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

UNITED STATES OF AMERICA Petitioner v. RANBAXY, INC., and PAREXEL CONSULTING Respondents.	)	Case No. 2008 cv 01764 PJM

RESPONSE OF RANBAXY, INC. TO
MOTION TO ENFORCE SUBPOENAS

Since Ranbaxy became aware of the government's investigation, it has cooperated fully. The government has hundreds of thousands of pages of Ranbaxy documents, and as a result of previous privilege waivers and non-assertions of privilege, the government already has over one hundred thousand pages of PAREXEL documents. While Ranbaxy believes that some of the work performed by PAREXEL is protected by the attorney client and work product privileges, Ranbaxy had already informed the government at the time this motion was filed that it had waived its privileges for all audits conducted by Parexel and as a result, there is not now and was not at the time the motion was filed any dispute requiring adjudication by the Court.

In its motion, the government has made some serious allegations concerning compliance with United States law. Except for issues that have already been fully aired with the government, Ranbaxy knows of no evidence to support these allegations. Nevertheless, the company expects to continue to cooperate with the government's investigation, and to address any concerns that government counsel may have. To the extent that government counsel would be willing to share its concerns in a form that permits timely investigation, Ranbaxy would welcome that opportunity.

The PAREXEL Audits

In 2006, Buc & Beardsley, counsel for Ranbaxy, Inc., hired Ronald F. Tetzlaff, PhD, and his company, PAREXEL Consulting. Dr. Tetzlaff, a former FDA inspector, and his team of former FDA employees have a well-deserved reputation in the industry for being thorough and tough. At the time, FDA was refusing to approve ANDA applications coming from Ranbaxy's Paonta Sahib facility, and concern about litigation was real. Counsel needed help in understanding technical issues related to FDA's requirements for Good Manufacturing Practices from experts in the field. Also, at that time, Ranbaxy was contemplating litigation with FDA for unlawfully withholding approval of Ranbaxy's simvastatin product. Thus, Buc & Beardsley expressly retained PAREXEL to assist counsel in these matters.

At a cost of millions of dollars to Ranbaxy, Dr. Tetzlaff and PAREXEL conducted inspections and produced approximately 12 separate audit reports of Ranbaxy's operations. Some were directly relevant to FDA's expressed concerns, while others were not. Those audits identified potential improvements to Ranbaxy's processes

and paperwork. Ranbaxy personnel made many of the improvements suggested in the audits, and, in some cases, asked PAREXEL to verify that the improvements had been accomplished, which PAREXEL did.

In addition to the audits, in response to FDA's expressed concern about Ranbaxy's stability data, Ranbaxy undertook, beginning in the fall of 2006, an extensive re-examination of the validity of stability data that had been submitted to FDA from the Paonta Sahib facility. PAREXEL was asked to assist in this re-examination by reviewing a statistically valid sample of Ranbaxy's findings. This effort was known as the Stability Verification. In its review, Ranbaxy detected no errors that would have affected product quality or safety.

At about the same time, PAREXEL was asked to assist by reviewing Ranbaxy's Paonta Sahib procedures more generally. Following that review, Ranbaxy retained PAREXEL to assist the company by conducting a review of Ranbaxy's key standard operating procedures. This initiative, which was known as the Quality Systems Improvement Program, was a far reaching and exhaustive program to help ensure that Ranbaxy's key procedures were at the cutting edge of compliance.

In meetings with FDA that occurred in 2006, Ranbaxy disclosed that PAREXEL had conducted two audits directly relevant to FDA's concerns, that it was assisting in the Stability Verification, and that it would be involved in the Quality Systems Improvement Program. Ranbaxy has provided these audits to the government; it has provided the review of stability samples to the government; and it has not claimed a privilege related to the Quality Systems Improvement Program. Ranbaxy has never sought to provide

portions of audits; it has always taken the position that, if it releases any part of an audit, it has waived privilege with respect to the entire audit.

