City of Winter Haven v. Cleveland Indians Baseball Company Limited Partnership Doc. 652

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF CONNECTICUT

IN RE: SUBPOENAS SERVED ON PAREXEL MMS AND SIMPSON HEALTHCARE EXECUTIVES	**Misc. Action No. 3:07mc264 JCH**

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
ORLANDO DIVISION

IN RE: SEROQUEL PRODUCTS LIABILITY LITIGATION **THIS RELATES TO:** **ALL CASES**	**MDL 1769**

PLAINTIFFS' MOTION FOR TRANSFER TO SEROQUEL PRODUCTS LIABILITY LITIGATION MDL, OPPOSITION TO PAREXEL MSS MOTION FOR PROTECTIVE ORDER, MOTION TO COMPEL NONPARTY DOCUMENTS, AND INCORPORATED MEMORANDUM OF LAW

Plaintiffs respectfully request the Court enter an order transferring this dispute involving nonparties, PAREXEL, MMS ("PAREXEL") and Simpson Healthcare Executives ("Simpson") to the Middle District of Florida, Orlando Division, where the Seroquel Products Liability Litigation, MDL 1769, is pending. Should the Court decide not to transfer this matter, Plaintiffs request the Court enter an order denying PAREXEL's Motion for Protective Order and compelling PAREXEL and Simpson to comply with the document subpoenas issued by this Court. If the matter is transferred, Plaintiffs request the MDL Court enter an order compelling the nonparties to comply with the document subpoenas and respond to the depositions upon

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written questions noticed in the MDL litigation and served on the nonparties in conjunction with the document subpoenas.

INTRODUCTION

1. The subpoenas before the Court were issued to PAREXEL and Simpson in connection with the product liability MDL involving the antipsychotic prescription drug "Seroquel" manufactured by AstraZeneca Pharmaceuticals LP and AstraZeneca LP ("AstraZeneca"), which is currently pending in the United States District for the Middle District of Florida, Orlando Division, the Honorable United States District Judge Anne C. Conway presiding. Plaintiffs took Seroquel for a variety of mental disorders and, as a result, suffered serious side effects. More than 6000 separate actions against AstraZeneca involving Seroquel have been transferred to the MDL by the Judicial Panel on Multidistrict Litigation pursuant to its Order of July 6, 2006. Judge Conway has assigned many of the pretrial discovery proceedings to United States Magistrate Judge David A. Baker.

2. PAREXEL and Simpson are third party vendors hired by AstraZeneca to provide services related to Seroquel such as speaker training, creation of promotional and marketing materials, media planning and medical publishing. Plaintiffs seek documents, communications and contracts between AstraZeneca and those vendors relating to Seroquel-specific projects.

BACKGROUND

3. Seroquel belongs to a class of neuroleptic drugs known as "atypical" antipsychotics. In September 1997, Seroquel was approved by the FDA for the treatment of adults with schizophrenia. On January 12, 2004, Seroquel was approved for the treatment of adults with acute mania associated with bipolar disorder. On October 20, 2006, Seroquel was

approved for the treatment of adults with major depressive episodes associated with bipolar disorder.

4. Seroquel has been associated with a number of serious side effects including weight gain, hyperglycemia and diabetes mellitus. Plaintiffs allege AstraZeneca, through its aggressive promotion of Seroquel, exaggerated the efficacy of Seroquel while downplaying these serious side effects and, in doing so, failed to provide physicians with critical safety information. Through its marketing campaigns and persistent sales representatives, AstraZeneca promoted Seroquel for a number of "off-label" uses, such as the treatment of dementia, anxiety disorders and depression. In an effort to expand its market audience and increase the number of prescriptions written for Seroquel, AstraZeneca targeted primary care physicians (PCPs) many of whom did not treat serious psychiatric disorders such as schizophrenia and bipolar disorder.

5. AstraZeneca has been repeatedly reprimanded by the FDA for its false and misleading promotional activities. In November 1998 and May 1999, the FDA admonished AstraZeneca for promoting Seroquel as being effective in a broader range of mental conditions than those for which it was approved, and for claiming Seroquel was proven safer and more effective than other antipsychotics. In 2006, the FDA again admonished AstraZeneca for downplaying the association between Seroquel and diabetes. The FDA found AstraZeneca's promotional activities (1) failed to warn doctors of the increased risk of treatment-emergent hyperglycemia-related adverse events in patients treated with Seroquel, thus undermining the FDA-approved labeling, (2) misrepresented the incidence of diabetes in post-marketing adverse event reports, and (3) failed to include relevant risk information about Seroquel.

6. In order to facilitate its promotional campaigns for Seroquel, AstraZeneca retained the services PAREXEL and Simpson. PAREXEL was retained by AstraZeneca in 2001

