ranbaxy referred to details of PAREXEL's audit efforts for verification. Exhibit 15 at p. 2.

The FDA and Ranbaxy again met on June 26, 2007, when the FDA again requested production of the PAREXEL audit reports. On July 27, 2007, Ms. Beardsley sent the FDA the PAREXEL stability reports and summarized these and other findings: "The PAREXEL reports were initially prepared under privilege and still bear that designation. However, because of the importance of resolving the hold, Ranbaxy is not asserting a privilege with regard to PAREXEL reports." Exhibit 16 at p. 1.

During this same time, in discussions with government counsel, counsel for Ranbaxy continued to assert attorney-client privilege regarding the PAREXEL audit documents. The assertions of privilege continued despite the many references to and discussions about PAREXEL's audits by the company, its counsel, and the consultants themselves during numerous exchanges with the FDA. Thereafter, counsel outlined the company's privilege assertions over the PAREXEL audits by letter dated August 14, 2007. Exhibit 17. According to counsel, PAREXEL audit work included the following subjects: 1) stability and quality laboratories at Paonta Sahib; 2) SOPs for the quality system ("GAP" Assessment); 3) two specific draft SOPs; 4) the Toansa plant; 5) selected manufacturing and laboratory areas at the API and Finished Pharmaceuticals Facility at Paonta Sahib; 6) validation protocols and reports for two products; 7) certain QC laboratory procedures; 8) Paonta Sahib API facility; and 9) Paonta Sahib Dosage Form Plant. Exhibit 17 at pp. 5-8.

As discussed *supra*, on December 4, 2007, the government served Ranbaxy with the administrative subpoena that is attached hereto as Exhibit 1. On December 19, 2007, Ranbaxy produced

the GAP Assessment, for which the company had initially claimed privilege notwithstanding that it was the subject of a direct contract between Ranbaxy and PAREXEL. Exhibit 11, Attachment A.

During late December 2007, counsel for Ranbaxy communicated with the FDA to try to persuade the agency to lift the hold on approval of the ANDA for clarithromycin so that Ranbaxy could market the drug by January 2, 2008. See Exhibit 18. The FDA had explained that it could not consider the request until Ranbaxy provided the PAREXEL audits so that the FDA could evaluate Ranbaxy's corrective actions to determine whether clarithromycin (and other drugs) would be safe and effective for their labeled indications. Exhibit 18 at p. 2. Ranbaxy counsel asked the FDA to identify the audits it sought to review and indicated that she would confer with Ranbaxy. Exhibit 18 at pp. 3-4. The FDA identified certain audits, using the August 14, 2007 letter, Exhibit 17 hereto, as a guide. Exhibit 18 at p. 2. Ultimately, Ranbaxy elected not to produce the audits at that time because the company "need[ed] to think through the implications for the criminal case of providing the audits." Exhibit 18 at p. 1.

3. Events in 2008

At Ranbaxy's direction, PAREXEL's counsel produced QSIP documents on January 25, 2008, indicating that documents had been redacted for "information that Ranbaxy counsel has referenced as protected by Ranbaxy's attorney-client privilege." Exhibit 19 at p. 1 and Table B.[11]

Apparently, by April 10, 2008, Ranbaxy determined that the benefits of producing at least some of the audits in order to persuade the FDA to lift the hold on ANDAs emanating from Paonta Sahib outweighed the disadvantages. Counsel produced to the FDA the following audits: 1) stability and

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[11] PAREXEL redacted the documents for information about its other clients. The government has no objection to these redactions.

quality laboratories at Paonta Sahib (2 audits); 2) selected manufacturing and laboratory areas at the Finished Pharmaceuticals Facility (but not the API Facility) at Paonta Sahib; and 3) Paonta Sahib Dosage Form Plant. Exhibit 20.

On April 23, 2008, counsel for Ranbaxy produced the same audits to government counsel, apparently appreciating that once it had produced the audits to the FDA to serve the company's commercial purposes, it could hardly refuse to produce the same audits in response to the subpoena.

