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VIA CM/ECF & HAND DELIVERY
The Honorable Richard G. Andrews
United States District Court for the District of Delaware
J. Caleb Boggs Federal Building
844 N. King Street
Wilmington, DE 19801-3555

Re: *Reckitt Benckiser, et al. v. Par Pharmaceutical, Inc,. et al.*, C.A. No. 13-1461-RGA;
Reckitt Benckiser, et al. v. Watson Laboratories, Inc., C.A. No. 13-1674-RGA;
Reckitt Benckiser, et al., v. Alvogen Pine Brook, Inc., et al., C.A. No. 13-2003-RGA

Dear Judge Andrews,

The parties in this action have been negotiating the language of a Proposed Stipulated Protective Order to govern access to confidential information produced during the litigation, but have reached an impasse regarding two issues: (1) Defendants Par and Watson (but not Alvogen) insist on a broad, one-sided FDA Bar preventing Plaintiffs' counsel from advising Plaintiffs on FDA matters, even when the FDA matter does not involve confidential information relating to the present action; and (2) Defendants Par and Alvogen (but not Watson) demand that their in-house counsel be allowed to view Plaintiffs' proprietary research and development information in a "middle tier" of confidential information.

Plaintiffs oppose the FDA Bar because it is overly broad and it is especially unfair to Plaintiffs. For instance, the FDA Bar prevents Plaintiffs' counsel from being involved in FDA communications even when those communications do not implicate confidential information and do not relate to the sublingual film at issue in the present litigation. Further, the FDA Bar explicitly allows Defendants' counsel to "communicat[e] with the FDA concerning their client's ANDA," but no similar provision extends to Plaintiffs' counsel. Additionally, the proposed FDA Bar could or would exclude Plaintiff RBP's General Counsel from seeing defendants' confidential information, effectively defeating the purpose of allowing RBP in-house counsel access to such information.

In addition, the "middle tier" of confidential information should be rejected because there is no legitimate reason for Defendants' (Par and Alvogen's) in-house counsel to have access to Plaintiffs' highly confidential information. The parties are direct competitors, and Defendants' in-house counsel should not have access to Plaintiffs' highly confidential information. Furthermore, a "middle tier" of information (especially as to two of three defendants) would add needless expense and complexity to the litigation.

1. The FDA Bar Is Unfair to Plaintiffs and Is Overly Broad.

Par and Watson seek to include the following language:

6.4. FDA Bar: Absent written consent from the Producing Party, any individual who receives access pursuant to ¶¶6.1(a)-(f) above to HIGHLY CONFIDENTIAL or HIGHLY CONFIDENTIAL-OUTSIDE COUNSEL'S EYES ONLY information produced by a party in C.A. 13-1461 or and/or C.A. 13-1674 must not be involved in communications with the FDA or any foreign counterpart organization directed to: a) Citizen Petitions, b) standards or requirements for approval of therapeutically equivalent products of Suboxone®, or c) involvement with United States Pharmacopeia Monographs or its counterpart in any foreign jurisdiction. Nothing in the foregoing shall preclude any individual who receives access pursuant to ¶¶6.1(a)-(f) from communicating with the FDA concerning their client's ANDA.

¶ 6.4. Proposed Stipulated Protective Order ("Proposed P.O."), attached as Exhibit 1 hereto ("FDA Bar").

Plaintiffs oppose the Par/Watson FDA Bar for several reasons.

First, an agreed-upon and more narrowly-tailored provision already prevents the use of confidential information for submissions to the FDA and addresses any concerns that Par and Watson may have about such use:

14.1. No person shall use any [information designated as confidential] ... for purposes other than the prosecution or defense of the Three Related Actions... Further, no person shall use any [information designated as confidential] ... or information derived therefrom, for purposes of filing a Citizen's Petition or other challenge to the FDA concerning any sublingual film containing buprenorphine hydrochloride and/or naloxone hydrochloride.

¶ 14.1. Proposed P.O. (emphasis added). In *Eli Lilly & Co. v. Actavis Elizabeth LLC*, 2008 U.S. Dist. LEXIS 53816 (D.N.J. July 15, 2008), the court determined that a general limitation of use provision was sufficient and that it was not necessary to have a redundant FDA Bar.