to provide publications planning, meetings support, branding strategy, marketing solutions, and advocacy programs relating to Seroquel. According to documents produced by AstraZeneca, PAREXEL personnel attend internal AstraZeneca meetings and have access to clinical trial data in order to formulate and distribute key product messages that would benefit the brand. PAREXEL was involved in the preparation of Seroquel-related promotional, educational and training materials such as (1) Sleep Disorders and Mental Health Slide Kit (designed to provide internal and external audiences with a background on sleep disorders and to train the Seroquel sales force); (2) Primary Care Physician Slide Kit (designed to educate PCPs on bipolar disorder, understand the high rate of misdiagnosis of bipolar disorder and that PCPs have an important role in diagnosis of the disorder); (3) Best in Class Slide Kit (designed to position Seroquel as the atypical antipsychotic of choice among healthcare providers); and (4) ICOSR (International Congress on Schizophrenic Research) Gianfrancesco Slide Presentation/Poster (addresses antipsychotic related diabetes risk). PAREXEL was involved in a number of Seroquel-related programs such as the Bipolar Depression Lecture Program and the Primary Care Physician Lecture Program. PAREXEL was also responsible for the development of several Seroquel-related plans including: (1) Seroquel Publication Plans; (2) Seroquel U.S. Proposed 2005 Activities; and (3) CATIE-SZ Strategy Planning Workshop Report Action Plan. Additionally, PAREXEL employees were members of various Seroquel teams that also included AstraZeneca and other third party vendor representatives, including the Bipolar Execution and Strategy Team (BEST) and were responsible for preparing the meeting agendas, minutes and summaries for that team.

7. Simpson is a medical communications firm. Simpson was hired by AstraZeneca to execute advisory board meetings, speaker training, and promotional events for Seroquel.

Simpson prepared brochures, visual slide kits and other materials for these events. Simpson was responsible for the development and planning of PCP speaker training, the implementation of PCP and American Association for Geriatric Psychiatry (AAGP) advisory boards, planning and support for PCP field based programming, timing and choreography of tactical activities and content development, identification of and contact with Key Opinion Leaders, and preparation of executive summaries of advisory boards. A member of Simpson's staff was deployed to AstraZeneca's "Seroquel Brand Team." Simpson prepared presentations which addressed the efficacy of Seroquel on mood in patients with schizophrenia and on anxiety and depression in elderly patients with dementia. Simpson developed a U.S. Seroquel Clinical Development Plan which addressed target claims relating to efficacy, dosing, mood disorders, safety/tolerability, dementia, and pediatric care.

8. Twenty-three (23) document subpoenas and depositions upon written questions have been served in the Seroquel product liability litigation on nonparty vendors, including PAREXEL and Simpson. *See* subpoenas served on PAREXEL and Simpson, attached hereto as Exhibits A-B. Pursuant to Rule 45, the subpoenas were issued and signed by Plaintiffs' counsel on behalf of ten (10) district courts: Southern District of New York, Middle and Eastern Districts of Pennsylvania, Northern District of Illinois, District of New Jersey, District of Connecticut, Eastern District of Kentucky, Eastern District of California, District of Columbia, and District of Massachusetts. FED. R. CIV. P. 45(a)(3)(B).

9. The depositions upon written questions were noticed in the MDL litigation and were served contemporaneously with the document subpoenas. *See* Depositions Upon Written Questions served on PAREXEL and Simpson, attached hereto as Exhibits C-D. AstraZeneca has

been served with the notices of deposition upon written questions for all nonparties. FED. R. CIV. P. 31(c).

10. The subpoenas and depositions upon written questions that are the subject of this Motion were served on the nonparties more than ten (10) weeks ago. PAREXEL was served at its office located at 181 Harbor Drive, Stamford, CT 06902 on July 2, 2007. *See* Exhibit A. Simpson was served at its office located at 255 Route 80, Killingworth, CT 06419 on July 3, 2007. *See* Exhibit B. The subpoenas required production of the requested documents at 10:00 a.m. on July 30, 2007 at those same office locations.

11. The subpoenas require production of six categories of documents: (1) any and all contracts or agreements between AstraZeneca and the third party vendor relating to Seroquel; (2) any and all communications between AstraZeneca and the third party vendor relating to Seroquel; (3) any and all communications between the third party vendor and any other person relating to Seroquel; (4) any and all documents prepared by, prepared for, or received by the third party vendor relating to Seroquel; (5) any and all marketing materials relating to Seroquel prepared by, prepared for, or received by the third party vendor; and (6) all documents reflecting the amount of money paid to the third party vendor by AstraZeneca relating to professional services provided by the third party vendor relating to Seroquel. *See* Exhibits A-B.

12. On July 12, 2007, Simpson served its objections to the subpoena and deposition upon written questions. *See* Exhibit E. Simpson asserts the subpoena does not allow reasonable time for compliance, is overly broad and burdensome. Simpson also objects to the electronic form of production required by the discovery. Simpson objects that the deposition upon written questions because it fails to name an officer before whom the deposition is to be taken. *See id.*

13. After serving its objections, Simpson provided Plaintiffs' with a list of its Seroquel-related projects. Based on the information provided, Plaintiffs were able to eliminate more than 2/3 of the project. Simpson has now indicated that its concerns regarding the scope of the subpoena have been addressed. The primary issue of contention between plaintiffs and Simpson concerns the reasonableness of the $102,153.50 in costs and fees reportedly incurred by Simpson in complying with the subpoena. *See Exhibit J.*

14. PAREXEL has not served any written objections to the subpoena or deposition upon written questions. However, on September 19, 2007, more than eleven (11) weeks after being served with the subpoena, PAREXEL filed a motion for protective order.

REQUEST FOR TRANSFER

15. Federal Rule of Civil Procedure 45 governs the issuance, service, and enforcement of subpoenas and the procedures for objecting to them. When a person or entity objects to a subpoena served on it, "the party serving the subpoena shall not be entitled to inspect and copy the materials or inspect the premises except pursuant to an order of the court by which the subpoena was issued." FED. R. CIV. P. 45(c)(2)(B). Rule 37 provides, "[a] party . . . may apply for an order compelling disclosure or discovery as follows" and then details in a subsection, "[a]n application for an order to a person who is not a party shall be made to the court in the district where the discovery is being, or is to be, taken." FED. R. CIV. P. 37(a).