PAREXEL has commenced production of backup documentation and workpapers relating to these audits. However, even as to these documents, Ranbaxy continues to assert privilege, and certain backup documents have been produced in redacted form, apparently for the remaining documents for which Ranbaxy continues to claim privilege. This process has created even more delay in the government's investigation because Ranbaxy's counsel now seeks to review PAREXEL's audit documents that had been previously redacted and produced before April 23.

E. The Outstanding Audit Documents That Are the Subject of This Motion

The remaining PAREXEL audits that are the subject of this Motion[12] are as follows: 1) two specific draft SOPs; 2) the Toansa plant[13]; 3) selected manufacturing and laboratory areas at the API Facility at Paonta Sahib; 4) validations protocols and reports for two products; 5) certain QC laboratory procedures; 6) Paonta Sahib API facility.

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[12] If PAREXEL performed other audits, assessments, or investigations for Ranbaxy, pursuant to the subpoena, the government requests that those audits also be produced, whether or not the audits are drafts, incomplete, or produced to Ranbaxy.

[13] Toansa is a manufacturing site for API used in drugs distributed in the United States.

The events and interactions described *supra*, some occurring after the execution of the search warrants at the New Jersey facilities and the service of administrative subpoenas, demonstrate Ranbaxy's strategy to use PAREXEL, and especially Dr. Tetzlaff, to persuade the FDA to look favorably on its pending ANDAs. Ranbaxy touted the audits undertaken by the PAREXEL team, "all of whom are former FDA investigators with more than 25 years FDA experience each." Exhibit 6 at p. 5. The company repeatedly proffered PAREXEL's involvement in its regulatory compliance measures as a badge of corporate responsibility and a demonstration of its good faith compliance efforts. As discussed more fully below, this strategy ultimately defeats any claim of privilege.

III. ARGUMENT

The government maintains that no privilege attaches to any of the PAREXEL audits and supporting documentation and seeks from the Court an Order so holding.

A. No Legitimate Basis Exists For Ranbaxy's Assertion of Privilege Over the Audits

Courts have strictly construed attorney-client privilege, recognizing that it is an impediment to the full and free discovery of the truth and in derogation of the public's right to every man's evidence. *In re Grand Jury Proceedings*, 727 F.2d 1352, 1355 (4th Cir. 1984). The privilege applies only when the person claiming it has consulted an attorney for the purpose of securing a legal opinion or services and, in the process, communicated information which the person intended to remain confidential. *Id.*

1. *Kovel* Privilege Does not Apply to the PAREXEL Audits

Ranbaxy seeks to extend to the PAREXEL audits the derivative attorney-client privilege that some courts have recognized in the context of accountants who advise attorneys to enable them to provide legal advice to clients. *See United States v. Kovel*, 296 F.2d 918 (2nd Cir. 1961). The underlying

theory is that accounting services performed ancillary to legal advice may fall within attorney-client privilege if the accountant "is translating complex tax terms into a form intelligible to a lawyer at the lawyer's behest." *United States v. Bornstein*, 977 F.2d 112 (4th Cir. 1992)(citations omitted). In *Bornstein*, the Fourth Circuit framed the issue on remand as whether the accountant prepared accounting workpapers to enable the attorney to give the client legal advice rather than accounting advice. *Id.* at 116. Derivative privilege has been recognized for other types of consultants, such as patent agents and non-testifying experts, as long as they are "hired to assist in the rendition of legal services." *United States Postal Service v. Phelps Dodge Refining Corp.*, 852 F.Supp. 156, 161 (E.D.N.Y. 1994), *citing United States v. Schwimmer*, 892 F.2d 237, 243 (2nd Cir. 1989).