Second, the proposed FDA Bar is too broad and prohibits anyone with access to such information from being "involved" with communications with the FDA (or foreign counterpart agencies) relating to: a) Citizen Petitions, b) "standards or requirements for approval of therapeutically equivalent products of Suboxone®, or c) involvement with United States Pharmacopeia Monographs (foreign counterparts). Defendants' broad prohibition operates to exclude counsel's involvement in FDA-related communications, as opposed to the use of confidential information as covered by ¶ 14.1 of Proposed P.O. (shown above). Moreover, this prohibition would apply even if no confidential information is implicated in such communications. Further, the FDA Bar prevents Plaintiffs' counsel from being involved even when the FDA communications do not relate to the sublingual film at issue in the present litigation. Plaintiffs' counsel should not be barred from working on any and all FDA communications relating to Citizens' Petitions, simply because they have had access to confidential information. RBP, for example, has a thinly staffed in-house legal department and its general counsel is both responsible for managing this litigation as well as approving legal challenges, including Citizen's Petitions filed with the FDA. Furthermore, such Citizen's Petitions are public and may therefore be readily policed by the parties for any disclosure of confidential information. This Court recently rejected a similar FDA Bar because the risk of inadvertent disclosure was minimal and Defendants did not meet their burden to show good cause. *See Alza Corporation et al v. Par Pharmaceutical Inc.*, Docket No. 1:13-cv-01104-RGA, D.I. 78 (Dec. 17, 2013 Tr. at 26:11-15) (Andrews, J.).

Third, the Par/Watson proposed FDA Bar is simply unfair to Plaintiffs. Indeed, the FDA Bar provision concludes with a one-sided statement that explicitly allows Defendants and their counsel to "communicat[e] with the FDA concerning their client's ANDA," while no similar provision or protection extends to Plaintiffs or their counsel. In short, Defendants should not be allowed to have it "both ways"; and the Proposed FDA Bar should be rejected.

2. Defendants' Proposed Confidentiality Tiers Are Unsuitable and Add Expense and Complexity.

Plaintiffs and Watson agree that a standard two-tier protective order is suitable for the issues in this litigation. Under the agreed framework, in-house counsel is not permitted to see "Highly Confidential" information, which is defined to include: (1) NDAs, (2) ANDAs, (3) research and development for future products, (4) non-public correspondence with FDA, (5) unpublished patent applications, and (6) financial information. (¶ 2.4, 2.5, Proposed P.O.).

Par and Alvogen, on the other hand, propose a "middle tier" that provides in-house counsel with access to information in all of categories (1) through (5), but not to financial information in category (6), which would be designated "Highly Confidential-Outside Counsel Eyes Only." (¶ 2.6, Proposed Stipulated Protective Order"). Under Defendants' proposal, Defendants' in-house counsel would have access to everything that is typically designated as available to outside counsel only.

In-house counsel at generic drug companies cannot have, and have no need for, access to Plaintiffs' proprietary research and development information, which is nonpublic and competitively sensitive, and which includes current research on "future products." Courts have recognized that in-house counsel are properly excluded from access to highly confidential information where counsel "has a role that is linked to competitive decision-making ... [including involvement] with settling patent litigation and licensing." *Affymetrix, Inc. v. Illumina, Inc.*, 2005 U.S. Dist. LEXIS 15482, *8 (D. Del. July 28, 2005) (permitting access where separate litigation unit had no role in competitive decision making). In this case, however, the generic companies are in the business of filing ANDAs, and the prosecution (and settlement) of the ensuing ANDA cases is at the core of their business and competitive decision-making; therefore, it is particularly critical in the present circumstances to prevent in-house patent counsel from having access to such competitively sensitive information.

Furthermore, the same tier classification system should apply to all parties. It will be problematic, unworkable, and confusing to have a three-tier system between two of the Defendants and Plaintiffs, and a two-tier system between one Defendant and Plaintiffs. This would require, for example, that Plaintiffs produce their financial documents with different confidentiality levels, depending on the Defendant.

For at least the above reasons, Plaintiffs propose that there be two levels--not three--of confidentiality pursuant to which in-house counsel, absent permission by the producing party, may not have access to any of the information falling into categories (1)-(6) above.

Respectfully Submitted,



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