16. Because the subject subpoenas were issued by this Court, Rules 37 and 45 require Plaintiffs to move for enforcement of the subpoenas in this Court. This obligation, however, does not bear on this Court's ability to transfer the dispute once the motion is brought. Of the twenty-three (23) nonparty vendors involved in this litigation, only a handful has complied with the subpoenas. This is just one of several motions Plaintiffs anticipate filing in an effort to

obtain the nonparty documents. Magistrate Judge Baker has expressed his willingness to accept transfer of these disputes to his court and, in fact, has stated he intends to encourage the courts in which the motions to compel are filed to refer the matters to him. *See* Transcript from September 11, 2007 Status Conference, 8:4-9:12, attached hereto as Exhibit F.

17. A number of courts have either transferred disputes concerning nonparty subpoenas to the district possessing the underlying action or commented on the appropriateness of doing so. *See In re Digital Equip. Corp.*, 949 F.2d 228, 231 (8th Cir. 1991) (court that issued deposition subpoenas pursuant to Rule 45 may remit consideration of objections to court where underlying case is pending); *Petersen v. Douglas County Bank & Trust Co.*, 940 F.2d 1389, 1391 (10th Cir. 1991) (finding that magistrate judge's transfer of motion to quash nonparty subpoena was proper) ("The absence of any language in Rule 45(d) prohibiting transfer of a motion to quash, coupled with this permissive language [in Rule 26] regarding transfer of motions for protective orders which refers to Rule 45 deponents as well as to parties, is enough to validate the [transfer] action of the Kansas magistrate.") (citation omitted); *United States v. Star Scientific,* 205 F. Supp. 2d 482 (D. Md. 2002) (transferring motion to compel nonparty to comply with subpoena to district in which the underlying action was going forward); *Smithkline Beecham Corp. v. Synthon Pharms., Ltd.,* 210 F.R.D. 163, 169 n.7 (M.D. N.C. 2002) ("The third-party subpoena route has the added benefit of allowing the court in which the main litigation is pending to make the ruling."); *Stanziale v. Pepper Hamilton LLP*, 2007 U.S. Dist. LEXIS 11320 (S.D.N.Y. Feb. 9, 2007) (Haight, Sr. D.J.) (transferring motion to compel nonparty documents to District Court for the District of Delaware in which underlying litigation is pending); *Devlin v. Transportation Communs. Int'l Union,* No. 95 Civ. 0742, 2000 U.S. Dist. LEXIS 2441, 2000 WL 249286, at *1 (S.D.N.Y. Mar. 6, 2000) (Francis, M.J.) ("There is substantial support in the

caselaw, among the commentators, and in the Advisory Committee Note to Rule 26(c) of the Federal Rules of Civil Procedure for the proposition that the court from which a subpoena has issued has the authority to transfer any motion to quash or for a protective order to the court in which the action is pending.").

18. Title 28, Section 1407 of the United States Code provides that pretrial proceedings in MDL cases "*shall* be conducted by a judge or judges to whom such actions are assigned," and the judge "may exercise the powers of a district judge in *any* district for the purpose of conducting pretrial depositions in such coordinated or consolidated pretrial proceedings." 28 U.S.C. § 1407(b) (emphasis added). The reason for this is plain: consolidation of pretrial matter allows "one judge to take control of complex proceedings, the better to avoid unnecessary duplication in discovery." *In re Orthopedic Bone Screw Prods. Liability Litig.*, 79 F.3d 46, 48 (7th Cir. 1996). With respect to the subpoenas at issue here, Judge Conway and Magistrate Judge Baker have all the powers of a federal district judge in the Southern District of New York, including the power to compel compliance with the subpoena. *See United States ex rel. Pogue v. Diabetes Treatments Ctrs. of Am., Inc.*, 238 F. Supp. 2d 270, 274-75 (D.D.C. 2002) (holding that the grant of authority in § 1407 extends to the enforcement of subpoenas duces tecum, even those not issued pursuant to a deposition notice); *In re Corrugated Container Antitrust Litigation*, 662 F.2d 875, 880-81 (D.C. Cir. 1981) ("The multidistrict judge is granted the same powers as a judge of those courts where the depositions are being taken.").

19. Courts have frequently transferred disputes relating to nonparty discovery to MDLs, finding that § 1407(b) expressly authorizes MDL judges to preside over such matters. *See In re Subpoenas Served on Wilmer, Cutler & Pickering and Goodwin Proctor LLP*, 255 F. Supp. 2d 1, 2 (D.D.C. 2003) (district court transferred a nonparty subpoena dispute on the basis

that such transfer would be to a district court presiding over the MDL, and 28 U.S.C. § 1407(b) explicitly authorizes the MDL court to hear discovery disputes from other districts); *In re Welding Rod Prods. Liab. Litig.*, 406 F.Supp.2d 1064, 1067 (N.D. Cal. 2005) (transferring motion to quash nonparty subpoena to district presiding over underlying MDL); *In re Subpoena Issued to Boies, Schiller & Flexner LLP*, No. M8-85, 2003 WL 1831426 (S.D.N.Y. Apr. 3, 2003) (transferring motion to quash subpoena to court presiding over underlying MDL). While the language of § 1407(b) provides a clearer textual basis for transfer, nothing in Rule 45 explicitly prohibits a transfer of the instant dispute.