Like the environmental experts retained in *ECDC Environmental, LLC v. New York Marine and Gen'l Ins. Co.*, 1998 WL 614478, *8 (S.D.N.Y. 1998), PAREXEL was retained to assess the condition of Ranbaxy's regulatory compliance and to formulate a remedial plan acceptable to the regulators. *Accord Phelps Dodge Refining Corp.*, 852 F.Supp. at 161; *In re Grand Jury*, 147 F.R.D. 82, 85 (E.D.Pa. 1992); *Coastline Terminals of Connecticut v. United States Steel Corp.*, 221 F.R.D. 14, 16 (D. Conn. 2003). As was true in those cases, PAREXEL consultants did not "translate" complicated technical or regulatory concepts so that Ranbaxy's counsel, who are highly experienced in FDA regulatory matters in their own right, could provide legal advice.

Like the consultants in the above cited cases, the PAREXEL consultants based their opinions on first-hand observations, and the audit findings were based on factual evidence gathered during the consultants' investigation of the Ranbaxy facilities. The audit activities included interviewing witnesses and observing plant operations in India, and reviewing test data, standard operating procedures,

laboratory reports, submissions to the FDA, and many other documents. Any communications between the consultants and Ranbaxy or counsel were based on these observations and the accumulation of facts from the investigations. Underlying factual data and evidence generated by experts' observations and investigations, rather than client confidences, cannot be privileged, nor can the recommendations and opinions that result. *Phelps Dodge*, 852 F. Supp. at 162.

Ultimately, the expert's function will determine whether his work is privileged. In *Occidental Chemical Corp. v. OHM Remediation Services*, 175 F.R.D. 431, 436-37 (W.D.N.Y. 1997), the court looked behind the fact that the consultant was hired by counsel to scrutinize the consultant's actual function. Because the consultant was hired by counsel to formulate a remediation plan acceptable to regulatory authorities, not to "put information gained from [plaintiff] into usable form for [its] attorneys to render legal advice, . . ." privilege did not attach. *Id.* at 437, *citing Phelps Dodge.* Moreover, because the consultant was not hired to assist in rendering legal services, communications to or from him were not privileged even if they contained legal opinions and strategic considerations from counsel. *Occidental Chemical Corp,* 175 F.R.D. at 436-37. PAREXEL was hired to assess conditions and practices at the plants in India, and for that, Ranbaxy needed former FDA inspectors, not lawyers. "A client may not 'buy' a privilege by retaining an attorney to do something that a non-lawyer could do just as well." *In re Grand Jury Subpoena*, 204 F.3d 516, 523 (4th Cir. 2000)(citations omitted).

The manner in which the services are performed is also relevant in assessing the consultant's function. Most of PAREXEL's audits and workpapers have been widely disseminated among Ranbaxy employees. At least 10 PAREXEL consultants worked on Project 81937, to which Ranbaxy claims privilege, as well as Project 85636, the Quality System Improvement Plan (QSIP), to which Ranbaxy has

never claimed privilege. Billing records establish that some of those consultants worked on both projects simultaneously over a period of months. As is obvious from the subject matters involved, substantial overlap exists between the two projects. Moreover, Project 85636, QSIP, was based on the investigations undertaken and the observations made under Project 81937. The obvious connections between the two projects suggests that neither should be considered privileged.

Payment by the law firm to the consultant does not control privilege, especially when the law firm clearly indicates that it is not liable for any fees. *In re Grand Jury*, 147 F.R.D. at 86. On November 3, 2006, Buc & Beardsley paid PAREXEL approximately $530,000 for its June through September, 2006 invoices. Ranbaxy reimbursed the law firm in full. Thereafter, PAREXEL's invoices were sent directly to Ranbaxy in India and paid by the company's wire transfer to PAREXEL. As of June 18, 2007, PAREXEL billed Ranbaxy more than $3 million for its services on Project 81937. As of June 22, 2007, Ranbaxy directly paid PAREXEL more than $2 million for work on QSIP, Project 85636.