In February, 2007, the Department of Justice executed search warrants at Ranbaxy's U.S. facilities. Since that time, Ranbaxy has been attempting to cooperate with DOJ's investigation, while also continuing a dialogue with the FDA. As part of its efforts to cooperate with DOJ's investigation and especially to reach some accommodation on the privilege issues related to the PAREXEL audits, in July 2007, Ranbaxy informed DOJ generally of the various audits PAREXEL had undertaken. DOJ requested that Ranbaxy produce all of PAREXEL's audits. In September, 2007, DOJ subpoenaed PAREXEL for the audits and all of its underlying work papers.

Ranbaxy argued to both FDA and DOJ that government requests for voluntary audits conducted at the request of counsel were bad policy. Ranbaxy's counsel explained to DOJ that, if drug manufacturers learned that the government would force them to disclose the results of voluntary audits to help build civil or criminal cases, companies would stop doing audits, or would stop hiring tough auditors like PAREXEL and instead hire auditors who would be less likely to be tough and thorough. Ranbaxy's counsel asserted privilege protection for the remaining audits, while maintaining its position that the company would address any particularized requests.

Apparently believing that Ranbaxy's assertion of a legitimate privilege meant that the remaining audits would reveal deep problems at the company, DOJ continued to challenge Ranbaxy's privilege and demand the remaining PAREXEL audits. In late 2007, FDA regulators told the company that FDA would not act on Ranbaxy applications from the Paonta Sahib facility without access to PAREXEL's audits. From a

business standpoint, Ranbaxy felt it had no choice but to waive privilege with respect to those audits Ranbaxy asked FDA which audits it needed to see in order to consider Ranbaxy's requests for product approvals, and FDA requested specific audits. In April, 2008, Ranbaxy turned those audits over to FDA, and waived privilege with respect to PAREXEL's workpapers related to those audits.

After April, 2008, several PAREXEL audits remained for which Ranbaxy maintained a privilege. Although Ranbaxy believed that its privilege claims for these audits were well-founded, the PAREXEL privilege issue seemed to be such a continuing concern for the government that Ranbaxy began internal discussions about waiving privilege for the remaining audits. In addition, Ranbaxy had recently provided information about the audits to a third party, which it believed would weaken its privilege claims. At the beginning of July, Ranbaxy decided to waive privilege. On July 3, within half an hour of the first call from government counsel informing Ranbaxy of the motion to compel, the company informed the government that it would waive privilege for the remaining audits. At the time this motion was filed, it was moot.

Ranbaxy counsel have notified PAREXEL counsel that Ranbaxy has waived privilege for the audits and workpapers. PAREXEL believes that it can produce the remaining documents within a month. The government has agreed to withdraw the motion once production is complete.

The Government's Allegations

In its papers supporting the motion to compel, the government included descriptions of various allegations that it is currently investigating. In response to these unconfirmed allegations in the governments motion papers, Ranbaxy makes the

following commitments to the Court, the FDA, the DOJ, and its employees, customers, and business partners:

1. Ranbaxy is fully committed to cooperating with FDA and DOJ.

2. Ranbaxy is in the process of producing requested supporting documentation for its ANDA applications to DOJ, and believes that the requested documentation will demonstrate that no data manipulation, fraud, or dishonesty occurred in those applications.

3. Ranbaxy has repeatedly requested that the government share the details of its concerns, so that Ranbaxy can assist the government in determining whether any problems exist. The government has chosen not to share such information yet, which is entirely consistent with DOJ's ordinary practice in investigations. If and when the government chooses to share the details of its concerns, Ranbaxy commits to responsibly respond to, and resolve, those concerns.

4. In the absence of such details from DOJ, Ranbaxy is not aware of any previously unreported problems with respect to any of the allegations in the government's motion papers. Ranbaxy knows that FDA collected over 200 samples of Ranbaxy products, and believes that FDA's testing of these samples did not uncover any product failures..

5. Ranbaxy is committed to develop and market high quality generic drug products. Ranbaxy makes that commitment to its customers, business partners, and employees every day.

Respectfully submitted,

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