20. This motion relates directly to the proceedings consolidated for pretrial purposes by the Judicial Panel on Multidistrict Litigation. At the core of the motions to compel and PAREXEL's motion for protective order are disputes about scope, relevancy, confidentiality, privilege, and cost sharing. If these disputes are decided by the various district courts from which the subpoenas were issued, there is a likelihood of inconsistent outcomes. Judge Conway and Magistrate Judge Baker have been presiding over the Seroquel litigation pretrial discovery matters for more than a year, making them fully familiar with the underlying litigation. They are familiar with Plaintiffs' theories of the case and AstraZeneca's defenses. Therefore, they are best suited to determine whether the documents sought from the nonparty vendors are relevant to those claims and defenses. Judge Conway and Magistrate Judge Baker are presently managing a number of confidentiality and privilege issues raised with respect to AstraZeneca's document production. Those issues are bound to overlap with the confidentiality and privilege issues raised by the nonparties. Moreover, the nonparty discovery is not likely to end with their subpoena compliance. Rather, there is a possibility that Plaintiffs may pursue oral depositions of these nonparties at some point in the future. Consequently, Judge Conway and Magistrate Judge

Baker are in the best position to resolve these nonparty discovery issues. *See In re Welding Rod Prods. Liab. Litig.*, 406 F. Supp. 2d 1064, 1067 (N.D. Cal. 2005) (finding that transfer served interests of justice, judicial efficiency, and consistency, especially where the action is complex and the judge in transferee district "readily familiar with the underlying issues" and "has already spent considerable time and effort coordinating the pretrial proceedings"); *Smithkline Beecham,* 210 F.R.D. at 169 n.7 ("[Transfer of the third-party subpoena dispute] may be particularly appropriate when relevancy of the discovery is a significant issue . . . . The court in which the litigation is pending will be in a better position to decide relevancy issues.") (citations omitted); *Star Scientific*, 205 F. Supp. at 488 (transfer of motion to compel subpoena compliance warranted where "the District of Columbia is in a better position to evaluate claims of confidentiality, undue burden, and relevancy involved in this discovery dispute.").

21. Discovery in the MDL is moving at a fast pace. The oral depositions of AstraZeneca's fact witnesses are scheduled to begin on October 10, 2007. Plaintiffs are entitled to discovery of the subject documents and sufficient time to review those documents before taking these depositions. Therefore, Plaintiffs respectfully request the Court enter an order transferring this dispute to the Seroquel Product Liability Litigation, MDL 1769, without delay.

REQUEST FOR ORDER COMPELLING COMPLIANCE WITH SUBPOENA AND COMPLETION OF DEPOSITION UPON WRITTEN QUESTIONS

22. The primary method for requesting that a nonparty produce documents is by subpoena under Federal Rule of Civil Procedure 45. FED. R. CIV. P. 34(c) and 45. Rule 45 subpoenas allow a party to command a non-party to produce books, documents, or tangible items in its possession, custody, or control. FED. R. CIV. P. 45(a)(1)(C). Rule 31 provides that "[a] party may take the testimony of *any person*, including a party, by deposition upon written questions . . . ." FED. R. CIV. P. 31 (emphasis added); *see Peterson v. Nadler*, 452 F.2d 754, 756-

57 (8th Cir. 1971), *overruled on other grounds*, *Mallard v. U.S. Dist. Ct. for S. Dist. of Iowa*, 490 U.S. 296, 109 S.Ct. 1814 (1989) (Rule 31 "expressly provides the right of any party to discover and perpetuate evidence from nonparty witnesses"). Pursuant to Rules 31 and 45, Plaintiffs have served the nonparties with document subpoenas and depositions upon written questions. As of the date of this filing, only three (3) nonparties have complied with the subpoenas and completed the depositions upon written questions. Although numerous objections have been asserted by PAREXEL and Simpson, Plaintiffs anticipate that the primary remaining issues that will need to be addressed by the Court relate to scope and costs.

23. **Confidentiality:** On August 20, 2007, Plaintiffs filed a Motion for Entry of an Order Governing Third Party Discovery which addressed, among other issues, the confidentiality of nonparty documents produced in the MDL. In conjunction with the motion, Plaintiffs submitted a proposed confidentiality order which was modeled after the confidentiality order found in the Manual of Complex Litigation and requested the MDL Court enter the order. During a recent status conference, Magistrate Judge Baker indicated he would enter a confidentiality order to protect nonparty documents produced in this litigation. *See* September 11, 2007 Status Conference Transcript, 10:12-11:8, attached hereto as Exhibit F. Plaintiffs informed Simpson and PAREXEL that the Court had agreed to enter a confidentiality order. On September 19, 2007, Magistrate Judge Baker entered the protective order. *See* Exhibit G. Upon receipt of the order on September 19, 2007, Plaintiffs' counsel provided the order to counsel for PAREXEL and Simpson have not voiced any objection to the order. To the extent they object to the protective order entered by Magistrate Judge Baker, Plaintiffs request the Court address those objections.

24. **Scope:** In an effort to narrow the scope of the subpoena lessen the burden on the nonparties, Plaintiffs have eliminating a significant number of Seroquel-specific projects identified by many of the nonparties in "project lists" provided to Plaintiffs. Although Plaintiffs believe they are entitled to most if not all documents relating to Seroquel-specific projects, Plaintiffs chose the projects that appeared the *most* pertinent to the claims in this litigation and agreed to limit the subpoena to documents, contracts and communications pertaining to those projects only, with the understanding that the lists may be revisited in the future.