Courts have recognized that a consultant hired first by the client to perform the same services that he subsequently performed for the attorney creates a risk that the attorney's retention of the agent was "simply a subterfuge." *Cavallaro v. United States*, 284 F.3d 236, 249 (1st Cir. 2002)(citations omitted). The same reasoning should apply when the client hires the consultant after the attorney. *See Occidental Chemical Corp.*, 175 F.R.D. at 433. PAREXEL's agreement with the law firm appears to be no more than legal fiction, given the August 29, 2006 letter from Alok Ghosh to the FDA indicating that Ranbaxy, not Buc & Beardsley, retained PAREXEL. Exhibit 6 at p. 1. And in December, 2007 Ranbaxy directly retained PAREXEL to perform QSIP. Exhibit 11.

PAREXEL's efforts on QSIP, which Ranbaxy concedes are not privileged, were based almost

entirely on PAREXEL's audit observations and findings, to which Ranbaxy asserts privilege. Thus, notwithstanding that Ranbaxy admitted that QSIP was not privileged, the company continues to assert privilege over certain documents or information contained in QSIP documents. Exhibit 20 at p. 1 and Table B. The fact that "privileged" audit activities and information are contained in QSIP documents demonstrates that both QSIP and the other audits arose out of the same investigations and observations. Consequently, none of PAREXEL's audit activities and documents should be privileged.

As demonstrated by the facts outlined *supra*, by asserting that PAREXEL was retained to assist counsel, Ranbaxy has tried to shield PAREXEL's factual investigations, including employee interviews and observations of plant operations in India, while at the same time the company has used the reports as a sword to obtain favorable regulatory consideration of its ANDAs. This subterfuge is unworthy of the protections accorded by the courts to legitimately privileged confidential communications between a client and his attorney.

2. Attorney-Client Privilege Does not Protect Communications That the Client Intends to Publish

Attorney-client privilege applies only to confidential communications between a client and attorney, and confidentiality is the "essence of the privilege." *In re Grand Jury Proceedings*, 727 F.2d at 1356, *citing United States v. Jones*, 696 F.2d 1069 (4th Cir. 1982). In *Jones*, individuals asserted that a legal tax opinion and related communications were privileged, but the Fourth Circuit denied privilege protection to documents and information that the individuals intended to publish to solicit investors. In *Grand Jury Proceedings*, the Fourth Circuit opined that the client's intention to publish, not publication in fact, controlled privilege. 727 F.2d at 1358. *Accord In re Grand Jury 83-2 John Doe No. 462*, 748

F.2d 871, 874-75 (4th Cir. 1984); *In re Grand Jury Subpoena*, 204 F.3d 516, 522 (4th Cir. 2000). *Compare In re Grand Jury Subpoena*, 341 F.3d 331, 336 (4th Cir. 2003)(client never intended his communications with counsel to be published, but client waived privilege by answering questions from third party). Moreover, if a client intends to publish the information that he communicates to his attorney, no privilege will attach to the information or "the details underlying the data which was to be published." *In re Grand Jury Proceedings*, 727 F.2d at 1356, *cited in In re Grand Jury*, 748 F.2d at 875. Details underlying the data include preliminary drafts, communications about the data, and attorneys' notes containing material used to prepare the documents. *In re Grand Jury,* 748 F.2d at 875 n.7.

Ranbaxy's privilege assertions are premised on the theory that the PAREXEL consultants served as agents of the company's counsel "to assist [counsel] in providing legal advice . . . in connection with Client's compliance with the FDA's Good Manufacturing Practices." Exhibit 5 at p. 1. Counsel represented the need for consulting assistance to analyze and prepare something that, when complete, "will represent the product of the attorney's work in preparing and presenting the case of [Ranbaxy]." Exhibit 5 at p. 1.