25. Simpson provided a project list which identified 215 Seroquel-related projects by title, date and location. These projects include symposiums, advisory boards, teleconferences, dinner meetings, psychiatry and PCP speaker training, virtual training, American Psychiatric Association meeting materials, onsite Simpson staff support, toolboxes, brochures, posters, videos, ad boards, and slide kits. Based on the limited information provided, Plaintiffs selected 75 projects all of which are likely relevant to Plaintiffs claims in this litigation. The projects included various advisory boards, including a Weight Gain Advisory Board, PCP National Advisory Board, and American Association for Geriatric Psychiatry (AAGP) Advisory Board, Sales Force Weight Gain Primer, PCP speaker training, depression and anxiety ad boards, Key Opinion Leader materials, and other related projects. Plaintiffs have agreed to limit the subpoena to documents and communications, contracts/agreements between Simpson and AstraZeneca, and documents reflecting the amounts paid to Simpson by AstraZeneca related to those 75 Seroquel-related projects.

26. Despite several requests, PAREXEL has declined to provide a project list. Alternatively, Plaintiffs suggested a deposition of a PAREXEL representative who could provide information about the company's Seroquel related projects so that Plaintiffs could refine their

document requests. PAREXEL declined. On August 10, 2007, Plaintiffs provided PAREXEL with a list of Seroquel-related projects and a list of PAREXEL employees involved in those projects Plaintiffs were able to identify by reviewing AstraZeneca's document production. *See* Exhibit H. Although Plaintiffs do not believe these lists are exhaustive, Plaintiffs hoped this information would move the parties closer to resolving the scope issue. To date, PAREXEL has made no effort to resolve this issue.

27. PAREXEL has not served written objections to the subpoena; however, on September 19, 2007, more than eleven (11) weeks after the subpoena was served, PAREXEL filed a motion for protective order requesting the United States District Court for the District of Connecticut to quash or modify the document subpoena. A motion to quash or modify a subpoena must be timely filed. FED. R. CIV. P. 45(c)(3)(A). Ordinarily, a motion to quash must be filed before the time of performance. *Estate of Ungar v. Palestinian Auth.*, 451 F. Supp. 2d 607 (S.D.N.Y. 2006); *Sony Music Entm't Inc. v. Does 1-40*, 326 F. Supp. 2d 556, 561 (S.D.N.Y. 2004); *In re Welling*, 40 F. Supp. 2d 491, 491 (S.D.N.Y. 1999); *see Kruse v. Sands Bros. & Co., Ltd.*, 2003 U.S. Dist. LEXIS 1230 (S.D.N.Y. 2003) (failure to file motion to quash until two months after the subpoena return date was alone justifies denial of motion). Performance was to have occurred on July 30, 2007 at 10:00 a.m. Plaintiffs granted a production deadline extension to August 15, 2007. PAREXEL did not file its motion to quash until September 19, 2007. PAREXEL's untimely motion to quash should be denied.

28. PAREXEL has not served objections to the deposition upon written questions. Rule 32 provides in relevant part that "[o]bjections to the form of written questions submitted under Rule 31 are waived unless served in writing upon the party propounding them within the time allowed for serving the succeeding cross or other questions and within 5 days after service

of the last questions authorized." FED. R. CIV. P. 32 (d)(3)(C); *Baranowski v. National Union Fire Ins. Co.*, 141 F.R.D. 55 (N.D. Tex. 1992). By not serving written objections to the depositions upon written questions, PAREXEL has waived its objections.

29. Even if the Court finds that PAREXEL has not waived its objections, and to the extent Simpson maintains that Plaintiffs' requests are overly broad despite Plaintiffs' elimination of nearly 2/3 of the Seroquel-specific projects identified by Simpson, PAREXEL and Simpson cannot demonstrate the discovery sought by Plaintiffs exceed the bounds of discovery permitted by the Federal Rules of Civil Procedure. The scope of discovery in federal litigation is broad. FED. R. CIV. P. 26(b)(1). The Federal Rules of Civil Procedure allow examination of a deponent concerning "any matter, not privileged, that is relevant to the claim or defense of any party, including the existence, description, nature, custody, condition, and location of any books, documents, or other tangible things and the identity and location of any persons having knowledge of any discoverable matter." FED. R. CIV. P. 26(b). It is well established that courts must employ a liberal discovery standard in keeping with the spirit and purpose of the discovery rules. *Tate v. United States Postal Serv.*, 2007 U.S. Dist. LEXIS 10086 *3 (S.D. Fla. 2007); *American Sec. Educators, Inc. v. Miami-Dade County*, 2006 U.S. Dist. LEXIS 81994 *2-3 (S.D. Fla. 2006); *Graham v. Casey's Gen. Stores*, 206 F.R.D. 251, 253 (S.D. Ind. 2002); *In re Theragenics Corp. Secs. Litig.*, 205 F.R.D. 631, 636-37 (N.D. Ga. 2002); *White v. Kenneth Warren & Son, Ltd.*, 203 F.R.D. 364, 366 (N.D. Ill. 2001). "Relevant information need not be admissible at the trial if the discovery appears reasonably calculated to lead to the discovery of admissible evidence." FED.R.CIV.P. 26(b)(1).

30. To sustain their objections in response to this motion to compel, Simpson and PAREXEL must show that the requested discovery at issue has no possible bearing on the claims

and defenses of the parties or otherwise on the subject matter of the action. *Tate*, 2007 U.S. Dist. LEXIS 10086 *4; *American Sec. Educators*, 2006 U.S. Dist. LEXIS 81994 *3; *Dunkin' Donuts Inc.*, 2001 WL 34079319 *2; *Flora v. Hamilton,* 81 F.R.D. 576, 578 (M.D.N.C. 1978); *see also Graham,* 206 F.R.D. at 254 ("The party opposing discovery has the burden of showing the discovery is overly broad, unduly burdensome, or not relevant."). This means Simpson and PAREXEL must show either that the requested discovery (1) does not come within the broad scope of relevance as defined under Rule 26 or (2) is of such marginal relevance that the potential harm occasioned by discovery would far outweigh the ordinary presumption in favor of broad disclosure. *Giardina v. Lockheed Martin Corp.,* 2003 U.S. Dist. LEXIS 9386, 2003 WL 21276348 (E.D. La. May 30, 2003); *Gober v. City of Leesburg,* 197 F.R.D. 519, 521 (M.D. Fla. 2000).

31. Plaintiffs limited their requests to Seroquel-specific documents. Plaintiffs have eliminated nearly 2/3 of the projects identified by Simpson. Plaintiffs have made repeated efforts to learn more about the projects conducted by PAREXEL to no avail. These documents relating to the Seroquel-related projects are relevant to Plaintiffs' claims that AstraZeneca's marketing and promotional campaigns overemphasized the efficacy of Seroquel, downplayed its dangerous side effects, targeted PCPs, and promoted Seroquel for use in the treatment of a number of "off-label" uses, including depression, anxiety, Attention Deficit Disorder (ADD), insomnia, dementia, and other related "mental" disorders. Simpson and PAREXEL were hired by AstraZeneca to research, design, create and implement these campaigns through marketing/promotional activities and materials and medical publishing. Therefore, the documents sought by the subpoenas are discoverable or, at a minimum, are reasonably calculated to lead to the discovery of admissible evidence.

32. To the extent the nonparties suggest the Plaintiffs can obtain the requested documents from AstraZeneca, the MDL Court is familiar with the problems Plaintiffs have encountered with AstraZeneca's electronic production, which Plaintiffs contend is far from complete and which the Court has described as incomplete and unusable. *See* Order on Plaintiffs' Motion for Discovery Sanctions (Doc. No. 393). Although Plaintiffs have been able to locate some of the requested documents in AstraZeneca's production, due to the widespread and recurring problems with AstraZeneca's production, Plaintiffs are far from confident that AstraZeneca's production of those documents is complete. For this reason, Plaintiffs have asked AstraZeneca to contribute to the reimbursement of the costs and fees incurred by the third parties. Additionally, there is no guarantee that the requested documents are located in the custodial file of the AstraZeneca employees identified by AstraZeneca, or the additional custodial files requested by Plaintiffs. Further, the nonparties are likely to have in their possession documents that AstraZeneca does not have, including documents that were not provided to or retained by AstraZeneca and communications between the nonparties and other nonparties, such as physicians and other vendors.

33. Plaintiffs continue their efforts to resolve this issue with the nonparties. To the extent the parties are unable to do so, Plaintiffs respectfully respect that the Court address and decide the nonparties' objections to the scope of the subpoenas.

34. **Costs:** Plaintiffs and AstraZeneca initially agreed to share copying costs incurred by the nonparties. However, many of the nonparties also seek costs and attorneys' fees associated with locating and reviewing the requested documents. Plaintiffs and AstraZeneca have now agreed to review and discuss the nonparty's costs and fees and will consider reimbursing the nonparties for some of their *reasonable* costs and fees.

35. PAREXEL initially represented it would cost between $5,000 and $10,000 to comply with the subpoena. *See* Exhibit I, August 9, 2007 email from PAREXEL's counsel to Plaintiffs' counsel. On September 13, 2007, counsel for PAREXEL verbally informed Plaintiffs' counsel the cost to comply with the subpoena would actually exceed $100,000. In the motion for protective order filed on September 19, 2007, PAREXEL indicated the cost to comply with the subpoena would actually exceed $150,000.

36. Although Plaintiffs eliminated nearly 2/3 of the Seroquel-related projects identified by Simpson, Simpson has advised that its production costs and attorneys' fees total $102,153.50. *See* Exhibit J. Although Simpson indicates that a whopping 775.25 hours have been spent locating the requested documents, Simpson has not provided any information about what was done during those 775.25 hours. Plaintiffs have requested a description of the work and searches performed during those 775.25 hours. The parties and the court have no way of determining whether Simpson's costs and fees are reasonable without this information. If Simpson fails to provide a basis for determining whether its costs and fees are reasonable, Plaintiffs request the court deny Simpson's request for reimbursement of costs and fees. *See In re Honeywell Int'l, Inc. Sec. Litig.*, 230 F.R.D. 293, 303 (S.D.N.Y. 2003) (court denied third party's request for reimbursement of costs where third party was not a classic disinterested nonparty and offered no basis for determining the reasonable costs for compliance with the subpoena).