The chronology, *supra*, shows that something else transpired. Ranbaxy intended from the inception of PAREXEL's involvement to publish the audits to the FDA, at least to the extent that Ranbaxy perceived that disclosure of the audits, or portions of them, would inure to the company's benefit in the regulatory process. If a company conducts an "internal investigation and audit with the intent to publish the results, the investigation and audit [are] never privileged in the first place." *United States ex rel. Mayman v. Martin Marietta Corp.*, 886 F.Supp. 1243, 1249 (D. Md. 1995).

Within a few months of the agreement, ostensibly between counsel and PAREXEL, Ranbaxy

informed the FDA that "[w]e have retained Ron Tetzlaff and his colleagues at PAREXEL Consulting" to verify Ranbaxy's various program improvements. Exhibit 6 at p. 1. Dr. Tetzlaff met with FDA staff on several occasions to describe the work undertaken by PAREXEL. *See In re Grand Jury*, 147 F.R.D. at 86 (expert met several times with regulatory authorities, even without counsel). As recently as April 10, 2008, with the production of the four audits, Ranbaxy continued to play the PAREXEL card with the FDA. Privilege does not and should not attach to calculated business strategies intended to serve a company's commercial interests.

B. Work Product Immunity

Ranbaxy's counsel have also asserted work product immunity. Work product immunity depends on whether, in light of all facts and circumstances, a document can be fairly said to have been prepared in anticipation of litigation, meaning "prepared *because* of the prospect of litigation when the preparer faces an actual claim or a potential claim following an actual event or series of events that reasonably could result in litigation." *National Union Fire Ins. Co. v. Murray Sheet Metal Co.*, 967 F.2d 980, 984 (4th Cir. 1992)(investigations following incidents are common not only out of concern for future litigation, but to prevent recurrences, improve safety and efficiency, and respond to regulatory obligations). Some immediate showing of some specific litigation, rather than a remote possibility of litigation, is required. *Occidental Chemical Corp.*, 175 F.R.D. at 439.

Ranbaxy hired PAREXEL to help develop a coherent business strategy to address its many operational and regulatory issues. Relying on the PAREXEL audits, Ranbaxy reassigned and hired more personnel, evaluated and changed manufacturing, laboratory, and testing processes, established monthly management review meetings, and verified stability reports and sample testing, among other things. The

factual record illustrates Ranbaxy's persistent efforts since the June 2006 Warning Letter to attempt to resolve its regulatory issues with the FDA. The company's production of the four audits in April, 2008, to try to persuade the agency to lift the hold on its ANDAs demonstrates that these efforts continue to the present day. This behavior is inconsistent with conduct undertaken in anticipation of litigation.

C. Ranbaxy Waived Any Privilege by Numerous Disclosures to the Government

The law in the Fourth Circuit could not be clearer on the issue of waiver when privileged information is voluntarily disclosed. The Fourth Circuit applies subject matter waiver to attorney-client privilege and non-opinion work product, but recognizes more limited waiver for opinion work product. *In re Martin Marietta Corp.*, 856 F.2d 619, 623, 625-26 (4th Cir. 1988). Subject matter waiver applies to "all information related to the same subject matter." *Id.* at 623. Martin Marietta disclosed portions of various documents during settlement discussions with the government, then sought to withhold the same documents when subpoenaed by a third party. The company argued that the documents were protected by attorney-client privilege or as work product. The Fourth Circuit rejected these arguments, concluding that a client who communicates information to his attorney with the understanding that it will be revealed to others waives the attorney-client privilege as to the information and the underlying details and data. *Id.* (citations omitted).

Moreover, work product enjoys only a qualified privilege and is also subject to waiver. *Id.* at 624 (citations omitted). Counsel who discloses factual work product waives privilege as to that subject matter. *Id.* at 625. This principle discourages attorneys from attempting to make affirmative use of work product while simultaneously shielding it from disclosure. *Id.* at 626, *citing Duplan Corp. v. Deering Milliken*, Inc., 540 F.2d 1215, 1223 (4th Cir. 1976).