37. Federal Rule of Civil Procedure 45(c) provides that "an order to compel production shall protect any person who is not a party . . . from significant expense resulting from the inspection and copying commanded." FED. R. CIV. P. 45(c)(2)(B). Protection from significant expense does not mean that the requesting party necessarily must bear the entire cost

of compliance. *See In re Exxon Valdez*, 142 F.R.D. 380, 383 (D.D.C. 1992); *Linder v. Calero-Portcarrero*, 180 F.R.D. 168, 177 (D.D.C. 1998) (in light of the nonparty government agency's resources and the significance of plaintiffs' litigation, conditioning the nonparty's compliance with the subpoena on plaintiffs' payment of half the reasonable copying and labor costs will sufficiently protect the agency from "significant expense"); *First Am. Corp. v. Price Waterhouse LLP*, 184 F.R.D. 234, 241 (S.D.N.Y. 1998) (the equities presented in this case, specifically the role played by the nonparty and the public importance of the action, warranted a reduction in the amount of reimbursement for subpoena compliance costs requested by the nonparty). The relevant factors employed to determine how much of the production expense the requesting party should bear include "whether the nonparty actually has an interest in the outcome of the case, whether the nonparty can more readily bear the costs than the requesting party, and whether the litigation is of public importance." *Linder*, 180 F.R.D. at 177 (citing *In re Exxon Valdez*, 142 F.R.D. at 383); *First Am. Corp.*, 184 F.R.D. at 241.[1] Finally, the nonparty is entitled only to reimbursement for its reasonable costs. *In re Propulsid Prods. Liab. Litig.*, 2003 U.S. Dist. LEXIS 16477 (E.D. La. 2003) (citing *Broussard v. Lemons*, 186 F.R.D. 396, 398 (W.D. La. 1999).

38. According to its website, Simpson was founded in 1998 and is now an established medical communications firm whose 50 employees provide the biopharmaceutical industry with a wide range of services in support of overall marketing strategies. Simpson describes itself as an extension of its clients' marketing department -- a claim that is aptly supported by the 215

[1] The *Exxon* court explained that "there is no indication that [the drafters of new Rule 45] also intended to overrule prior Rule 45 case law, under which a nonparty can be required to bear some or all of its expenses where the equities of a particular case demand it." *In re Exxon Valdez*, 142 F.R.D. at 383. The relevant factors considered under the old rule in determining how much of the costs the requesting party should bear apply to the amended rule as well. *Exxon Valdez*, 142 F.R.D. at 383; *First Am. Corp.*, 184 F.R.D. at 241; *In re Law Firms of McCourts & McGrigor Donald*, 2000 U.S. Dist. LEXIS 20287 (S.D.N.Y. 2000).

Seroquel-related projects undertaken by Simpson on behalf of AstraZeneca. Documents produced by AstraZeneca suggest Simpson has been paid millions of dollars in connection with these projects.

39. Documents produced by AstraZeneca suggest PAREXEL has been paid multiple millions of dollars for its work on Seroquel-related projects. According to its website, PAREXEL is one of the largest biopharmaceutical services companies in the world and has supported nearly all of the top 50 drugs on the market. PAREXEL operates in 55 locations throughout 43 countries around the world and has more than 6,300 employees. PAREXEL generated $614.9 million in revenue during its 2006 fiscal year.

40. In contrast, Plaintiffs are persons who suffer from various mental disorders including bipolar disorder and schizophrenia. There is no question that PAREXEL and Simpson can more readily bear the costs than Plaintiffs. *In re Exxon Valdez*, 142 F.R.D. 380 (D.D.C. 1992)("[T]here can be little doubt that API, which in 1989 had gross receipts of $58 million and a net worth of $17 million . . . would be able to absorb at least some of the costs of production and copying . . . . This is especially true in comparison with the financial situation of petitioners, who are five disparate classes of Native Alaskans, fishermen, business persons, property owners, and cannery workers affected by the spill.") (citing *Wilk v. Am. Med. Ass'n*, 28 Fed. R. Serv. 2d 580 (D.D.C. 1979) (given nonparty professional association's "obvious and understandable substantial interest in the outcome," costs of compliance held to be "business overhead").

41. Further, the nonparties' interest in the outcome and the public importance of this case warrants a conclusion that PAREXEL and Simpson bear a portion of the costs. *Cf. United States v. Int'l Bus. Machs.*, 71 F.R.D. 88, 92 (S.D.N.Y. 1976) (ruling in an antitrust action brought on behalf of the People that the nonparty had a duty to absorb the cots of complying with

the subpoena because the case raised significant public issues and its outcome offered the nonparty certain competitive benefits). The pharmaceutical industry spends billions of dollars a year on promoting its products. Television and print advertisements promoting pharmaceutical products are everywhere. Plaintiffs believe the evidence in this litigation will overwhelmingly demonstrate that AstraZeneca paid its vendors, including PAREXEL and Simpson, billions of dollars to promote Seroquel to the medical community and consumer public. The FDA has repeatedly reprimanded AstraZeneca for its false and misleading promotional activities aimed at the public and the medical community. PAREXEL and Simpson contributed to design and development of those activities.

42. Depending on the outcome of this litigation, AstraZeneca and the nonparties could continue or be deterred from continuing such disapproved marketing and promotional activities. The outcome could affect the parties' relationships and the nonparties' revenue generated from projects relating to Seroquel and other pharmaceutical products. Therefore, PAREXEL and Simpson arguably have a significant financial interest in the outcome of the case. Consequently, PAREXEL and Simpson should bear at least a portion of their costs and fees, if not the entire expense.

43. Plaintiffs have taken reasonable steps to avoid imposing undue burden or expense on the nonparties. Plaintiffs asked AstraZeneca to share the reasonable costs and fees incurred by the nonparties, which AstraZeneca has agreed to do. Plaintiffs asked the MDL Court to enter a confidentiality order to protect the nonparty documents, which the Court has done. Plaintiffs have identified projects, documents and employees with the hope of assisting the nonparties in more quickly locating the requested documents. Plaintiffs have requested project lists to nonparties in an effort to narrow the document requests, thereby reducing the nonparties'

expenses. As a result, Plaintiffs were able to eliminate nearly 2/3 of the Seroquel-related projects identified by Simpson. Plaintiffs suggested an oral deposition of a PAREXEL representative in order to obtain better information about PAREXEL's Seroquel-related projects which would allow Plaintiffs to refine their document requests. PAREXEL declined. Plaintiffs' counsel has had numerous telephone conversations with counsel for PAREXEL and Simpson and has exchanged multiple emails/letters with counsel in an effort to address all of the nonparties' concerns. Plaintiffs' counsel has agreed to numerous extensions of deadlines for the nonparties to assert objections to the subpoena and deposition upon written question and to produce documents,[2] all the while making it very clear that Plaintiffs are under considerable time pressure in this litigation and that the depositions of AstraZeneca's witnesses would begin in October. Plaintiffs respectfully request the Court take these efforts into consideration when entertaining the nonparties' request for costs and attorneys' fees, including those fees incurred in responding to this Motion. *See Prescient Acquisition Group, Inc. v. MJ Publ’g Trust*, 2006 U.S. Dist. LEXIS 75383, *6 (S.D.N.Y. 2006) (considering the willingness of the serving party to narrow the scope of the subpoena when apportioning costs).

44. Given the number of nonparties involved, and the exorbitant and excessive cost and fee estimates Plaintiffs have received, Plaintiffs respectfully request the Court set some parameters on the reasonable costs and fees, and assist in determining the apportionment, if any, of these costs and fees between Plaintiffs, AstraZeneca and the nonparties.

[2] Simpson was given four extensions to object and/or respond to the subpoena on July 19, 2007, August 15, 2007, August 29, 2007, and September 12, 2007. PAREXEL was given an extension to object and/or produce documents on July 27, 2007.

CONCLUSION

For these reasons, Plaintiffs respectfully request the United States District Court for the District of Connecticut enter an order transferring this dispute to the Middle District of Florida, Orlando Division, where the Seroquel Products Liability Litigation, MDL 1769, is pending. Should the Court decide not to transfer this matter, Plaintiffs request the Court enter an order denying PAREXEL's Motion for Protective Order and overruling any existing objections and compelling PAREXEL MMS and Simpson Healthcare Executives to comply with the document subpoenas issued by this Court. If the matter is transferred, Plaintiffs request the MDL Court enter an order overruling any existing objections and compelling the nonparties to comply with the document subpoenas and respond to the depositions upon written questions noticed in the MDL litigation and served on the nonparties in conjunction with the document subpoenas.

Date: October 9, 2007

Respectfully submitted,

Ed Blizzard by Stu

Edward Blizzard
PHV No.: 02178
Holly M. Wheeler
BLIZZARD, MCCARTHY & NABERS, L.L.P.
440 Louisiana, Suite 1710
Houston, Texas 77002
Telephone: (713) 844-3750
EBlizzard@blizzardlaw.com
Counsel for Plaintiffs

Paul Pennock
WEITZ & LUXENBERG, P.C.
180 Maiden Lane - 17th Floor
New York, NY 10038
Telephone: (212) 558-5504
Ppennock@weitzlux.com

Camp Bailey
BAILEY PERRIN BAILEY LLP
The Lyric Centre
440 Louisiana, Suite 2100
Houston, TX 77002
Telephone: (713) 425-7232
cbailey@bpblaw.com
Co-Lead Counsel for Plaintiffs in MDL 1769

RULE 26 CERTIFICATE

I, Holly M. Wheeler, an attorney for the Seroquel Product Liability MDL Plaintiffs, hereby certify that I have conferred in good faith with the attorneys for PAREXEL MMS, Marty Mahoney, Kurt Kusiak and Robert Mendillo, and the attorneys for Simpson Healthcare Executives, Jennifer Morgan DelMonico and Jocelyn Griffin, in an effort to resolve the dispute at issue without judicial intervention, but we have been unable to do so.

Holly Wheeler by Steve Ay
Holly M. Wheeler

CERTIFICATE OF SERVICE

I hereby certify that, on this 9th day of October, 2007, the foregoing *Plaintiffs' Motion for Transfer to Seroquel Products Liability Litigation MDL, Motion to Compel Non-Party Documents, and Incorporated Memorandum of Law,* was served in compliance with *Rule 5* of the *Federal Rules of Civil Procedure* on the parties listed below:

For PAREXEL MMS
Edward Kurmeich
William I. Haslun, III
IVEY, BARUM & O'MARA, LLC
170 Mason St.
Greenwich, CT 06830

Kurt S. Kusiak, Esq.
Robert M. Mendillo, Esq.
SALLY & FITCH, L.L.P.
One Beacon Street, 16th Floor
Boston, MA 02108

For Simpson Healthcare Executives, Inc.
Jennifer Morgan DelMonico
Joselyn Griffin
MURTHA CULLINA, L.L.P.
Whitney Grove Square, Two Whitney Avenue
New Haven, CT 06510-1220

For AstraZeneca:
Fred T. Magaziner
DECHERT LLP
Cira Centre
2929 Arch Street
Philadelphia, PA 19103

Kenneth E. Friedman
Sidley Austin LLP
555 West Fifth Street, Suite 4000
Los Angeles, California 90013

Holly Wheeler by Steve M
Holly M. Wheeler