Subsequent cases have clarified the breadth of these principles. Waiver does not depend on the reaction of a third party to the disclosure, promises of completeness of the disclosure, "basic fairness," or precise reference to a specific privileged communication. *Martin Marietta*, 886 F.Supp. at 1250 . "A summary, paraphrase or clear reference to the substance of a communication can waive the confidentiality of that communication." *Id.*, *citing In re Grand Jury Proceedings*, 727 F.2d at 1356. Waiver by disclosure extinguishes privilege regardless of whether the communication was intended for disclosure from inception. 886 F.Supp. at 1250.

The facts here and in *Martin Marietta* are strikingly similar. Ranbaxy has selectively disclosed those portions of PAREXEL's audits that it believes will be beneficial while withholding other parts that the company apparently perceives as problematic. Such "[s]elective disclosure for tactical purposes waives the privilege." *United States v. Jones*, 696 F.2d at 1072, *cited in Martin Marietta*, 886 F.Supp. at 1252. Moreover, there should be no doubt that given Ranbaxy's course of conduct here, the company would have disclosed the audits in full had the company perceived disclosure would have inured to its benefit.

Redactions to the documents that have been produced demonstrate Ranbaxy's overly inclusive operational definition of privilege and apparent oblivion to the principle of waiver. Ranbaxy redacted large segments of internal PAREXEL emails concerning project progress and resources (PAR007383-84, PAR009580,[14] PAR009638-39, PAR017936, PAR018897-901, PAR018975-77), and references contained in draft SOPs (PAR09642-45). Exhibit 21. Ranbaxy redacted the last two pages

[14] Documents PAR009578, -79, and -81 are included for completeness.

(PAR016415-15) of a 40-page PowerPoint presentation made jointly by Bruce Little of PAREXEL and Umesh Kale of Ranbaxy to Ranbaxy personnel on December 13, 2006, entitled "Quality System Improvement Project Overview." Ranbaxy also heavily redacted pages 5 through 9 from the same PowerPoint (PAR019226-30). Exhibit 22. These redactions are inexplicable because Ranbaxy has conceded that QSIP is not privileged. Moreover, Ranbaxy produced these same pages 5 through 9 in unredacted form (PAR016380-84). Exhibit 23. These PowerPoint pages refer to the GAP Assessment, which Ranbaxy produced to the government on December 19, 2007, thereby waiving privilege. The government is at a loss to understand how these pages could possibly qualify as privileged, other than the self-serving footer running along the bottom.

Counsel for Ranbaxy prepared a privilege log for one box of documents assembled by PAREXEL pursuant to the government's subpoena. The log, attached hereto as Exhibit 23, is 44 pages long, and illustrates Ranbaxy's overbroad interpretation of privilege. With few exceptions, all of these documents were prepared by PAREXEL consultants and appear to represent audit work papers. Most of the document descriptions indicate that they relate to audit activities, not legal advice. Very few were even circulated to Ranbaxy's counsel, but even if they were, counsel's receipt of a copy of a document does not confer automatic privilege over those communications. *United States v. Cohn*, 303 F.Supp.2d 672, 683-84 (D.Md. 2003). For privilege to attach, legal advice, not some business purpose, must be the objective of the communication. *Id.* "It is the destination and purpose of a communication, not its content, which determines whether it is privileged. *See Under Seal,* 748 F.2d at 871. The inclusion of identical facts, opinions and conclusions in two documents does not assure that both will be protected if only one is directed to an attorney for the purpose of soliciting legal advice." *Glaxo Inc. v. Novopharm*

LTD, 148 F.R.D. 535, 541 (E.D.N.C. 1993).

IV. CONCLUSION

Under these facts and relevant case law, the PAREXEL audits are not protected under attorney-client or work product privileges. Accordingly, the government respectfully requests that the Court so rule and issue an Order directing Ranbaxy and PAREXEL to produce all audit documents responsive to the subpoena.

Respectfully submitted,

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